JUVENILE COURT HEALTH SERVICES LABORATORY PROCEDURES

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Clinitest HCG Point of Care Test	Supersedes:	Effective Date: 6/30/2021

Departments Consulted:	Approved By:	Approved by:
Department of Nursing	(Signature on File) Laboratory Supervisor (Signature on File) Laboratory Director	(Signature on File) Health Services Administrator

DEFINITION

Point of Care Testing (POCT) involves the performance of laboratory tests at a location where a patient receives care.

OPERATORS:

Registered Nurses and LVN who are properly trained on the Clinitek Status Testing System perform the procedure. All personnel must demonstrate their proficiency in performing Quality Control and patient testing activity in the annual skills lab competency or peer review. New employees will have their competency assessed six months after initial competency and annually thereafter.

PRINCIPLE:

The Clinitest hCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid determination of hCG in urine. The membrane is precoated with anti-alpha hCG capture antibody on the test line region (T) and goat anti-mouse IgG on the control line region (C). During testing, the urine specimen is allowed to react with colloidal gold particles coated with anti-beta hCG monoclonal antibody. The mixture then chromatographically moves along the membrane by capillary action. For a positive or borderline result, a pink colored line with a specific antibody-hCG-antibody-colloidal gold particle complex will form on the membrane in the test line region. A pink-colored line at the reference region (R), the area between the control line region and the test line region has been adjusted to a level approximating 25 mIU/mL hCG. Absence of a pink-colored line in the test line region indicates a negative result. The appearance of a colored line in the control region and the reference region serves as verification that sufficient volume has been added and that proper flow has occurred.

CLINICAL APPLICATION AND USEFULNESS:

The Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotropin (hCG) in urine specimens. The test is utilized with the Clinitek Status Analyzer and is intended for near-patient (point of care) and centralized.

SUMMARY AND EXPLANATION OF THE TEST:

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in serum as early as 7 days following conception. Recent studies suggest that urine hCG concentrations are approximately one-half of, or less than one-half of corresponding serum hCG concentrations. Thus, hCG can likely be detected in urine as early as 14 days after conception (approximately 28 days since the last menstrual cycle), doubling in concentration about every two days until it peaks at approximately 8-10 weeks after the last menstrual period. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth makes it an excellent marker for the early detection of pregnancy. The Clinitest hCG Pregnancy Test is a rapid chromatographic immunoassay for the qualitative determination of hCG in urine. Hormone levels greater than 25 mIU/mL are reported as positive. Samples containing less than 25 mIU/mL are reported as either negative or borderline. Samples reported as borderline are considered indeterminate and the operator is advised to repeat the test in 48-72 hours or obtain a serum hCG. The test uses monoclonal antibodies to selectively detect elevated levels of hCG in urine specimens. The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

SPECIMEN COLLECTION AND HANDLING:

Patient Identification/Preparation: Urine Point of Care HCG Testing will be performed only when ordered by a physician. Patient is identified using their identification band to verify name and date of birth. A label with the patient's name, date of birth and medical record is affixed to the urine container.

Biohazard:
All clinical specimens should be handled, before and after cleaning, as if capable of transmitting infectious diseases.

- Wear appropriate facial protection, gloves, and protective clothing.
- Urine is the only acceptable sample type for this assay.
- This assay requires 200 uL of sample for a single determination.
- Collect urine into a clean, dry container.
- Specimens collected at any time of day may be used.

Specimen Storage and Stability:

- Refrigerate specimens at 2º - 8º C (36-46º F) for up to 72 hours, if the testing is not performed immediately.
- If samples are refrigerated, bring them to room temperature during testing.
- Do not use samples that have been stored for longer than 72 hours.

REAGENTS:

Storage and Stability:

- Store Clinitest hCG cassettes either refrigerated or at room temperature, 2-30º C (36-86º F).
- Cassettes are stable for the duration of the shelf life when packaged in the protective pouch.

CAUTION: **Do not use the Clinitest hCG cassettes beyond the expiration date**.

Reagent Special Preparation:

- No special preparation for Clinitest hCG cassettes is required.

CALIBRATION

The Clinitek Status Analyzer performs a "self-test" and calibration each time it is turned on. In addition, the analyzer performs an automatic calibration each time a test is run. The white calibration bar (on the test table) provides NIST traceable calibration.

INTERNAL QUALITY CONTROL (QC):

Each test includes two procedural controls, which indicate that sufficient sample was added for capillary flow to occur and the correct procedural technique was used. If the instrument does not detect the Reference (R) and control (C) regions within two minutes after starting the test an error is reported and the test must be repeated.

QC Materials:
Control material consists of two levels, a negative and a positive. Use MAS Level I as the negative control and MAS Level II as the positive control. Test negative and positive liquid controls whenever a new reagent kit is first opened, at a minimum of once a month. If both controls are in range, proceed with patient testing. If a control is out of range, repeat it once. If control is in range, proceed with patient testing. If control is still out of range, forward testing to central lab. Notify Point of Care Coordinator.

QC PROCEDURE:

1. At the main Select screen, touch **Cassette Test**. The **Operator ID** screen will appear.
2. If you were the last operator to enter an ID on the analyzer, touch **Last Operator**. The **Patient Information** screen will appear.
3. If you are a new operator, touch **Cassette Test**. The **Operator ID** screen will appear.
4. Use the keypad to enter your ID. Touch enter.
5. The **Patient Information** screen will appear. Touch the **Enter New Patient** key at the bottom right of the screen.
6. The **Patient ID** screen will appear.

7. Touch the **ABC** button in the upper left portion of the screen. Type in neg for the negative control (Level I) or pos for the positive control Level II).

8. Touch **Enter**. The **Test type** screen will appear.

WARNING: **If refrigerated, bring the test cassette and qc sample to room temperature 20- 30º C (68-86º F) prior to testing.**

9. Touch **Clinitest hCG Cassette**. A **Prepare Test** screen will appear displaying the following two steps:

a. Adjust test table insert for cassette tests.

b. Place cassette on test table and touch start.

10. Touch **START.** Another **Prepare Test** screen will appear displaying the next two steps:

WARNING: **Once you touch the START button, you have eight seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.**

a. Draw the sample into pipette.

b. Add sample to sample well.

WARNING: **Do not push or pull the test table**.

11. At the end of the 8 second countdown, the test table and cassette will automatically be pulled into the instrument.

12. The analyzer will perform an automatic calibration and finish analyzing the sample.

WARNING: **Do not move or bump the table while the instrument is calibrating**.

13. When analysis is complete, the **Results** screen will be displayed. Record results on the hCG quality control log. Staple the printout to the back of the form.

14. Remove the used cassette and dispose of it in biohazard container.

15. Touch **Done** to complete the test and return to the main **Select** screen.

EQUIPMENT AND SUPPLIES:

- Clinitest hCG cassette with disposable pipette.
- Clinitek Status Analyzer.
- Specimen collection container.

The Clinitek Status Analyzer is a portable instrument powered by batteries or by an electrical outlet for bench top use. It is for in vitro diagnostic use in the detection of human Chorionic Gonadotropin (hCG) in urine samples, when Clinitest hCG cassette tests are used.

The optical system consists of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light from the LEDs travel along the light guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture on the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed by the instrument's microprocessor and converted into clinically meaningful results.

SYSTEM START-UP AND MAINTENANCE:

The system is turned on by pressing the on/off button located at the front of the instrument. The analyzer automatically runs a system diagnostic check during which it performs a series of electronic, signal and memory checks, as well as ensures there is sufficient battery voltage to operate the instrument (if powered by batteries).

The test table insert and the test table should be kept clean if the analyzer is to operate properly.

WARNING: **Do not autoclave the test table or test table insert**.

WARNING: Care should be taken not to scratch the white calibration bar. If it is scratched or scuffed, obtain a new test table. Solvents of any kind must not be used to clean the bar.
Refer to your Clinitek Status analyzer Operator's Manual for detailed cleaning and maintenance instructions.

PROCEDURE STEPWISE

1. At the main Select screen, touch **Cassette Test**. The **Operator ID** screen will appear.
2. If you were the last operator to enter an ID on the analyzer, touch **Last Operator**. The **Patient Information** screen will appear.
3. If you are a new operator, touch **Cassette Test**. The **Operator ID** screen will appear.
4. Use the keypad to enter your ID. Touch enter
5. The **Patient Information** screen will appear. Touch **the Enter New Patient** key at the bottom right of the screen.
6. The **Patient ID** screen will appear.
7. Use the keypad to enter the patient's ID using the 6 digit medical record number.
8. Touch **Enter.** The **Test type** screen will appear.

WARNING: If refrigerated, bring the test cassette and patient sample to room temperature 20-30º C (68-86º F) prior to testing.

9. Touch **Clinitest hCG Cassette**. A **Prepare Test** screen will appear displaying the following two steps: c. Adjust test table insert for cassette tests. d. Place cassette on test table and touch start.
10. Touch START. Another Prepare Test screen will appear displaying the next two steps:

WARNING: Once you touch the START button, you have eight seconds to draw the urine sample into the pipette and add the urine sample into the well on the cassette.

c. Draw the sample into pipette.
d. Add sample to sample well.

WARNING: Do not push or pull the test table.

11. At the end of the 8 second countdown, the test table and cassette will automatically be pulled into the instrument.
12. The analyzer will perform an automatic calibration and finish analyzing the sample.

WARNING: Do not move or bump the table while the instrument is calibrating.

13. When analysis is complete, the **Results** screen will be displayed.
14. Remove the used cassette and dispose of it in biohazard container.
15. Touch Done to complete the test and return to the main Select screen.

REPORTING RESULTS:

JCHS has verified the manufacturer's reference ranges as listed below as appropriate for our patient population.

Reference Interval for Healthy Men and Healthy Non-pregnant Women:

1. No detectable hCG level occurs when using the Clinitest hCG Pregnancy Test.

Reference Interval for Pregnant Females:

1. 100 mIU/mL on the day of the first missed menstrual period.
2. Peak levels of hCG occur at 8-10 weeks after the last menstrual period.
3. Lower levels of hCG occur during the remainder of the pregnancy.
4. A rapid decrease and usually a return to normal in hCG levels occurs within days of delivery.

Units for Reporting Results:
The system reports hCG results in mIU/mL.

Reportable Range:
The Clinitest hCG Pregnancy Test detects urinary hCG concentrations greater than 25 mIU/mL (calibrated to the World Health Organization 3rd International Reference Preparation). Result reporting accomplished via interface into Wellsoft by way of Sunquest.

PROCEDURE NOTES:

Urine Specimens:
Specimens collected at any time of day may be used.

Positive Results:
The instrument automatically determined that the Test (T) region intensity is equal to or more intense than a 25 mIU/mL urine sample and confirmed that the control (C) and Reference (R) regions met minimum intensity specifications.

Borderline Results:
The result is indeterminate, repeat in 48-72 hours, or perform serum quantitative hCG in Central Lab.

Negative Results:
The instrument automatically determined Test (T) region is less intense than the 25 mIU/mL hCG concentration level that the device can detect and confirmed the Reference (R) and Control (C) regions meet minimum intensity specifications. Negative test results in patients suspected to be pregnant should be retested with a sample obtained 48 to 72 hours later, or by performing a quantitative serum hCG in the Central Lab.

Invalid Results:
The instrument will automatically determine if a procedural error or test reagent deterioration has occurred by confirming the Reference (R) and Control (C) regions meet minimum intensity requirements. If not, the user will be advised to repeat the test and to contact the Bayer Health Care Technical Care Center and Lab Point of Care Testing Coordinator if the problem persists.

Disposal:
Dispose of hazardous or biologically contaminated materials in a biohazard container. Discard all materials in a safe and acceptable manner, and in compliance with all federal, state, and local requirements.

METHOD LIMITATIONS:

The test is not intended to detect conditions other than pregnancy. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, can cause elevated levels of hCG.

As is true with any diagnostic test, clinical diagnosis should not be based solely on a single test result. Clinical diagnosis should incorporate all clinical and laboratory data. Because of lag between conception and the appearance of hCG in urine (See Summary and Explanation of the Test), to exclude pregnancy with the highest degree of certainty, it may be necessary to repeat the test on a fresh sample obtained 2-3 days after obtaining a "negative" result on the initial sample.

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

The presence of heterophile antibodies or non-specific protein binding may cause false-positive results in sensitive immunoassays. If a qualitative interpretation is inconsistent with the clinical evidence, results should be confirmed by a quantitative serum hCG in the Central Lab.

The specificity of the Clinitest hCG Pregnancy Test was determined from cross-reactivity studies with known amounts of human Luteinizing Hormone (hLH), human Follicle Stimulating Hormone (hFSH) and human Thyroid Stimulating Hormone (hTSH), all tests yielded negative results when used with 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH.

For additional information on performance characteristics including cross-reactivity, see the product information in the Clinitest hCG product insert.

REFERENCES:

1. Siemens Clinitest hCG Test Package Insert. NDC 8620-1760-25, SMN 10310618
2. Siemens Clinitex Status Analyzer Operator's Manual, 132387, Rev T, 2008-05 3. National Committee for Clinical Laboratory Standards (NCCLS), Clinical Laboratory Procedure Manuals, 3rd edition (GP2-A3), 1996.

QUALITY ASSESSMENT

A. Audit/Monitoring

- Perform once a month
- A summary of the audit is distributed to the nurse manager
- Compliant: 90% or greater; Non-compliant: Less than 90%, requires corrective action

B. Proficiency Testing

Upon receipt:

- Specimen are stored in POCT laboratory according to CAP (College of American Pathologist) instructions until they are ready for analysis
- Specimens are delivered to the testing sites for analysis

Analysis of CAP Survey specimens:

- Are rotated among the performing staff
- Are analyzed in the same manner as the patient sample
- Are not referred to another laboratory for analysis

Reporting of Proficiency Testing results by the POCT Laboratory:

- Information regarding the results are not be shared with the other testing sites until the results have been submitted to College of American Pathologist
- Results are submitted within ten working days or prior to the due date indicated on the instruction sheet

Results Evaluation from the College of American Pathologist:

- Evaluation of the CAP survey are received and reviewed by the Department Laboratory and Pathology
- The testing locations are notified by the POCT Laboratory for any unacceptable evaluation
- Investigation and corrective action are performed on any unacceptable evaluation

C. Training Policy

1. Training may be provided by the:
    - Manufacturer
    - Point of Care Testing Laboratory
    - On-site Trainer
2. New Employees:
    - Must receive proper education and training in the use and maintenance of the device
    - Competence is assessed prior to performing the test
3. Certification or authorization to perform the test is valid for a year. Competency assessment is performed every year after initial training. Only trained and re-certified operators are authorized and able to perform the test.
4. All testing sites must maintain Staff Competency at 100%. **All operators are trained and/or within a year of certification.**

$$\text{Staff Competency} = \frac{\text{Total \# of certified staff - \# of certified staff with expired certificate} \times 100}{\text{Total \# of certified staff}}$$