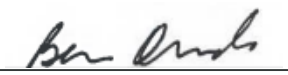
RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

7601 IMPERIAL HIGHWAY DOWNEY CALIFORNIA 90242

# MOBILE CLINIC
# LABORATORY SAFETY MANUAL

## POLICY & PROCEDURE

| | |
|---|---|
| **DIVISION:** | LABORATORY |
| **SECTION:** | SAFETY MANUAL |
| **ORIGINAL ISSUE DATE:** | JANUARY 3, 2022 |
| **REVISION DATE:** | |
| **APPROVED DATE:** | FEBRUARY 9, 2022 |
| **PREPARED BY:** | RICHARD M. SOMBILLO RN. |
| **APPROVED BY:**  | DR. ABSALON GALAT MD.<br>MEDICAL DIRECTOR<br><br>Signature: |

# TABLE OF CONTENTS

25. PROPER USE OF PERSONAL PROTECTIVE CLOTHING/EQUIPMENT PROTECTIVE CLOTHING AND EQUIPMENT - CLOTHING - GLOVES EYE/FACE PROTECTION ENGINEERED SHARPS INJURY PROTECTION DEVICES, NEEDLELESS SYSTEMS, ETC
26. PERSONNEL EDUCATION ON STANDARD PRECAUTIONS GENERAL PRECAUTIONS BLOODBORNE PATHOGENS VACCINES HIV TESTING NEEDLE STICKS, CUTS, ETC CLEANING AND DECONTAMINATING SPILLS OF BLOOD OR OTHER BODY FLUIDS
27. LAUNDRY
28. LABELING INFECTIVE WASTE
29. FOLLOW-UP PROCEDURES AFTER POSSIBLE AND KNOWN SKIN EXPOSURE TO HUMAN IMMUNODEFICIENCY VIRUS (HIV) OR HEPATITIS B VIRUS (HBV)
30. EXPOSURE CONTROL PLAN RISK CATEGORIES - JOB CLASSIFICATION
31. PERSONAL HYGIENE POLICIES USED IN ALL TECHNICAL WORK AREAS
32. PERSONAL HYGIENE PERSONAL HYGIENE PRACTICES
33. LATEX ALLERGY PRECAUTIONS PROGRAM
34. EMERGENCY PREPAREDNESS
35. BIOSAFETY & EXCESSIVE NOISE LEVELS
36. PERSONNEL ACCESS TO CHCLS PROGRAMS DOCUMENTED REVIEW OF THE SAFETY PROGRAM REFERENCES

# LABORATORY
# SAFETY MANUAL

## PURPOSE

To provide a safe working environment for personnel, minimize the risk of injury and to maintain Los Angeles County's industrial accident costs to a minimum.

## POLICY STATEMENT

Each member of Mobile Clinic Staffs must support and actively participate in the elimination of unsafe conditions or acts that cause the bulk of on-the-job accidents. Safety must be a major ingredient in personnel orientation, job training, and in the planning, organizing, and execution of all work assignments.

This safety program is available to all laboratory personnel and is to be reviewed on an annual basis as part of safety training. All new personnel will be oriented to all aspects the program. Documentation of their understanding of the program will be maintained by the Laboratory Manager and Mobile Clinic Designee. There is at least biennial review of safety policies and procedures by the Laboratory Director or designee. There are periodic reviews (at least annually) of safe work practices to reduce hazards.

## GENERAL LABORATORY GUIDELINES

- It is the responsibility of all personnel to report unsafe working conditions or practices to the Laboratory Manager or Mobile Clinic Designee.
- Clean up spills and trash from floors promptly to prevent falls.
- Walk carefully in congested areas, never run in the laboratory. Use caution at corridor intersections.
- NEVER engage in practical jokes or horseplay in the work area.
- Observe warning signs.
- Report broken or defective equipment to Laboratory Manager IMMEDIATELY and take equipment out of use until it is repaired.
- Use proper lifting techniques as per safety training.
- Use approved step stools or ladders to reach high places. Chairs and stools are unsafe for this purpose.
- Do not use or repair equipment unless trained and authorized to do so.
- Know location of Safety Data Sheets (SDSs)/Material Safety Data Sheets (MSDSs) for chemicals/ reagents in use. ALWAYS comply with the SDS/MSDS.
- Do not eat, drink, smoke, apply cosmetics, lip balm, or manipulate contact lenses in the laboratory. These are FORBIDDEN because of the danger of infection or ingestion of toxic materials
- ALWAYS wear personal protective equipment while handling blood, tissue, or body fluids. Gloves and cover garments are not to be worn out of the work area.
- NEVER pipet by mouth. Use a rubber bulb or other device.
- Only wear closed-toe shoes in the laboratory testing areas. Because canvas shoes will absorb chemicals or infectious fluids, they are not recommended (if worn, they should be covered with disposable, fluid-resistant shoe covers). Leather or a synthetic, fluid-impenetrable material is recommended. Shoes should enclose the entire foot.
- Dispose of waste in the correct type of container.
- ALWAYS use a hood for any procedures which so state. When in doubt, ask the Laboratory Manager.
- ALWAYS discard chipped or cracked glassware, and then notify the Laboratory Manager or their designee for inventory purposes.

# LABORATORY
# SAFETY MANUAL

- Know the fire/disaster drill procedure posted in the laboratory. Know the location of safety equipment and how to use it.
- Report all injuries and accidents to a Laboratory Manager as soon as possible.
- All personnel are encouraged to take the free Hepatitis B vaccine available through the Employee Health Service.
- ALWAYS secure long hair and beards so that they do not come into contact with contaminated surfaces, flames, or get caught in the moving parts of equipment.
- Use face shields whenever working with opened specimens where splashing can occur. Contact lenses may absorb chemical vapors and prevent adequate eye washing in the event of a splash. You are advised to consult your ophthalmologist about precautions you may need to take and whether you should continue to wear contact lenses while working in the laboratory.
- Visitors, especially young children, should be kept out of the work area except for brief, carefully supervised occasions. Personnel must not work and supervise children at the same time.
- Per the CDC, for good infection control, nails should not be longer than one quarter inch beyond the tip of the finger. Nails that are longer don't fit into gloves properly and can hinder blood collection as well as testing.

**DISINFECTION:**

A. LABORATORY BENCH TOPS

Disinfect all work areas at the beginning or end of the work shift with 10% bleach solution with a contac time of 1O minutes, facility approved disinfectant, i.e., phenol, or approved disinfectant wipes.

B. CENTRIFUGES

- Exteriors are to be wiped clean with 10% bleach solution with a contact time of 1O minutes, facility approved disinfectant, i.e., phenol, or approved disinfectant wipes, when contaminated. Note that bleach may harm metal and painted surfaces. Rinse with water after disinfection.

Preparing 10% bleach:

1. Use commercial (household) bleach.
2. Dilute with 9 parts water and one-part bleach.
3. Make the solution fresh daily (CDC requirement), or automatic 10% bleach mixing spray bottle or commercially available 10% stable bleach solution.
4. If preparing 10% bleach, write the date of preparation, expiration date (24 hours later) and initials of the individual who made up the solution on the reagent identification label or on a new label just below the name of the reagent.
5. Spills should be wiped up and decontaminated with 10% bleach with a contact time of? 10 minutes, or other approved disinfectant, IMMEDIATELY to prevent the formation of aerosols.
6. Broken glass should be removed immediately from the interior
    - Remove specimen buckets from the centrifuge
    - Treat wet broken glass with 10% bleach or approved disinfectant
    - Put on heavy vinyl protective gloves
    - Remove shards of glass from the interior
    - Dampen paper towels and CAREFULLY remove the remaining glass from the interior of the centrifuge
    - Place all glass and paper towels in a sharps container
    - CAREFULLY rinse off the interior with approved disinfectant
    - Put gloves back with personal protective equipment supplies
    - Replace specimen buckets

7. Once per month, the interior should be thoroughly wiped clean with approved disinfectant. Do not flood the interior with disinfectant as this could damage the motor and bearings.
8. Centrifuge surfaces should be dry before using.

C. REFRIGERATORS

- The interior should be wiped clean as needed.
- Soap and water can be used, followed by 10% bleach solution, facility approved disinfectant, i.e. phenol, or approved disinfectant wipes as needed.
- Exteriors should be cleaned more frequently as needed.

D. DISINFECTANTS

Disinfectants are used in the Mobile Clinic:

- 10% solution of household bleach (sodium hypochlorite).
- 70% Ethanol or isopropyl alcohol; it is purchased and used in this strength.
- Facility approved disinfectant, i.e., phenol. D Approved disinfectant wipes

**NEEDLE POLICY**

The Rancho Los Amigos Rehabilitation Center Infection Control Manual (and/or each facility specific infection control manual) and ACN ED-01.002 (Bloodborne Pathogen Exposure Control Plan) have a policy prohibiting the recapping, purposeful bending, breaking, removing from disposable syringes, or other manual manipulations of needles. Our policy is to select appropriate and effective engineering controls to prevent or minimize exposure incidents. Engineering controls means sharps disposal containers, needleless systems and sharps with engineered sharps injury protection (ESIP). This policy is for safety and infection control.

**HOUSEKEEPING BY MOBILE CLINIC STAFF**

A clean, neat, uncluttered work area contributes towards good chemical hygiene and safety. Appropriate measures are:

- Keep all aisles, hallways, and stairs clear of all chemicals.
- Keep all work areas and workbenches as free of clutter and obstructions as possible.
- Clean all work surfaces at beginning and at end of shift.
- Never block access to emergency equipment, showers, eye washes and exits.
- Store waste in the proper container with a proper label citing the chemical constituents and associated hazards.
- Clean equipment and glassware frequently.

**LABORATORY ACCIDENTS RESULTING IN PROPERTY DAMAGE OR INVOLVING SPILLAGE OF HAZARDOUS SUBSTANCES**

A. Policies and procedures have been developed regarding the reporting of all occupational injuries or illnesses that require medical treatment. These policies are contained in the Rancho Los Amigos Rehabilitation Center Network Infection Control Manual (and/or each facility specific infection control manual), facility Environment of Care Manual, and facility Injury and Illness Prevention Program.

B. All serious accidents resulting in fatalities or in the hospitalization of three or more personnel are reported to the Occupational Safety and Health Administration (OSHA) within 8 hours by the facility Safety Officer or Lab Manager.
C. Evaluation of laboratory incidents follows the guidelines in the facility safety manual. The facility Risk Manager is notified of any accidents resulting in property damage or hazardous materials.

**FIRE PREVENTION AND CONTROL**

A. Policies and procedures are documented for fire prevention and control in each facility's Environment of Care Manual. This documentation is maintained by the facility Safety Officer at Rancho Los Amigos.
B. Staff in free-standing buildings classified as business occupancy, as defined by the Life Safety Code, neec only participate in one fire drill per shift annually. It is at the discretion of facility Administrator and Safety Officer whether to follow more stringent requirements, i.e. quarterly fire drills. All fire drills are to be documented. Any deficiencies are noted and brought to the attention of the Laboratory Manager for documentation and resolution.
C. If the more stringent requirement is followed, two of the four drills are to be complete evacuation drills of the facilities and include all personnel and customers. The other drills are non-evacuation drills and may or may not include the entire facility.
D. All laboratory personnel are instructed in the use of portable fire extinguishers either by hands-on use of the extinguishers or through yearly review of videos especially designed to teach fire extinguisher training. Laboratory safety bulletin boards may contain instructions regarding fire extinguishers and their classifications.

**LABORATORY EVACUATION DURING EMERGENCIES, FIRE, DISASTER**

- Refer to facility Environment of Care manual for detailed procedures (Emergency Preparedness section). Each laboratory has a minimum of 2 separate exit routes.
- Each laboratory may have designated emergency response team members (and alternates), which have specific responsibilities.
- Priorities for patients/staff/visitors:
    - o Those closest to danger
    - o Ambulatory patients/visitors/staff
    - o Wheelchair/disabled patients escorted by staff using the wheelchair lift.
    - o Roll call is taken at the designated evacuation meeting area to assure all staff is accounted for.

**SAFE HANDLING OF ELECTRICAL EQUIPMENT (Also see QA 20 - Electrical Safety) ELECTRICAL HAZARDS**

Policies and procedures are documented in each facility's Environment of Care Manual. This documentation is maintained by the facility Safety Officer at Rancho Los Amigos Rehabilitation Center.

It is necessary for mobile clinic personnel working in laboratories to have knowledge of general electrical regulations and precautions. The presence of large numbers of electrical instruments, along with the presence of water, flammable liquids and corrosive chemicals, make laboratories a hazardous location in regard to electricity.

# LABORATORY
# SAFETY MANUAL

## GROUNDING REQUIREMENTS

Ground wires, preferably with a three-prong plug, are required on all equipment which has conductive surfaces, except those that are double insulated and have an Underwriters Laboratories (UL) approval. The ground wire is intended to carry small leakage currents as well as large fault currents resulting from shorts from hot conductors to the exposed chassis of the electrical device. All underground equipment problems should be reported to facility coordinators and the contracted maintenance service for correction. Electrical safety checks are extended to include post repairs/modifications.

## GENERAL PRECAUTIONS – ELECTRICITY

All Laboratory personnel should follow the following precautions:

- Do not use extension cords.
- Do not use equipment which is suspected of being electrically defective. If a tingle is felt when touching an electrical device, disconnect it immediately and report it to your Laboratory Manager or Mobile Clinic designee who MUST follow up on the problem.
- Do not attempt to make repairs on electrical equipment. Some instruments may retain high-voltage danger points even when they are switched off. Certain electrical components that retain voltage pose a significant hazard to the unqualified repairman.
- Make sure your hands are dry when operating electrical equipment. Moist hands can greatly increase electrical conductivity and your chances of becoming a part of the electrical circuit.
- Never allow electrical cords to contact sink or water baths.
- ALWAYS use flammable liquids and gases with caution around electrical equipment. Electrical sparks may ignite the flammable vapors.
- Disconnect the electrical source before touching a victim of electrocution. If this is impossible, a nonconductive device, such as a rope or wooden stick, can be used to remove the victim from the electrical contact point.
- Caution must be taken when attempting to rescue an electrocution victim. The rescuer must protect himself from being electrocuted, which can occur from touching a victim who is still in contact with an electrical source.

## EMERGENCY POWER

The Mobile Clinic is connected to a back-up battery and solar power cells. All essential refrigerators (preservation of specimens/reagents), freezers, and instrumentation are connected on a backup generator for emergency power circuits.

## EXPOSURE TO ULTRAVIOLET LIGHT

N/A

## ANTI-SIPHON DEVICES

N/A

# LABORATORY
# SAFETY MANUAL

## CONTROL OF HAZARDS FROM CHEMICAL TOXINS (Also see S 2 - Chemical Hygiene Plan)

Policies and procedures are documented for chemical toxin hazard control. These are contained in the Rancho Los Amigos Chemical Hygiene Plan. The Laboratory Manager is the chemical hygiene officer for the laboratory. Chemical safety is achieved by awareness of the chemical hazards and by keeping chemicals under control through a variety of engineering safeguards. Guidelines for control include: The Mobile Clinic focus more on safe blood and specimen handling and transporting.

## FUME HOODS

N/A

## GLOVES, GOGGLES, FACE SHIELDS

- If personnel are splashed or their clothes soaked by chemicals, then all affected clothing is to be removed as soon as possible, the affected skin washed copiously with water, and clothing replaced with disposable garments.

## FLAMMABLE STORAGE CABINETS/SAFETY CANS

N/A

## SPECIAL PROCEDURES FOR CARCINOGENS, REPRODUCTIVE TOXINS AND ACUTELY TOXIC SUBSTANCES:

N/A

## FIRE ALARM SYSTEM/FIRE FIGHTING EQUIPMENT

Fire-fighting equipment in the form of fire extinguishers are located in the mobile clinic. Fire extinguishers are examined monthly for proper charge and documented. Emergency evacuation routes are posted in the mobile clinic. Special carriers are available if the patient must be moved down using the automatic wheelchair lift.

## EMERGENCY EYE WASH

A system of eye washes exists in the mobile clinic.

- Full face eye washes are to be flushed/ activated weekly at a minimum to ensure workability.
- Documentation is to be done on all safety devices.
- There is documentation defining where each safety device is located in the mobile clinic.
- Personnel are to familiarize themselves with the location of the eyewash station in the mobile clinic.

## HAZARDOUS WASTE DISPOSAL AND CONTROL

A. Regulated Biohazardous and Sharps waste disposal must meet the provisions of California's Medical Waste Management Act. Under the Medical Waste Management Act, the Comprehensive Health Centers are rated a large quantity generator of regulated waste (2200 or more pounds per month). The disposal of this Biohazardous and Sharps waste is currently contracted by the County of Los Angeles to

***Stericycle Inc.***
***277 East 26th Street Vernon, California 90023***
***323-362-3000***

# LABORATORY
# SAFETY MANUAL

## SAFETY PROCEDURES

By contract, the above vendor is to meet all prevailing local, state and federal (EPA) regulations and is reviewed for compliance by Contracts and Grants, County of Los Angeles. Documentation of this is found in the Contracts and Grants Section, Department of Health Services, County of Los Angeles. Copies of the contract are maintained by the Procurement Officer of each facility and reviewed by the facility Safety Officer. The laboratory collection and disposal protocol of biomedical waste is documented in the facility Medical Waste Management Act Program contained as a sub-section of the facility Rancho Los amigos Infection Control Manual (and/or each facility specific infection control manual).

Distribution:

- The Mobile Clinic must put all sharp objects (i.e., needles, glass, broken glass, pipet tips) in red puncture-resistant sharps containers.
- Sharps containers should be only 3/4 filled and/or designated fill line before sealing.
- Sharps containers that do not self-seal must be taped shut to prevent spillage.
- Sealed sharps containers are to be put in large 5-gallon red lined biohazardous barrels.
- The 5-gallon barrels will be exchanged with empty containers by
- housekeeping on daily basis.
- If the containers are not exchanged daily, laboratory personnel must call housekeeping to exchange them.
- Place all other biohazardous material/infectious wastes, in red lined "biohazard" labeled containers that do not leak and have solid, tight-fitting covers. These will be emptied daily by housekeeping.

B. Other hazardous solid and liquid waste disposal is contracted out by the County of Los Angeles through a Board of Supervisors Contract that includes approximately ten vendors (it is variable each year) that must meet local, state and federal (EPA) regulations and is reviewed by Contracts and Grants, County of Los Angeles. The contracts are on file in each facility and documentation that the vendors have met the requirement. The procedure for disposal of hazardous solid and liquid waste is as follows:

- The hazardous material is collected by Mobile Clinic staff and will be disposed appropriately.
- The material is inventoried and stored in a secured area while waiting for pick up.
- The facility Safety Officer is contacted.
- Upon approval, the facility Safety Officer arranges for a pickup and completes proper documentation via the Uniform Hazardous Waste Manifest.
- Once the invoice is received, records are verified, and invoices submitted for payment to Rancho Los Amigos Materials Management.
- These manifests are then filed and compiled in order to compute State fees based on hazardous material pick up.
- Hazardous materials must be removed within 180 days of receipt of facility storage.

## PROTECTIVE CLOTHING AND EQUIPMENT

The mobile staff are provided with gloves, face shield (if needed), and safety needle when drawing blood specimen to prevent blood spills, splashing and exposure.

### 1. GLOVES

Use of gloves is defined in the Rancho Los Amigos Chemical Hygiene Plan. In addition: Only non-latex or powder free latex gloves are to be utilized due to latex allergy dangers. All personnel are to undergo an education program covering the areas of latex allergy prevention and control strategies.

- Gloves must ALWAYS be worn during specimen collection.
- Glove liners are available for individuals who desire them.
- Gloves MUST always be changed between patients.

- Gloves must be worn whenever handling ANY patient specimen.
- Hands must be cleaned with soap and water, or use other approved alcohol-based hand rub, immediately after gloves are removed.
- Gloves must be REMOVED when using door handles, telephones, clean areas, filing cabinets or any public access area.
- All personnel are to be instructed in the proper use and care of disposable gloves, including: The need for properly fitting gloves; The need to replace gloves immediately when tom or contaminated; The need to avoid washing or disinfecting gloves for reuse; The availability of hypoallergenic gloves, based on patient and healthcare provider history; The need for washing/decontamination of hands after glove removal.

**2. EYE/FACE PROTECTION**

Protection of the face and eyes is defined in the Rancho Los Amigos Hygiene Plan, however, for biohazardous purposes; eye/face protection includes coverage of face in form of a safety face shield.

- Eye protection should be worn when OPENING or CLOSING any laboratory specimen where there is a risk of splashing.
- If an area has a high risk of injury due to use of cryogenic, explosive, corrosive, or caustic materials it may be necessary to use both goggles and face shields to provide sufficient protection. An example is a glassware washing area that uses corrosive chemicals as the cleaning agent.

**3. ENGINEERED SHARPS INJURY PROTECTION DEVICES, NEEDLELESS SYSTEMS, ETC.**

- New protective devices shall be evaluated as they become available. New devices and protective equipment shall be reviewed in meetings with health care workers, Rancho Los Amigos Infection Committee Core Group, facility Safety Officers, and administrative representatives. Final approval of all purchases of these devices and protective equipment shall reside with the Rancho Los Amigos Infection Committee Core Group.
- Procedures shall be reviewed annually and modified whenever progress in implementing sharps prevention technology mandates revisions.
- All bloodborne pathogen exposure shall be recorded on the Sharps Injury Log, to include type and brand and/or product name of the device involved in the incident.
- Each facility in the network shall make reports of bloodborne pathogen exposure to the Rancho Los Amigos Infection Committee Core Group and facility risk manager. Reports of such injuries will be reviewed for consideration of the implementation of new engineering controls or the purchase of newly engineered personal protective devices and for facility quality improvement and risk management activities.
- If needleless systems are not used, needles with engineered sharps injury protection shall be used for withdrawal of body fluids, accessing a vein or artery, any other procedure involving the potential for an exposure incident. Plastic blood withdrawal tubes shall be used when feasible over glass products as an engineering control.

**A. GENERAL PRECAUTIONS TO PREVENT TRANSMISSION OF HIV, HEPATITIS VIRUSES, AND OTHER BLOODBORNE PATHOGENS.**

Since medical histories and physical examinations cannot reliably identify all patients infected with HIV or other blood-borne pathogens, blood and body fluid precautions are to be used for all patients. This approach, referred to a Standard Precautions, must also be used in the care of patients in the phlebotomy and urine collection areas.

- All health-care personnel must routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Non-latex or powder free latex gloves must be worn for touching blood and body fluids, mucous membranes, or nonintact skin of all patients, for handling items or surfaces soiled with blood or body fluids, and for performing venipuncture and other vascular access procedures. Gloves must be changed after contact with each patient. Masks and protective eye wear or face shields must be worn during procedures that are likely to generate droplets of blood or other body fluids in order to prevent exposure from mucous membranes of the mouth, nose, and eyes. Gowns or aprons must be worn during procedures that are likely to generate splashes of blood or other body fluids.
- Hands and other skin surfaces must be cleaned with soap and water or use sanitizing solution (approved alcohol-based hand rub), immediately and thoroughly if contaminated with blood or other body fluids. Hands must be cleaned with soap and water, or use other approved alcohol-based hand rub, immediately after gloves are removed.
- All health-care personnel must take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures. To prevent needle stick injuries, needles must not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After use, disposable syringes and needles, scalpel blades, and other sharp items must be placed in puncture-resistant containers for disposal. Engineered sharps injury protective devices or needleless systems shall be used whenever available, including the use of plastic tubes when feasible.
- Health-care personnel who have exudative lesions or weeping dermatitis must refrain from all direct patient care and from handling patient care equipment until the condition resolves. Mobile Clinic staff is to advise their Laboratory Manager/Mobile Clinic designee of such conditions at the beginning of the work shift.
- ALL specimens of blood and body fluids must be put in a well-constructed container with a secure lid to prevent leaking during transport. Care must be taken when collecting each specimen to avoid contaminating the outside of the container and the laboratory fom1s accompanying the specimen.
- Specimens collected outside the laboratory are to be submitted in two pouch bags; a sealed area for specimer and a slot for the requisition.
- Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles outlined under Standard Precautions MUST be followed.
- Laboratory work surfaces should be decontaminated with an appropriate and designated chemical gem1icide after a spill of blood or other body fluids and when work activities are completed.
- Contaminated materials used in laboratory tests should be decontaminated if reprocessed (i.e. glassware) or be placed in bags and disposed of in accordance with institutional policies for disposal of infective waste.
- Scientific equipment that has been contaminated with blood or other body fluids MUST be decontaminated and cleaned (according to the manufacturer's guidelines or in accordance with the Mobile Clinic Chemical Hygiene Plan) before being repaired or transported to the manufacturer.
- All persons must wash their hands after completing laboratory activities and must remove protective clothing before leaving the laboratory.

**B. VACCINES**

Hepatitis B vaccine is available free-of-charge to laboratory personnel expected to have direct contact with body fluids through the Employee Health Services. All personnel of Mobile Clinic staff are urged to take advantage of the opportunity to be immunized against Hepatitis B.

Those personnel who decline Hepatitis B vaccination must sign a declination fom1 but can in the future decide to have the vaccination.

Occupational safety regulations mandate than many types of health care facilities make seasonal influenza vaccine available to all personnel with occupational exposure and ensure that personnel who refuse the vaccine sign a statement declining vaccination.

The Los Angeles County Directory and Health Officer has ordered every licensed acute care hospital, skilled nursing facility, and intermediate care facility within the County of Angeles public health jurisdiction to implement a program under which healthcare personnel at each facility receive an annual influenza vaccination for the current season or wear a mask for the duration of the influenza season while in contact with patients or working in patient-care areas.

**C. HIV TESTING**

HIV immune-status testing is available anonymously and free-of-charge through Alternative Test Site Clinic or through contracted Industrial Accident physician offices. Personnel that have an occupational exposure to HIV are to follow the guidelines found in the Rancho Los Amigos Healthcare Network Infection Control Manual {and/or each facility specific infection control manual) and the California State law governing occupational exposure {January 1995).

**D. NEEDLE STICKS, CUTS, ETC.**

All on-the-job accidents MUST be reported to the Laboratory Manager/Mobile Clinic Manager promptly. He/she will then instruct personnel with the appropriate measures to take as defined in the ACN EC-01.002 (Bloodborne Pathogen Exposure Control Plan), OHS EHS' Bloodborne Pathogens Exposure Control Program. Mobile Clinic Healthcare Network Infection Control Manual (and/or each facility specific infection control manual). In case of emergency follow industrial accident, procedures established by the Department of Health and your facility Risk Manager.

**E. CLEANING AND DECONTAMINATING BLOOD SPILLS OR OTHER BODY FLUIDS**

10% bleach, 70% alcohol, facility approved disinfectant, i.e., phenol or approved disinfectant wipes, are approved for use in the Mobile Clinic and are active against HIV, hepatitis and are also tuberculocidal when used at recommended dilutions. They can be used to decontaminate spills of blood and other body fluids. Contact time with various disinfectants may vary. Consult recommended contact times for each disinfectant.

**F. LAUNDRY**

Hygienic storage and processing of clean and soiled laundry are required.

- Soiled laboratory coats should be handled as little as possible and with minimum agitation to prevent gross contamination of the air and of persons handling the items.
- All soiled laundry should be bagged at the location where it was used.
- All soiled coats are placed and transported in plastic bags designated "contaminated linen" that prevents leakage.

# LABORATORY
# SAFETY MANUAL

## G. LABELING

Biohazard warning labels are affixed to containers of regulated waste, refrigerators and freezers containing blood and OPIM; and other containers used to store, transport or ship blood or OPIM. All biohazardous regulated or medical waste and sharps waste is placed into containers with the international biohazard symbol and the word "BIOHAZARD". Labels are fluorescent orange or orange-red or predominately so, with lettering and symbols in a contrasting color.


## H. INFECTIVE WASTE

Identifying wastes for which special precautions are defined in the Rancho Los Amigos Chemical Hygiene Plan and the Rancho Los Amigos Healthcare Network Infection Control Manual (and/or each facility specific infection control manual).

## FOLLOW-UP PROCEDURES AFTER POSSIBLE AND KNOWN SKIN EXPOSURE TO HUMAN IMMUNODEFICIENCY VIRUS (HIV), HEPATITIS A, B, C OR SYPHILIS.

A program for follow-up procedures after possible and known percutaneous, mucous membrane or abraded skin exposure to HIV, Hepatitis B, Hepatitis C or Syphilis is contained in the Rancho Los Amigos Healthcare Network Infection Control Manual (and/or each facility specific infection control manual). The following areas are elucidated:

- The California State Law governing Occupation Exposure is followed with HIV testing.
- HAV, HBV, HCV and Syphilis testing of the source patient after consent is obtained.
- Appropriate clinical and serologic evaluation of the health-care worker as documented in the California Health and Safety Code, Section 211.5.
- Follow-up procedures including consideration of appropriate prophylaxis for personnel acutely exposed to HIV, HAV, HBV, HCV or Syphilis based upon medical indications, the serologic status and the informed consent of the health-care worker.
- All incidents must be handled through Rancho Los Amigos Employee Health guidelines.

## EXPOSURE CONTROL PLAN RISK CATEGORIES - JOB CLASSIFICATION

Exposure determination is based upon an employee's reasonable potential for exposure to blood or any other infectious materials that they may contact during their job duties. Exposure determination is made without regard to the use of personal protective equipment. OSHA requires exposure evaluations based on the potential for job-related tasks leading to exposure.

# LABORATORY
# SAFETY MANUAL

Per ACN - Bloodborne Pathogen Exposure Control Plan - EC-01.002, personnel are evaluated by risk of exposure into risk categories by job classifications:

- Category I - (Routine contact with blood and body fluids)
- Category II - (Occasional or rare contact with blood or body fluids)
- Category Ill – (Requires no contact with blood or body fluids)
-

Category I
Laboratory Heath Care Workers
PERSONAL HYGIENE POLICIES USED IN ALL TECHNICAL WORK AREAS
A. PERSONAL HYGIENE
The damaging effects of toxic chemicals and infections are dependent on the routes of entry into the body. They are:

- Inhalation
- Ingestion
- Injection
- Eye/Skin contact

B. PERSONAL HYGIENE PRACTICES
By proper protection procedures elimination or significant reduction of the chemical's ability to do harm can be attained. Personal hygiene practices include:

- Wash the affected area immediately with water if skin contact is made with any chemical, regardless of corrosivity.
- Avoid inhalation of all chemicals. Do not "sniff' chemicals to identify them. READ THE LABEL.
- Do not eat, drink, manipulate contact lenses, apply cosmetics or lip balm, store food, or smoke in designated laboratory testing areas. Food, drink, and especially tobacco absorb chemical vapors and gases from the air.
- Do not touch or taste chemicals.
- All laboratories, chemical storerooms, and Comprehensive Health Center facilities are designated as "No Smoking" areas.
-

LATEX ALLERGY PRECAUTIONS PROGRAM

- The laboratory recognizes that health care workers and patients are at risk of developing latex allergy because workers use latex gloves or other latex products frequently and patients may be exposed to latex products.
- Only non-latex or powder free latex gloves are to be utilized in the laboratory.
- Non-latex tourniquets are available for patients with latex allergy or patients requesting them.
- Use non-latex gloves for activities that are not likely to involve contact with infectious materials.
- Use appropriate work practices to reduce the chance of reaction to latex, i.e. do not use oil-based hand creams when wearing latex gloves, washing
- hands after removing latex gloves, clean areas that may contain latex dust.
- The laboratory provides Latex Allergy Prevention and Control Strategies
- training to personnel.
- When personnel are diagnosed with a new latex allergy due to exposure to use of latex products, there will be an evaluation of the current latex prevention and control program.

# LABORATORY
# SAFETY MANUAL

## EMERGENCY PREPAREDNESS

- Emergency preparedness policies and responsibilities are posted on safety bulletin boards in each of the Mobile Clinic along with a Fire/Disaster Evacuation Roster. An example of a facility emergency is a fire in which the department requires evacuation. Other facility emergency events may include utility failures, such as loss of power, and bomb threats.
- Evacuation routes are posted on the bulletin boards.
- Fire/emergency preparedness policies are established by the Safety Committee of each facility and are documented in the facility Environment of Care Policy and Procedure Manual.
- System-wide Emergency preparedness policies and procedures are established by the Safety Committee of each facility and are documented in the facility Environment of Care Policy and Procedure Manual. System-wide Emergency preparedness policies are coordinated through County DHS Disaster Services which establishes plans, procedures and training programs for Department-wide operations and recovery services. Examples of system wide events are earthquakes and civil disorders.
- Emergency preparedness is expressed and implemented via the Disaster Coordinator for each facility. It is based on the Hospital Emergency Incident Command System (HEICS) which has been adopted throughout Los Angeles County. HEICS is an emergency management system which employs a management structure, responsibilities, reporting channels, and common nomenclature to unify hospitals with emergency responders.
- Handicapped, non-ambulatory patients/staff are assisted by facility personnel using the motorized wheel-chair lift in exiting the mobile clinic during a fire or disaster using evacuation chairs or gurneys when appropriate. The equipment is found in the clinic areas.

## BIOSAFETY

The Mobile Clinic do not perform microbiological activities other than wet mounts for the PAP Smears.

## EXCESSIVE NOISE LEVELS

Protection against the effects of noise exposure shall be provided to personnel when sound levels equal or exceed an 8-hour time weighted average sound level of 85 decibels. This protection includes the use of administrative or engineering controls as necessary. The Mobile Clinic do not exceed an 8-hour time weighted average sound level of 85 decibels. If there is a significant increase in noise levels, i.e., due to the acquisition of additional laboratory devices, further noise monitoring will be performed, and the noise level documented. OSHA Standard 29 CFR, part number 1910 can be referenced in regard to Occupational noise exposure.

## MOBILE CLINIC PERSONNEL ACCESS TO SAFETY WORK PROGRAMS

Personnel have access to all of the following documents:

- The contents of current Safety Data Sheets/Material Safety Data Sheets and other references that list the details of hazards and the precautions for safe handling and storage.
- The written CHCLS Chemical Hygiene Plan of the laboratory.
- Code of Federal Regulations. Title 29, Part 1910.1450 and its appendices.
- California Code of Regulations, Title 8 (8 CCR), section 5194 - Hazard Communication, Adopted May 6, 2013
- California Code of Regulations, Title 8 (8 CCR), section 5191 - Hazard Chemicals in the Laboratory
- The written CHCLS Laboratory Safety Manual and facility Safety Manual.
- The written CHCLS Hazard Communication Program
- The written LAC+USC Healthcare Network Infection Control Program (and/or each facility specific infection control manual).

# LABORATORY
# SAFETY MANUAL

- The written facility Environment of Care Manual.
- Facility Injury and Illness Prevention Program (IIPP)
- DOCUMENTED REVIEW OF THE CHCLS SAFETY PROGRAM
- The CHCLS Safety Program is reviewed and updated annually by the CHCLS Lab Managers for evaluation and approval by the Laboratory Director. In addition, the laboratory areas are inspected quarterly for any deficiencies, either by the facility Safety Committee and/or the Laboratory Manager.

**REFERENCES:**


1. LAC+USC Infection Control Plan - Bloodborne Pathogen Exposure Control Plan, Policy IC3

2. Los Angeles County OHS Employee Health Services (EHS) Bloodborne Pathogen Exposure Control Program, Policy 925.2.

3. LAC+USC Healthcare Network Infection Control Manual (and/or each facility specific infection control manual)

4. Ambulatory Care Network Bloodborne Pathogen Exposure control Plan (EC-01.002).

5. CDC - BMBL, Section 111, Laboratory Biosafety Level Criteria, updated 12/2/2000.

6. Federal Register, Occupational Exposure to Hazardous Chemicals in Laboratories, 29 CFR 1910 Subpart 2, section 1910.1450.

7. Federal Register, Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030.

8. California Code of Regulations, Title 8 (8 CCR), section 5191 - Hazard Chemicals in the Laboratory

9. California Code of Regulations, Title 8 (8 CCR), section 5193- Bloodborne Pathogens

10. California Code of Regulations, Title 8 (8 CCR), section 5194- Hazard Communication, Adopted May 6, 2013

11. Cal/OSHA Injury and Illness Prevention Program (8 CCR 3203).

12. Federal Register, Air contaminants - Permissible Exposure Limits, 29 CFR 1910.1000.

13. EPA Hazard Classification List

14. California Health and Welfare Agency, Safe Drinking Water and Toxic Enforcement Act of 1986, Chemicals Know to the State to Cause Cancer or Reproductive Toxicity.

15. OSHA Regulation, Hazard Communication, 20 CFR 1910.1200.

16. Bioterrorism Syndromes, California State and Local Health Department Bioterrorism Surveillance and Epidemiology Working Group, 2001.

17. United Stated Environmental Protection Agency, Reducing Mercury Use in Health Care, www.epa.gov/glnpo.bnsdocs/merchealth, January 2005.

18. U.S. Department of Labor, Occupational Safety and Health Administration, Occupational Noise Exposure – 1910.95.

19. College of American Pathologists, Laboratory Checklists, 325 Waukegan Road, Northfield, IL 60093-2750.

20. Conducting Drills and Exercises, A Guide for Hospitals, County of Los Angeles Department of Health Services, Emergency Medical Services Agency, Disaster Services

21. Exposure Control Plan, University of California, Berkeley

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

**LOS ANGELES COUNTY – DEPARTMENT OF HEALTH SERVICES**
**RANCHO LOS AMIGOS – MOBILE CLINIC**

# LABORATORY POLICY AND PROCEDURE

## TABLE OF CONTENT

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.3.5 |
| **SUBJECT:** REPORTING POCT RESULTS AND POLICY ON CRITICAL VALUES | **PAGE:** 1 OF 3 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN.<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalatIII | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE
To establish an adequate system for reporting Point of Care Test results.

## PRINCIPLE AND CLINICAL SIGNIFICANCE
While POCT results are often initially reported orally or in temporary written form (e.g., instrument printout or log sheet), these results must be appropriately and promptly recorded in the permanent medical record.

## SAFETY PRECAUTIONS (IF APPLICABLE)
N/A

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS
N/A

## REAGENT AND/OR MEDIA, MATERIALS
Instrument printout or screen result.

## EQUIPMENT CALIBRATION AND MAINTENANCE
N/A

## PROCEDURES
A. Get an instrument printout for non-interface meter or dock meter for interface meter.
B. Enter the result in the computer under POC testing result section for the non-interface meter, make sure, you use the correct FIN number.
C. For the interface POCT instrument, dock the meter then check the computer for your result.
D. Policy on Critical Values:
    1. Notify the physician or other clinical personnel responsible for the patient care of results of all critical results.

2. Duplicate POCT per physician's request.
3. Send specimen to Central Laboratory for verification of test result, per physician's request.

| CRITICAL VALUES | | | | |
|---|---|---|---|---|
| **TEST** | **PATIENT AGE** | **UNIT** | **LOW** | **HIGH** |
| **GLUCOSE** | 0 – 1 month | mg/dl | <41 | >199 |
| | >1 month to 16 years | mg/dl | <41 | >249 |
| | >16 years to adult | mg/dl | <41 | >449 |
| **HEMOGLOBIN** | <1 month | g/dl | <6.6 | >21.9 |
| | 1 month to 12 years | g/dl | <6.6 | >19.9 |
| | >12 years to adult | g/dl | <6.6 | >19.9 |

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

Mobile Clinic MD on duty will be notified of the critical result in real-time as an immediate response. Enter appropriate comments when critical values are obtained (person notified, test result and comment or course of action) in the computer.

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Friedman BA, Mitchell W. Integrating information from decentralized laboratory testing sites. The creation of a value-added network> am J Pathol. 1993;99; 537-542.
2. NCCLS. Point of care connectivity; approved standard POCT1-A. Wayne, PA: NCCLS, 2002.
3. CAP POCT Checklist Result Reporting p 14-16, June 15, 2009 revision.
4. JCAHO PC 16.40
5. ORCHID Training for Ambulatory nurse, 12-5-2014

| SUBJECT: REPORTING POCT RESULTS AND POLICY ON CRITICAL VALUES | | PAGE 3 OF 3<br>SOP #: POC-1.3.5 |
|---|---|---|

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.4a.4 |
| **SUBJECT:** COMPETENCY TESTING AND TRAINING | **PAGE:** 1 OF 3 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalatII | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To evaluate the competency of all POC testing personnel and ensure that employees maintain their competency to perform test procedures and report test results accurately as mandated by the regulatory agencies: (CAP), JCAHO, and CLIA '88.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

The Pathology Department developed a mechanism to evaluate the effectiveness of its policies and procedures for assuring that Point of Care operators are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities.

A. Point of Care operators are evaluated initially and followed-up every six months for non-waived testing for the first year and annually thereafter for competence in performing POC laboratory tests. For waived testing after an operator has performed testing for one-year competency must be reassessed annually.
B. The Pathology POC supervisor/ designee, or nursing supervisor/designee observes the employee performing the POC procedure.
C. The employee must correctly demonstrate:
   Procedure for patient and control testing.
   Proper documentation of patient and control test results.

## SAFETY PRECAUTIONS

See POC-1.8

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIAL

A. Worksheets
B. Reagents
C. Test Instrument
D. Racks
E. Procedure manual

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURE:

A POC supervisor, nursing supervisor or designee will perform competency assessment using the following applicable methods:

A. Direct Observation of POCT Operator:
   1. Explaining procedure, including any changes.
   2. Performing procedure setup.
   3. Performing quality control procedure.
   4. Performing test procedure
   5. Reading control and patient test results.
   6. Recording control and patient test results.

B. Monitoring the recording and reporting of results
   1. Random check of patient test results on form
   2. Check instrument's memory

C. Review of intermediate results on worksheets, QC, PT, and PM
   1. Review of records

D. Direct observation of instrument maintenance
   1. Performance of actual maintenance of the instruments.

E. Assessment of test performed of previously analyzed samples.
   1. Review of forms or instruments memory.

F. Evaluation of problem-solving skills.
   1. Direct questioning of the operators regarding different scenarios.

G. In-service or re-training
   1. To be conducted only by the POCT staff.

## COMPETENCY TESTING RESULTS:

A. When employees successfully pass the competency test, the employee should continue to correctly perform the laboratory procedure. When the operator is observed performing the patient and/or quality control tests improperly, and/or failing to comply with established guidelines for documentation:
   1. When the competency failure is due to failure to document properly, the employee is required to review the written procedure and then be reassessed.
   2. If the competency assessment failure is due to a technical or skill deficiency, retraining is required.

B. The operator is retrained and then reassessed for competency in the procedure. Immediately after competency testing observation, the Point of Care observer will offer helpful suggestions to the POCT operator concerning performance of the procedure.

**REFERENCES:**

1. Medical Laboratory Observer, 1993.
2. Department of Health Services, Health Care Financing Administration. Clinical Laboratory Improvement Amendments of 1988; Final Rule. FEDERAL REGISTER. 1992(Feb 28): 7166 [42 CRF 493.1218(f)(2)].
3. Encore QA Manual, 1994.
4. JCAHO PC.16.30
5. College of American Pathologists Checklist, 2013

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.4b.3 |
| **SUBJECT:** POINT OF CARE ASSESSMENT FORM | **PAGE:** 1 OF 4 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN.<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR A Galat III | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

Rancho Los Amigos - Mobile Clinic Units are monitored on a regular basis to assess compliance. Actions taken are checked for effectiveness through continued monitoring.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

N/A

## SAFETY PRECAUTIONS

See POC 1.8

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIALS

N/A

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

A. Interview

1. A representative sample of point-of-care staff are interviewed regarding patient identification, testing, knowledge of procedure, and documentation of POCT results. Reagents are checked for proper storage and noting open dates. The interview process serves as an opportunity to assess and re-educate staff in other areas as well.

B. Observation

1. POCT operators are observed while they are performing quality control tests, proficiency tests, and occasionally patient testing.

C. Focused Review
1. POCT supervisor reviews report from staff assessment.
2. POCT supervisor reviews computer reports of QC testing and documentation of action taken for QC failure.
3. The POCT supervisor also reviews the reports of documentation of action taken for critical value.
4. Documentation of cleaning meters is reviewed.

D. Action
1. The POCT supervisor communicates with nurse managers of the various units. It is the responsibility of the nurse managers to enforce POCT policies in their respective areas. The POCT supervisor reports successes and deficiencies to the Pathology IOP Committee where further recommendations for improvements are made. The lab POCT staff works with individual nurses in initial training and one on one follow up training as needed.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

A. The POCT staff records the assessment finding on a "Quarterly Point of Care Assessment" form.

B. This form provides the assessment guidelines, such as, but is not limited to the following areas:
1. Use of point-of-care chart form
2. Dates opened on reagents bottles
3. Knowledge of critical values
4. Documentation of action for critical values
5. Documentation of QC failures
6. Documentation of meter cleaning

C. The results from "Quarterly Point of Care Assessment" form is given to the POCT supervisor monthly to include the data in the POCT monthly report.

D. This process is repeated using the same form until three months of data is recorded on a single record.

E. Result Reporting includes interpretation of results, recognition of results that exceed critical values and the guidelines for entering results in the laboratory's information system. As appropriate, reporting of results is incorporated into the procedure and clearly defined.

The record retention procedures are listed either as separate procedures or as part of a procedure. Reporting of imminently life-threatening (critical) results is outlined as separate procedures.

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. College of American Pathologists, POCT Checklist, Northfield, Illinois, October 2006 revision
2. Annual Review
3. POCF-29 (10-25-0

**RANCHO LOS AMIGOS – MOBILE CLINIC**

| SUBJECT: POINT OF CARE ASSESSMENT FORM | | PAGE 4 OF 4 |
|---|---|---|
| | | SOP#: POC-1.4b.3 |

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.5.6 |
| **SUBJECT: PROFICIENCY TESTING** | **PAGE:** 1 OF 5 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

Participation in external PT surveys provides an ongoing mechanism for monitoring performance in POCT using unknown samples which mimic patient samples. PT surveys also provide valuable data which permits inter laboratory comparison to identify any significant bias or other unusual behavior for a particular system. The Point of Care Testing Services subscribes to the College of American Pathologists Proficiency Testing Survey for all Point of Care Tests. The results of CLIA monitored analytes are sent to the State of California, and Joint Commission.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

N/A

## SAFETY PRECAUTIONS

See POC -1.8

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

A. Follow the CAP Survey instruction.
B. Each Proficiency Testing Survey is delivered to the Administrative Coordinator or Compliance Officer, who distributes it to the Point of Care Testing section.
C. Forms are prepared for recording the results by each Point of Care Testing site.
D. Distribution sites are chosen based on the previous sites and operators.
E. Surveys are spread among as many testing sites and operators as possible.
F. Point of Care Testing sites perform the test in the same manner as patient specimen.
G. Proficiency testing samples are integrated into the routine workload using POCT operator's routine methods and technique.

## REAGENT AND/OR MEDIA, MATERIALS

A. COLLEGE OF AMERICAN PATHOLOGISTS PROFICIENCY TEST

| | | |
|---|---|---|
| 1. GLUCOSE | WBG | SERIES A, B, C |
| 2. HEMOGLOBIN | HE | SERIES A, B, C |
| 3. URINALYSIS | CM | SERIES A, B |
| 4. PREGNANCY TEST | CM | SERIES A, B |

B. CAP worksheet
C. CAP unknown reagents
D. Applicable instruments
E. Gloves

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

A. Laboratory POC personnel order test in outreach and take the samples to the various POC testing sites.
B. MLK OC coordinator observes the POC operator performing the proficiency testing.
C. POC operator must follow the CAP Survey instructions.
D. Perform the analysis of the specimens in the same manner as regular patient samples.
E. After the tests are run, results are posted in computer and printed. The POC personnel sign the CAP attestation form.
F. The staff is prohibited from:
   1. Referring proficiency testing specimens to any reference laboratory,
   2. Interlaboratory communication about proficiency testing sample and/or comparison of any results.
G. Violation of the above will result to disciplinary action.
H. Tests for which the CAP does not require proficiency testing or proficiency testing on multiple instruments must be evaluated by an alternate method at least semi-annually.
I. Appropriate alternative performance may include:
   1. split sample analysis with reference or other laboratories,
   2. split samples with established in-house method,
   3. assayed material,
   4. use CAP sample as secondary instruments after the primary PT event due date has elapsed.
   5. clinical validation chart review, or
   6. other suitable and documented means.
J. When CAP evaluation results are returned, results are examined and scrutinized for any "unacceptable" test results. Corrective action documentation must include the specific reasons for the "unacceptable" results and steps taken to reduce the likelihood of recurrence.

K. If no problems are observed, no further action is required. Document review of proficiency testing results and forward to the Laboratory Director for review and signature.
L. If test results do not have comparative peer review, POC must examine results and provide documentation that the results submitted are reviewed and found acceptable either by statistical data, quality control records, or correlation studies on instrument used. Submit to Laboratory Director for review after supervisory review is complete.
M. Supervisor review must be done within one month after receiving the evaluation. The medical director/ or designee must review all documentation as soon as possible thereafter.
N. If corrective action is needed because an unacceptable result was submitted, the evaluation is given to the Point of Care Testing supervisor to investigate and write the necessary response. The investigation involves reviewing the reported unacceptable result and supporting data and discussing the situation with the actual nurse(s) who did the test. Once the investigation and remedial corrective action is complete, a CAP Corrective Action Report is written and signed by the Point of Care Testing supervisor. It is forwarded to the Point of Care Testing Section Head for review and signature. Next it goes to the laboratory's Administrative Coordinator or Compliance Officer for review. Finally, it goes to the Laboratory Director for review and signature. If the Section Head or Laboratory Director needs additional information, the report is returned to the Point of Care Testing supervisor and the process repeats.
O. If a CAP survey exception report is required by the CAP Proficiency Testing Services, it follows the same process with the final report being sent to the College of American Pathologists. After the Laboratory Director or designee has signed the evaluation and any accompanying documents, it is returned to the Laboratory Administrative Coordinator or Compliance Officer for filing and distribution. The original is filed in the Laboratory Administrative Coordinator's office and copy is given to the Point of Care Testing Supervisor for review, further distribution, and filing.
P. Proficiency testing results, including corrective action, are stored in the laboratory for two years.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

A. CAP results form filled out by transcribing the CAP result from the POCT result form.
B. The attestation form must be signed by all testing personnel.
C. Enter results in the CAP website and double check the entries.
D. The POCT supervisor or designee must approve the results that have been submitted.
E. The original CAP attestation form must be signed by the Lab Director or designee.

**Note**

To prevent transcription errors in reporting proficiency testing, the supervisor of POCT or designee will double check and compare the written results to the actual raw data before submission.

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Department of Health Services, Health Care Financing Administration. Clinical Laboratory Improvement Amendments of 1988; Final Rule. FEDERAL REGISTER. 1992(Feb. 28): 7166 [42 CRF 493.1218(f)(2)].

2. College of American Pathologists, Commission on Laboratory Accreditation. STANDARDS ON LABORATORY ACCREDITATION, Standard III. Northfield, IL: CAP, 2003.

3. JCAHO PC.16.50

## REVISIONS

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## Biennial Review

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.6.3 |
| **SUBJECT: DETECTING CLERICAL AND ANALYTICAL ERRORS** | **PAGE:** 1 OF 3 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/20/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To employ review techniques designed to detect and correct significant clerical and analytical errors and unusual or unexpected test results in quality control and patients testing.

To correct departure from acceptable standards and to document steps taken to prevent and resolve problems with clerical errors

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Clerical errors may be detected by a method known as data validation, in which data is checked and accepted or rejected based on a set of pre-established criteria. This involves a critical review of a body of data in order to identify spurious values or outlying observations.

## SAFETY PRECAUTIONS

N/A

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIALS

N/A

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURE

A. Process control is checked by performing quality control on samples with known values.
B. Out of limit controls are rejected and corrective actions are taken as follows:
   1. Document that control results are out of range and corrective action taken.
      a. Repeat testing of controls prior to testing patient samples.
      b. Controls must be within acceptable range before testing patient samples and releasing patient results.
      c. If controls are still out of range after repeat testing, the following steps should be taken.

2. Document that equipment or reagents are not working correctly, and corrective action taken.
   a. Replace reagents or equipment.
   b. Obtain in-house assistance.
   c. Obtain Manufacturer assistance.

C. Isolating spurious values since such values are not automatically rejected.
   1. Testing personnel must check extreme values for possible transcription errors.
      For manual tests transcription errors must be corrected immediately to avoid error in reporting.
      Testing personnel must report unusual or unexpected test results to charge nurse and physician.
   2. The supervisor (charge Nurse) on point of care testing units must be consulted by testing personnel for detailed evaluation of test results.
      a. The extreme value should be evaluated by supervisory personnel and patient's clinical condition evaluated by treating physician.
      b. When extreme values (unusual or unexpected test results) are obtained and verified, the point of care testing sites should send a test sample to the clinical laboratory for verification. This serves as a check of point of care testing equipment, procedure and technique, against equipment used in the clinical laboratory.

D. Analytical errors caused by faulty instruments will result in removal and replacement of the Point of Care equipment.

E. Records of values that are judged to be invalid or are otherwise doubtful will be retained. These records become a useful source of information for judging data (test information) quality.

F. Quality Control results are reviewed at regular intervals by the Laboratory Point of Care control coordinator.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

The Laboratory Point of Care Quality Control Coordinator based on observed results makes recommendations.

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES:

1. Ratcliff, Thomas A. the Laboratory Quality Assurance System, Van Nostrand Reinhold, New York, 1995.

2. JCAHO PC.16.50

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.7.2 |
| **SUBJECT: SPECIMEN COLLECTION. IDENTIFICATION AND LATEX ALLERGY** | **PAGE:** 1 OF 4 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

All samples collected for Point of Care Testing must be labeled promptly upon collection, OR, to ensure identity of the specimen, the individual performing the test must remain with the sample at the testing site until the test is complete.

All nurses performing Point-of-Care Testing must ask the patient if they have allergies to latex or any rubber products.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Point of Care patient's samples must be identified using at least two unique identifiers (name, MRN number, and/or birthdate).
Latex allergy of Point of care patient must be assess before collecting blood sample.

## SAFETY PRECAUTIONS

The laboratory recognizes that patients, healthcare workers, and staff are at risk for developing latex allergy due to latex gloves:

A. If latex gloves or any latex materials are being used during Point-of-Care Testing on a patient, the nursing staff needs to check for latex allergy to ensure patient safety.
B. If a patient has a latex allergy, non-latex or powder-free gloves are to be used, as well as latex-free tourniquets.
C. When wearing latex gloves, do not use oil-based hand creams or lotions (which can cause glove deterioration) unless they have been shown to reduce latex-related problems and maintain glove barrier protection.

D. Learn to recognize the symptoms of latex allergy: skin rashes; hives; flushing; itching: nasal, eye, or sinus symptoms; asthma; and shock.
E. If you develop symptoms of latex allergy, avoid direct contact with latex gloves and products, report to Employee Health or see a physician experienced in treating latex allergy.
F. The laboratory provides Latex Allergy Prevention and Control Strategies training to employees.
G. When an employee is diagnosed with latex allergy, there will be re-evaluation of the current latex prevention and control program.

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIALS

N/A

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURE

In order to minimize transcription errors, samples at Point of Care testing samples are drawn and measured immediately without the sample-specific identification step. (Example: fingerstick glucose and fingerstick hemoglobin.) The minimal specimen amounts used for the majority of these tests and the direct introduction of samples to testing cuvettes or test strip, no sample identification is required. However, patient must be identified using the standard 2-patient identifiers.

A. Specimen collection using single use testing device for finger or heel stick.
   1. Testing personnel will wash hands and put on a new pair of gloves.
   2. Identify patient by the standard two Patient identifiers utilized in this facility.
   3. Once correctly identified, will explain to the patient what they will be doing to draw sample.
   4. Sterilize the patient's finger or heel using 70% alcohol preps wiping in a circular motion at the site and allow to air dray for a few seconds.
      Using a single use Lancets, personnel will puncture the site to draw a blood sample. The first drop will be wiped away with sterile gauze and then staff will allow site to be gently milked to draw a new drop of blood and that drop will be collected in a microcuvette for hemoglobin testing or on a test strip for Glucose testing.
   5. The Lancet will be discarded in the proper Biohazards Sharps Container.
   6. Gauze applied and taped to patient puncture site or an adhesive bandage.
   7. Once completed, gloves will be removed and properly discarded, and personnel will wash hands to prepare for next patient.

B. The standard specimen identification process should be followed in cases when:
   1. The collection container is large enough to accommodate a label (Urinalysis and Urine Pregnancy)
   2. The specimen does not remain with the testing personnel.
   3. Testing is not performed soon after the specimen is collected.

C. While some venipuncture samples are acceptable, these samples for POCT whole blood glucose and hemoglobin are collected by puncture of heel or finger and applied to the test strip immediately, in order to minimize unnecessarily large blood draw volumes
   1. Blood Glucose
      Sodium, lithium, and ammonium heparin are the recommended anticoagulants
   2. Hemocue Hemoglobin
      Capillary blood samples may be taken from any site, usually the finger or heel.
      Venous or arterial blood may also be used. With venous blood, use EDTA, heparin or fluoride as anticoagulants, preferably in solid form to avoid dilutional effect. Samples of blood collected with the recommended anticoagulants must be used within 24 hours.
      All samples must be allowed to come to room temperature before use.
      Mix the venous samples at least 10 minutes prior to use.
   3. Urine Dipstick or Pregnancy Test:
      First morning clean voided urine sample is preferred, but a random specimen, whether it is clean voided, non- clean voided or catheterized is acceptable.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

N/A

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Nova StatStrip® Glucose Meter Instructions for Use Manual
   Printed in the U.S.A. Copyright 2011, Nova Biomedical Corporation, Waltham, MA 02454-9141

2. HemoCue, Inc., Technical Specifications, Sample Material, p. 60 40 Empire Drive
   Lake Forest, CA 92630 800-323-1674

3. MLK -OC Chemical Hygiene Plan, Revision 2008, pp 11-12

4. College of American Pathologists Checklist Standards Gen.40100, Revision 10/31/2006

5. MLK -OC Chemical Hygiene Plan, Rev 2008, pp 11-12

6. Preventing Allergic to Natural Rubber Latex in the Workplace NIOSH Publication No.97-135, June 1997

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1.8.1 |
| **SUBJECT: SAFETY AND INFECTION CONTROL GUIDELINES** | **PAGE:** 1 OF 4 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To prevent accidental injury and transmission of infectious diseases to the POCT staff and patients alike, the following guidelines were established while performing the following tests:

Urine Pregnancy Test (Siemens Clinitek Status)
Hemoglobin (Hemocue Hb 201 DM)
Glucose (Nova StatStrip)
Urinalysis (Siemens Clinitek Status)

## PRINCIPLE AND CLINICAL SIGNIFICANCE

N/A

## SAFETY PRECAUTIONS (IF APPLICABLE)

N/A

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIALS

N/A

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

A. A thorough routine hand washing is done according to hospital policy, (15 seconds).
B. Standard and Universal Precautions are practiced with all patients. Caution is used when handling specimens.

1. Hands are washed before glove barriers are put on for all personnel who perform point of care testing to protect patient and the employee.
2. Remove gloves, wash hands and replace with a new pair of gloves between each patient tested.
3. Proper glove hygiene is to be practiced at all times. Remove and replace when the glove is NOT intact, when you as testing personnel have broken skin, when performing skin puncture procedure, when you are in training, and especially when you have completed testing on one patient and preparing to test a new patient, you change to a new pair of gloves after removing them and washing your hands to put on a new pair.

C. Mouth pipetting is not done. Automatic devices are used for pipetting when applicable.

D. Eating, drinking, smoking, application of cosmetics and manipulation of contact lenses in testing area is prohibited.

E. Employees receive ongoing in-service program on infection control given by either the Supervisor or the Infection Control Nurse.

F. Recapping, purposeful bending, breaking, removal from disposable syringes, or other manipulation of needles is prohibited.

G. Personal protective equipment (PPE) (gloves, gowns, mask) is available and shall be used, when needed.

H. To allow NO chance of contamination between patients:
1. Clean meters before and after QC
2. Clean meters before and after each patient testing
3. Clean meters when blood or dirt is visible
4. Clean meters when an error occurs as displayed on the meter screen

I. Waste Disposal
1. All waste is disposed of in compliance with the institutional waste disposal policy.
2. Urine specimens may be poured into a designated sink drain. (Always avoid splashing.) Sinks should be flushed with running water.
   Decontamination should be done using hospital approved disinfectant at the end of each shift.

J. Occupational Health
Exposure to blood or body fluids is reported to the supervisor and the Occupational Health Office immediately for follow-up according to the Bloodborne Exposure Plan.

K. Processing of Items
1. Disposable items are not reused.
2. Refer to individual procedure for cleaning the instrument's exterior.
   For non-disposable equipment (instrument case, carts) are cleaned thoroughly at least monthly or when contaminated using appropriate personal protection equipment (PPE) as follows:
   a. Using germicidal wipes or refer to individual equipment
   b. Thoroughly wipe instrument/equipment being careful not to wet areas sensitive to moisture. Should areas sensitive to moisture become contaminated, notify POC personnel or assistance.
   c. Allow to air dry.

3. All testing work surfaces are wiped daily or when soiled with hospital disinfectant. Any accidental leaks or spills of specimens are cleaned up immediately wearing appropriate PPE.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

N/A

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. College of American Pathologists Checklist POC.09172, Rev. 06/15/09

2. MLK-OC Pathology Infection Control Policy AD 9-02

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-2.8.2 |
| **SUBJECT: NOVA STATSTRIP® GLUCOSE METER** | **PAGE:** 1 OF 7 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR Abalat II | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To provide blood glucose level in a timely manner while performing Street Medicine out in the field.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Glucose (Glu) is measured amperometrically, using an enzyme-based test strip.

## SAFETY PRECAUTIONS

See POC-1.8

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

A. Whole Blood: Capillary, Arterial, and Venous.

B. Handling Conditions:

1. Staff must use standard precautions when collecting and handling all specimens. (Refer to POC-1.7).
2. When not analyzing from a lancing device, whole blood should be analyzed within 30 minutes of collection. Storing samples on ice is not recommended.
3. Sodium, lithium, and ammonium heparin are the recommended anticoagulants when sampling with syringes or vacutainer tubes.
4. Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. [Examples include, but are not limited to, severe hypotension, shock, hyperosmolar hyperglycemia (with or without ketosis) and severe dehydration].

REAGENT AND/OR MEDIA, MATERIALS

A. Materials:

1. StatStrip® Glucose Test Strips
2. StatStrip® Glucose Control Solutions: Levels 1 and 3

B. Reagents storage

1. Store the StatStrip® Glucose Test Strips at 15 to 30° C.
   a. The expiration date is printed on the vials. Once opened, the Statstrip® test strip stored as indicated will be stable for up to 180 days or until the expiration date, whichever comes first.

2. Store the StatStrip® Glucose Control Solutions at 15 to 30° C.
   a. The expiration date is printed on the vials. Once opened, solutions stored as indicated will be stable for up to 3 months or until the expiration date, whichever comes first.

## EQUIPMENT CALIBRATION AND MAINTENANCE

Equipment:

Nova StatStrip® Glucose Meter
NovaNet Blood Glucose Management System.

The meter does not require calibration.

A. Disinfection

NOTE: All staff must adhere to the following disinfection measures to prevent transmission of infection via portable/handheld devices used for POC testing.

1. Materials:
   a. Germicidal Disposable Wipe. (EPA Reg. No 67619-12)
   b. Soft cloth or tissue
   c. Water

B. When to disinfect the meter:
1. Before and after performing the QC.
2. Before and after patient testing.
3. Whenever the meter had been contaminated with blood or other body fluids.

C. Disinfect the meter.
1. Remove a fresh germicidal wipe from the canister and wipe the external surface of the meter thoroughly.
2. Using a fresh germicidal wipe, thoroughly wipe the surface of the meter (top, bottom, left and right sides) 3 times horizontally and vertically avoiding the meter's bar code scanner and electrical connector.
3. Gently wipe the surface area of the test strip port making sure that no fluid enters the port.
4. Ensure the meter surface stays wet for duration of contact time (see contact time requirement on the canister) and then allow to air dry for an additional 1 minute.
5. Wipe dry with soft cloth or tissue.
6. Enter comment 'Cleaned meter' after performing QC.

Caution:
**DO NOT** immerse the meter or hold the meter under running water.
**DO NOT** spray the meter with a disinfectant solution.

## PROCEDURES

A. RUNNING PATIENT SAMPLE
1. From the Patient Test screen, press the Accept soft key.
2. The Enter Strip Lot screen displays. Enter or scan the strip lot number.
3. Once the Lot Number has been added, press the Accept soft key.
4. The screens will display: Enter Patient ID.

5. From the Enter Patient ID screen, enter the Patient ID: from Patient ID List screen (press List soft key), by pressing numeric/alphanumeric soft keys (press the ABC... soft key), or scanning the barcode ID (optional).
   **NOTE:** To scan the patient ID or Accession Number, press the Scan soft key on the screen. Or press one of the side Scan buttons. Then scan the patient's barcode with the bottom of the meter.
6. Once the Patient's ID/Accession Number has been entered, press the Accept soft key.
7. The Insert Strip screen displays. Insert a test strip as shown on the meter screen.
8. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.
9. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.
10. Use the Safety Lancet to puncture the finger.
11. Squeeze the finger to form a drop of blood.
    **NOTE:** Staff must use only the safety lancet auto-disabling single-use fingerstick devices provided for point-of-care testing. Discard the device in the biohazard puncture resistant sharps container provided.
12. The Apply Sample screen should be displaying. When the blood drop appears, touch the end of the test strip to the blood drop until the well of the test strip is full and the meter beeps.
    **WARNING:** The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.
13. The test results will appear in 6 seconds.
    **NOTE:** Do not remove the test strip while the countdown is in progress.
14. To accept the result, press the Accept soft key.
    To reject the result, press the Reject soft key.
    To add a comment, press the Comment soft key.
    All data are stored into memory.

B. CALCULATIONS

C. The Nova StatStrip® Glucose Meter automatically performs all the calculations.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

A. The StatStrip® Glucose Control Solutions have known glucose values that are used to confirm that the meter and test strips are working correctly. The control solution test results should fall within the range of results printed on the control solution insert sheets.

B. Two different levels of the Stat Strip Glucose Control Solutions are run during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:
   1. Each new operator
   2. Before using the StatStrip Meter for the first time
   3. If a patient test has been repeated and the blood glucose results are still lower or higher than expected
   4. If there are other indications that the system is not working properly

5. Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).
6. As required by the institution's quality control policy or local regulatory requirements.

## C. RUNNING QUALITY CONTROL

1. From the Patient Test screen, press the QC soft key.
2. The Enter Strip Lot screen displays. Enter the Strip Lot Number or scan the barcode. To scan the barcode presses the Scan soft key.
   **NOTE:** *If the Strip Lot Number is invalid*, the screen displays the invalid number with *"is not a valid Strip Lot #* Try again."
3. Press the Accept soft key if the lot number is correct.
4. The Enter QC Lot screen displays. Enter the QC lot number, select from the QC Lot List screen (press the List soft button) or scan the barcode. To scan the barcode, press the Scan soft key.
   **NOTE:** *If the QC Lot Number is invalid*, the screen displays the invalid number with "*is not a valid QC* Lot Try again."
5. Press the Accept soft key if the lot number is correct.
6. Insert a Test Strip.
7. With the test strip correctly inserted, the Apply Sample screen displays.
8. Gently mix the StatStrip Glucose Control Solution before each use.
9. Discard the first drop of control solution from the bottle to avoid contamination.
10. Place a drop of control solution from the bottle at the end of the test strip until the solution is drawn into the well of the test strip.
    When enough sample has been drawn into the strip, an audible beep is sounded by the meter.
11. Recap the control solution. The Testing Sample screen displays. The screen shows a clock with seconds remaining below the clock.
12. When the meter completes the test, the QC Result screen displays with the results in mg/dL.
    **NOTE:** Result is displayed with either PASS or FAIL.
    **WARNING**: Do not test patient sample until a control solution test result is within expected range.
13. To add a 'Disinfect meter' or other comment to the result, press the Comment soft key.
14. To accept the result, press the Accept soft key.
    **NOTE:** Acceptable control assay ranges are printed on the Nova Glucose Control Solutions vial label. If a QC test does not fall within the specified range, verify that the Nova Glucose Stat Strips and Control Solutions are not past their expiration dates.
    Repeat the test with a new strip. If the second test fails, inspect and clean the meter according to Section 6.3, Cleaning the Meter.
    If the third test fails, contact Nova Biomedical Technical Support at 1-800-345-NOVA.

## RESULT REPORTING

A. Reportable Range: 50-450 mg/dL

B. The operating range of the StatStrip Glucose Meter is 10 - 600 mg/dL or 0.6 - 33.3 mmol/L. For samples exhibiting values at or above 600 mg/dL or 33.3 mmol/L, the screen displays Hi.

C. REFERENCE RANGES:

| AGE | SEX | RANGE |
|---|---|---|
| <1 Month | F/M | 41 – 130 mg/dl |
| >1 Month to 16 years | F/M | 65 – 99 mg/dl |
| > 16 years | F/M | 65 – 99 mg/dl |

D. Critical values: Report critical values directly to the ordering physician and/or contact lead physician of the service

| CRITICAL VALUES | | | | |
|---|---|---|---|---|
| TEST | PATIENT AGE | UNIT | LOW | HIGH |
| GLUCOSE | <1 Month | mg/dl | <41 | >199 |
| | >1 Month to 16 years | mg/dl | <41 | >249 |
| | > 16 years | mg/dl | <41 | >449 |

*Also refer to the following: PROCEDURE ON REPORTING RESULTS: See POC-1.3 / POLICY ON CRITICAL VALUES: See POC-1.3

## LIMITATIONS

A. If needed, sodium, lithium, and ammonium heparin are the recommended anticoagulants for use with the StatStrip® Glucose Meter.

1. Depending on the amount of heparin used in the collection syringe and whether it is filled to capacity with blood, the concentrations of heparin may be 20 I.U. per mL to over 100 I.U. per mL. When liquid heparin is present in excess, it may cause dilution errors.
2. A lyophilized lithium heparin giving a final concentration in blood of not more than 20 I.U. per mL is acceptable.

B. EDTA, citrate, oxalate, and sodium fluoride are not recommended for use.

C. Glucose Interferences:

1. The StatStrip Glucose meter exhibits no interference from the following substances up to the Following concentration levels:

| Tested Interfering Substances | Tested Concentration Level |
|---|---|
| Acetaminophen | 10.0 mg/dL |
| Ascorbic Acid | 10.0 mg/dL |
| Bilirubin | 15.0 mg/dL |
| Cholesterol | 500.0 mg/dL |
| Creatinine | 6.0 mg/dL |
| Dopamine | 10.0 mg/dL |
| Ephedrine | 0.9 mg/dL |
| D (+) Galactose | 350.0 mg/dL |
| Hematocrit (RBC) | 20% - 65% |
| Ibuprofen | 48.0 mg/d |
| L-Dopa | 100.0 mg/dL |
| D (+) Maltose Monohydrate | 240.0 mg/d |
| D (+) Maltotetraose | 240.0 mg/d |
| D (+) Maltotetriose | 240.0 mg/dL |
| Methyl-Dopa | 1.0 mg/dL |
| Oxygen | All Concentrations |
| Salicylate | 30.0 mg/dL |
| Tetracycline | 30.0 mg/dL |
| Tolazamide | 15.0 mg/dL |
| Tolbutamide | 45.0 mg/dL |
| Triglycerides | 750.0 mg/dL |
| Uric Acid | 20.0 mg/dL |

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1999. Tietz Textbook of Clinical Chemistry. Philadelphia, PA: W. B. Saunders Co.

2. Nova biomedical, CIB NO: 04-11SS. Cleaning and Disinfection Procedure StatStrip and StatSensor.

## REVISIONS

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

## Biennial Review

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-3.1.3 |
| **SUBJECT: HEMOCUE Hb 201 DM SYSTEM** | **PAGE:** 1 OF 7 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To provide hemoglobin level in timely manner while performing Street Medicine out in the field.

Total hemoglobin is a direct measurement of the blood's potential to transport oxygen, vital information essential for reducing the risk of developing tissue hypoxia during the care of the critically ill patient.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Hemoglobin is a conjugated protein consisting of an iron-containing pigment called heme and of simple proteins called globins. Ninety-eight percent of oxygen is carried by hemoglobin to tissues from the lungs and to transport carbon dioxide from tissues to the lungs.

The hemoglobin concentration in blood is determined as azidemethemoglobin utilizing a microcuvette with a dry reagent system and a dual wavelength photometer. The erythrocyte membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrite converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin, which then combines with sodium azide to form azidemethemoglobin. Measurements are taken at 570nm and 880nm; the latter to correct for turbidity.

## SAFETY PRECAUTIONS

See POC-1.8

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

Whole Blood: Capillary, Arterial, and Venous.
Appropriate anticoagulants in solid form (e.g. EDTA, heparin or heparin/fluoride) may be used Staff must use standard precautions when collecting and handling all specimens. (See POC-1.7).

## REAGENT AND/OR MEDIA, MATERIALS

A. Materials:
1. Hemocue Hb 201 Microcuvettes
2. Hemocue Control Solutions: Levels 1 and 3

B. Reagents Storage

1. Store the Hemocue Hb microcuvette at 15-30°C or 59-86°F, ***"Do not refrigerate".*** The expiration date on unopened vial is 2 years from date of manufacture, once opened with the container properly closed, 3 months or until the manufacturer expiration date, whichever comes first.
2. Store the control solution at 2-8°C. The expiration date is printed on the vials. Once opened, control solutions stored at 2-30°C will expired in one month.

## EQUIPMENT CALIBRATION AND MAINTENANCE

A. Equipment:

1. Hemocue Hb 201 DM Analyzer
   Hemocue Hb 201 Microcuvette – serves as pipette, reaction vessel and as a measuring Microcuvette
2. Hemocue DM Docking Station - allows the transfer of data between the Hemocue Hb 201 DM analyzer and the PC server.
3. Hemocue Management System.

B. Calibration: Calibrated by the manufacturer against the hemoglobin cyanide (HiCN) method, the reference method for the determination of hemoglobin concentrations in blood.

C. Maintenance:

1. When to clean the meter
   a. Staff must use standard precautions when collecting and handling all specimens. (SeePOC-1.7).
      **NOTE:** All staff must adhere to the following disinfection measures to prevent transmission of infection via portable/handheld devices used for POC testing.
   b. Clean the cuvette holder before and after performing quality control testing.
   c. Clean cuvette holder and instrument exterior before and after each patient.
   d. Whenever dirt or blood is present on the meter.
2. Procedure for cleaning cuvette holder
   a. Turn off the analyzer.
   b. Pull the cuvette holder out to the loading position.
   c. Using a pointed object, carefully press the small catch in the upper right-hand corner of the cuvette holder.

      While pressing the catch, carefully rotate the cuvette holder to the left for removal. Clean the cuvette holder with alcohol or a mild detergent and allow dry completely before replacing.
   d. Enter the daily maintenance performed on the device by attaching the comment "Cln Cuv Hlder" to the liquid QC results.
   e. Clean exterior of the analyzer daily with gauze moistened with alcohol or mild soap followed by gauze moistened with water.
3. Clean the optronic unit as needed:
   a. Turn off the analyzer.

b. Pull the cuvette holder out to the loading position.
c. Using a pointed object, carefully press the small catch in the upper right-hand corner of the cuvette holder.
d. While pressing the catch, carefully rotate the cuvette holder to the left for removal.
e. Remove the cleaner from the package and insert into the instrument.
f. Move the cleaner over the entire optronic unit.
g. Inspect the cleaner, if it is dirty; repeat the procedure with a new cleaner.
h. Wait for 15 minutes before replacing the cuvette holder. Check the system as required.

4. As Needed:
   a. Clean exterior of the docking station with gauze moistened with alcohol or mild soap followed by gauze moistened with water.

D. Transfer of Data to the Workstation:
1. Perform data transfer as frequently as possible.
2. Slide the analyzer into and out of the docking station by means of the tracks.
3. Screen displays an hourglass and a message – Data Transfer.
4. Never try to lift the analyzer out of the docking station or press the analyzer downward into the docking station

## PROCEDURES

Gloves must always be worn during the testing procedure and all appropriate laboratory safety guidelines must be followed.

A. Start-up
1. Pull the cuvette holder out to the loading position.
2. Press and hold the On/Off button (left button) until the display is activated.
3. The display shows the version number of the program, after which it will show an hourglass and "Hb".

B. Internal QC (Self-Test)
1. During the time that the hourglass is on display, the analyzer will automatically perform the internal QC – Self-Test.
2. Enter your operator ID at the prompt: Enter Operator ID
3. The screen displays the Main Menu

C. Patient Sample
1. Use 2 identifiers to verify patient's identification prior to performing the test.
2. The hand should be warm and relaxed. It is a good idea to heat cold hands in warm water before sampling to increase the blood circulation.
3. The cuvette holder must be in the loading position and the display should show three flashing dashes and the HemoCue symbol.
4. Remove a cuvette from the vial and recap the vial immediately.
5. Clean the puncture site with alcohol.
6. Wipe off the alcohol with a clean dry lint-free wipe or allow it to air dry completely.
7. Using your thumb, lightly press the finger from the top of the distal knuckle to the tip to stimulate the blood flow towards the sampling point.

8. While maintaining gentle pressure on the tip of the finger, perform the stick off- center on the fingertip.
9. Discard the lancet in an approved container.
10. Wipe away the first two or three large drops blood with gauze or other lint-free tissue.
11. Apply light pressure as needed again until another drop of blood appears.
12. From the Main Menu, select the microcuvette with a drop of blood icon.
13. Make sure that the drop of blood is big enough to fill the cuvette completely.
14. Hold the cuvette opposite the filling end and introduce the cuvette tip into the middle of the drop of blood.
15. Fill the cuvette in one continuous process. Do not refill a partially filled cuvette.
16. Wipe off any excess blood from the outside of the cuvette using a clean, lint-free tissue. Do not touch the open end of the cuvette.
17. Visually inspect the cuvette for air bubbles in the optical eye. Discard the cuvette if bubbles are present.
    The filled cuvette must be analyzed within 10 minutes of filling.
18. Place the filled cuvette into the cuvette holder and gently slide the holder into the measuring position.
19. At the prompt, enter the following information: Microcuvette batch number Patient ID.
20. Verify Cuvette Batch and Patient ID entered.
    **NOTE:** Staff must use only the safety lancet auto-disabling single-use fingerstick devices provided for point-of-care testing.
    Discard the device in the biohazard puncture resistant sharps container provided.
21. Select OK, screen displays patient's result.
22. **To add a comment(s), with the result on display:**
    a. Press the Comment button
    b. Press ADD
    c. Using the arrows on the right-hand side, select the appropriate comment (maximum of four comments may be entered)
    d. Select OK, to go back to the Main Menu.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

A. Internal – "Self-test"
   1. Automatically performed when the analyzer is turned ON
   2. Verifies the performance of the optronic unit
   3. Result is stored as an Electronic Quality Control

B. External Liquid Quality Control – 2 levels of Hemo-Trol
   1. Control by EUROTROL
   2. Must be done on the day of patient test and as needed
   3. Verifies the performance of the analyzer and the performing staff.
   4. The analyzer is configured to prompt the user to analyze the Liquid Quality Control.
   5. The QC reminder icon will be displayed in the Main Menu to warn the user of impending QC.

6. The analyzer will perform a lockout if the impending QC is not performed at the pre-defined time.
7. To unlock the analyzer, the required QC must be Analyzed and Approved.
8. Allow the vials to come to room temperature (15-30°C) for 20 minutes.
9. Mix thoroughly by gently inverting the vials and rolling them between the palms until all cellular components are completely suspended.
10. From the Main Menu, press the QC button.
11. Screen displays QC Test, select QC level to be analyzed.
12. At the prompt "Please Fill and Insert a Cuvette", dispense a drop of control onto a hydrophobic surface e.g. para film.
13. Make sure that the drop of blood is big enough to fill the cuvette completely.
14. Hold the cuvette opposite the filling end and introduce the cuvette tip into the middle of the drop of blood.
15. Fill the cuvette in one continuous process. Do not refill a partially filled cuvette.
16. Wipe off any excess blood from the outside of the cuvette using a clean, lint-free tissue. Do not to touch the open end of the cuvette.
17. Visually inspect the cuvette for air bubbles in the optical eye.
18. Discard the cuvette if bubbles are present.
19. The filled cuvette must be analyzed within 10 minutes of filling.
20. Place the filled cuvette into the cuvette holder and gently slide the holder into the measuring position.
21. At the prompt enter the following information:
22. Microcuvette batch/lot number
23. Selected QC lot number
24. Invalid Control Lot will be displayed if a QC lot number has not been previously stored in the analyzer or has expired.
25. The result will be displayed within 15 to 60 seconds.
26. Enter comment cleaned meter or other appropriate comment.
27. Touch OK to go back to the Main Menu.

**Note:**

a. The analyzer will not permit analysis of patient specimen unless both levels of liquid quality controls are acceptable.

b. If any of the liquid quality control results is unacceptable, follow the procedure as follows:

i. Check the micro cuvettes and the liquid quality control for:

- Storage
- Expiration
- Handling

ii. Check the optronic unit of the analyzer, clean if necessary.

iii. Repeat analysis and evaluate the result, if the repeated result is still unacceptable, call POCT x 4448.

28. Pull the cuvette holder out to the loading position and discard the cuvette in an appropriate biohazard container.
29. The analyzer is ready for the next measurement.

## RESULT REPORTING

Analytical Measuring Range:

Vendor's measurement range is 0-25.6 g/dL

Validated measurement range is 3.8-20.2 g/dl (may change from time to time)

Report critical values directly to the ordering physician and/or contact lead physician

PROCEDURE ON REPORTING RESULTS: See POC-1.3

POLICY ON CRITICAL VALUES: See POC-1.3

| AGE | REFERENCE RANGE | | | CRITICAL VALUES | |
|---|---|---|---|---|---|
| | MALE | FEMALE | UNITS | FEMALE & MALE | UNITS |
| < 1 Month | 15.0 – 24.0 | | g/dl | < 6.6 and > 21.9 | g/dl |
| 1 Month to 2 Years | 10.5 – 14.0 | | g/dl | < 6.6 and > 19.9 | g/dl |
| 2 Years to 12 Years | 11.5 – 14.5 | | g/dl | < 6.6 and > 19.9 | g/dl |
| 12 Years to 18 Years | 12.5 – 16.0 | 12.0 – 15.0 | g/dl | < 6.6 and > 19.9 | g/dl |
| > 18 Years | 13.5 – 18.0 | 12.5 – 16.0 | g/dl | < 6.6 and > 19.9 | g/dl |

## LIMITATIONS

A. The HemoCue Hb 201 analyzer corrects for turbidity in specimens, and therefore might produce lower results than those expected for other hemoglobin instruments that do not have this correction feature. Therefore, only controls that are assayed for the HemoCue Hb 201 system are recommended.

B. Values above 20.0 g/dL must be confirmed using a suitable laboratory method. Sulfhemoglobin is not measured with this method.
Carboxyhemoglobin levels up to 10% do not interfere with the system.

C. The Hemocue Hb 201 DM is only to be used together with Hemocue Hb 201 Micro cuvettes.

D. Troubleshooting:
Please refer to the attachment for the list of error codes. If unable to resolve the problem by following the troubleshooting guide, please call POCT X81393/81407.

## ASSOCIATED FORMS

N/A

## REFERENCES

1. HemoCue Hb 201+ Operating Manual
2. HemoCue Hb 201 Microcuvette Package Insert

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-3.3.1 |
| **SUBJECT: HEMO-TROL HEMOCUE CONTROL** | **PAGE:** 1 OF 3 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/06/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

HEMO-Trol is a multi-level reference control designed for use on HemoCue Hb 201 systems.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Accepted laboratory procedure requires that stable reference controls be periodically used to monitor accuracy and precision. HEMO-Trol HGB Controls may be used as one would use whole blood in obtaining the stated parameters for HemoCue photometers.

## SAFETY PRECAUTIONS

See POC-1.8

HEMO-Trol is an Animal Blood Product.Bovine based materials do not carry biohazard for man, such as hepatitis B surface antigen (HBsAg), hepatitis C virus, and anti-HIV-1, as well as for anti-HIV-2. This product is free from TSE.
It is recommended that HEMO-Trol Controls be handled with the same precautions used for patient specimens.
HEMO-Trol Control should be treated the same as a patient specimen and run in accordance with the instructions accompanying the instrument being used.
HEMO-Trol Control is intended solely for in vitro diagnostic use for the purpose described on the labeling.

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA, MATERIALS

HEMO-Trol HGB Control is composed of purified bovine hemolysate.
Storage and stability
Hemo-Trol Control is stable through the expiration date indicated on the labeling, when stored at 2-8°C. After opening the vials, it is stable for one month when properly capped and stored at 2-30°C

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

1. Allow the vials to come to room temperature (15°-30°C) for 15 minutes.
2. Gently mix the vial 8-10 times before sampling
3. Remove the cap from the vial. Dispense a drop of product. Fill the HemoCue microcuvette with HEMO-Trol Control as you would a patient sample.
4. Wipe any excess material from the vial and the cap with a clean tissue. Recap the vial tightly

Expected results
An expected range is given for each level based on data generated from multiple lab analyses using HemoCue photometers. Variations between labs will be greater than the precision for any one instrument. Results depend upon differences in equipment, reagents, supplies and techniques.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

HEMO-Trol Control is a reliable liquid product manufactured under rigid quality control standards. To obtain good results, the product requires proper storage and handling as described.

## RESULT REPORTING

See POC-3.1

## LIMITATIONS

1. HEMA-Trol HGB Control may not be appropriate for certain instruments other than the HemoCue photometer.
2. Inaccuracies in test results may occur as a result of inappropriate mixing procedures. Precisely follow all mixing instructions before sampling.

## ASSOCIATED FORMS

N/A

## REFERENCES

1. HemoCue B-Hemoglobin Photometer Operating Manual, HemoCue AB, Angelholm, Sweden.
2. HemoCue B-Hemoglobin Microcuvette Package Insert, HemoCue AB, Angelholm, Sweden.
3. Koepke, Bull, Gilmer and Goldblatt; Hematology in Quality Assurance Practices for Health Laboratories. Interdisciplinary Books: American Public Health Assn., 1978.
4. Bergmeyer: Methods of Enzymatic Analysis 1 (1974), Chemie publishers, Weinheim.
5. Eurotrol Hemo Trol Package insert

**REVISIONS**

| Date | Changes | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-4.1.5 |
| **SUBJECT: CLINITEK STATUS + ANALYZER SIEMENS HEALTHCARE DIAGNOSTICS REAGENT STRIPS FOR URINALYSIS** | **PAGE:** 1 OF 11 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

Routine urinalysis involves determining the pH, specific gravity and the presence or absence of protein, glucose, ketones, bilirubin, blood and leukocytes in the urine. This is done by the use of a small paper stick impregnated with the appropriate chemicals to detect urinary analytes.

## PRINCIPLES AND CLINICAL SIGNIFICANCE

POCT urinalysis testing allows clinicians to manage the patient in real-time by providing diagnostic information regarding kidney function, urinary tract infections, metabolic disorders (such as diabetes mellitus), and liver function. The urinalysis strips also measure physical characteristics, including acid-base balance and urine concentration. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

## SAFETY PRECAUTIONS

(See POC 1.8)

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

OBSERVE STANDARD PRECAUTION in specimen collection, waste disposal, meter cleaning, blood or body fluid exposure and item processing

FOLLOW THE PROTOCOL IN PATIENT IDENTIFICATION AND LATEX ALLERGY. All samples collected for Point of Care Testing must be labeled promptly upon collection, **OR**, to ensure identity of the specimen, the individual performing the test must remain with the sample at the testing site until the test is complete.

### A. Specimen Collection and Storage

1. Wear facial protection, gloves, and protective clothing.
   Obtain a fresh, urine specimen. A first-morning specimen is preferred but random collections are acceptable. Specimens should be at room temperature for less than two hours before testing.
2. Collect the urine in a clean, dry, covered container.
3. The urine specimen should be well mixed and uncentrifuged.

4. In the event that cultures are ordered concurrently, to avoid contamination of the specimen, collect urine in sterile urine culture container (per Microbiology collection instructions) and immediately transfer a sample of the urine to the urine culture preservative tube. The remaining urine can be used to perform the urinalysis testing.
5. If testing is delayed (>2 hours after collection), specimen should be refrigerated for preservation.
6. Allow urine specimen to return to room temperature before testing.

**B. Specimen Rejection Criteria**

1. Specimens that have remained at room temperature for longer than two hours
2. Specimens with urine preservatives
3. Specimens that arrive in unsterile containers (glass jars, pill bottles, etc.)
4. Leaking specimen containers

**C. Disposition for rejected specimen**

1. Write the reason for rejection on the test requisition and request a new, acceptable specimen form the patient. Acceptable collection container and collection instructions should be provided to the patient.
2. Never dispose of unacceptable specimen until the caregiver has been notified. Some urine specimens may have been collected during a critical procedure or by means of an invasive procedure.

**D. Specimen Referral Criteria**

Send specimen to the Central Lab to verify critical values

**REAGENT and/or MEDIA, MATERIALS**

- Clinitek Status Analyzer+
- Multistix 10SG reagent strip
- BioSys Plus Liquid urine control
- Gloves and PPE
- Patient properly labeled urine sample
- Gauze, lint free wipes
- Disposable dropper

**EQUIPMENT CALIBRATION and MAINTENANCE**

The Clinitek Status +TM Analyzer performs a "self-test" as a function check of the meter, self-test must be successful in order for the meter to run and calibrates automatically before each time it is turned on. In addition, the analyzer performs an automatic calibration before each measurement. The white calibration bar (on the test table) was tested on a reference spectrophotometer. By calibrating the reference spectrometer with the National Institute of Standards and Technology (NIST) traceable calibrators, it shows traceability to NIST.

**Record all maintenance in the maintenance log.**

**NOTES:** Do not push or pull the test table because the calibration might fail, or the movement might cause table positioning errors. Do not move or bump the table while the analyzer calibrates. The calibration might fail.

**A. When to clean the meter**

1. Clean the test table weekly and Outside of the meter monthly.
2. Clean the Test table insert before and after each quality control testing and patient testing.

3. Whenever dirt or urine is present on the meter.
4. When the meter has been exposed to contamination with body fluids

**B. Procedures for cleaning the test table insert per use**

1. Remove test table insert from the test table
2. Thoroughly clean both sides of the table insert with damp (not wet) paper towel with water. Wipe dry.
3. Replace insert onto test table.

**C. Procedure for weekly cleaning of test table**

1. Remove the test table by pulling it slowly out of the analyzer
2. Lift the table insert to remove it from the test table. Drain the drip tray, if necessary.
3. Scrub the test table and table insert with damp paper towel with water, except for white calibration bar.
4. Rinse both sides of the table insert and test table under running water.
5. Dry the test table thoroughly (except for white calibration bar) with a soft cloth or tissue.
6. Examine the white calibration bar. If the bar appears dirty, follow the procedure to clean the calibration bar.
7. If the calibration bar is clean, insert the test table, pushing it in than halfway into the meter.
8. Insert the table insert.

**D. Procedure for cleaning the White Calibration Bar**

For the CLINITEK Status+ analyzer to perform as intended and provide reliable test results, the white calibration bar on the test table needs to be clean and not discolored. With normal use, the white calibration bar should not become dirty or discolored. To clean the white calibration bar, perform the following steps:

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Drain the drip tray, if necessary.
4. Examine the white calibration bar on the test table for dirt or discoloration.
5. If the white calibration bar appears clean and unmarked, perform the following steps:
   a. Place the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
   b. Push the test table firmly but slowly, just over halfway into the analyzer.
   c. Place the test table insert.
   d. **CAUTION:** Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. When you examine the white calibration bar, do it carefully under good lighting.
6. If the white calibration bar is dirty or discolored, perform the following steps:
   a. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bars.
   b. Allow the calibration bar to air dry.
   c. Inspect the surface for dust, foreign material, scratches, or scuffs. If you cannot completely clean the calibration bar or if the bar still has marks, order a new test table.
   d. Place the test table, as described in step 5.

**E. Cleaning the outside of the meter:**

1. Turn off analyzer by pressing the on/off button.
2. Wipe the outside of the analyzer (including the display) with damp (not wet) paper towel and mild detergent.

**F. Disinfection Requirements and Procedures**

Disinfect the test table and the test table insert annually and/or as necessary. Use a recommended disinfection solution to prevent contamination and bacterial growth. Using the recommended disinfection solution prevents damage to the test table and insert.

**Disinfecting test table and test table insert:**

1. Remove the test table from the analyzer.
2. Using empty bottle of multistix, filled with 70% Isopropyl Alcohol to a depth about 4 inches place the table insert and test table into the solution with the white calibration bar on the test table above the liquid level.
3. Soak the test table and the table insert for a minimum of 2 minutes and a maximum of 10 minutes.
4. Rinse the test table and the table insert thoroughly with water.
5. Dry the test table and the table insert thoroughly with a soft cloth. Take caution not to touch the calibration bar.
6. Insert the test table and the table insert in the analyzer.

**Disinfecting the display of the analyzer**

1. Disinfect the display with the70% Isopropyl Alcohol.
2. Wipe the display with the70% Isopropyl Alcohol and let it remain for 10 minutes.
3. Wipe the display with a clean cloth dampened with water.
4. Dry the display with a clean cloth.

Disinfection is performed by POCT staff annually. Disinfection may also be performed as needed for troubleshooting.

**CLINITEK STATUS+ OPERATING PROCEDURES**

**A. Entering Operator and Patient Information**

Enter or select an operator name, patient name, and patient ID.

To enter operator and patient information, perform the following steps:

1. On the **Select Ready** screen, select **Strip Test**.
2. On the **Operator ID** and **Operator Name** screen, enter your user code
3. Select **Enter New Patient**

   Enter the patient name (maximum of 20 characters) on the **Enter Patient Name** screen.
   Select **Enter**

   **Note**: To enter text, use the alpha keyboard **(ABC).** To enter numbers, select **123**.
4. Enter the patient ID (use FIN number) on the **Enter Patient ID** screen, and select **Enter**

**B. Preparing a Urinalysis Strip Full Test**

Before you run a urinalysis Test, prepare the strip and the analyzer.

To prepare a urinalysis strip Full Test, perform the following steps:

1. Enter the strip lot number and expiration date, as follows:
   a. To use the last strip number and begin the test, select **Use Last Lot.**
   b. To enter new strip data, select **Enter new lot and expiration.**
   c. Enter the strip lot number and select **Enter.**
   d. Use the arrow keys to enter the strip expiration date and select **Enter.**
   e. Remove a strip from the bottle and replace the cap immediately.
2. Make sure the reagent strip holder faces upward in the test table insert.
3. Have the urinalysis strip and paper towel ready.

**C. Running a Urinalysis Strip Full Test**

When you run a urinalysis strip Full Test, the analyzer calibrates and then analyzes the strip.

To run a urinalysis strip Full Test, perform the following steps:

1. Select **START.**
2. After you select **START**, you have 8 seconds to dip the reagent strip in the urine sample and place the strip in the test table channel.
3. The **Prepare Test** screen displays steps on how to perform the test.
4. A timer displays the amount of time remaining to complete the task
5. Mix specimen well just before testing.
6. Dip the reagent strip in the urine sample and wet all the pads.
7. The ID band allows auto-strip identification to ensure that the analyzer reports the correct strip configuration when you perform a urinalysis test.
   **Note:** Be sure to use the proper dipping technique.
8. Immediately remove the strip from the urine.
9. Drag the edge of the strip against the side of the sample container as you remove it.
10. Blot the edge of the strip on a paper towel to remove the excess urine.
11. Place the reagent strip in the test table channel with the test pads facing up.
12. Slide or push the strip to the end of the channel. Do not touch the pads on the strip.
13. After the 8-second countdown ends, the analyzer pulls in the test table and strip, and then calibrates.
14. After the calibration finishes, the analyzer starts analyzing the strip, and the **Analyzing** screen displays. **CAUTION:**
    a. Do not push or pull the test table because the calibration might fail, or the movement might cause table positioning errors.
    b. Do not move or bump the table while the analyzer calibrates. The calibration might fail.

**D. Selecting the Appearance of the Urine Sample**

1. While the analyzer analyzes the strip, a **Select Appearance** screen displays.
2. To select the appearance of the urine sample, perform the following Steps:
3. Visually observe the urine sample and determine the appropriate color and clarity.
4. Select the urine sample color and clarity:
   a. If the urine sample is yellow and clear, select **Yellow and Clear.**
   b. If the urine sample is not yellow and clear, select **Other**, and select a color.
5. Next, select a **Clarity** option and select **Next.**
6. A time indicator on the **Select Appearance** screen counts down the time remaining in the analysis of the strip.
7. The analyzer displays either of the following screens:
   a. **Analyzing** if the strip is still being analyzed.
   b. **Results** if analyzing the strip is complete.
   c. A timer counts down the time remaining in the strip analysis process.
   d. After the countdown ends, the analyzer displays the first page of the test results on the **Results** screen. The analyzer will print test result automatically.
   e. The results display on the screen for 2 minutes.
   f. Then, the display returns to the **Select Ready** screen.
   g. The test table and strip move out of the analyzer.
   h. Record result in the power chart.

**E. Viewing the Urinalysis Strip Full Test Results**

1. The first page of test results display on the **Results** screen.
2. You can view additional pages of the test results on the **Results** screen.
3. To view additional pages of the urinalysis strip Full Test results, perform the following steps:
4. Select **More** to view the remaining test results.
5. Select **Done** to return to the main **Results** screen.

**F. Completing the Urinalysis Strip Full Test**

1. Complete the testing for one strip or continue testing one strip at a time, until you finish testing all the strips you want to analyze.
2. To complete the urinalysis strip Full Test, perform the following steps:
3. Remove the used urinalysis strip from the test table and disposed.
4. Clean the table insert
5. Report the results to the provider.
6. Select **Done** to complete the test and return to the **Select Ready** Screen
7. Select **Done** to return the **Strip Test Prepare** screen.
8. You are ready to start the next test. If you completed your testing.
9. Select **Back** to return to the **Select** screen.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

Quality Control (QC) testing helps assure that the reagent strips are reacting correctly and that the instrument is accurately reading them. It can also help detect errors resulting from user techniques.

**A. Control procedure**

1. Two levels (positive and negative) of Quantimetrix control are run on the day of patient testing and when you open a new bottle of urinalysis strips.
2. Water should not be used as a negative control.
3. You can run QC tests for strips at any time or when a QC test is due.
4. When a QC test is due, the test icon on the Select Ready screen is blinking.
5. It displays the type of test (strip or cassette) that is due.

**B. Running a QC Strip Test**

1. Make sure the controls are in room temperature.
2. On the Select Ready screen, select **QC Test due**. The **QC Test** screen displays.
3. Select **QC Strip Test Required.**
4. Enter the operator ID in lieu of operator name.
5. The **Control and Level** screen displays; shows Control name and level name
6. To enter control lot information, **press Enter lot and exp. Date** icon.
7. The **Control Lot** screen displays. Enter the control lot and select **Enter.**
8. The **Control Expiration** screen displays.
9. Use the arrow keys to indicate the control lot expiration date and select **Enter.**
10. The **Strip Lot** screen displays.
11. To enter the strip information:
    a. Enter the strip lot or scan and select **Enter.** The **Strip Expiration** screen displays.
    b. Use the arrow keys to indicate the strip expiration date.
    c. Select **Enter.**
    d. Make sure the reagent strip holder faces upward in the test table insert.
    e. Have the urinalysis strip and paper towel ready
    f. The **Prepare Test** screen displays steps on how to perform the test.
    g. A timer displays the amount of time remaining to complete the task

    **Note:** After you select **START,** you have 8 seconds to apply control solution onto the reagent strip and place the strip in the test table channel. Select **Start.**
12. Remove the control cap and invert bottle.
    a. While holding dipstick, gently squeeze the sides of the bottle, and touch the tip of the bottle to dipstick pads.
    b. Draw across the reagent pads, thoroughly saturating each pad.
    c. Do not aspirate excess control solution back into the bottle. Wipe off bottle tip with clean paper towel and recapped.
    d. Blot the edge of the strip on a paper towel to remove the excess control.
    e. Place the reagent strip in the test table channel with the test pads facing up.
    f. Slide or push the strip to the end of the channel. Do not touch the pads on the strip.

g. After the 8-second countdown ends, the analyzer pulls in the test table and strip, and then calibrates.
h. After the calibration finishes, the analyzer starts analyzing the strip, and the **Analyzing** screen displays.
**Note:** Each time you run a test, the analyzer calibrates
i. A timer counts down the time remaining in the strip test analysis process.
j. After the countdown ends, the analyzer displays the test results on the Results screen. The test table move out of the analyzer.
k. Remove the test strip when the analysis is complete the Results screen displays.
**Note:** if the test results pass, the **Results-QC Test: Pass** screen displays. If the test results fail, the **Results-QC Test: Fail** screen displays.
l. To print the results, select **Print.**
m. To navigate the results:
a. To view the next page, select **More.**
b. To return to the previous page, select **Back.**
n. Select **Done.** The control and level screen display the next control name and level.
o. Enter control lot and expiration date.
p. Press the use last lot icon to record the strip lot number and expiration date.
q. Make sure the reagent strip holder faces upward in the test table insert.
r. Have the urinalysis strip and paper towel ready.
s. Repeat step 12 a through r for remaining controls.

13. To repeat a failed QC test, select **Repeat failed QC test** under the **QC Test-Results Summary screen displays**
NOTE: If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.
14. Select Done to return to the Select Ready screen.

**C. Corrective actions for out range QC.**

1. If the control results are out of control:
a. Start over and repeat the quality control test.
b. Check expiration date on the reagent.
2. If the control results are still out of control:
a. Use a new tube of reagent control.
b. Notify area supervisor.
3. Seek assistance from the clinical laboratory

## REFERENCE INTERVALS

| | EXPECTED VALUES | CRITICAL VALUES |
|---|---|---|
| Glucose | Negative | Positive in Newborn |
| Bilirubin | Negative | |
| Ketone | Negative | Positive in Newborn<br>Positive in Pediatric Patient |
| Specific Gravity | 1.003 – 10.35 | |
| Occult Blood | Negative | |
| PH | 5 - 8 | |
| Protein | Negative | |
| Urobilinogen | Normal (0.2 – 1.0) | |
| Nitrite | Negative | |
| Leukocytes | Negative | |
| Color | Yellow and Amber | |
| Clarity | Clear | |

### Units for Reporting Results

The Clinitek Status+™ Analyzer reports results in conventional units.

| Test | Reporting Unit |
|---|---|
| Glucose | mg/dL |
| Bilirubin | N/A |
| Ketone | mg/dL |
| Specific Gravity | <1.005 - >1.030 (in0.005 increments) |
| PH | 5.0 - >9.0 (0.5 increments) |
| Protein | mg/dl |
| Urobilinogen | mg/dL |
| Nitrite | N/A |
| Leukocytes | N/A |
| Color | N/A |
| Clarity | N/A |

### Detectable Range

| Reagent Area | Sensitivity |
|---|---|
| Glucose | 75 – 125 mg/dL glucose |
| Bilirubin | 0.4 – 0.8 mg/dL bilirubin |
| Ketone | 5 – 10 mg/dL acetoacetic acid |
| Blood | 0.015 – 0.062 mg/dL hemoglobin |
| Protein | 15 – 30 mg/dL albumin |
| Nitrite | 0.06 – 0.1 mg/dL nitrite ion |
| Leukocytes | 5 15 cells/hpf in clinical urine |

**Acceptable Results**

1. Patient test results are acceptable and may be reported when:
   a. Quality control is within expected limits and procedures have been followed.
   b. The instrument maintenance, monitoring and ongoing evaluation of the quality of the testing process have been deemed acceptable by the laboratory.

**Corrective Action**

1. Patient test results must be repeated, and corrective action taken when:
   a. QC Results fall outside acceptable range.
   b. Patient results are judged to be invalid or otherwise doubtful.

## LIMITATIONS

See POC 4.4 for Urinalysis limitation and interfering substances

**A. Troubleshooting**

1. If an operational or analyzer problem occurs, in most cases, an error number with an explanation of the problem displays on the Select Ready screen.
2. If a problem persists, write down the error number that displays and contact: Technical Support at **877-229-3711** for assistance.
3. If you think a Siemens urinalysis strip is causing the problem, see its product insert for troubleshooting information.
4. After an error occurs, if you power off the analyzer, be sure to retest the sample that was in Progress. When you power on the analyzer, restart the test.

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Henry, Clinical Diagnosis and Management by Laboratory Methods, 17th edition, pp. 380-435.

2. Clinitek Status + Operator's Guide. 10490853 Rev. C, 2011-12

3. Clinitek Status Connect System Operator's Guide. 10490852 Rev. B, 2011-06

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-4.3.5 |
| **SUBJECT: CLINITEK STATUS+ ANALYZER SIEMENS HEALTHCARE DIAGNOSTICS CLINITEST HCG FOR URINE PREGNANCY TEST** | **PAGE:** 1 OF 12 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalaf | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>STAFF WITH CURRENT TRAINING AND COMPETENCY RECORDS FOR POCT. | **SUPERSEDES DATE:** |

## PURPOSE

The Clinitest hCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid determination of hCG in urine.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

POCT urine pregnancy allows clinicians to manage the patient in real-time by providing information regarding early detection of pregnancy. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

## SAFETY PRECAUTIONS

(See POC 1.8)

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

OBSERVE STANDARD PRECAUTION in specimen collection, waste disposal, meter cleaning, blood or body fluid exposure and item processing

FOLLOW THE PROTOCOL IN PATIENT IDENTIFICATION AND LATEX ALLERGY.
All samples collected for Point of Care Testing must be labeled promptly upon collection, OR to ensure identity of the specimen, the individual performing the test must remain with the sample at the testing site until the test is complete.

**A. Specimen Collection and Storage**

1. Wear facial protection, gloves, and protective clothing.
2. Obtain a fresh, urine specimen. A first-morning specimen is preferred but random collections are acceptable. Specimens should be at room temperature for less than two hours before testing.
3. Collect the urine in a clean, dry, covered container.
4. The urine specimen should be well mixed and uncentrifuged.
5. In the event that cultures are ordered concurrently, to avoid contamination of the specimen, collect urine in sterile urine culture container (per Microbiology collection instructions) and immediately transfer a sample of the urine to the urine culture preservative tube. The remaining urine can be used to perform the urinalysis testing.

6. If testing is delayed (>2 hours after collection), specimen should be refrigerated for preservation.
7. Allow urine specimen to return to room temperature before testing.

**B. Specimen Rejection Criteria**

1. Specimens that have remained at room temperature for longer than two hours
2. Specimens with urine preservatives
3. Specimens that arrive in unsterile containers (glass jars, pill bottles, etc.)
4. Leaking specimen containers

**C. Disposition for rejected specimen**

1. Write the reason for rejection on the test requisition and request a new, acceptable specimen form the patient. Acceptable collection container and collection instructions should be provided to the patient.
2. Never dispose of unacceptable specimen until the caregiver has been notified. Some urine specimens may have been collected during a critical procedure or by means of an invasive procedure.

**D. Specimen Referral Criteria**

1. Send specimen to the Central Lab to verify critical values

## REAGENT AND/OR MEDIA, MATERIALS

Clinitek Status Analyzer+
Clinitest hCG Pregnancy Test
BioSys Plus Liquid urine control
Gloves and PPE
Patient properly labeled urine sample
Gauze, lint free wipes
Disposable dropper
Store Urine HCG test kit at either refrigerated or at room temperature, 2 to30°C.
If refrigerated, bring the wrapped cassettes to room temperature before opening the protective pouch to avoid moisture condensation on the membrane

## EQUIPMENT CALIBRATION AND MAINTENANCE

The Clinitek Status +TM Analyzer performs a "self-test" as a function check of the meter, self-test must be successful in order for the meter to run and calibrates automatically before each time it is turned on. In addition, the analyzer performs an automatic calibration before each measurement. The white calibration bar (on the test table) was tested on a reference spectrophotometer. By calibrating the reference spectrometer with the National Institute of Standards and Technology (NIST) traceable calibrators, it shows traceability to NIST.

**NOTES:** Do not push or pull the test table because the calibration might fail, or the movement might cause table positioning errors. Do not move or bump the table while the analyzer calibrates. The calibration might fail.

A. WHEN TO CLEAN THE METER
1. Clean the Outside of the meter monthly.
2. Clean the Test table insert before and after each quality control testing and patient testing.
3. Whenever dirt or urine is present on the meter.
4. When the meter has been exposed to contamination with body fluids

B. Procedures for cleaning the Test table insert.
1. Remove test table insert from the test table
2. Thoroughly clean both sides of the table insert with damp (not wet) paper towel. Wipe dry
3. Replace insert onto test table.

C. Procedure for cleaning the White Calibration Bar

For the CLINITEK Status+ analyzer to perform as intended and provide reliable test results, the white calibration bar on the test table needs to be clean and not discolored. With normal use, the white calibration bar should not become dirty or discolored. To clean the white calibration bar, perform the following steps:

1. Remove the insert from the test table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Drain the drip tray, if necessary.
4. Examine the white calibration bar on the test table for dirt or discoloration.
5. If the white calibration bar appears clean and unmarked, perform the following steps:
   a. Place the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upward.
   b. Push the test table firmly but slowly, just over halfway into the analyzer.
   c. Place the test table insert.

   **CAUTION:** Do not touch the calibration bar while you examine it or after you clean it. Your fingerprints or lint on the bar could cause unreliable test results. When you examine the white calibration bar, do it carefully under good lighting.
6. If the white calibration bar is dirty or discolored, perform the following steps:
   a. Wet a new cotton-tipped stick or lint-free cloth with distilled water and gently wipe and clean the calibration bars.
   b. Allow the calibration bar to air dry.
   c. Inspect the surface for dust, foreign material, scratches, or scuffs. If you cannot completely clean the calibration bar or if the bar still has marks, order a new test table.
   d. Place the test table, as described in step 5.

D. CLEANING THE OUTSIDE OF THE METER:
A. Turn off analyzer by pressing the on/off button.
B. Wipe the outside (including the display) with damp (not wet) paper towel and mild detergent.
C. Record cleaning in the maintenance log.

## PROCEDURES

### A. Entering Operator and Patient Information

Enter or select an operator name, patient name, and patient ID.

To enter operator and patient information, perform the following steps:

1. On the **Select Ready** screen, select **Cassette test**
2. On the **Operator ID** and Operator Name screen, enter your user code
3. Select **Enter New Patient**
   Enter the patient name (maximum of 20 characters) on the **Enter Patient Name** screen.
   Select **Enter.**
4. Enter the patient ID (7-digit MRUN number) on the **Enter Patient ID** screen. Select **Enter**.

### B. Preparing a Cassette Full Test

To prepare a cassette Full Test, perform the following steps:

1. On the **Select Ready** screen, select **Cassette Test**.
2. On the **Test Type** screen, select **Clinitest hCG cassette**.
3. Enter the cassette lot number and expiration date:
   a. To use the last cassette number and begin the test, select **Use Last Lot.**
   b. To enter new cassette data, select **Enter new lot and expiration**.
      Enter the cassette lot number and select **Enter**.

      Use the arrow keys to enter the cassette expiration date and select **Enter**.
4. Position the test table insert in the test table for a cassette test.
5. Remove the test cassette from the foil package and place the cassette on the test table.

### C. Running a Cassette Full Test

To run the test, you have 8 seconds to perform the following 2 steps:

**Note:** After you select **START**, you have 8 seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.

1. Select **START.**
   The **Prepare Test** screen displays steps on how to perform the test.
   A timer displays the amount of time remaining to complete the task.
2. Draw sample from the patient container and completely fill the pipette stem. Empty only one pipette stem (200 µL) into the well.
3. Add the entire contents of the pipette into the sample well of the test cassette.
   a. After the 8-second countdown ends, the analyzer pulls in the test table and cassette, and then calibrates.
   b. After the calibration finishes, the analyzer starts analyzing the cassette.
   c. The **Analyzing** screen displays.
   d. The analyzer displays either of the following screens:
      i. **Analyzing** If the cassette is still being analyzed
      ii. **Results** If analyzing the cassette has been completed.

e. A timer counts down the time remaining in the cassette analysis process.
f. After the countdown ends, the analyzer displays the test results on the Results screen.
g. The results display on the screen for 2 minutes.
h. Then, the display returns to the **Select Ready** screen.
i. The test table and cassette move out of the analyzer.

**D. Viewing the Cassette Full Test Results**

The test results display on the **Results** screen. Select **Done** to return to the main **Results** screen.

**E. Completing the Cassette Full Test**

Complete the testing for one cassette or continue testing one cassette at a time until you finish testing all the cassettes you want to analyze.

1.To complete the cassette Full Test, perform the following steps:
a. Remove the used cassette from the test table and disposed.
b. Clean the table insert.
c. Report the results to the provider.
d. Select **Done** to complete the test.
e. Select **Back** to return to the **Select Ready** screen.

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

Quality Control (QC) testing helps assure that the cassettes are reacting correctly and that the instrument is accurately reading them. It can also help detect errors resulting from user techniques.

**A. Control procedure**

1. Two levels (positive and negative) of BioSys Plus Liquid Control are run on the day of patient testing and when you open a new box of urine HCG cassettes
2. Water should not be used as a negative control.
3. You can run QC tests for cassettes at any time or when a QC test is due.
4. When a QC test is due, the test icon on the **Select Ready** screen is blinking. It displays the type of test (strip or cassette) that is due.

**B. Running a QC Cassette Test**

1. Make sure the controls are at room temperature.
2. On the **Select Ready** screen, select **QC Test due**. The **QC Test** screen displays.
3. Select **QC Cassette Test Required**.
4. Enter the operator ID in lieu of operator name.
5. The **Control and Level** screen displays; shows Control name and level name
6. Press **Enter lot and exp. Date** icon. The **Control Lot** screen displays.
   a. Enter the control lot and select **Enter**.
   b. The **Control Expiration** screen displays.
   c. Use the arrow keys to indicate the control lot expiration date and select **Enter**.
   d. The **Cassette Lot** screen displays.
7. To enter the cassette information:
   Enter the cassette lot or scan and select **Enter.**

a. Use the arrow keys to indicate the cassette expiration date.
b. Select **Enter.**
c. Position the test table insert in the test table for a cassette test.

8. Remove the test cassette from the foil package and place the cassette on the test table.
   **Note:** After you select **START**, you have 8 seconds to add control into the well on the cassette.
   a. Select **START**.
   b. The **Prepare Test** screen displays steps on how to perform the test.
   c. A timer displays the amount of time remaining to complete the task.
   d. Draw sample from the Control bottle and completely fill the pipette stem. Empty only one pipette stem (200 µL) into the well.
   e. After the 8-second countdown ends, the analyzer pulls in the test table and cassette, and then calibrates.
   f. After the calibration finishes, the analyzer starts analyzing the cassette.
   g. A timer counts down the time remaining in the cassette analysis process.
   h. After the countdown ends, the analyzer displays the test results on the **Results** screen.
   i. The test table and cassette move out of the analyzer.
   j. Remove the cassette when the analysis is complete
   k. The instrument is set to determine pass/fail, if the test results pass, the **Results-QC Test: Pass** screen displays. If the test results fail, the Results-QC Test: Fail screen displays.
   l. Select **Done**.
   m. The control and level screen display the next control name and level.
   n. Enter control lot and expiration date.
   o. Press the use last lot icon to record the cassette lot number and expiration date.
   p. Position the test table insert in the test table for a cassette test.
   q. Repeat step 8 (a through q) for all controls.
9. To repeat a failed QC test, select **Repeat failed QC** test under **QC Test-Results Summary screen displays**.
   a. If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.
10. Select **Done** to return to the **Select Ready** screen.
11. The QC **Results** screen displays.
    **Note** When the instrument is set to determine pass/fail, if the test results pass, the Results-QC Test: **Pass** screen displays. If the test results fail, the **Results-QC Test: Fail** screen displays.
12. To print the results, select **Print**.
13. To navigate the results:
    a. To view the next page, select **More**.
    b. To return to the previous page, select **Back**.

14. Select **Done**.
15. The control and level screen display the next control name and level.
16. Enter control lot and expiration date.
17. Press the use last lot icon to record the strip lot number and expiration date.
18. Make sure the reagent strip holder faces upward in the test table insert.
19. The **QC Test-Results Summary** screen displays.
20. To repeat a failed QC test, select **Repeat failed QC test**. If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.
21. Select **Done** to return to the **Select Ready** screen.

**C. Running a QC Cassette Test**

1. Make sure the controls are in room temperature.
2. On the **Select Ready** screen, select **QC Test due**. The **QC Test** screen displays.
3. Select **QC Cassette Test Required**.
4. Enter the operator ID in lieu of operator name.
   **Note** To enter text, use the alpha keyboard (**ABC**). To enter numbers, select **123**.
5. The **Control and Level** screen displays; shows Control name and level name
6. Press Enter lot and exp. Date icon
7. The **Control Lot** screen displays.
8. Enter the control lot and select **Enter**.
9. The **Control Expiration** screen displays.
10. Use the arrow keys to indicate the control lot expiration date and select **Enter.**
11. The **Cassette Lot** screen displays.
12. To enter the cassette information:
    a. Enter the cassette lot and select **Enter**.
13. The **Cassette Expiration** screen displays.
    a. Use the arrow keys to indicate the cassette expiration date.
    b. Select **Enter**.
14. Position the test table insert in the test table for a cassette test.
15. Remove the test cassette from the foil package and place the cassette on the test table.
    **Note** After you select **START**, you have 8 seconds to add control into the well on the cassette.
16. Select **START**.
17. The **Prepare Test** screen displays steps on how to perform the test.
18. A timer displays the amount of time remaining to complete the task.
19. Place 4 drops of control into the sample well of the test cassette.
20. After the 8-second countdown ends, the analyzer pulls in the test table and cassette, and then calibrates.
21. After the calibration finishes, the analyzer starts analyzing the cassette, and the **Analyzing** screen displays.

22. A timer counts down the time remaining in the cassette analysis process.
23. After the countdown ends, the analyzer displays the test results on the Results screen. The test table and cassette move out of the analyzer.
24. Remove the cassette when the analysis is complete.
25. The **Results** screen displays.
    **Note** When the instrument is set to determine pass/fail, if the test results pass, the **Results QC Test: Pass** screen displays. If the test results fail, the **Results-QC Test: Fail** screen displays.
26. Select **Done.**
27. The control and level screen display the next control name and level.
28. Enter control lot and expiration date.
29. Press the use last lot icon to record the cassette lot number and expiration date.
30. Position the test table insert in the test table for a cassette test.
31. Repeat step 15 through 27.
32. The **QC Test-Results Summary** screen displays.
33. To repeat a failed QC test, select **Repeat failed QC test**. If you set more than 1 QC test control level, such as negative and positive, be sure to run all control levels within 10 minutes of each other. Otherwise, the CLINITEK Status+ analyzer times out and the QC fails. Any successful QC does not count.

**D. Select Done to return to the Select Ready screen.**

**E. Corrective actions for out range QC.**

1. If the control results are out of control:
   a. Start over and repeat the quality control test.
   b. Check expiration date on the reagent.
2. If the control results are still out of control:
   a. Use a new tube of reagent control.
   b. Notify area supervisor.
3. Seek assistance from the clinical laboratory.

## RESULT REPORTING

**A. POSITIVE:** The instrument will automatically determine if the Test (T) region intensity is equal or more intense than a 25 mu/mL urine sample and confirm that the Control (C) and Reference (R) regions meet minimum intensity specifications.

**B. BORDERLINE:** Result is indeterminate, repeat in 48-72 hours.

**C. NEGATIVE:** The instrument will automatically determine that the Test (T) region is less intense than 25 mlu/mL hCG Concentration level that the devise can detect and confirm that the Control (C) and Reference (R) regions meet minimum intensity specifications.

**INVALID:** The instrument will automatically determine if a procedural error or test reagent deterioration has occurred by confirming that the Reference (R) and Control (C) regions meet minimum intensity requirements.

**D. DOCUMENT RESULT:** (refer to POC 1.9)

After testing, use POCT Testing Record form to record results by affixing the instrument result printout. Document all point of care test results on an appropriate form with accompanying reference ranges. This form serves as a chart form and doubles as a log sheet when applicable. Include the patient's name, MLK-OC number, date of birth, date, time and result of test, operator ID and appropriate comments when critical values are obtained.

**E. REFERENCE INTERVALS**

N/A

**F. REPORTING PROTOCOLS FOR CRITICAL VALUES**

Record test results in the patient's medical record. Information must include test results, date, time, operator ID, appropriate comments, action taken when critical values are obtained.

**G. ACCEPTABLE RESULTS**

Patient test results are acceptable and may be reported when:

The laboratory has established a followed written quality control procedure.

The procedures for monitoring and evaluating the quality of testing process assure the accuracy and reliability of patient test results.

**H. CORRECTIVE ACTION**

Patient test results must be repeated, and corrective action taken when:

1. Results fall outside acceptable range.
2. Results that are judged to be invalid or otherwise doubtful

**LIMITATIONS**

A. Negative test result in patients suspected to be pregnant should be retested with sample obtained 48 to 72 hours later, or by performing a quantitative assay.

B. The test is not intended to detect conditions other than pregnancy. A number of conditions other than pregnancy, including trophoblastic disease and certain nontrophoblastic neoplasm, can cause elevated level of hCG.

C. As is true with any diagnostic test, clinical diagnosis should not be based solely on single test result. Clinical diagnosis should incorporate all clinical and laboratory data.

D. Because of the lag between conception and appearance of hCG in urine, to exclude pregnancy with highest degree of certainty, it is traditional to repeat the test on a fresh sample obtained 2-3 days after obtaining a "negative" result on the initial sample.

E. Patients on antibody therapies may obtain invalid results due to the presence of interfering antibodies in the medications.

F. The presence of heterophile antibodies or non-specific protein binding may cause false-positive results in sensitive immunoassays. If qualitative interpretation is inconsistent with clinical evidence, results should be confirmed by an alternative hCG detection method.

**G. Interfering Substances:**

1. False positive results may be obtained in urine with high HCG levels of patients suffering from chorionic epithelioma or hydatid mole. False negative results may be obtained in cases like extra uterine pregnancy, toxemia of pregnancy or threatened abortion since excretion of HCG

is often decreased.

2. The following potentially interfering substances were added to hCG free urine and 20 mIU/mL hCG spiked urine. No interference was observed in all cases. In addition, the effect of urine pH from 5 to 9 was tested at these hCG concentrations. The pH of the urine did not affect the outcome of the result.

| SUBSTANCE | LEVEL | SUBSTANCE | LEVEL |
|---|---|---|---|
| Acetaminophen | 20 mg/dL | Caffeine | 20 mg/dL |
| Acetylsalicylic | 20 mg/dL | Brompheniramine | 20 mg/dL |
| Ampicillin | 20 mg/dL | Cannabinol | 10 mg/dL |
| Ascorbic Acid | 20 mg/dL | Hemoglobin | 1 mg/dL |
| Atropine | 20 mg/dL | Codeine | 10 mg/dL |
| Albumin, human serum | 10 mg/dL | Gentrisic Acid | 20 mg/dL |
| Bilirubin | 1 mg/dL | Dextromethorphan | 20 mg/dL |
| Ephedrine | 10 mg/dL | Diphenhydramine | 20 mg/dL |
| Ethanol | 1% | Glucose | 2 mg/dL |
| Ibuprofen | 20 mg/dL | Methamphetamine | 10 mg/dL |
| Morphine | 600ug/dL | Ranitidine | 20 mg/dL |
| Salicylic Acid | 20 mg/dL | | |

**H. Troubleshooting**

3. If an operational or analyzer problem occurs, in most cases, an error number with an explanation of the problem displays on the Select Ready screen.
4. If a problem persists, write down the error number that displays and contact: Technical Support at **877-229-3711** for assistance.

I. If you think a Siemens urinalysis strip or an hCG cassette is causing the problem, see its product insert for troubleshooting information. Patients on antibody therapies may obtain invalid results due to the presence of interfering antibodies in the medications.

J. The presence of heterophile antibodies or non-specific protein binding may cause false-positive results in sensitive immunoassays. If qualitative interpretation is inconsistent with clinical evidence, results should be confirmed by an alternative hCG detection method.

**K. Interfering Substances:**

5. False positive results may be obtained in urine with high HCG levels of patients suffering from chorionic epithelioma or hydatid mole. False negative results may be obtained in cases like extra uterine pregnancy, toxemia of pregnancy or threatened abortion since excretion of HCG is often decreased.
6. The following potentially interfering substances were added to hCG free urine and 20 mIU/mL hCG spiked urine. No interference was observed in all cases. In addition, the effect of urine pH from 5 to 9 was tested at these hCG concentrations. The pH of the urine did not affect the outcome of the result.

| SUBSTANCE | LEVEL | SUBSTANCE | LEVEL |
|---|---|---|---|
| Acetaminophen | 20 mg/dL | Caffeine | 20 mg/dL |
| Acetylsalicylic | 20 mg/dL | Brompheniramine | 20 mg/dL |
| Ampicillin | 20 mg/dL | Cannabinol | 10 mg/dL |
| Ascorbic Acid | 20 mg/dL | Hemoglobin | 1 mg/dL |
| Atropine | 20 mg/dL | Codeine | 10 mg/dL |
| Albumin, human serum | 10 mg/dL | Gentrisic Acid | 20 mg/dL |
| Bilirubin | 1 mg/dL | Dextromethorphan | 20 mg/dL |
| Ephedrine | 10 mg/dL | Diphenhydramine | 20 mg/dL |
| Ethanol | 1% | Glucose | 2 mg/dL |
| Ibuprofen | 20 mg/dL | Methamphetamine | 10 mg/dL |
| Morphine | 600ug/dL | Ranitidine | 20 mg/dL |
| Salicylic Acid | 20 mg/dL | | |

**L. Troubleshooting**

7. If an operational or analyzer problem occurs, in most cases, an error number with an explanation of the problem displays on the Select Ready screen.
8. If a problem persists, write down the error number that displays and contact: Technical Support at **877-229-3711** for assistance.
9. If you think a Siemens urinalysis strip or an hCG cassette is causing the problem, see its product insert for troubleshooting information.
10. After an error occurs, if you power off the analyzer, be sure to retest the sample that was in progress. When you power on the analyzer, restart the test.

**Associated forms**

N/A

**REFERENCES**

1. Henry, Clinical Diagnosis and Management by Laboratory Methods, 17th edition, pp. 380-435.

2. Clinitek Status + Operator's Guide. 10490853 Rev. C, 2011-12

3. Clinitek Status Connect System Operator's Guide. 10490852 Rev. B, 2011-06

4. Siemens Clinitest hCG Pregnancy Test insert.06878007, 2008-08

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-4.4.1 |
| **SUBJECT: CLINITEK STATUS/SIEMENS REAGENTS STRIPS** | **PAGE:** 1 OF 8 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalatMD | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

Routine urinalysis involves determining the pH, specific gravity and the presence or absence of protein, glucose, ketones, bilirubin, blood and leukocytes in the urine. This is done by the use of a small paper stick impregnated with the appropriate chemicals to detect urinary analytes.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

Siemens reagent strips are impregnated with dried chemicals that produce color reaction products upon exposure to certain substances that are present in urines.

| Test Name | Chemical Ingredients and Principle |
|---|---|
| **Glucose** | 2.2% w/w glucose oxidase (microbial, 1.3 IU): 1.0% w/w peroxidase (horseradish, 3300 IU); 8.1% w/w potassium iodide/; 69.8% w/w buffered; 18.9% w/w nonreactive ingredients Glucose oxidase catalyzes the formation of gluconic and hydrogen peroxide from the oxidation of glucose. Peroxidase catalyzes the reaction of hydrogen peroxide with a potassium iodide the chromogen to colors ranging from green to brown. |
| **Bilirubin** | 0.4% w/w 2,4-dichloroaniline diazonium salt; 37.3% w/w buffer; 62.3% 2/2 nonreactive ingredients. Bilirubin couples with diazotized dichloroaniline in a strongly acid medium. Colors range through various shades of tan. |
| **Ketone** | 7.1 w/w sodium nitroprusside; 92.9% w/w buffer. Acetoacetic acid reacts with nitroprusside. Colors range from buff-pink, for a negative reading, to maroon for a positive reading's |
| **Specific Gravity** | 2.8% w/w bromothymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.0% w/w sodium hydroxide. PKA changes occur for certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue green in urine of low ionic concentration through green and yellow green in urine of increasing ionic concentration. |

| | |
|---|---|
| **Blood** | 6.8% w/w disopropylbenzene dihydroperoxide; 4.0% w/w 3,3',4,4'-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w nonreactive ingredients. Hemoglobin catalyzes the reaction of disopropyl benzene dihydroperoxide and 3,3',5,5' – tetramethylbenzidine. Colors range from orange through green; very high levels of blood may cause the color development to continue to blue. |
| **PH** | 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97% w/w nonreactive ingredients. The double indicator principles give a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue. |
| **Protein** | 0.3% w/w tetrabromophenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients. At a constant pH, the development of any green color is due to the presence of protein (protein error-of-indicators principle). Colors range from yellow for "Negative" though yellow-green and green to green blue for "Positive" reactions. |
| **Urobilinogen** | 0.2% w/w p-diethylamino benzaldehyde; 99.8% w/w nonreactive ingredients. In a modified Ehrlich reaction, p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color. |
| **Nitrite** | 1.4% w/w p-arsanilic acid; 1.3% w/w 1, 2, 3, 4-tetrahydrobenzo (h) quinoline- 3-ol; 10.8% w/w buffer; 86.5%w/w nonreactive ingredients. Nitrite (derived from the dilate) is converted to nitrite by the action of Gram-negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. This diazonium compound couples with 1,2,3,4-tetrahydrobenzo (h) quinolin-3-ol to produce a pink color |
| **Leukocytes** | 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients. Esterase is granulocytic leukocytes catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product. |

The strips have been determined to be non-hazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

**SAFETY PRECAUTIONS**

See POC-1.8

**SAMPLE/SPECIMEN PREPARATION REQUIREMENTS**

N/A

## REAGENT AND/OR MEDIA, MATERIALS

Storage and Stability:

- Store Siemens Reagent Strips at room temperature, 15 - 300C (59 - 860F)
- Do not store the reagent strips in direct sunlight. Protection from exposure to light, heat and ambient moisture is mandatory to guard against altered reagent reactivity.
- Store the unused reagent strips in the original bottle. Transferring unused reagent strips to other containers may cause the strips to deteriorate and become unreactive.
- Do not remove desiccants from bottle.
- Do not use reagent strips beyond the expiration date.
- Initial and date the reagent bottle when you first open it.
- Do not remove the strip from the bottle until immediately before use. Replace cap immediately and tightly after removing the strip.
- Avoid touching the test areas of the reagent strip.
- Discoloration or darkening of the reagent areas may indicate deterioration. If this happens, confirm the expiration date and/or check performance with known negative and positive controls. If acceptable results are not obtained, discard the deteriorated strips and retest using a new, unopened bottle of reagent strips.
- Due to the nature of the urobilinogen and leukocytes reagents found on the strips, these two results may be decreased at temperatures below 220C (720F) and increased at temperatures above 260C (790F).
- It is especially important to use fresh urine to obtain optimal results with the test for bilirubin and urobilinogen, as these compounds are very unstable when exposed to room temperature and light
- Using a first morning specimen or one that has incubated in the bladder for four hours or more optimizes nitrite test results

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

N/A

## QUALITY CONTROL AND METHOD PERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

N/A

## LIMITATIONS

Interfering substances

Substances that cause abnormal urine color may affect the readability of test pads on urinalysis reagent strips. These substances include drugs containing azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantano®), nitrofurantoin (Macrodantin®, Furadantin®), riboflavin, visible levels of blood or bilirubin. These are the list of substances and conditions that my affect rest results.

| *Test Name* | *False Positive or Increased Values* | *False negative or Decreased Values* |
|---|---|---|
| **Glucose** | - Temperature | - Ascorbic acid (>50 mg/dL) may affect a 75 to 125 mg/dL glucose level Ketones (>50mg/dL may affect a 75 to 125 mg/dL glucose level.<br>- High specific gravity.<br>- Temperature |
| **Bilirubin** | - Indican™ (indoxyl sulfate) may impart a yellow orange to red color on the pad.<br>- Metabolites of Lodine™ (Etodolac) | - Ascorbic acid (>25 mg/dL). Small amounts (less than 0.4 mg/dL) may need to be detected with ICTOTEST® Reagent Tablets.<br>- Urine specimen was more than one hour old (instability of bilirubin).<br>- Contamination with chlorhexidine (found in some skin cleansers) |
| **Ketone** | - Highly pigmented urine.<br>- Large amounts of levodopa (L-dopa) metabolites.<br>- Compounds that contain sulfhydryl group | |
| **Specific Gravity** | - Moderate (100 – 750 mg/dL quantities of protein.<br>- Contamination with chlorhexidine (found in some skin cleansers) | - Highly buffered/alkaline urine |
| **Blood** | - Oxidizing contaminants (e.g. bleach). Microbial peroxidase from urinary tract infections | - High specific gravity.<br>- Capoten® (Captopril) |
| **PH** | - Bacterial growth that converts urea to ammonia | - Run over from the protein reagent pad |
| **Protein** | - Highly buffered or alkaline urine.<br>- Contamination with quaternary ammonium compounds (from some antiseptics and detergents) or Chlorhexidine (found in some skin cleansers) | |

| | | |
|---|---|---|
| **Urobilinogen** | - Temperatures >260C (790F).<br>- *p-amino salicylic acid* (PAS) and sulfonamides.<br>*p-aminobenzoic acid* (PABA) may cause atypical color development | - Temperature <220C (720F) |
| **Nitrite** | | - Infections caused by organisms that don't contain reductase.<br>- Urine was not in bladder long enough (at least 4 hours).<br>- Absence of dietary nitrate.<br>- High specific gravity.<br>- Ascorbic acid (<25 mg/dL) may affect a low positive nitrate level (<0.06 mg/dL nitrate ion). |
| **Leukocytes** | - Formalin.<br>- Temperature >260C (790F) | - Elevated glucose (>3,000 mg/dL).<br>- High specific gravity.<br>- Cephalexin (Keflex®) or Cephalothin (Keflin®).<br>- High concentrations of oxalic acid. - Tetracycline.<br>- Temperature <220C (720F) |
| **Color** | - Concentration.<br>- Food Pigments.<br>- Dyes.<br>- Blood.<br>- Various pathological conditions. | - These all can affect negatively as well. |

**Glucose:** Ascorbic acid concentration of 50 mg/dl or greater may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dl), ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dl) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dl) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature

**Bilirubin:** Indicial (indoxyl sulfate) can produce a yellow orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading. Metabolites of Lodine (etodolac) may cause false positive or atypical results; ascorbic acid concentrations of 25mg/dl or greater may cause false negatives. Since very small amounts of bilirubin may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Bayer Reagent strips to bilirubin is sufficient for the intended use. When very small amounts of bilirubin in urine are sought (e.g., earliest phase of viral hepatitis), ICTOTEST reagent tablets should be the method of choice.

**Ketone:** False positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2- mercaptoethane sulfonic acid) that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

**Specific Gravity:** The chemical nature of the Bayer SG test may cause slightly different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.

**Blood:** Elevated specific gravity may reduce the reactivity of the blood test. Capoten (Captopril) may also cause decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of ascorbic acid normally found in urine do not interfere with this test.

**PH:** If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as run over may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering of the pH result.

**Protein:** False positive results may be obtained with highly buffered or alkaline urines, Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with skin cleansers containing chlorhexidine may also produce false positives.

**Urobilinogen:** The reagent area may react with interfering substances known to react with Erlich's reagent, such as p-aminobenzoic acid. False negative results may be obtained if formalin is present strip reactivity increases with temperature; the optimum detection of porphobilinogen. The absence of urobilinogen cannot be determined with this test.

**Nitrite:** Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive result suggesting the presence of 10 or more organisms per ml. But color development is not proportional to the number of bacteria present. A negative result does not itself prove that there is no significant bacteriuria. Negative results may occur when urinary tract infections are caused by organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urines with high specific gravity. Ascorbic acid concentrations of 25 mg/dl or greater may cause false negative results with specimens containing small amounts of nitrite ion (0.06 mg/dl or less).

**Leukocytes:** Elevated glucose concentrations (>3 g/dl) or high specific gravity may cause decreased test results. The presence of cephalexin (Keflex) cephalothin ((Keflin), or high concentrations of oxalic acid may also cause decreased reactivity, and high levels of the drug may cause a false negative reaction. For additional information on method limitations and performance characteristics, see the product information in the Siemens Multistix 10 SG Reagent Strips package insert.

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Siemens Multistix 10 SG Reagent Strips Package Insert, TN30516A, Rev. 06/10

2. Clinitek Status + Operator's Guide. 10490853 Rev. C, 2011-12

3. National Committee for Clinical Laboratory Standards (NCCLS), Clinical Laboratory Procedure Manuals, Third Edition (GP2-A3), 1996

**Technical Assistance**

Siemens Healthcare Diagnostics: 1-877-229-3711 www.siemens.com/diagnostics
Siemens Healthcare Diagnostics Inc. Tarrytown, NY 10591-5097 USA

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** POC-1500.0 |
| **SUBJECT: ALERE ICUP DX PRO URINE DRUG SCREEN (CLIA-WAIVED)** | **PAGE:** 1 OF 20 |
| **SECTION:** POINT OF CARE TESTING | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

The Alere iCup® Dx Pro 2 test cup is a rapid, screening test for the qualitative detection of multiple drugs in human urine at specified cut off levels. The customized 10-drug Alere iCup® Dx Pro 2 Drugs of Abuse Cup tests for the possible use of Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Buprenorphine (BUP), Cocaine (COC), Marijuana (THC), Methadone (MTD), Methamphetamine (MET), Morphine 300 (MOP/OPI300) and Oxycodone (OXY).

## PRINCIPLE AND CLINICAL SIGNIFICANCE

The Alere iCup® Dx Pro 2 Drugs of Abuse Cup is a competitive immunoassay that is used to screen for the presence of various drugs in urine. It is chromatographic absorbent device in which drugs in a urine sample competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites. When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When the drug levels within the urine sample are below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip that regardless of its intensity indicates a negative test result.

When the sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), of each strip, if the test has been performed properly.

**Amphetamine/Methamphetamine (AMP/MET)** and their metabolites are potent central nervous system stimulants. Acute doses induce euphoria, alertness, and sense of increased energy and power. Responses from chronic use can include anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine and amphetamine are excreted in the urine as unchanged drug along with deaminated or hydroxylated derivatives. Methamphetamine also metabolize to amphetamine in the body. As a result, urine specimens from most methamphetamine users contain both the unchanged parent drug and the amphetamine metabolite.

**Barbiturates (BAR)** are classified as central nervous system depressants. These products produce a state of intoxication that is similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination and impaired judgment. Depending on the dose, frequency, and duration of use, tolerance, physical dependence and psychological dependence can occur. Barbiturates are taken orally or by intravenous and intramuscular injections. Members of the barbiturate drug class typically excrete in urine as parent compound and metabolites.

**Benzodiazepines (BZO)** are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses, and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection and are extensively oxidized in the liver to metabolites. Most benzodiazepines are excreted in the urine as conjugates and metabolites.

**Buprenorphine (BUP)** is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™; all of which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. A substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

**Cocaine (COC)** is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in the urine primarily as benzoylecgonine in a short period of time. Benzoylecgonine has a biological half-life of 5 to 8 hours, which is much longer than that of cocaine (0.5 to 1.5 hour) and can be generally detected for 24 to 60 hours after cocaine use or exposure.

**Marijuana (THC)** is generally accepted to be the principle active component in marijuana. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. The primary metabolite of marijuana excreted in the urine is 11-nor-*-9-tetrahydrocannabinol-9-carboxylic acid. The elimination of THC and metabolites in urine is highly dependent on frequency of drug use and physiology of the user.

**Methadone (MTD)** is a synthetic analgesic drug originally used for the treatment of narcotic addiction and pain management. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Overdose of methadone may cause coma or even death. Methadone is taken orally or intravenously and is metabolized in the liver and has a biological half-life of 15-60 hours.

**Opiates (OPI/MOP/OPI300)** such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma. Heroin is quickly metabolized to 6-acetylmorphine (6-AM), morphine, and morphine glucuronide. Codeine also partially metabolizes to morphine and morphine glucuronide. Thus, the presence of morphine or morphine glucuronide in the urine can indicate heroin, morphine, and/or codeine use.

**Oxycodone (OXY)** is a semi-synthetic opioid with a structural similarity to codeine. It produces potent euphoria, analgesic and sedative effects, and has a dependence liability similar to morphine. Oxycodone is most often administered orally and is metabolized by demethylation to nor oxycodone and oxymorphone followed by glucuronidation. The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine. smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. The primary metabolite of marijuana excreted in the urine is 11-nor-*-9-tetrahydrocannabinol-9-carboxylic acid. The elimination of THC and metabolites in urine is highly dependent on frequency of drug use and physiology of the user.

## SAFETY PRECAUTIONS

- This kit is for external use only.
- Do not use if pouch is punctured or not sealed.
- Discard after first use. The test cannot be used more than once.
- Do not use test kit beyond expiration date.
- Keep out of the reach of children.
- Do not read results after 5 minutes.

Always handle urine specimens and quality controls containing human sourced material with care using proper PPE (Personal Protective Equipment) and use Universal Precautions as they might be infectious.

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

### TIME OF COLLECTION

Collect urine sample after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drug of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the table below to determine the minimum/maximum detection times, and cut-off level for each drug.

Cut-off Value and Approximate Detection Time

| Drug (Identifier) | Cut-off Level | Minimum Detection Time | Maximum Detection Time |
|---|---|---|---|
| Marijuana (THC) | 50 ng/mL | 2 hours | Up to 5+ days |
| Cocaine (COC) | 300 ng/mL | 1 – 4 hours | 2 – 4 days |
| Amphetamine (AMP) | 1000 ng/mL | 2 – 7 hours | 2 – 4 days |
| Methamphetamine (MET) | 1000 ng/mL | 2 – 7 hours | 2 – 4 days |
| Morphine (MOP/OP1300) | 300 ng/mL | 2 hours | 2 – 3 days |
| Buprenorphine (BUP) | 10 ng/mL | 4 hours | 1 – 3 days |
| Oxycodone (OXY) | 100 ng/mL | 1 – 3 hours | 1 – 2 days |
| Barbiturates (BAR) | 300 ng/mL | 2 – 4 hours | 1 – 3 weeks |
| Benzodiazepine (BZO) | 300 ng/mL | 2 – 7 hours | 1 – 4 days |
| Methadone (MTD) | 300 ng/mL | 3 – 8 hours | 1 – 3 days |

### URINE COLLECTION PROCEDURE

1. Remove a test cup from the foil pouch by tearing at the notch. Use it as soon as possible.
2. Place a patient demographic label on the cup. Verify patient's identity before giving the cup to the patient for collection.
3. Instruct the donor (patient) to remove the cap from the test cup and void directly into the test cup. Instruct the donor to fill the cup to the 30 mL mark. It is acceptable to collect an extra sample.
4. Immediately read the temperature to verify that the urine temperature is within the acceptable range 32-38°C (90-100°F).
5. If urine temperature is not within acceptable range, reject the specimen and re-collect a fresh specimen.

## REAGENT AND/OR MEDIA, MATERIALS

- Alere iCup Dx Pro 2 – 10 drugs (Supplier part number: I-DXP-2107-01)
- Desiccant Pouch - Remove desiccant from cup. The desiccant is for storage purposes only.
- One (1) Instruction Sheet.
- One (1) Adulteration color comparison chart for interpretation of adulteration test results
- Professional Cup Urine Drug Controls: negative and positive levels (Supplier part number: 88010)

## EQUIPMENT CALIBRATION AND MAINTENANCE

No applicable calibration and equipment maintenance.

## TEST PROCEDURES

Test must be performed at room temperature, 18-30°C (65-86°F).
The urine drug screen testing on Alere iCup Point-of-Care is performed as needed by the direction of medical providers.

1. Obtain a patient demographic label. Place the label on the patient result log.
2. After the urine has been collected, tighten lid, and place the test cup on a flat surface. Keep the cup upright.
3. Read the temperature immediately to verify that the urine temperature is within the acceptable range 32-38°C (90-100°F). Record the temperature reading on the result log.
4. Remove cup label and verify that adulterant pad colors are within acceptable range according to adulteration guide.
5. Wait 5 minutes to start reading for results. Do not read results earlier than 5 minutes.
6. Do not read results after 5 minutes. Results after more than 5 minutes may be not accurate and should not be read.
7.

## QUALITY CONTROL

### QUALITY CONTROLS

The AlereTM Professional Cup Urine Drug Controls (catalog#: 88010) are designed to monitor and validate the performance of drugs of abuse detection methods at levels established by SAMHSA, CAP/AACC and many state programs. The AlereTM Professional Cup Urine Drug Controls are compatible with all quantitative and qualitative drug detection procedures which are sufficiently sensitive to detect the control constituents. They should be treated as any "unknown" specimen while following the specific protocol of the assay being used. This product is intended to be used by health care professionals as an integral part of a quality control system.

The DEA exempt AlereTM Professional Cup Urine Drug Control product line of controls is manufactured using a human based matrix that has been stabilized to ensure that the product will be viable until the date of expiration. Positive control urines have been spiked with authentic reference drug standards and/or appropriate metabolites. Negative control urines are certified negative by immunoassay screening methods and GC/MS for the constituents listed in the Target Analyte Table below.

| Drug Assay Class | Drug | Negative Control | Positive Control |
|---|---|---|---|
| Amphetamine | d-Amphetamine | 0 | 3000 |
| Barbiturates | Secobarbital | 0 | 900 |
| Buprenorphine | Buprenorphine Glucuronide | 0 | 30 |
| Benzodiazepine | Oxazepam | 0 | 900 |
| Cocaine | Benzoylecgonine | 0 | 900 |
| Methadone | Methadone | 0 | 900 |
| THC | Delta-9-THC-COOH | 0 | 150 |
| Methamphetamine | d-Methamphetamine | 0 | 3000 |
| Opiates | Morphine (High Opiate) | 0 | 6000 |
| Oxycodone | Oxycodone | 0 | 300 |

## QUALITY CONTROLS – STORAGE CONDITION

- Unopened controls are stable until the expiration date when stored at -20 to -10°C and protected from light.
- Unopened controls are stable until the expiration date when stored at 2 - 8°C. However, no stability claims can be made for Oxazepam as it may deteriorate over time when stored refrigerated.
- Opened controls can be aliquoted and frozen.
- Opened controls are stable for six months or until the expiration date, whichever comes first, when stored at -20 to -10°C.
- Opened controls are stable for 31 days or until the expiration date, whichever comes first, when stored tightly capped at 2 - 8°C.
- If controls are stored frozen, thaw controls as needed; allow controls to come to room temperature followed by gentle swirling before use.
- Controls are protected from exposure to direct sunlight
- Do not use beyond the expiration date.

## QUALITY CONTROLS – FREQUENCY

- QCs are available in 2 levels: negative and positive
- Both QCs need to be acceptable to allow patient testing on the lot number and/or shipment of the iCups.
- Quality controls are run with every new shipment and/or with a new lot number of the iCup

## QUALITY CONTROLS – SAFETY

- For *In Vitro* Diagnostic Use only.
- Follow the same safety precautions as for processing any "unknown" urine sample containing potentially infectious biological materials.

- Control product contains sodium azide used to prevent formation of explosive metal azides dispose of waste by flushing with copious amounts of water or according to local governing regulations.

## QUALITY CONTROLS – PROCEDURE

- The controls are to be performed by Laboratory staff (or Point-of-Care personnel) on a new-lot and/or new-shipment basis to determine the validity of the test device prior to distributing it to clinical personnel for patient testing.
- Once the QCs are performed, reviewed and accepted, the lot or shipment of the iCups is deemed to have acceptable test performance and can be distributed to clinics for patient testing.
- Allow controls to come to room temperature followed by gentle swirling or inversion before use.
- Do not shake controls.
- Pipette **10 mL** of Alere™ Professional Cup Urine Drug Control sample as required by the drugs of abuse test device or screening method.
- Follow steps 2-6 under TEST PROCEDURES.
- Record QC results on the QC Log.

## QUALITY CONTROLS – EXPECTED RESULTS AND FAILURE PROCEDURE

- The positive control must test positive on the drugs of abuse device or screening method.
- The negative control must test negative.
- If any level of the controls failed:
    - check the temperature of the control solution
    - check the manufacturer's expiration date (if unopened)
    - check the new open expiration date (if opened)
    - repeat using a new, unopened Alere iCup Dx Pro 2
    - if failed again, obtain a new control bottle and repeat testing again
    - consult with Abbott Tech Support 1-800-433-382
- Document control testing failure and steps taken as corrective actions.

## QUALITY CONTROLS – LIMITATIONS

This control is meant to be used to validate the performance of immunoassay drug screening methods. Consult test manufacturer's instructions when using this product; changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the Alere iScreen® Urine Drug Controls, each laboratory should run controls as unknowns in order to establish "in-house" assay values for them. This product is not meant to be used as a standard or calibrator.

This control is meant to be used to validate the performance of immunoassay drug screening methods. Consult test manufacturer's instructions when using this product; changes in reagents, sample requirement, or methodology may affect test results. Although target values are provided with the Alere iScreen® Urine Drug Controls, each laboratory should run controls as unknowns in order to establish "in-house" assay values for them. This product is not meant to be used as a standard or calibrator.

**Alere™ Professional Cup Urine Drug Controls, Oxazepam Stability**
Oxazepam has known stability problems in urine stored refrigerated and, to a lesser degree, frozen. Our experience indicates that Oxazepam will not deteriorate more than 10% of target level for at least one year when stored frozen at -20°C. Further deteriorations may occur beyond this period although Oxazepam ordinarily tests positive throughout the control's shelf life.

**Alere™ Professional Cup Urine Drug Controls, THC Stability**
Alere™ Professional Cup Urine Drug Controls are stable for the length of time under the storage conditions stated in the package insert. In spite of this fact, under certain conditions, there may be observed a gradual decline in THC levels, over time, from continuous use of a single bottle of control material. This drop in THC values may occur from any THC sample (i.e. calibrators, controls and samples). The apparent loss of THC most often occurs from handling and not from product instability. It is well known that THC-COOH binds to surfaces, especially certain plastics. [1], [2] in order to minimize this adsorption loss we recommend the following when handling any sample (including Alere™ Professional Cup Urine Drug Controls) which may contain THC:

1. Preferably, use glass pipettes or pour controls into sample cups. As an alternate, pipettors with disposable plastic tips may be used. Soft plastic transfer pipettes should be avoided.
2. Do not rinse the pipette back and forth into the sample.
3. Sample volume to surface area ratio should be as high as possible (i.e. when transferring, sample containers should be filled as much as possible with sample). Avoid rough surface plastic containers.
4. When pipetting, immerse the pipette tip as little as possible into the sample solution.
5. Do not return any unused material back into the original sample. These same guidelines should also be followed when aliquoting a control (or sample) for future use.

## METHOD PERFORMANCE SPECIFICATIONS

### ACCURACY
1120 (eighty of each drug) clinical urine specimens were analyzed by GC/MS and by each corresponding Alere iCup® Dx Pro 2 Drugs of Abuse Cup. Each test was read by three viewers. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

| Drug Test | Alere iCup® Dx Pro 2 Result | | Drug Free | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) | %Agreement with GC/MS (95%CI) |
|---|---|---|---|---|---|---|---|---|
| AMP | Viewer A | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 10 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 10 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| BAR | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| BZO | Viewer A | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| COC | Viewer A | + | 0 | 0 | 1 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 11 | 29 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| THC | Viewer A | + | 0 | 0 | 2 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 16 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| MET | Viewer A | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 16 | 13 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 16 | 12 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 16 | 13 | 0 | 0 | 97.5% (82% - 100%) |

| Drug Test | Alere iCup® Dx Pro 2 Result | | Drug Free | Less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) | %Agreement with GC/MS (95%CI) |
|---|---|---|---|---|---|---|---|---|
| MDMA | Viewer A | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 18 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 10 | 19 | 0 | 0 | 97.5% (82% - 100%) |
| MOP/ OPI300 | Viewer A | + | 0 | 0 | 1 | 20 | 20 | 100% 84.5% - 100%) |
| | | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 19 | 9 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 20 | 20 | 100% (84.5% - 100%) |
| | | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| MTD | Viewer A | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 16 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 17 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 12 | 16 | 0 | 0 | 95% (79.5% - 100%) |
| OPI | Viewer A | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| PCP | Viewer A | + | 0 | 0 | 2 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 13 | 15 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 13 | 15 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 2 | 18 | 22 | 100% (84.5% - 100%) |
| | | - | 10 | 13 | 15 | 0 | 0 | 95% (79.5% - 100%) |
| TCA | Viewer A | + | 0 | 0 | 1 | 10 | 30 | 100% (84.5% - 100%) |
| | | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 10 | 30 | 100% (84.5% - 100%) |
| | | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 10 | 30 | 100% (84.5% - 100%) |
| | | - | 10 | 19 | 10 | 0 | 0 | 97.5% (82% - 100%) |
| OXY | Viewer A | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 8 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer B | + | 0 | 0 | 2 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 8 | 0 | 0 | 95% (79.5% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 19 | 21 | 100% (84.5% - 100%) |
| | | - | 10 | 20 | 9 | 0 | 0 | 97.5% (82% - 100%) |
| BUP | Viewer A | + | 0 | 0 | 1 | 16 | 24 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer B | + | 0 | 0 | 1 | 16 | 24 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |
| | Viewer C | + | 0 | 0 | 1 | 16 | 24 | 100% (84.5% - 100%) |
| | | - | 10 | 18 | 11 | 0 | 0 | 97.5% (82% - 100%) |

## PRECISION AND SENSITIVITY

To investigate the precision and sensitivity, each drug sample was analyzed at the following concentrations: cutoff -100%, cutoff -75%, cutoff -50%, cutoff -25%, cutoff, cutoff +25%, cutoff +50%, cutoff +75% and the cutoff +100%. All concentrations were confirmed with GC/MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding Alere iCup® Dx Pro 2 Drugs of Abuse Cup. In total, 3 operators participated in the study of the corresponding Alere iCup® Dx Pro 2 Drugs of Abuse Cup. Each of the 3 operators tested 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot of the corresponding Alere iCup® Dx Pro 2 Drugs of abuse Cup.

| Drug test | Approximate concentration of sample (ng/mL) | Number of determinations per lot | Result (Negative/Positive) | | |
|---|---|---|---|---|---|
| | | | Lot 1 | Lot 2 | Lot 3 |
| AMP | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 250 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 50/0 | 50/0 | 50/0 |
| | 750 | 50 | 50/0 | 50/0 | 50/0 |
| | 1000 | 50 | 5/45 | 5/45 | 4/46 |
| | 1250 | 50 | 0/50 | 0/50 | 0/50 |
| | 1500 | 50 | 0/50 | 0/50 | 0/50 |
| | 1750 | 50 | 0/50 | 0/50 | 0/50 |
| | 2000 | 50 | 0/50 | 0/50 | 0/50 |
| BAR | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 150 | 50 | 50/0 | 50/0 | 50/0 |
| | 225 | 50 | 50/0 | 50/0 | 50/0 |
| | 300 | 50 | 7/43 | 5/45 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| BZO | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 150 | 50 | 50/0 | 50/0 | 50/0 |
| | 225 | 50 | 50/0 | 50/0 | 50/0 |
| | 300 | 50 | 7/43 | 6/44 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| COC | 0 | 50 | 0/50 | 0/50 | 0/50 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 150 | 50 | 50/0 | 50/0 | 50/0 |
| | 225 | 50 | 50/0 | 50/0 | 50/0 |
| | 300 | 50 | 5/45 | 5/45 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |

| Drug test | Approximate concentration of sample (ng/mL) | Number of determinations per lot | Result (Negative/Positive) | | |
|---|---|---|---|---|---|
| | | | Lot 1 | Lot 2 | Lot 3 |
| THC | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 12.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 25.0 | 50 | 50/0 | 50/0 | 50/0 |
| | 37.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 50.0 | 50 | 5/45 | 6/44 | 5/45 |
| | 62.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 75.0 | 50 | 0/50 | 0/50 | 0/50 |
| | 87.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 100.0 | 50 | 0/50 | 0/50 | 0/50 |
| MET | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 250 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 50/0 | 50/0 | 50/0 |
| | 750 | 50 | 50/0 | 50/0 | 50/0 |
| | 1000 | 50 | 4/46 | 5/45 | 5/45 |
| | 1250 | 50 | 0/50 | 0/50 | 0/50 |
| | 1500 | 50 | 0/50 | 0/50 | 0/50 |
| | 1750 | 50 | 0/50 | 0/50 | 0/50 |
| | 2000 | 50 | 0/50 | 0/50 | 0/50 |
| MDMA | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 125 | 50 | 50/0 | 50/0 | 50/0 |
| | 250 | 50 | 50/0 | 50/0 | 50/0 |
| | 375 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 6/44 | 5/45 | 6/44 |
| | 625 | 50 | 0/50 | 0/50 | 0/50 |
| | 750 | 50 | 0/50 | 0/50 | 0/50 |
| | 875 | 50 | 0/50 | 0/50 | 0/50 |
| | 1000 | 50 | 0/50 | 0/50 | 0/50 |
| MOP/OPI300 | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 150 | 50 | 50/0 | 50/0 | 50/0 |
| | 225 | 50 | 50/0 | 50/0 | 50/0 |
| | 300 | 50 | 5/45 | 6/44 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| MTD | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 150 | 50 | 50/0 | 50/0 | 50/0 |
| | 225 | 50 | 50/0 | 50/0 | 50/0 |
| | 300 | 50 | 6/44 | 4/46 | 5/45 |
| | 375 | 50 | 0/50 | 0/50 | 0/50 |
| | 450 | 50 | 0/50 | 0/50 | 0/50 |
| | 525 | 50 | 0/50 | 0/50 | 0/50 |
| | 600 | 50 | 0/50 | 0/50 | 0/50 |
| OPI | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 50/0 | 50/0 | 50/0 |
| | 1000 | 50 | 50/0 | 50/0 | 50/0 |
| | 1500 | 50 | 50/0 | 50/0 | 50/0 |
| | 2000 | 50 | 5/45 | 5/45 | 6/44 |
| | 2500 | 50 | 0/50 | 0/50 | 0/50 |
| | 3000 | 50 | 0/50 | 0/50 | 0/50 |
| | 3500 | 50 | 0/50 | 0/50 | 0/50 |
| | 4000 | 50 | 0/50 | 0/50 | 0/50 |

| Drug test | Approximate concentration of sample (ng/mL) | Number of determinations per lot | Result (Negative/Positive) | | |
|---|---|---|---|---|---|
| | | | Lot 1 | Lot 2 | Lot 3 |
| PCP | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 6.25 | 50 | 50/0 | 50/0 | 50/0 |
| | 12.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 18.75 | 50 | 50/0 | 50/0 | 50/0 |
| | 25 | 50 | 5/45 | 4/46 | 5/45 |
| | 31.25 | 50 | 0/50 | 0/50 | 0/50 |
| | 37.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 43.75 | 50 | 0/50 | 0/50 | 0/50 |
| | 50 | 50 | 0/50 | 0/50 | 0/50 |
| TCA | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 250 | 50 | 50/0 | 50/0 | 50/0 |
| | 500 | 50 | 50/0 | 50/0 | 50/0 |
| | 750 | 50 | 50/0 | 50/0 | 50/0 |
| | 1000 | 50 | 5/45 | 6/44 | 5/45 |
| | 1250 | 50 | 0/50 | 0/50 | 0/50 |
| | 1500 | 50 | 0/50 | 0/50 | 0/50 |
| | 1750 | 50 | 0/50 | 0/50 | 0/50 |
| | 2000 | 50 | 0/50 | 0/50 | 0/50 |
| OXY | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 25 | 50 | 50/0 | 50/0 | 50/0 |
| | 50 | 50 | 50/0 | 50/0 | 50/0 |
| | 75 | 50 | 50/0 | 50/0 | 50/0 |
| | 100 | 50 | 6/44 | 6/44 | 5/45 |
| | 125 | 50 | 0/50 | 0/50 | 0/50 |
| | 150 | 50 | 0/50 | 0/50 | 0/50 |
| | 175 | 50 | 0/50 | 0/50 | 0/50 |
| | 200 | 50 | 0/50 | 0/50 | 0/50 |
| BUP | 0 | 50 | 50/0 | 50/0 | 50/0 |
| | 2.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 5.0 | 50 | 50/0 | 50/0 | 50/0 |
| | 7.5 | 50 | 50/0 | 50/0 | 50/0 |
| | 10.0 | 50 | 6/44 | 4/46 | 4/46 |
| | 12.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 15.0 | 50 | 0/50 | 0/50 | 0/50 |
| | 17.5 | 50 | 0/50 | 0/50 | 0/50 |
| | 20.0 | 50 | 0/50 | 0/50 | 0/50 |

**SPECIFICITY AND CROSS REACTIVITY**

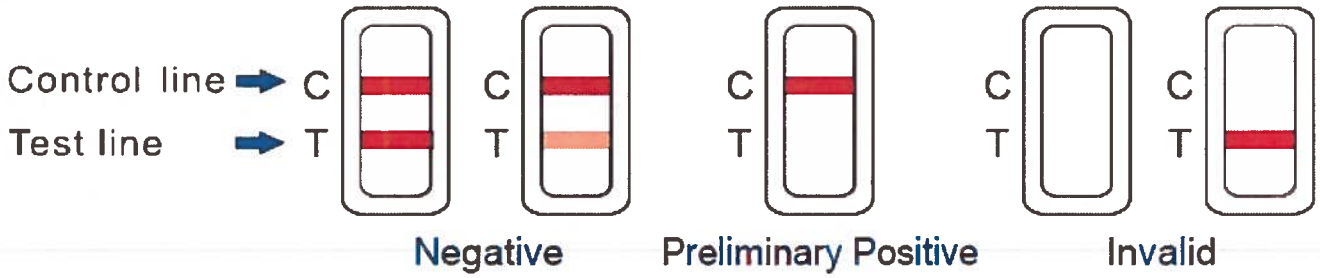
To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components of the same class that are likely to be present in urine. All the components were added to drug-free normal human urine. The following structurally related compounds produced positive results with the test when tested at levels equal to or greater than the concentrations listed below.

| Item | Concentration (ng/ml) | Item | Concentration (ng/ml) |
|---|---|---|---|
| **Amphetamine (AMP)** | | **Methamphetamine (MET)** | |
| d-Amphetamine | 1,000 | D(+)-Methamphetamine | 1,000 |
| d,l-Amphetamine | 3,000 | D-Amphetamine | 50,000 |
| l-Amphetamine | 50,000 | Chloroquine | 50,000 |
| (+/-) 3,4-methylenedioxyamphetamine (MDA) | 5,000 | (+/-)-Ephedrine | 50,000 |
| Phentermine | 3,000 | (-)-Methamphetamine | 25,000 |
| d-methamphetamine | >100,000 | (+/-)3,4-methylenedioxumethamphetamine(MDMA) | 2,000 |
| l-methamphetamine | >100,000 | ß-Phenylethylamine | 50,000 |
| 3,4-Methylenedioxyethylamphetamine(MDE) | 100,000 | Trimethobenzamide | 10,000 |
| (+/-)3,4-methylenedioxumethamphetamine | 100,000 | **Methylenedioxymethamphetamine (MDMA)** | |
| **Barbiturates (BAR)** | | 3,4-Methylenedioxymethamphetamine HCl | 500 |
| Secobarbital | 300 | 3,4-Methylenedioxyamphetamine HCl (MDA) | 3,000 |
| Amobarbital | 300 | 3,4-Methylenedioxyethylamphetamine (MDE) | 300 |
| Alphenol | 150 | **Morphine (MOP/OPI300)** | |
| Aprobarbital | 200 | Morphine | 300 |
| Butabarbital | 75 | Codeine | 300 |
| Butathal | 100 | Ethyl Morphine | 300 |
| Butalbital | 2,500 | Hydrocodone | 5,000 |
| Cyclopentobarbital | 600 | Hydromorphone | 5,000 |
| Pentobarbital | 300 | Morphine-3-ß-d-glucuronide | 1,000 |
| Phenobarbital | 10,000 | Thebaine | 30,000 |
| **Benzodiazepines (BZO)** | | **Opiate (OPI2000)** | |
| Oxazepam | 300 | Morphine | 2,000 |
| Alprazolam | 200 | Codeine | 2,000 |
| a-Hydroxyalprazolam | 1,500 | Ethylmorphine | 5,000 |
| Bromazepam | 1,500 | Hydrocodone | 12,500 |
| Chlordiazepoxide | 1,500 | Hydromorphine | 5,000 |
| Clonazepam HCl | 800 | Levorphanol | 75,000 |
| Clobazam | 100 | 6-Monoacetylmorphine | 5,000 |
| Clonazepam | 800 | Morphine 3-ß-D-glucuronide | 2,000 |
| Clorazepate dipotassium | 200 | Norcodeine | 12,500 |
| Delorazepam | 1,500 | Normorphone | 50,000 |
| Desalkylflurazepam | 400 | Oxycodone | 25,000 |
| Diazepam | 200 | Oxymorphine | 25,000 |
| Estazolam | 2,500 | Procaine | 150,000 |
| Flunitrazepam | 400 | Thebaine | 100,000 |
| D,L-Lorazepam | 1,500 | **Phencyclidine (PCP)** | |
| Midazolam | 12,500 | Phencyclidine | 25 |
| Nitrazepam | 100 | 4-Hydroxyphencyclidine | 12,500 |
| Norchlordiazepoxide | 200 | **Tricyclic Antidepressants (TCA)** | |
| Nordiazepam | 400 | Nortriptyline | 1,000 |
| Temazepam | 100 | Nordoxepin | 1,000 |
| Triazolam | 2,500 | Trimipramine | 3,000 |
| **Marijuana (THC)** | | Amitriptyline | 1,500 |
| 11-nor-Δ9-THC-9-COOH | 50 | Promazine | 1,500 |
| 11-nor-Δ8-THC-9-COOH | 30 | Desipramine | 200 |
| 11-hydroxy-Δ9-Tetrahydrocannabinol | 2,500 | Imipramine | 400 |
| Δ8- Tetrahydrocannabinol | 7,500 | Clomipramine | 12,500 |
| Δ9- Tetrahydrocannabinol | 10,000 | Doxepin | 2,000 |
| Cannabinol | 100,000 | Maprotiline | 2,000 |
| Cannabidiol | 100,000 | Promethazine | 25,000 |
| **Cocaine (COC)** | | **Oxycodone(OXY)** | |
| Benzoylecgonine | 300 | Oxycodone | 100 |
| Cocaine HCl | 750 | Dihydrocodeine | 20,000 |
| Cocaethylene | 12,500 | Codeine | 100,000 |
| Ecgonine | 32,000 | Hydromorphone | 100,000 |
| **Methadone (MTD)** | | Morphine | ≥100,000 |
| Methadone | 300 | Acetylmorphine | ≥100,000 |
| Doxylamine | 50,000 | Buprenorphine | ≥100,000 |
| **Buprenorphine(BUP)** | | Ethylmorphine | ≥100,000 |
| Buprenorphine | 10 | | |
| Buprenorphine -3-D-Glucuronide | 15 | | |
| Norbuprenorphine | 20 | | |
| Norbuprenorphine 3-D-Glucuronide | 200 | | |

## RESULT INTERPRETATION AND REPORTING

## INTERPRETATION OF RESULTS

**Preliminary positive (+)**
A rose-pink band is visible in each control region. If no color band appears in the appropriate Test Region (T), a preliminary positive result is indicated for the corresponding drug of that specific test zone.
**Negative (-)**
If a rose-pink band is visible in each control region and the appropriate Test Region (T), it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.
**Invalid**
If a color band is not visible in the Control Region (C) or a color band is only visible in the Test Region (T), the test is invalid. Another test should be opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.




**Note:** There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line. Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST REGION (T), NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A **NEGATIVE** RESULT.

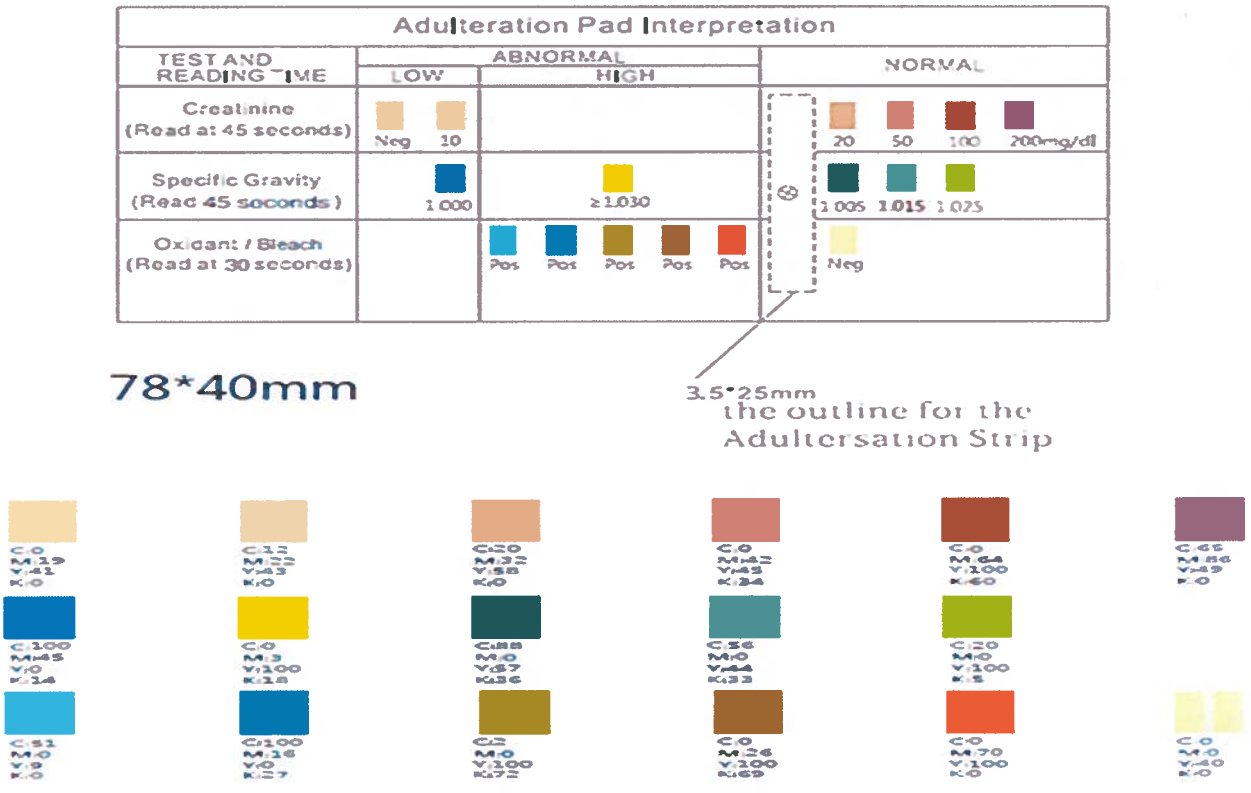
IMPORTANT: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography-mass spectrometry (GC-MS) and liquid chromatography–tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

## CONFIRMATORY TESTING

- Any specimen with results that are discordant with clinical assessment needs to be sent out for a lab urine drug screen by immunoassay. The urine needs to be submitted to the lab in a urine tube free from any preservatives in a timely manner for processing.
- Further confirmatory testing by mass spectrometry can be ordered by the test performing lab if indicated by the screening results.
- Buprenorphine (BUP) testing is not included in the DHS-standardized urine drug screen testing. A preliminary buprenorphine result on the iCup point-of-care needs to be confirmed by ordering the buprenorphine confirmatory testing sent to a reference lab by mass spectrometry directly.

## ADULTERATION/SPECIMEN VALIDITY TEST

**Cr:** Creatinine reacts with a creatinine indicator in an alkaline medium to form a purplish-brown color complex if creatinine in the urine is present at the normal level. The color intensity is directly proportional to the concentration of creatinine. A urine sample with creatinine concentration of less than 20 mg/dl produces a very light, or no pad color change, which indicates adulteration in the form of specimen dilution.
**S.G.:** The specific gravity test is based on the pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. The pad colors will change from dark blue to blue green in urine of low ionic concentration to green and yellow green in urine of higher ionic concentration. A urine specific gravity below 1.003 or above 10.25 is considered abnormal. **OX:** Bleach or other oxidizing agents react with an indicator to form a color complex. Observation of a blue green, medium to dark brown or orange color indicates adulteration with bleach or other oxidizing agents.



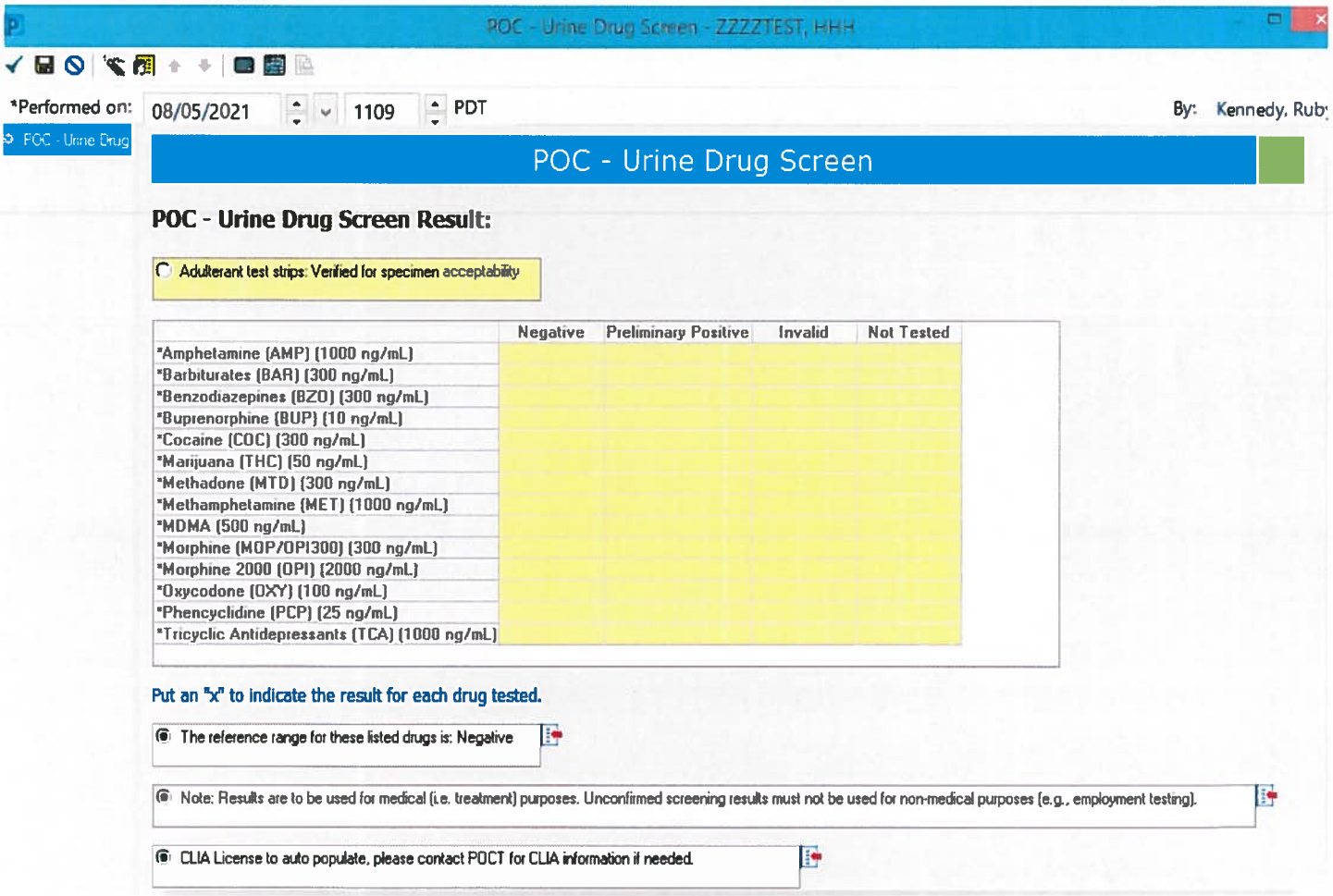
- If any one of the adulteration pads is not within these normal acceptable colors, this indicates that the urine might have been adulterated and that results may not be accurate.
- If any one of the adulteration pads is not acceptable, reject the specimen. Obtain a new drug screen cup and repeat steps in URINE COLLECTION PROCEDURE section to obtain a fresh specimen.

## RESULT REPORTING

Interpretation of results must be performed with caution, as the interpretation process may be subjective to the individual operator and the manual process may be prone to errors. Only trained personnel with ongoing and passing competency assessment can perform any part of the urine drug screen on the Alere iCup. Trained individuals must adhere to the policy.

- **Patient Result Log** – All patient testing must be recorded in the patient result log. This serves as quality assurance on manual result transcription in Electronic Health Records. The log also serves for downtime result documentation.

- **AdHoc Urine Drug Screen – POC**



- Yellow fields are required. The form cannot be signed with any yellow field left blank.
- Only one response for every drug is accepted.
- Signed AdHoc results will be visible to providers under Results Review.
- NOTE: **MDMA, Morphine 2000 (OPI), Phencyclidine (PCP)** and **Tricyclic Antidepressants (TCA)** are NOT TESTED on the Alere iCup used at the facility.

- **Problem Log** – As a measure for quality assurance, any issues with testing need to be recorded in the Problem Log for review and corrective actions.
- **Quality Assurance** – Periodic audits are done to ensure accuracy in result documentation.

## CRITICAL LAB RESULTS

There is no critical lab result for urine drug screen – POC.

## CLEANING, DISINFECTION AND WASTE DISPOSAL

Clean up any spilled urine with dampened paper towel with water. Disinfect the testing surface with 70% isopropyl alcohol or 5% bleach (sodium hypochlorite) solution. Dispose all non-sharp, biohazard/infectious materials into a red bag container. Dispose all non-sharp, non-biohazard/non-infectious materials into a white plastic bag container. Practice hand hygiene according to departmental policy.

## LIMITATIONS

Results are to be used for medical (i.e. treatment) purposes. Unconfirmed screening results must not be used for non-medical purpose (e.g. employment testing.)

## INTERFERRING SUBSTANCES

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, with a drug concentration 25% below the cutoff, and urine with a drug concentration 25% above the cutoff and were tested with the Alere iCup® Dx Pro 2 drugs of abuse Cup. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetaminophen (4-Acetamidophenol) **(except OXY test)**
Acetophenetidin
N-Acetyl procainamide **(except OXY test)**
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
Apomorphine
Aspartame
Atropine **(except BAR test)**
Benzilic acid
Benzoic acid
Benzoylecgonine **(except COC, OXY test)**
Bilirubin
Cannabidiol **(except THC, OXY tests)**
Chloralhydrate
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chlorquine
Cholesterol
Clonidine
Codeine **(except MOP/OPI300, BZO, OXY tests)**
Cortisone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Ecgonine methyl ester
Erythromycin **(except BZO test)**
□-Estradiol **(except BZO test)**
Fenoprofen
Furosemide
Gentisic acid
Hydralazine **(except BZO test)**
Hydrochlorothiazide **(except BZO test)**
Hydrocodone **(except BZO, MOP/OPI300, OXY test)**
Hydrocortisone
O-Hydroxy hippuric acid
3-Hydroxytyramine
Ibuprofen **(except OXY test)**
D, L-Isoproterenol **(except AMP, BAR test)**
Isoxsuprine
Ketamine **(except OXY test)**
Ketoprofen
Labetalol
Loperamide
Maprotiline **(except TCA, OXY tests)**
Meperidine **(except THC, OXY tests)**
Meprobamate
Methadone **(except MTD, OXY tests)**
Methoxyphenamine **(except AMP BAR test)**
Morphinie-3-β-d-glucuronide **(except BZO, MOP/OPI300 tests)**
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein **(except MOP/OPI300, BZO, OXY tests)**
Norethindrone
D-Nor propoxyphene
Noscapine
D, L-Octopamine
Oxalic acid
Oxazepam **(except BZO, OXY tests)**
Oxalinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentobarbital **(except BZR, OXY test)**
Perphenazine
Phenelzine
Phencyclidine **(except PCP, OXY tests)**
Prednisone
Procaine **(except BZO, MOP/OPI300, OXY tests)**
DL-Propranolol
D-Propoxyphene **(except OXY, test)**
D-Pseudoephedrine **(except AMP, BAR tests)**
Quinine
Ranitidine
Salicylic acid
Secobarbital **(except BAR, OXY tests)**
Serotonin (5- Hydroxy tyramine)
Sulfamethazine
Sulindac
Tetra hydrocortisone, 3-acetate **(except AMP, BAR, OXY tests)**
Tetra hydrocortisone 3-(β-Diglucuronide) **(except AMP, BAR, OXY tests)**
Tetrahydrozoline
Thiamine
Thioridazine
Triamterene
DL-Tyrosine
Trifluoperazine
Trimethoprim
D L-Tryptophan **(except AMP, BAR tests)**
Tyramine **(except AMP, BAR tests)**
Uric acid
Verapamil
Zomepirac

## ASSOCIATED FORMS

POCTF 1500.0 – Patient Result Log
POCTF 1500.1 – Quality Control Log
Quick Reference – Result Interpretation
Quick Reference – Adulteration Pad Interpretation

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** AD OB.1 |
| **SUBJECT:** POCT SPECIMEN IDENTIFICATION PROCEDURES | **PAGE:** 1 OF 4 |
| **SECTION:** LABORATORY | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR AGalat | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To ensure appropriate patient test management for quality Point-of-Care Testing (POCT).

## POLICY

All patients are to be identified and prepared for POC testing following established protocols. Tests performed on the patient must be documented in the appropriate testing log(s), electronic files or manual medical record. The patient has the right to refuse testing, but notification of the refusal must be documented. The patient has a right to present complaints and these complaints must be documented through the QANI process.

Any problems regarding patient test management and customer service are to be reviewed for process improvement.

All patient data are accessible only to those persons who are authorized to review test results.

## GUIDELINES

## THE PATIENT AND PATIENT SPECIMENS

POCT specimen collection and subsequent testing is not to be performed without a valid request by the medical provider.

## PATIENT IDENTIFICATION

All patients shall be identified by NAME and DATE OF BIRTH. This identification for Point-of Care testing is to be done by directly asking the patient, or patient's parent or guardian to verbally give full name and birth date. Never ask the client "Are you John XXX?" Always ask "What is your name and what is your birth date." Compare this information with the information in the patient's medical record,

For patients who do not understand the language, ask the patient to write this information by asking an interpreter. Interpreter services are offered at no charge to the patient.
For patients with impaired hearing, write the questions and show it to him/her, so he/she can respond verbally.
For patients who are totally disabled (impaired hearing, speech problems and blind), unconscious, too young, or mentally incompetent, have the accompanying person to produce the patient's identification card and one other form of identification, preferably one with a picture of the patient.
Document the name of the individual who has identified the patient or relationship to the patient.

Outpatients with Wristbands - Facility specific clinic areas may issue wristbands to patients for specific purposes. If this situation is encountered, always check the identification wristband. The band must be on the patient and must list the patient's full name, unique MRUN#, and birth date. Ask the outpatient to give full name and birth date. Compare this information with the information in the patient's medical record.

**Specimen Identification**

If a specimen for POCT requires a container for collection, the patient's identification must be clearly and legibly written or an electronically printed label must be on the specimen with a minimum of two patient identifiers e.g. patient name, birth date, MRUN#.

If applicable, date, time ID initials of person collecting the specimen may also be documented. Identifiers may be in a machine-readable format, such as a barcode.

**Patient Preparation/ Specimen Collection**

Specimens are to be collected per written collection guidelines and in compliance with manufacturer's instruction of the test requested. The patient is to be provided with verbal and, if possible or necessary, written instructions. (e.g. urine sample collection for dipstick testing) Instructions are always to be given using clear, precise statements in terms that the patient can understand, and in a courteous and friendly manner. The patient should be asked to repeat the instructions back.

If problems arise during patient preparation and/ or collection (e.g. finger sticks, etc.}, contact the respective Nursing Supervisor/ designee or Provider for proper handling and/ or resolution. All problems are to be documented, along with any suggestions, for review and process improvement.

**Patient Refusal**

If a patient refuse to be instructed in specimen collection or blood collection (finger stick), immediately contact the respective Nursing Supervisor/ designee or the Provider for handling and/ or resolution. Document the incident in the patient's chart and notify the Provider who ordered the Point-of-Care test(s).

Patients are covered by the AHA Patient Bill of Rights. The patient has the right of refusal of any procedure.

**POCT Reporting**

Results in the Medical Record - All POCT test results are to be entered into the patient's medical record by the person performing the test. The test results can be entered electronically or manually by accessing the patient's electronic medical record. Manual Point-of Care test results may also be uploaded into the electronic medical record at a later time.

The following are the components of a chartable result:

- Patient identifiers
- Test ordered/performed and provider name/ID
- Date/time of specimen collection
- Test result with units as applicable
- Reference interval with units as applicable
- Person who performed the test

**POCT Patient Test Log**

If applicable, Point-of-Care tests are to be recorded in a corresponding POCT Patient Test Log, e.g. urine POCT pregnancy tests in areas without electronic medical record access, with the following:

- Patient name Patient MRUN #
- Collection time (if necessary)
- Test results
- Initials of the person performed the POCT
- All repeat/ recheck results if critical/ abnormal values obtained.
- Documentation of the provider notified and/ or second or split specimen submitted to laboratory for confirmation of abnormal/ critical results.

**Note:** Not all POCT tests are recorded in specimen logs. For example, POCT glucose meter test results are electronically stored in the glucose meter and the test information downloaded into POCT servers located in specific County facilities. PPMP wet mount results may be entered directly into the patient electronic medical record.

**SAFETY INTELLIGENCE**

Safety Intelligence reporting includes incidents of patient safety issues such as Sentinel/ Critical Clinical Events, patient or employee injury, medical device events, specimen/ patient mislabeling errors, and any incident that is not resolved and continues to be an issue affecting patient care.

**PATIENT INFORMATION AND CONFIDENTIALITY**

All staff must comply with HIPPA regulation to protect patient information confidentiality. Any document that contains identifiable patient information must not be discarded in regular trash. These are to be disposed of in designated containers for shredding per facility and HIPAA guidelines. Only those healthcare personnel who are authorized to access patient data may review test results.

Mobile Clinic adheres to DHS Policies to Protect Patients' Health Care Information:

- DHS Policy 361 Safeguards for Protected Health Information (PHI) and
- DHS Policy 935.18 Data Transmission Security
- OHS Policy 935.16 Information Integrity
- DHS Policy 935.20 Acceptable Use of County IT Resources

**DHS Policy 361 Safeguards for Protected Health Information (PHI)**

OHS implements appropriate administrative, technical, and physical safeguards that will reasonably safeguard protected health and confidential information from intentional or unintentional acquisition, viewing, access, use or disclosure that is in violation of DHS' Privacy Policies.

**DHS Policy 935.18 Data Transmission Security**

DHS maintains controls to ensure the integrity of information transmitted electronically within or outside of OHS Information Resources, including public and private connections to any part of the OHS communication network.

**DHS Policy 935.16 Information Integrity**

OHS facilities ensure authentication mechanisms are utilized to corroborate that stored data within its possession has not been altered or destroyed in an unauthorized way.

**OHS Policy 935.20 Acceptable Use of County Information Technology Resources**
Each OHS workforce member is required to adhere to all policies and procedures with respect to the proper use of County information technology resources in accordance with the CHS Privacy and Security Compliance Program.

**Patient Data Accessibility:** CUA Program and HIPAA Privacy Rule: Patient's Access to Test Reports, Final Rule, Fed Reg 79:7290 (2014); 45CFR164.502(g); 45CFR164.514. The rule specifies that upon the request .of the patient, laboratories subject to CUA may provide the patient, the patient's personal representative (defined as the individual who has authority under applicable law to make health care decisions for the patient), with copies of completed test reports that can be identified as belonging to the patient. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable. For completed tests, these results must generally be provided no later than 30 days after such a request. The facilities continue to utilize the established mechanisms for providing access to individuals requesting their test reports that are compliant with the provisions of the HIPAA Privacy Rule. Patients also have online access to their laboratory test results through a DHS patient portal.

**PATIENT PROCESS IMPROVEMENT**
Rancho Los Amigos Laboratory Managers/ Mobile Clinic designees, POCT CUA certificate holder and POCT Nursing Supervisors shall evaluate Patient Safety Net Reports, Internal Incident Reports, and Sentinel/ Critical Clinical Event regarding POCT related events for identification of new or old process improvement problem.

Recommendations shall be discussed between the Laboratory Managers, the Laboratory Director/ Mobile Clinic designee, POCT CUA Certificate Holder, and POCT Nursing Supervisors for process improvement action/ implementation. Documentation is to be kept and cases/events/policies included in the QANI reports.

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** LABORATORY | **POLICY NUMBER:** AD04.1 |
| **SUBJECT: BIOHAZARD/WASTE MANAGEMENT PLAN** | **PAGE:** 1 OF 4 |
| **SECTION:** ADMINISTRATION | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## INTRODUCTION

The following Hazardous Material Communication/Training/Monitoring Plan is provided to ensure and enhance employee's health and safety and to communicate with employees their right regarding existence of hazardous substances. The intent is to provide information, training and monitoring of chemical hazards, the control of hazards via the hazardous Materials/ Communications/ Training/ Monitoring program, including container labeling, SDS training, and documentation of comprehension of employee's understanding by conducting post-testing along with sporadic one on one monitoring throughout the Mobile Clinic program.

## PURPOSE

- To provide the guidelines for the identification and labeling format of hazard substances.
- To communicate with employees their rights regarding the existence of hazardous materials.
- To establish a training program for employees regarding hazardous substances.
- To make available SDS sheets on all hazardous materials.

## POLICY

The laboratory Director/Designee to mobile clinic will ensure that all hazardous materials utilized have SDS readily available to all personnel and that hazardous substances are store appropriately.

## GUIDELINES

### A. CONTAINER LABELING

No container of hazardous materials will be released for use by employees until the following label information is verified.

- Containers are clearly labeled as to the contents.
- Appropriate hazard warnings are noted.
- The name and address of the manufacturer is listed.
- The date of receipt and the date the substance is opened are clearly marked on the container.
- If the substance has an expiration date, it is clearly marked on the container.
- This responsibility has been assigned to any individual who receives and disseminates the hazardous substance(s).

- To further ensure that employees are aware of the hazards of materials used in their work areas, it is the facility's policy to label all secondary containers.
- All applicable personnel will ensure that all secondary containers are labeled with either an extra copy of the original manufacturer' label or with generic labels which have a block for identification and block for the hazard warning.

**B. CHEMICAL IDENTIFICATION**

A complete comprehensive list of chemicals/substances used in the work area will be updated on an annual basis.

All employees shall be responsible for ensuring that all hazardous materials used in the course of their duties meet the hazardous identification and labeling requirements.

Before handling/using a hazardous substance, employee will:

- Ensure that an SDS sheet is on file.
- Check the label on each container for the identity of the hazardous substances and the hazard warning.
- Check the container for the name and address of the manufacturer.
- Label secondary containers with information pertaining to the hazardous substance transferred from the original container.
- Replace label with proper information in the event that a container of hazardous substances is unlabeled, incomplete or difficult to read.

If no SDS is available and the substance has been identified on the Environmental Protection Agency (EPA) list of hazardous and extremely hazardous Chemicals or the State of California's list of Chemicals known to the state that cause cancer or reproductive toxicity (See Appendixes), the following steps are to be followed:

- Check the Laboratory Director/Designee of the mobile clinic to obtain the SDS.
- Retain a copy of the request.
- Manufacturers are obligated to supply an SDS within 25 working days from the request.
- If the manufacturer or supplier refuses to provide an SDS or fails to respond to the request, the Laboratory Supervisor should be notified.
- CAL/OSHA will be notified if the SDS cannot be obtained from the manufacturer or supplier in a timely manner.

**C. SDS (SAFETY DATA SHEET)**

- All SDS's received must be complete and accurately cover all safety and health aspects of each hazardous substance used in the mobile clinic work area.
- All area SDS's will be placed in a yellow binder, appropriately labeled and displayed, to afford reasonable access to employees.
- All SDS's must be kept current. They are to be reviewed annually or when a new hazardous substance is utilized.

- If the work area ceases to use a hazardous substance, the old SDS must be archived and kept for 20 years.
- The Lab will post a *Hazardous Substances Table of Contents and Control Log* on their area Safety Bulletin Board along with the Table of Contents and Control Log in the SDS yellow binder.

## D. ADVISING CONTRACTORS AND NON-EMPLOYEES OF HAZARDOUS SUBSTANCES

- It is the policy to inform all contractors, contractor's employees, temporary employees, or volunteer workers, of any hazardous substance they may be exposed to when working in the mobile clinic.
- The Laboratory Director, or their designee for the mobile clinic will inform the individuals of any hazardous substances prior to any work activity and to inform them of the appropriate protective measures to follow.

## E. REVIEW AND MONITORING OF THE HAZARDOUS MATERIALS/ COMMUNICATION/ TRAINING/MONITORING PROGRAM

- The program will be reviewed on an annual basis or whenever there is a change in hazardous substances by the Laboratory Director/Designee for the mobile clinic. Monitoring will occur by the Lab Director/Designee during the laboratory's monthly safety inspections.
- A copy of the Hazardous Materials/Communication/Training/Monitoring Program will be kept in the laboratory.

## F. EMPLOYEES "RIGHT TO KNOW" TRAINING

The Laboratory Director/Designee for the mobile clinic shall instruct and/ or inform employees on:

- Requirements of the Hazardous Communication regulation.
- Identification of any operations where hazardous substances are present.
- Identity of hazardous substances to which employees may be exposed.
- Physical and health hazards of the hazardous substance(s) as provided in the SDS's.
- SDS training and additional training when new hazardous substances are used in the work area.
- Access to SDS's during working hours.
- Methods and observations that can be used to detect and presence of hazardous substances (i.e. appearance, color, etc.).
- Protective measures to be used, such as work practices, personal protective equipment and emergency procedure.
- Instruction on and availability of personal protective equipment.
- Availability of the of their physician and collective bargaining agents to receive information regarding the hazardous substances to which the employee may be exposed.
- Against discharge or other discrimination due to the employee's exercise of the rights afforded pursuant to the provisions of the *Hazardous Substances and Information Training Act.*

## G. CHEMICALS CONSIDERED TO BE HAZARDOUS

- Chemicals regulated by OSHA in 29 CFR, Part 1910, subpart Z, Toxic and Hazardous Substances.
- Substances included in the American Conference of Governmental Industrial Hygienist (ACGIH) latest edition of Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment.
- Agents found to be suspected or confirmed carcinogens by the *National Toxicology Program* (NTP) or by the *International Agency for Research on Cancer* (IARC).
- Any substance which presents a physical or health hazard as determined by scientific evidence.

## H. TRAINING

The Hazardous Materials/Communication/Training Program shall be coordinated for employees by the Rancho Los Amigos Safety Officer and Nursing Education Department.

## REFERENCE

1. SDS: *Safety Data Sheet of Rancho Los Amigos*

## REVISIONS

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## Biennial Review

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** AD 17.1 |
| **SUBJECT: ANALYTIC SYSTEM - POCT CONTROL POLICY** | **PAGE:** 1 OF 4 |
| **SECTION:** ADMINISTRATION | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:**<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To ensure quality patient care through precise and accurate Point-of-Care testing (POCT), yielding test results used by clinicians to make diagnoses and/ or decisions involving the care of the patient.

## POLICY

Quality Control (QC) guidelines are to be implemented and practiced by all POCT staff at all times.
For waived tests, manufacturer instructions are adhered to without modification. If any manufacturer instruction is modified, the test is considered a laboratory developed assay, is no longer considered a waived test and subject to the requirements for high complexity testing. Personnel must follow manufacturer's instructions for quality control, reviewing results, and records acceptability prior to reporting patient results.

## GUIDELINES

### Frequency of Control Testing

Quality Control must be performed for each analyte/ test for which patient results are to be reported (for those tests which control material is available). All controls must be treated in the same manner as patient samples.

For waived tests, the minimum frequency controls are tested is set by the manufacturer.

Quality control must be run once a day on day of use for the following prior to reporting patient results following manufacturer's instructions.

- Urine dipstick (Clinitek Status)
- Glucose meter testing
- HemoCue - hemoglobin testing
- Urine Drug Screen

Quality control must be performed upon opening each box of test kits for the following:

- Urine pregnancy testing

Please refer to the specific POCT SOP for exact details on running controls on that test system.
Daily QC - For nonwaived tests controls are run at least daily, or more frequently if specified in manufacturer's instructions, or laboratory procedure, for quantitative and qualitative tests, and when changes occur that may impact patient results.

There may be procedures for which no control materials are available, e.g. PPMP — wet mount/ KOH. An alternative control mechanism to detect errors is assessing the clinical discriminating ability of applicable providers by proficiency testing performance at least twice a year (semiannually).

In addition, quality control for wet prep and KOH microscopic examinations may take the form of an elemental comparison with a chart or reference book pictures illustrating white blood cells, red blood cells, epithelial cells, bacteria, Trichomonas, clue cells, budding yeast or hyphae.

**Levels of Controls to be tested**

Normally, at least two levels of controls are to be run or as defined by the manufacturer or regulatory/ accrediting agency. Control testing is not necessary on days when patient testing is not performed.

**Assessment of Control Results**

Control results must be assessed (if applicable per manufacturer's instruction) prior to testing of patient samples, unless the controls are part of a test kit which specifically designates that the controls are to be run with each patient sample.

Acceptable control limits are defined for control materials that have numeric limits established by the manufacturer. For qualitative control limits, the negative and positive control results must match exactly the qualitative positive/negative manufacturer defined result.

With respect to internal controls, acceptable control results are to be recorded, at a minimum, once per day of patient testing for each device. Acceptable internal controls need not be recorded if an unacceptable instrument control automatically locks the instrument and prevents release of patient results.

Assessment is to be made by the trained personnel performing the quality control or the testing. Assessment is to include repeat of controls if applicable per test procedure, review of previous runs, reagent(s) status, equipment status, etc.

The POCT Quality Coordinator/ designee and POCT personnel may collaborate with the Nursing Supervisor/ designee (as assigned by the Laboratory Director (CLIA Certificate Holder), as applicable, to review and assesses the POCT quality control, patient results and initials on the appropriate log sheets to document such assessment/ review on at least a monthly basis.

Whenever the controls are out of range or non-compliant with expected results, the following must be adhered:

- No patient testing is to be performed/ no patient results are to be reported.
- The POCT Nursing Supervisor/ POCT coordinator/ or designee shall be notified.
- All information regarding the controls must be documented on the Out of Control/ Corrective Action Log as applicable.
- Patient testing should be repeated when the problem(s) is resolved, and the control results are within limits.

**Definition of Out-of-Control**

Out of control occurs when the expected results are not obtained:

- Positive instead of negative
- Negative instead of positive
- Greater or less than the expected defined value
- Color other than the expected defined color
- Interference causing results to be misinterpreted
- No results obtained when either a positive or negative result is expected
- Absence of expected results for either internal or external controls

**Release of Patient Results**

Patient results must not be released until control problems are resolved and/or evaluations by the POCT Nursing Supervisor/ Laboratory Manager/ or designee are completed.

Verification of Critical Values or Unusual/ Abnormal Findings
Critical values are to be verified prior to reporting (the exception to this is if patient has had a similar critical test value on the same day). This may include, as necessary, repeat testing, obtaining an additional sample for testing, confirmation of acceptable control values results for that run, or duplicate sample sent to the main laboratory for confirmation of results.

Unusual findings should be verified as above, if applicable, and POCT Nursing Supervisor/ Laboratory Manager/ or designee notified.

Abnormal results verification shall include (as applicable):

1. QC status assessed and documented
2. Valid Specimen collection, followed collection protocol
3. Recheck for correct patient identification
4. Results do not match clinical data, e.g. diagnosis, age, sex, medications, drugs
5. Results not possible physiologically
6. Validation of results, repeat of test in the main laboratory

The requesting provider must be notified of the critical values and unusual/ abnormal findings immediately.

**Calibration Calibration/Verification — Waived Tests**

For waived tests, manufacturer instructions are followed for applicable calibration, calibration verification, and related functions.

**Proficiency Testing and Results Review**

If applicable to non-waived testing, external Proficiency testing must be completed within the time frame designated by the vendor. Once the samples are opened and/or reconstituted, they are to be handled as if patient samples. The laboratory may not refer any proficiency samples to a laboratory located at another site with a different CLIA number. Interlaboratory communications about proficiency testing samples is prohibited until after the deadline for submission of data to the proficiency testing provider. Proficiency testing records are not shared with personnel of other laboratories until after the deadline for submission of results. Laboratory computer system proficiency testing records are not readily accessible by other laboratories.

***The laboratory will notify the Centers for Medicare & Medicaid Services (CMS), State of California Laboratory Field Services, of proficiency testing samples received from another laboratory for testing.***

**Ceasing of Patient Testing for Repeat PT Failures**

After repeated PT failures, the proficiency testing vendor may instruct the laboratory to cease patient testing for an analyte or subspecialty. No patient results are to be released on the pertinent analyte or subspecialty until after approval from the proficiency testing vendor to resume patient testing. Internal Proficiency testing if applicable shall also be handled and tested similarly as the external proficiency testing.

***Evaluation of proficiency results must be reviewed and signed off by the Laboratory Director/ POCT CLIA Certificate Holder or qualified designee.***

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** AD 21.1 |
| **SUBJECT:** TEST REPORT | **PAGE:** 1 OF 2 |
| **SECTION:** ADMINISTRATION | **ORIGINAL ISSUE DATE:** 12/27/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To establish an adequate system for reporting Point of Care Test results.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

While POCT results are often initially reported orally or in temporary written form (e.g., instrument printout or log sheet), these results must be appropriately and promptly recorded in the permanent electronic medical record (ORCHID).

## SAFETY PRECAUTIONS (IF APPLICABLE)

N/A

## SAMPLE/SPECIMEN PREPARATION REQUIREMENTS

N/A

## REAGENT AND/OR MEDIA. MATERIALS

Instrument printout or screen result.

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURES

A. Get an instrument printout for non-interface meter or dock meter for interface meter.
B. Enter the result in the computer under POC testing result section for the non-interface meter, make sure you use the correct FIN number.
C. For the interface POCT instrument, dock the meter then check the computer for your result.
D. Policy on Critical Values:

1. Notify the Medical Provider in the mobile clinic or other clinical personnel responsible for the patient care of results of all critical results.
2. Duplicate POCT per physician's request.
3. Send specimen to Central Laboratory for verification of test result, per physician's request.

## QUALITY CONTROL AND METHODPERFORMANCE SPECIFICATIONS

N/A

## RESULT REPORTING

Enter appropriate comments when critical values are obtained (person notified, test result and comment or course of action} in the computer.

## LIMITATIONS

N/A

## ASSOCIATED FORMS

N/A

## REFERENCES

1. Friedman BA, Mitchell W. *Integrating information from decentralized laboratory testing sites. The creation of a value-added network> am* J Pathol. 1993;99; 537-542.

2. NCCLS. Point of care connectivity; approved standard POCT1-A. Wayne, PA: NCCLS, 2002.

3. CAP POCT Checklist Result Reporting p 14-16, June 15, 2009 revision.

4. JCAHO PC 16.40

5. ORCHID Training for Ambulatory nurse, 12-5-2014

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** AD 22.1 |
| **SUBJECT:** POST-ANALYTICAL SYSTEM POLICIES | **PAGE:** 1 OF 2 |
| **SECTION:** LABORATORY | **ORIGINAL ISSUE DATE:** 12/27/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## POLICY:

The post- analytical phase is the last phase of laboratory testing. It comprises all steps that begin with the verification and review of the results, communication of the results and their interpretation by the attending clinician.

The quantity of errors in the post-analytical phase makes it the second most affected process in laboratory testing that can result in adverse patient events. As with the pre-analytic phase, the errors of the post-analytical can occur either inside or outside of the laboratory.

In the post-post-analytical phase dealing with the actions of the clinicians including the review and interpretation of the results is extremely important because adverse events can occur if patient management is altered based on erroneous interpretation of results.

The procedures performed in the laboratory which include the verification of the results, entering the results in the computer information system of the laboratory and the proper communication of the results to the corresponding clinician can result in delayed patient management if results are not provided timely or the communication of a critical value is delayed.

The most common errors found in this phase are delay of the delivery of the results, failure to report or reporting to the wrong health care provider, transcription errors, incorrect results, misunderstanding of the results by the clinician, failure of clinician to see the report.

After performing the root cause analysis it has been determined that some of these errors come from the pre-analytic phase and are related to labeling errors, some others come from the analytic phase related to poor formulation of the report, while some others are originated in the post-analytic phase in relation to operational issues during the report delivery (post-analytical phase within the laboratory), or within the doctor's office (pot-post-analytical phase).

Critical values are important component of the lab result reporting and must be fully documented.

Monitoring activities for the post-analytical phase should include:

- POCT/Stat test result turn-around-times
- Timeliness of Critical Value reporting
- Verification of read-back of critical and non-critical results
- Percent of corrected reports

**POST-ANALYTIC PROCESS PROCEDURES**

**TEST REPORT:**
See AD 22.1- TEST REPORT

**POST-ANALYTIC SYSTEMS QUALITY ASSESSMENT POLICY AND PROCEDURE:**
See AD21.1 POCT QUALITY ASSESSMENT PROCEDURE (Section F3)- POST-ANALYTIC SYSTEMS QUALITY ASSESSMENT SECTION

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** MV POC 3.1 |
| **SUBJECT: COMPETENCY ASSESSMENT** | **PAGE:** 1 OF 3 |
| **SECTION:** ADMINISTRATION | **ORIGINAL ISSUE DATE:** 12/20/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalaft | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To evaluate the competency of all POC testing personnel and ensure that employees maintain their competency to perform test procedures and report test results accurately as mandated by the regulatory agencies: (CAP), JCAHO, and CUA '88.

## PRINCIPLE AND CLINICAL SIGNIFICANCE

The ACN Pathology and Laboratories staffed by Pathologists and Clinical Laboratory Scientists are tasked with oversight for competency at CHC sites and have developed a mechanism to evaluate the effectiveness of policies and procedures for assuring that Point of Care operators are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities.

A. Point of Care operators are evaluated initially and followed-up every six months for nonwaived testing for the first year and annually thereafter for competence in performing POC laboratory tests. For waived testing after an operator has performed testing for one-year competency must be reassessed annually.
B. The Laboratory Director, Pathologist consultant, QC Coordinator, Pathology POC supervisor/designee, or nursing supervisor/designee observes the employee performing the POC procedure.
C. The employee must correctly demonstrate:
   1. Procedure for patient and control testing.
   2. Proper documentation of patient and control test results.

## SAFETY PRECAUTIONS

See Safety Protocol

## SAMPLE/SPECIMEN PREPARATION REQUIREMENT

N/A

## REAGENT AND/OR MEDIA MATERIAL

- Worksheets
- Reagents Racks
- Test Instrument
- Procedure manual
-

## EQUIPMENT CALIBRATION AND MAINTENANCE

N/A

## PROCEDURE:

Competency assessment is performed using the following applicable methods:

A. Direct observation of POCT Operator:
1. Explaining procedure, including any changes.
2. Performing procedure setup.
3. Performing quality control procedure.
4. Performing test procedure.
5. Reading control and patient test results.
6. Recording control and patient test results.

B. Monitoring the recording and reporting of results
1. Random check of patient test results on form
2. Check instrument's memory

C. Review of intermediate results on worksheets, QC, PT, and PM
1. Review of records

D. Direct observation of instrument maintenance
1. Performance of actual maintenance of the instruments.

E. Assessment of test performed of previously analyzed samples.
1. Review of forms or instruments memory.

F. Evaluation of problem-solving skills.
1. Direct questioning of the operators regarding different scenarios.

G. In-service or re-training
1. To be conducted only by the POCT staff.

## COMPETENCY TESTING RESULTS

A. When employees successfully pass the competency test, the employee should continue to correctly perform the laboratory procedure. When the operator is observed performing the patient and/or quality control tests improperly, and/or failing to comply with established guidelines for documentation:
1. When the competency failure is due to failure to document properly, the employee is required to review the written procedure and then be reassessed.
2. If the competency assessment failure is due to a technical or skill deficiency, retraining is required.

B. The operator is retrained and then reassessed for competency in the procedure. Immediately after competency testing observation, the Point of Care observer will offer helpful suggestions to the POCT operator concerning performance of the procedure.

## REFERENCES:

1. Medical Laboratory Observer, 1993.

2. Department of Health Services, Health Care Financing Administration. Clinical Laboratory Improvement Amendments of 1988; Final Rule. FEDERAL REGISTER. 1992(Feb 28): 7166 [42 CRF 493.1218(f)(2)1.

3. Encore QA Manual, 1994.

4. JCAHO PC.16.30

5. College of American Pathologists Checklist, 2013

**RANCHO LOS AMIGOS – MOBILE CLINIC**

| SUBJECT: COMPETENCY ASSESSMENT | | PAGE 3 OF 3 |
|---|---|---|
| | | SOP#: POC-MV 3.1 |

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** MV POC 4.1 |
| **SUBJECT: CORRECTIVE ACTION POLICY** | **PAGE:** 1 OF 7 |
| **SECTION:** ADMINISTRATION | **ORIGINAL ISSUE DATE:** 12/27/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD.<br>MEDICAL DIRECTOR AGalat MD | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:**<br>ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

To establish a process for identifying the basic or causal factor(s) underlying variation in performance, including the occurrence or possible occurrence of a Sentinel Event/ Critical Care Event. Root cause analysis can be used to uncover the factors that lead to patient safety events and move organizations to deliver safer care. Corrective action must be documented.

**Definitions:**
Root Cause Analysis -A systematic process identifying the causal factor(s) that underlie errors or potential errors in care. A root cause analysis focuses on systems and processes, not individual performance. The objective is not to assign individual blame.

A root cause analysis is to be performed on all Sentinel Events/ Critical Care Events and any event as determined by the Risk Manager/ QI Coordinator/Patient Safety Coordinator, in collaboration with the Laboratory Manager, Laboratory Director, Chief Medical Officer, facility Administrator and/ or Mobile Clinic designees, in accordance with Just Culture principles.

Sentinel Event (College of American Pathologists)-An unexpected occurrence that reaches a patient and results in death, permanent harm, or severe temporary harm, unrelated to the natural cause of the patient's illness or underlying condition.

(County of Los Angeles - DHS): is an unexpected occurrence that requires immediate investigation based on the judgment of the Chief Medical Officer, Risk Manager, Chief Nursing
Officer, and/or Chief Executive officer per DHS Policy 311.2. DHS further explains a "Sentinel Event" as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury incudes loss of limb or function. The phrase "or risk thereof includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

For examples of Sentinel Events, see DHS Risk Management and Employee Safety Handbook, pg. 10, and DHS Policy 311.202 - Adverse Event Reporting.

Nonconforming event (College of American Pathologists)-An occurrence that:

- Deviates from the laboratory's policies or procedures
- Does not comply with applicable regulatory or accreditation requirements
- Has the potential to affect (or has affected) patients, donor, the general public, or personnel safety.

Nonconforming events can include the following:

- Adverse Event - An occurrence that resulted in harm to the patient {includes a Sentinel/ Critical Clinical Event).
- No-harm Event - an occurrence that reaches the patient but does not cause harm. •Near Miss (close call or good catch)- an occurrence that did not reach the patient. Near misses are much more common that adverse events.

Just Culture - A guiding principle and practice that: recognizes adverse events are an inevitable part of the human professional experience; focuses on identifying and fixing systemic factors; and strives to prevent harm fairly without placing inappropriate blame on individuals for system flaws.

**A Root Cause Analysis is used to:**

- Standardize the components of the focused review to ensure a common approach and to understand the events under assessment.
- Promote a positive impact on improving patient care.
- Identify opportunities for improvement of both systems and personnel performance.
- Ensure focused review of certain events due to the risk of litigation and conflict within the organization.
- Assess a Sentinel Event/ Critical Clinical Event and to understand how and why events occurred and to prevent the same or similar event from happening again.
- Understand the underlying cause of an adverse event.
- Also be used to determine the cause of multiple occurrences of low-harm events.
- Reduce variation in a process by determining and classifying causes.

"Common cause" variation is inherent in every process and is a consequence of the way the process is designed to work. A process that varies only because of common causes is said to be stable.

"Special cause" variation arises from unusual circumstances or events that may be difficult to anticipate and may result in marked variation. A process that varies from special causes is an unstable process.

## POLICY

All Root Cause Analysis documents are privileged and confidential under State law, including Evidence Code Section 1157 relating to medical professional peer review documents and Government code section 6254 relating to personnel records.

**The Root Cause Analysis is:**

- Inter-disciplinary, involving those knowledgeable about the process involved in the event.
- Focuses on systems and processes rather than individual performance
- Continually digs deeper by asking why, why, why and each level until no additional logical answer is identified.
- A process that is impartial as possible,
- Identifies changes in systems and processes through redesign or development of new processes or improve systems and reduce the risk of a particular Sentinel Event, or Nonconforming Event (Adverse Event, No-Harm Event, and Near Miss Event}.

**To be thorough a Root Cause Analysis must include:**

- Determination of human and other factors.
- Determination of related processes and systems.
- Analysis of underlying cause and effect systems through a series of "why" questions.
- Identification of risks and their potential contributions.
- Determination of potential improvement in processes and systems.
- For planned improvement actions, identify who is responsible for implementation, when the actions will be implemented, and how the effectiveness will be evaluated.

**To be credible, the Root Cause Analysis must:**

- Include participation by the leadership of the organization and those most closely involved in the process.
- Be internally consistent or leave obvious questions unanswered.
- Include consideration of relevant literature.
- Include corrective actions, outcomes measures and leadership approval

If in the course of conducting the Root Cause Analysis, it appears the event being reviewed is the result of an intentionally unsafe act, the team must refer the event to facility leadership for further consideration. In such a case, the team will discontinue their efforts, at which time leadership will assume responsibility for any further fact finding or investigation.

**GUIDELINES**

When the need for a Root Cause Analysis is identified at the direction of the ACN Medical Director and in relation to the laboratory, the facility Administrator or designee, Medical Director or designee, Risk Manager/QI Coordinator/Patient Safety Coordinator, Laboratory Director, and Laboratory Manager will organize a Root Cause Analysis Team. This should be performed no longer than two (2) business days after the discovery of a Sentinel Event/ Critical Clinical Event.

The Root Cause Analysis team will include the Risk Manager/QI Coordinator/Patient Safety Coordinator, Laboratory Director or designee, Laboratory Manager, and any front-line staff deemed knowledgeable in regard to the event.

The focus of the RCA team will be on identifying possible causal factors, identifying the root, and recommending and implementing solutions.

Findings will be compared to accepted standards from literature review, including Joint Commission and College of American Pathologists.

Summaries and recommendations for improvement opportunities will be reported to ACN Executive Staff and facility Executive Staff for implementation.

Director and in relation to the laboratory, the facility Administrator or designee, Medical Director or designee, Risk Manager/QI Coordinator/Patient Safety Coordinator, Laboratory Director, and Laboratory Manager will organize a Root Cause Analysis Team. This should be performed no longer than two (2) business days after the discovery of a Sentinel Event/ Critical Clinical Event.

The Root Cause Analysis team will include the Risk Manager/QI Coordinator/Patient Safety Coordinator, Laboratory Director or Mobile Clinic designee, Laboratory Manager, and any front-line staff deemed knowledgeable in regard to the event.

The focus of the RCA team will be on identifying possible causal factors, identifying the root, and recommending and implementing solutions.

Findings will be compared to accepted standards from literature review, including Joint Commission and College of American Pathologists.

Summaries and recommendations for improvement opportunities will be reported to ACN Executive Staff and facility Executive Staff for implementation.

**Develop Solution**

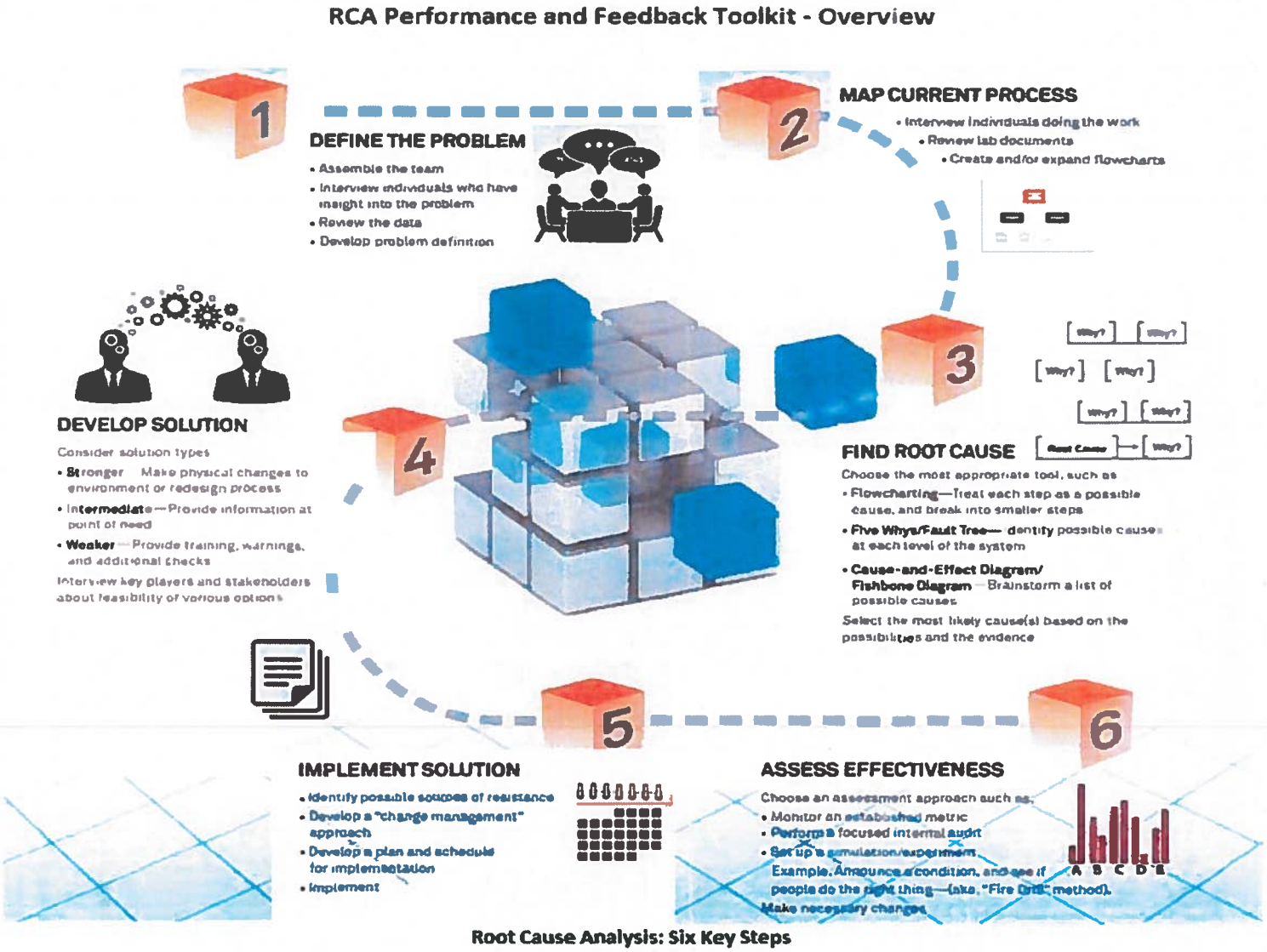
- Stronger - Make physical changes to environment or redesign process
- Intermediate - Provide information at point of need
- Weaker - Provide training, warnings, and additional checks

**Implement Solution**

Identify possible sources of resistance - approach
Develop a plan and schedule for implementation
Implement

**Assess Effectiveness**

Choose an assessment approach o a focused internal audit o Set up a simulation/ experiment (Fire drill method) o Make changes




**Root Cause Analysis: Six Key Steps**

**The toolkit consists of:**

- Performance Tool - Guides the project team through key steps
- Feedback Tool- Provides leadership with an assessment structure to give feedback
- RCA Projects Scorecard - Provides leadership with a tool to display and compare ratings.

**Attachment includes:**

- Root Cause Analysis Check Sheet
- RCA Performance and Feedback Toolkit - Overview
- Performance Tool
- Feedback Tool- Input and Output RCA
- Projects Scorecard

## REFERENCES

1. Root Cause Analysis in Health Care: Tools and Techniques; Joint Commission Resources, Fifth Edition. 2015.

2. CAP Accreditation Updates 2019, College of American Pathologists, October 2019.

3. CAP Root Cause Analysis Performance and Feedback Toolkit - Overview, College of American Pathologists, 2019.

4. Quality Improvement Patient Safety and Clinical Risk Reduction Program and Plan, Los Angeles County Ambulatory Care Network (ACN), 2016.

5. Risk Management and Employee Safety Handbook, Los Angeles County Department of Health Services, 2018.

6. Adverse Event Reporting Policy 311.202, Los Angeles County Department of Health Services, 2012.

7. Communication of Unanticipated Outcomes Policy 311.201, Los Angeles County Department of Health Services, 2014

8. Patient Safety Event Reporting and Follow-up Guidelines Policy 311, H. Claude Hudson CHC

9. Safety Intelligence/ Patient Safety Net Reports/ Internal Incident Reports/ Sentinel/ Critical Event Reports/ Device Related Adverse Patient Event Reports, QA 22. 7, CHC Laboratory Services, 2019.

10. Case Review and Response and Root Cause Analysis Policy and Procedure HA 501, Martin Luther King Jr. /Drew Medical Center, 2006.

11. Root Cause Analysis Policy and Procedure Policy 1.203, Martin Luther King Jr. /Drew Medical Center, 2016.

12. Root Cause Analysis Policy and Procedure Policy 508 Pl, Long Beach CHC Administration, 2008.

13. Sentinel and Critical Clinical Event Reporting, Investigation, and Follow-Up Policy 303, LAC+USC Medical Center, 2014.

14. Investigation of Incidents Involving Potential Claims Policy 311, LAC+USC Medical Center, 2013.

**REVISIONS**

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Biennial Review**

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

| RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER | **MOBILE CLINIC POLICY AND PROCEDURE** |
|---|---|
| **DIVISION:** POCT - MOBILE CLINIC | **POLICY NUMBER:** QA 1.1 |
| **SUBJECT:** QUALITY ASSURANCE IMPROVEMENT PLAN | **PAGE:** 1 OF 5 |
| **SECTION:** LABORATORY | **ORIGINAL ISSUE DATE:** 12/13/2021 |
| **PREPARED BY:** RICHARD M. SOMBILLO RN<br>**APPROVED BY:** ABSALON GALAT MD. MEDICAL DIRECTOR | **REVISION DATE:**<br>**APPROVED DATE:** 02/09/2022 |
| **TO BE PERFORMED BY:** ALL APPLICABLE EMPLOYEES | **SUPERSEDES DATE:** |

## PURPOSE

Each Los Angeles County Comprehensive Health Center (CHC) Laboratory participates in a Quality Management/Quality Assurance Value Improvement (QANI) Program integrated within the CHC Laboratory Services (CHCLS). This is a performance improvement (Pl) process to identify and thus improve patient safety and the quality of care to the CHCLS customers-nurses, physicians, and patients. The quality and appropriateness of laboratory services is evaluated systematically to pursue opportunities to improve patient care and resolve identified problems. Any required corrective action must be evaluated for effectiveness. At all times possible, the program is to encompass interdepartmental participation as it relates to patient care service and patient safety.

## POLICY

POCT employs a multi discipline team approach within the Department of Health Services that involves representation and involvement in planning, implementation, and monitoring from each facility within the department. Testing platforms are standardized based on input and representation from the departments of medicine, nursing, and Pathology Departments.

Quality Management & Performance improvement is an ongoing responsibility of every CHCLS employee and shall include quality control, equipment maintenance, patient care test management, proficiency testing, standardized testing, personnel education, performance indicators, statements of concern, guidelines for problem solving, and whenever feasible, utilization management and laboratory practice guidelines. The CHCLS staff shall participate in internal and external Quality board meetings (as applicable) and the preparation of QA reports.

Management of the program shall be under the direction of the Laboratory Director/ Mobile Clinic designee. Responsibility is also defined in the delegation of duties protocol. A designee shall attend the ACN Quality Board meetings. The ACN Laboratory Quality Coordinator shall preside over the ACN Quality Board section of the CHC Laboratory Administration meetings. QA reports shall be prepared by each Laboratory Manager at least quarterly, benchmarking key indicators of quality and comparing them against the other CHC laboratories, or published benchmarks, or against benchmarks agreed upon by the laboratory and the providers its serves. The key indicators cover the pre-analytical, analytical, and post-analytical phases of the laboratory critical to patient outcomes. The reports will be reviewed by the Laboratory Director/Mobile Clinic designee.

An annual evaluation of the program shall be prepared by each Laboratory Manager for approval by the Laboratory Director/ designee. The annual evaluation shall serve as the basis for modification of the program.

## GUIDELINES

1. Policies, Procedures, and POCT equipment must first be approved by the POCT committee and/or by the POCT medical director.
2. If there is a change in POCT directorship, the new director must ensure that the POCT procedures are reviewed (over a period of time) and/or changes made biannually.
3. Develop and maintain a nursing staff that is competent in Point of Care Testing.
4. Train, test and document the competency of each newly hired nurse performing Point of Care Tests.
5. Annual re-certification training provides a means to reinforce Point of Care Testing policies and procedures and specifically address observed problem areas. Retraining of nurses who repeatedly fail to properly perform Point of Care Tests completes the training process.
6. Monitor test results to detect and prevent problems/errors through training and effective procedures.
7. Monitor all test results using audits and feedback to detect and address problems.
8. Problems are brought to the attention of the nurse manager for correction, counseling, and feedback to complete the cycle.
9. Address identified problem areas with modified Point of Care Testing policies and procedures to improve the effectiveness and efficiency of processes.
10. Quality issues associated with POC testing are the same as those associated with traditional laboratory testing; however, QA procedures must be designed with POC test systems in mind.

Monitoring may include the following key indicators/ aspects of care and service as applicable:

**Pre-Analytical**

- Accuracy of patient Identification - 2 identifiers
- Specimen container labeling in presence of the patient
- Compliance with hand hygiene guideline

**Analytical**

- Quality Control monitoring
- Test performance
- Instrument Correlation Verification
- Equipment Instrument issues
- Supply/reagent issues

**Post -Analytical**

- Timeliness of Critical Value reporting
- Verification of read-back of critical and non-critical results
- Percent of corrected reports

**OTHER QUAUTY MEASURES INCLUDE:**

- QUALITY CONTROL
- Monitoring Proficiency Testing, External
- Monitoring Proficiency Testing, Internal
- System QC
- Procedures control

**HUMAN RESOURCES**

- Personnel Competency Testing
- Adequacy of staff

**RISK MANAGEMENT/SAFETY/SECURITY/INFECTION CONTROL**

- Safety - includes Chemical Hygiene, Ergonomics, Bloodborne Pathogen, Hazard
- Waste
- Statements of Concern (patients/non-patients)
- Sentinel Events/ Critical Clinical Events
- Root Cause Analysis
- Safe Medical Device Act
- Safety Intelligence (SI) Reporting
- Complaint Investigations
- Communication breakdowns
- Occupational injuries - needle sticks, falls

**SPECIAL PROJECTS - Performance Improvement Projects**

QANI Reports: Distribution and Presentation QC Monthly Summary Report
The CHCLS participates in the following Quality Management Committees:

- CHC Quality Board Committee
- OHS Laboratories Directors Committee
- CHC Safety/Environment of Care Committee
- CHC Point of Care Committee

Data from the following quality measures are reported to the CHC Laboratory Quality Board committee on a quarterly basis.

| Performance Measure | Unit of Measurement | Acceptable | Frequency of Monitoring | Basis for Performance Measure |
|---|---|---|---|---|
| Proficiency Testing Results | Percent | 80% of reportable analytes - any outliers require corrective action | Per CAP PT Schedule | CAP/CLIA |
| Safety - needle sticks, falls, HazMat Exposure | Incidents | 0 incident | Report as occur, QANI report quarterly | CAL/OSHA |
| Accuracy of patient ID | Percent | >90% | Monthly | CAP/National Patient Safety Goal |
| Label specimen containers in presence of patient | Percent | >90% | Monthly | National Patient Safety Goal |
| POCT monitoring | Percent | >90% | Monthly | National Patient Safety Goal |
| Complaints | Occurrences | 0 | Report as occur | CAP/National Patient Safety Goal |

Summary of POCT testing requirements- moderate complexity testing (waived testing exempt):

i. Reagents
- New lot validation required
- Follow manufacturer instructions for handling and validating.

ii. Competency
a. For CUA waived testing, after an operator has performed waived testing for one year competency must be reassessed annually.

iii. Correlation
a. Initial correlation between instruments.
b. Multi-instrument comparison required every 6 months.

iv. Quality Control
a. Follow manufacturer instructions.
b. Be sure QC results are judged acceptable and recorded before releasing patient results. Document corrective action if control results exceed tolerance limits. Internal control results need not be documented for instruments using such controls if and only if, an unacceptable instrument control automatically locks the instrument and prevents the release of patient results.
c. External controls as required by the manufacturer.

v. Calibration and calibration verification
a. Follow manufacturer instructions.
b. Calibration verification every six months per instrument protocol as applicable.

vi. Analytical measurement range
a. Follow manufacturer instructions. Initial analytical measurement range validation and six-month interval validation is performed per instrument protocols if required by the manufacturer.

vii. Method performance specifications

Initial verification of instruments is performed; if reference range cannot be established (e.g. Troponin, it may be taken from the literature).

**Downtime reference range verification:** A copy of POCT reference ranges is available on the Intranet under Pathology Shared Documents, the document "POCT Reference Ranges". See attachment.

Minimum POCT quality control/quality assurance requirements

| PROCESS | SCOPE |
|---|---|
| 1. Record Retention | 2 Years |
| 2. Minimum Daily Quality Control | Perform & Record Two levels of controls each day of us |
| 3. Monthly Quality Control Review | Laboratory Quality Coordinator/Mobile Clinic Designee |
| 4. Staff who should perform POC Testing<br><br>Staff Training for POCT | License Personnel<br>a. RN<br>b. LVN<br>c. Medical Provider<br>d. CMA<br>Coordinated by POCT Supervisor |
| 5. Documenting problems & corrective action taken | POCT Operators<br>POCT Supervisor<br>Nurse Manager |
| 6. Proficiency Testing | POCT Operators & POCT Supervisors |
| 7. Internal Proficiency Testing | POCT Operators & POCT Supervisors |
| 8. Competency Testing | POCT Supervisor or Mobile Clinic Designee |

## REFERENCE:

1. Department of Health and Human Services, Health Care Financing Administration. Clinical Laboratory Improvement Amendments of 1988; Final Rule. FEDERAL REGISTER. 2003(Jul 24): CMS 226-F [42 CFR 493.1236].

## REVISIONS

| Date | Change | Authorized by: |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

## Biennial Review

| Date: | Signature: |
|---|---|
| 2022 | |
| 2024 | |
| 2026 | |
| 2028 | |
| 2030 | |
| 2032 | |
| 2034 | |
| 2036 | |
| 2038 | |
| 2040 | |

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER

# MOBILE CLINIC
# MICROBIOLOGY SPECIMEN COLLECTION

**Total Fix**

- **Ova and parasite**
- **Cryptosporidium/ Giardia DFA**
- **Stool WBCs***
- **-Protozoa and Helminths**

**Cary-Blair**

- **Stool culture** (which includes the GI PCR panel)

**Sterile container**

- Body Fluid Culture
- Catheter tip
- Body Fluid Fungal Culture
- AFB Culture
- Tissue/Biopsy Culture
- KOH Prep (skin, nail and hair)
- Fungal Urine Culture

**Stool specimen:**

- Clostridium *difficile*
- Helicobacter *pylori*
- Occult Blood
- Fecal Fat
- Stool for WBCs* (must be received by the lab **within 2 hours**)

**Strep A Antigen Kit**

Strep A antigen collection kit.

When ordering Strep A antigen test, an **ESwab must also be submitted for a throat culture.**

**Universal Viral Transport Medium**

Influenza/RSV PCR

**Swab Specimen – Chlamydia/GC**
- Urethral/Endocervical (In House)
- Rectal/Throat – Chlamydia/GC (Send-Out)

**Urine – Chlamydia/GC**

**Serological Tests**

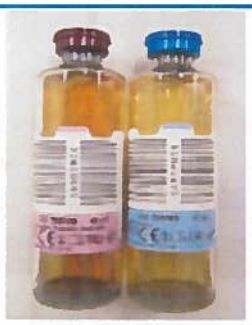
Ex. HIV, Hepatitis, Cocci, Crypto, RPR, etc.

**Urine Culture**

- Vaginal Wet Mount (must be received by the lab **within 30 minutes.**)
- Body Fluid Cultures
- Fungal or AFB Culture
- KOH Prep (skin, nail, hair)

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

# MOBILE CLINIC
# MICROBIOLOGY SPECIMEN COLLECTION



**Blood Culture Bottles (BacT Alert)**

Requires a **minimum** specimen volume of:
- 5-10mL per bottle.

May be used for **bone marrow** and **body fluid** as well

**Pediatric Blood Culture Bottles (BacT Alert)**

Requires a **minimum** specimen volume of:
- 0.5 mL

Used for pediatric patients

**Sodium heparin**

If a **gram stain** is requested for a **Bone Marrow** specimen, submit a green top tube.

- **Blood/Bone marrow specimen**

**-AFB/ Fungal culture**

**Malaria Smear**

**EDTA**


Occult Blood, Stool

**FOBT – Fecal Occult Blood Test**

**Sterile Conical Tube**

If AFB sputum x3, please order 1st specimen as a bundle.
(AFB culture/smear/PCR)

**Sputum specimen:**
- AFB (**minimum of 6mL**)
- Fungal Culture
- Respiratory Culture

**ESwab**

**Wound Specimen:**
- Aerobic Culture
- Anaerobic Culture
- GC Culture
- Fungal Culture
- AFB Culture
- Group B Strep
- MRSA

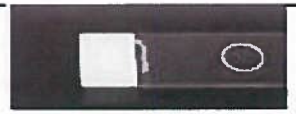
RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

# MOBILE CLINIC
# STD SPECIMEN COLLECTION GUIDE

| SOURCE | ORDER | NOTES | COLLECTION KIT |
|---|---|---|---|
| • Female cervical ≥ 14 y/o<br>• Male Urethra ≥ 14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA | • Use white swab for cleaning and discard.<br>• Use only blue swab for collection. |  <br>APTIMA UNISEX SWAB SPECIMEN COLLECTION KIT |
| • Female cervical <14 y/o<br>• Male Urethra < 14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA w/reflex to Alternate Target-SO | • Sent to Quest | |
| • Female cervical < 14 y/o | ***Trichomonas vaginalis*** NAAT<br>**ENDOCERVICAL SWAB-PHL** | • Sent to Public Health Lab | |
| • Male Urethra | ***Trichomonas vaginalis*** RNA TMA **Males-SO** | • No age restrictions | |
| • Throat | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA<br>Throat-SO | • Sent to Quest | |
| • Rectal | ***Chlamydia /Neisseria gonorrhea*** *RNA*, TMA<br>Rectal-SO | | |
| • Female cervical ≥ 14 y/o | ***Trichomonas vaginalis*** **RNA, TMA Qual.** | • In-house | |
| • Urine<br>Male/Female ≥ 14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA | • In-house<br>• Transfer 2 mL of urine(must be between to black lines) |  <br>APTIMA URINE SPECIMEN COLLECTION KIT |
| • Urine <14 y/o<br>Male/Female <14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA w/reflex to Alternate Target-SO | • Sent to Quest<br>• Transfer 2 ml of urine(must be between 2 black lines). | |
| • Female Urine<br>No age restrictions | ***Trichomonas vaginalis*** RNA, Qualitative-SO | • Female urine sent to Quest<br>• Transfer 2 ml of urine (must be between 2 black lines).<br>• Lab orderable only<br>• Send miscellaneous request slip | |
| • Male Urine<br>No age restrictions | ***Trichomonas vaginalis*** RNA TMA **Males-SO** | • Male urine sent to Quest<br>• Transfer 2 ml of urine( must be between 2 black lines). | |

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

# MOBILE CLINIC
# STD SPECIMEN COLLECTION GUIDE

| SOURCE | ORDER | NOTES | COLLECTION KIT |
|---|---|---|---|
| • Vaginal ≥ 14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA | • In-house |  APTIMA MULTITEST SWAB SPECIMEN COLLECTION KIT |
| • Vaginal < 14 y/o | ***Chlamydia /Neisseria gonorrhea*** RNA, TMA w/reflex to Alternate Target-SO | • Sent to Quest | |
| • Vaginal ≥ 14 y/o | ***Trichomonas vaginalis*** RNA, TMA Qual. | • In-house | |
| • Vaginal < 14 y/o | ***Trichomonas vaginalis*** NAAT **VAGINAL-PHL** | • Sent to Public Health Lab | |
| • Eye<br>• Nasopharyngeal | ***Chlamydia trachomatis*** Antigen, DFA | • Use Miscellaneous Request<br>• DFA collection kit not available, submit specimen on a clean cytospin microscope slide fixed with methanol or in a VCM medium tube.<br>• VCM collection kit available only In 1A127 (SPEC PROC)<br>• No PCR test available<br>• Sent to Quest<br>• No age restrictions |  Cytospin Microscope Slide OR  3 ml VCM/Swab set |
| • Eye | GC Culture | • No PCR test available<br>• No age restrictions |  ESWAB |
| • Vaginal<br>• Cervical | Wet Mount-microscopic examination to detect trichomonas, clue cells, & wbc's. For better detection of *T.vaginalis* ,order RNA, TMA. | • Use 1 sterile cotton swab for collection and transport to a sterile red top tube w/ 0.5-1.0 ml of saline. **Do not refrigerate**<br>•Must be received within 30 min. |  RED TOP TUBE |

NAME: _____

EMP#: _____

# PHLEBOTOMY MONITORING TOOL
# RANCHO LOS AMIGOS MOBILE UNIT

**LEGEND**

**PS - Performed Satisfactorily**

**U– Unsatisfactorily Performed**

*** See Comments**

**Note:**
**If other than direct observation, attach documentation.**

| Year: | On Going Monthly Monitoring | Age Specific Behavior / Performance | Correct Patient ID/used 2 unique identifiers (100%) Age Specific | Hands washed/gel used between patients (100%) | Gloves changed between patients (100%) | Needle safety Device Used (100%) | As Needed Monthly Monitoring | Correct Tubes Collected in Proper Order (100%) | Timed Tests Drawn Timely (100%) | Correct Site of Draw (100%) Age Specific | Blood Culture Contamination (≤3%) | Mislabelled Specimens (0%) | Clotted Specimen (0%) | Hemolyzed Specimen (0%) | QNS Specimen (0%) | Patient Injury (0%) | Expired Tube Used (0%) | Validated Patient Complaints (0%) | Validated Complaints from Others (0% | Patient Interaction / Age Specific | Patient Communication (+) Compliments / Complaints | Compliance with Posted Patient Care Instructions (100%) | Monitored By/Date |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| JANUARY | | | | | | | | | | | | | | | | | | | | | | | |
| FEBRUARY | | | | | | | | | | | | | | | | | | | | | | | |
| MARCH | | | | | | | | | | | | | | | | | | | | | | | |
| APRIL | | | | | | | | | | | | | | | | | | | | | | | |
| MAY | | | | | | | | | | | | | | | | | | | | | | | |
| JUNE | | | | | | | | | | | | | | | | | | | | | | | |
| JULY | | | | | | | | | | | | | | | | | | | | | | | |
| AUGUST | | | | | | | | | | | | | | | | | | | | | | | |
| SEPTEMBER | | | | | | | | | | | | | | | | | | | | | | | |
| OCTOBER | | | | | | | | | | | | | | | | | | | | | | | |
| NOVEMBER | | | | | | | | | | | | | | | | | | | | | | | |
| DECEMBER | | | | | | | | | | | | | | | | | | | | | | | |

Comments:

# DHS LABS PHLEBOTOMY MONTHLY QA MONITORING PROGRAM

The phlebotomist collects and delivers the proper specimen for testing in a timely manner and does so while maintaining an appropriate client relationship with the patient.

**Technical Indicators:**

- Correct Patient ID – Use 2 Unique Identifiers **
- Hands Washed or Gel Used Between Patients **
- Gloves Changed Between Patients **
- Needle Safety Device Used **

- Correct tubes collected in proper order
- Time Test drawn timely
- Correct site of draw = Not above the IV, not in arm with shunt/fistula, not on same side as Mastectomy, not if there is IV infiltration/similar conditions & not from foot without prior approval from clinicians.
- No Blood culture contamination
- No mislabeled specimen = wrong label put on specimen
- No Clotted specimen = did not mix anticoagulant immediately.
- No Hemolyzed specimen
- No QNS specimen = as determined by the CLS at initial testing
- No Patient injury = No hematoma, no bruises (in non-coagulopathy/hematological condition), tourniquet left on or excessively too tight, no compartmentalization, bed rails not left down if up at arrival, no phlebotomy supplies left on bed or in room.

**Client Service Indicators**

- No validated patient complaints
- No validated complaints from others
- Patient interaction – compliments received
- Patient communication
- Compliance with patient care instructions

In addition to the first four on-going indicators, this list would constitute the QA Indicators of which one or more may be selected at any time for review during a given month while observation and review or employee at work. Violation of any of the indicators must be documented.

**COMMENTS:**_____

_____

_____

_____

_____

_____

_____

** On-going Indicators Secondary to Regulatory Requirements

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

# MOBILE CLINIC
# SPECIMEN COLLECTION TOOLS

| Patient Sticker | Was patient identified with 2 identifiers? | Was the specimen labeled in the presence of the patient? | Collected by:<br>Name_____<br>Title: _____ |
|---|---|---|---|
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |
| | ☐YES ☐NO | ☐YES ☐NO | |

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

7601 IMPERIAL HIGHWAY DOWNEY CA. 90242
PHONE:

LOS ANGELES COUNTY
DEPARTMENT OF HEALTH SERVICES

Affix Patient Label Here If Available

# MOBILE CLINIC LABORATORY DOWNTIME REQUEST FORM

| Date of Request | Patient Last Name | Patient First Name | Patient Sex | |
|---|---|---|---|---|
| Medical Record Number | Patient Location | Date of Birth | Diagnosis | |
| FIN Number | Ordering Provider ID# | Medical Provider Full Name | Contact Number | |
| Collection Date/Time: | Collection ID# (also on tubes) | Medical Provider Signature Authorizing the Test: | Date: | Time: |

PLEASE COMPLETE ALL RED FIELDS AND WRITE LEGIBLY – SEND TO THE LABORATORY DEPARTMENT AT THE END OF YOUR SHIFT

**CHEMISTRY**
**(GOLD TOP TUBE)**

☐Basic Metabolic Panel ☐Comprehensive Metabolic Panel ☐Magnesium & Phosphorus ☐Lipase
☐RPR (New Syphilis Screen) ☐HEP A/B/C screen ☐HIV Ag/Ab Screen
☐Hepatic Function Panel ☐Acetaminophen ☐Ethanol Level ☐FLP (Fasting Lipids)

*Red Top is acceptable in place of Gold Top*

HEMATOLOGY
(LAVANDER TOP TUBE)

☐CBC with Diff ☐CBC – No Diff ☐HgbA1c

**OTHER TEST**

UA - (Yellow/Red or "Tiger") Preservative Tube
URINE DRUG SCREEN - Yellow (No Preservative) Tube
URINE-HCG – Urine Cup
URINE GC/CT – Aptima Tube (Yellow)
MICROBIOLOGY: ☐Blood Culture ☐Urine Culture ☐Wound Culture

OTHER TEST :(PLEASE WRITE IN BELOW)

_____

* Please make sure that you check & label all specimen accurately and order it to Orchid before sending it to the Laboratory Department.

RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER

MOBILE CLINIC
SPA: 1 2 3 4 5 6 7 8

NAME: _____ DOB: _____
MEDICAL PROVIDER: _____ MRN: _____
ENCAMPMENT LOCATION: _____

## URINE TOXICOLOGY WORKSHEET

| | |
|---|---|
| Specimen Temperature: _____<br>Room Temperature: _____ | Acceptable Range<br>32 – 38° C (90 - 100°)<br>18 – 30° C (65 – 86°) |

Report given to: _____
(Name of Medical Provider)
Medical Provider Initial: _____ Date: _____ Time: _____

Clinical Staff Initial & Print Name:
_____ _____
Clinical Staff Initial & Print Name:
_____ _____

**Note: Do not read results after 5 minutes**

| TEST | CUT-OFF LEVEL | REFERENCE RANGE | RESULTS | REQUIRES 2 NURSES INITIALS TO VERIFY RESULT | |
|---|---|---|---|---|---|
| Marijuana (THC) | 50 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Cocaine (COC) | 300 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Amphetamine (AMP) | 1000 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Methamphetamine (MET) | 1000 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Morphine 2000 (OPI) | 300 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Barbiturates (BAR) | 10 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Benzodiazepines (BZO) | 100 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Methadone (MTD) | 300 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Oxycodone (OXY) | 300 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |
| Buprenorphine (BUP) | 300 ng/mL | NEGATIVE | ☐POSITIVE ☐NEGATIVE ☐INVALID | | |

### READING THE RESULTS

**PRELIMINARY POSITIVE (+)**
A rose-pink band is not visible in each control region. If no color band appears in the appropriate Test Region (T), a preliminary positive result is indicated for the corresponding drug of that specific test zone.

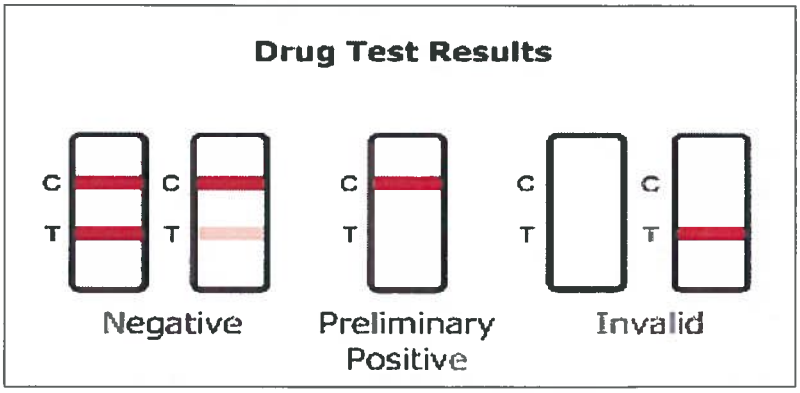
**NEGATIVE (-)**
If a rose-pink band is visible in each control region and the appropriate Test Region (T). It indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

**INVALID**
If a color band is not visible in the Control Region (C) or a color band is only visible in the Test Region (T), the test is invalid. Another test should be opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number of the test.

**NOTE:** There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line, which is interpreted as negative.

Certain lines may appear lighter or thinner than other lines.
ANY COLORED LINE VISIBLE IN THE TEST REGION (T).
NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A **NEGATIVE** RESULT.

**IMPORTANT:** This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography-mass spectrometry (GC-MS) and liquid Chromatography-tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration & professional judgement should be applied to any drug test result, particularly when preliminary positive results are indicated.




MOBILE CLINIC - POINT OF CARE TESTING
RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER
7601 IMPERIAL HIGHWAY DOWNEY CALIFORNIA 90242-3456
PHONE: FAX
LABORATORY DIRECTOR: DR. ABSALON GALAT M.D.
CLIA LICENSE NUMBER:

(Insert FIN Number Here)

RANCHO LOS AMIGOS
NATIONAL REHABILITATION CENTER

7601 IMPERIAL HIGHWAY
DOWNEY CA. 90242
PHONE:

**DOWNTIME FORM**
**SPA 1 2 3 4 5 6 7 8**

PATIENT NAME: _____

DOB: _____ AGE: _____ MRN: _____

ENCAMPMENT LOCATION: _____

**MOBILE CLINIC**
**POINT OF CARE TESTING**
CLIA LICENSE NUMBER:
_____
LABORATORY DIRECTOR:
DR. ABSALON GALAT M.D.

| POINT OF CARE TEST | AGE | REFERENCE RANGE | CRITICAL VALUES LOW | CRITICAL VALUES HIGH | RESULT |
|---|---|---|---|---|---|
| GLUCOSE (mg/dl) | 0 – 1 Month Old: | 41 - 130 | <41 | >199 | |
| | >1 Month to 16 Years Old: | 65 - 99 | <41 | >249 | |
| | > 16 Years Old: | 65 - 99 | <41 | >449 | |

*PRINT NAME OF CLINICAL STAFF WHO PERFORMED THE TEST:* _____ *DATE:* _____ *TIME:* _____
*MEDICAL PROVIDER WHO RECEIVED CRITICAL RESULT:* _____ *DATE:* _____ *TIME:* _____

| | | | | | |
|---|---|---|---|---|---|
| TOTAL HEMOGLOBIN (g/dL) | <1 Month: | 15 - 24 | | <6.6 | >21.9 |
| | 1 Month to 2 Years: | 10.5 – 14.0 | | <6.6 | >19.9 |
| | 2 Years to 12 Years: | 11.5 – 14.5 | | <6.6 | >19.9 |
| | 12 Years to 18 Years: | Male 12.5 – 16 | Female 12 – 15 | <6.6 | >19.9 |
| | >18 Years: | Male 13.5 – 18 | Female 12.5 - 16 | <6.6 | >19.9 |

*PRINT NAME OF CLINICAL STAFF WHO PERFORMED THE TEST:* _____ *DATE:* _____ *TIME:* _____
*MEDICAL PROVIDER WHO RECEIVED CRITICAL RESULT:* _____ *DATE:* _____ *TIME:* _____

| | REFERENCE RANGE | RESULT | RESULT PRINTOUT |
|---|---|---|---|
| URINE PREGNANCY TEST | NEGATIVE | ☐NEGATIVE<br>☐POSITIVE<br>☐ INVALID | (Affix Printout) |

*PRINT NAME OF CLINICAL STAFF WHO PERFORMED THE TEST:* _____ *DATE:* _____ *TIME:* _____
*MEDICAL PROVIDER WHO RECEIVED CRITICAL RESULT:* _____ *DATE:* _____ *TIME:* _____

| | REFERENCE RANGE | RESULT | RESULT PRINTOUT |
|---|---|---|---|
| URINE DIPSTICK TEST | GLUCOSE: NEGATIVE | | (Affix Printout) |
| | BILIRUBIN: NEGATIVE | | |
| | KETONE: NEGATIVE | | |
| | SPECIFIC GRAVITY: 1.005 –1.030 | | |
| | BLOOD: NEGATIVE | | |
| | pH: 5.0 – 8.0 | | |
| | PROTEIN: NEGATIVE | | |
| | UROBILINOGEN: 0.2 – 1.0 | | |
| | NITRITE: NEGATIVE | | |
| | LEUKOCYTE: NEGATIVE | | |

*PRINT NAME OF CLINICAL STAFF WHO PERFORMED THE TEST:* _____
*INITIAL:* _____ *DATE:* _____ *TIME:* _____

*MEDICAL PROVIDER WHO RECEIVED CRITICAL RESULT:* _____
*INITIAL:* _____ *DATE:* _____ *TIME:* _____

**MOBILE CLINIC - POINT OF CARE TESTING**
RANCHO LOS AMIGOS NATIONAL REHABILITATION CENTER
7601 IMPERIAL HIGHWAY DOWNEY CALIFORNIA 90242-3456
PHONE: FAX
LABORATORY DIRECTOR: DR. ABSALON GALAT M.D.
CLIA LICENSE NUMBER:

(Attached FIN NIMBER Here)