OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 11712
VERSION: 1

SUBJECT/TITLE: POCT -08-02 POC URINE PREGNANCY BY SIEMENS CLINITEST® HCG

5POLICY: Urine Pregnancy By Siemens CLINITEST® hCG

PURPOSE: The Siemens Healthcare Diagnostics 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 CLINITEK Status® systems and is intended for near patient (point of care) and centralized laboratory locations.

DEPARTMENTS: PATHOLOGY

DEFINITIONS: The CLINITEST hCG Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid determination of hCG in urine. The membrane is precoated with anti-hCG capture antibody on the test line region (T) and goat anti-mouse IgG antibody 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 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.

PROCEDURE: **TEST UTILIZATION:**

The Siemens 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 CLINITEK Status® systems and is intended for near patient (point of care) and is a screening tool to determine pregnancy. Test results must always be evaluated with other data available to the physician.

TEST PERFORMANCE AND SUPERVISION:

The Siemens CLINITEST hCG Pregnancy Test may be performed by Olive

View-UCLA Medical Center personnel, including physicians, registered nurses, licensed vocational nurses, clinical laboratory scientists, and other staff members, who satisfy California State and CLIA requirements for testing personnel and have been trained and authorized to do such testing under the Olive View-UCLA Medical Center Point-of-Care Testing Program. Supervision of testing personnel is the responsibility of the testing site section managers, i.e. nursing, clinical laboratory, radiology, etc.

SPECIMEN:

Urine
Collect urine into a clean, dry container. Specimens collected at any time of day may be used. Refrigerate specimens at 2-8°C (36-46°F) for up to72 hours, if the testing is not performed immediately. If samples are refrigerated, bring them to room temperature before testing. Do not use samples that have been stored for longer than72 hours.

EQUIPMENT AND MATERIALS:

Equipment:
Clinitek Status®+

Materials:
Siemens Clinitest® hCG cassettes (including pipettes)
Biosys Plus Urinalysis Control
Level 1 (Negative)
Level 2 (Positive)
Distilled water
Absorbent paper towels
5% Bleach wipes
70% alcohol prep pads

REAGENT STORAGE REQUIREMENTS:

Urine Reagent Cassettes:

- The test kit can be stored either refrigerated or at room temperature, 2-30°C (36-86°F), unopened stable until the expiry date on package.
- Do not use the test beyond the expiration date.
- If refrigerated, bring the wrapped cassettes to room temperature before opening the protective pouch to avoid moisture condensation on the membrane.

Urine Pregnancy Controls:

- Biosys Plus Urinalysis Negative and Positive controls must have an open

dated documented on the bottle and are stable until the expiration date stated on the label, when stored between 2°-8°C.

- Do not freeze. Biosys Plus can be stored at room temperature (15°-25°C) for up to 30 days.
- Label the bottle with the date it was originally brought to room temperature to ensure proper performance (open expiration date).
- Discard QC bottle solutions if turbidity or any evidence of microbial contamination has been observed.
- Discard QC bottle solution in the same manner as other biological specimens.

Warnings:

Biosys Plus Urinalysis Control solutions contain urine of human origin. Human source material used in the preparation has been found non-reactive for HBsAg when tested by RIA, and also negative for HIV-1 antibody when tested by ELISA. However, no known test method can assure that a product derived from human source does not contain hepatitis or HIV-1 viruses. Universal standard precautions must be practiced when handling and disposing of specimens and testing components.

QUALITY CONTROL:

External Quality Control

A POSITIVE AND NEGATIVE EXTERNAL CONTROL MUST BE RUN EACH DAY OF PATIENT TESTING AND WITH NEW BOX OF hCG CASSETTES.

1. External Positive Control: Process the control solution as you would a patient sample. A positive result will be reported by the instrument.

2. External Negative Control: Process the control solution as you would a patient sample. A negative result will be reported by the instrument.

Internal Control Features

- 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 detects a failure of either of these two procedural controls, an error is reported and the test must be repeated.

If the controls do not perform as expected, repeat the test or contact POCT at X73684, X73153 or Siemens Technical Support at 1-877-229-3711 for assistance.

TEST PROCEDURES:

Procedure –Quality Control:

1. Remove control solutions from the refrigerator and allow to reach room temperature before testing.
2. Turn **ON** the instrument by pressing the ON/OFF button. The analyzer will run an automatic system diagnostic test each time it is turned ON.
3. From the SELECT Ready Screen: Touch **QC Test Due**.
4. Select QC Cassette Test required.
5. Enter/Scan **Operator ID.** Enter your 6-digit employee number or pre-approved employee ID format.
6. Screen would show Control Biosys Level 1. Touch "**Enter Lot and Expiration Date**".
7. Enter/Scan the **QC lot number** indicated in the control bottle and **QC expiration date: YY/MM/DD**.
   Note: Expiration date listed as month and year only is good until end of the month.
8. Screen shows **Cassette Lot**. Touch "**Enter new lot and expiration date**" then enter/scan the lot number of Cassette and the expiration.
9. PREPARE TEST: Remove a cassette from the pouch and place it onto the test table. Gently mix the Level 1 control solution by inversion. Remove cap and invert bottle. Press **START**. (You have **8 seconds** to complete step 10.)
10. Gently squeeze the dropper bottle dispensing 4 drops into the sample well of the test cassette.
11. After 8 seconds, the test table and cassette will automatically be pulled into the analyzer. A timer will count down the time remaining in analyzing the cassette result.
    Calibrating: The Clinitek Status® analyzer will perform an automatic calibration each time a test is run.
    Analyzing: Displayed after calibration completed and the analysis of the urine has begun.

12. When the analysis is complete, the Results screen displays:
    • QC Test: PASS
    • QC Test: FAIL
    • Select **Add QC notes** and repeat if any of the results FAILED then press **print**, otherwise proceed to QC Level 2.
    • QC notes in free text:
      Repeat Test
      Procedure Error
      New Cassette Lot
      New Control Lot

- After analyzing both QC levels, a QC Test Results Summary will be displayed
- Touch Done, if both levels "PASS"

13. Touch Done, results will be automatically transmitted to Telcor.
14. Repeat steps 6-13 for Biosys Level 2. Return the controls to the refrigerator promptly.

Note: If any cassette test result fails, repeat the control. The device has QC lock-out; testing will not proceed unless both QC levels pass. If the control results continue to fail, notify the supervisor and POCT Department. Record action and trouble-shooting procedures done on the Corrective Action Log sheet. Use back-up instrument, if applicable or send all urine samples to OV-UCLA Medical Center Laboratory until issues with QC are resolved.

Procedure – Patient Test:

1. Turn **ON** the instrument by pressing the ON/OFF button. The analyzer will run an automatic system diagnostic test each time it is turned ON.
2. Turn the table insert so cassette holder is facing upwards.
3. On the Select screen press **Cassette Test** screen button.
4. Enter/Scan **Operator ID.** Enter your 6-digit employee number or pre-approved employee ID format.
5. Select **NEW PATIENT** then on **ENTER PATIENT NAME**: Use the keyboard to enter Patient's Last Name, First Name, press **ENTER**.
6. **ENTER PATIENT ID**: Scan/Use the keyboard to type in patient's 10-digit FIN or pre-approved alternative patient's ID number. Press **ENTER**.
7. **ENTER PATIENT INFORMATION**: Use the keyboard to enter patient's date of birth by typing **DOB MM-DD-YY**. Press **ENTER**.
8. On the **Cassette Lot** screen, select **Use Last Lot** or **enter new lot and expiration date**. Scan/enter the new lot and expiration.
9. PREPARE TEST: Remove a cassette from the pouch and place it onto the test table. Make sure the test table insert has the cassette holder facing upward, set up to receive the sample cassette. When the cassette, pipette and urine sample are ready, touch **START** to begin. There are 8 seconds allowed to aliquot and process the sample cassette.
10. Holding the pipette at a slight angle, squeeze the upper bulb and draw enough sample into the pipette to fill the stem completely, with an overdrawn amount going into the reservoir (lower bulb).
11. Discharge the sample in the pipette stem into the sample well of the test cassette by squeezing the upper bulb in one squeeze. The excess fluid will remain in the reservoir. Do not push or pull the test table.
12. After 8 seconds, the test table and cassette will automatically be pulled into the analyzer. A timer will count down the time remaining in analyzing the cassette result.

Calibrating: The Clinitek Status® analyzer will perform an automatic calibration each time a test is run.

Analyzing: Displayed after calibration completed and the analysis of the urine has begun.

13. **PRINTING** will be displayed, and the analyzer will automatically print the result. The results will be displayed on the screen after printing has been completed and will automatically transfer to patient's electronic health record (Cerner) when required entries are met.
14. Remove the used cassette and discard into proper container.
15. Wipe the cassette holder with a damp, lint-free tissue. Do this as often as needed to prevent urine from building up.

INTERPRETATION OF RESULTS

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

Borderline Result:
Result is indeterminate, repeat in 48-72 hours.

Negative Result:
The instrument will automatically determine that the Test (T) region is less intense that the 25mIU/mL hCG concentration level that the device can detect, and confirms that the Control (C) and Reference (R) region meet minimum intensity specification.

Invalid Result:
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. If not, the user will be advised to repeat the test and or contact Siemens Technical Support at 1-877-229-3711 for assistance.

If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and tested or send a blood sample to Olive View-UCLA Laboratory for serum B-hCG.

Recall Results:

1. Touch **Recall Results** button.
2. **SELECT TEST RESULTS**. The test results are in chronological order. The most recent test result is displayed at the top of the screen and is highlighted
3. Use the up and down arrow keys to scroll through the patient you would like to

recall.

4. To view details of the patient results, touch the **SELECT** button.
5. Press **PRINT** to print a copy. Press **EXIT** to return to the Main Menu.

EXPECTED RESULTS

Healthy men and healthy non-pregnant women do not have detectable hCG levels when using the CLINITEST hCG Pregnancy Test. For pregnant women, hCG levels of 100 mIU/mL can be reached on the first day of the missed menstrual period. hCG levels peak about 8-10 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. hCG levels rapidly decrease and usually return to normal within days after delivery.

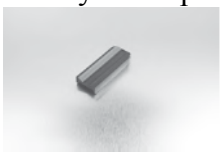
MAINTENANCE:

The test table insert and test table should be kept clean if the analyzer is to operate properly. Wear personal protective equipment. Use universal precautions when working with bio-hazardous materials.

Daily Maintenance:

Table Insert:

1. Remove insert and thoroughly clean.
2. Rinse both sides of the table insert under running water.
3. Dry and replace insert. Do not use cotton balls.

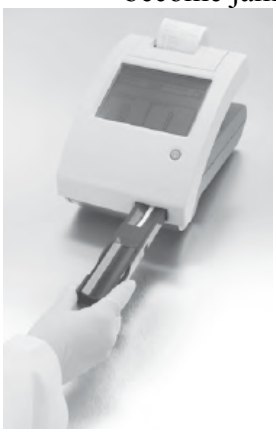


Test Table:

1. Remove the test table by pulling it slowly out of the analyzer. Lift the test table insert from the test table and drain the drip tray if necessary.
2. Wet a cotton-tipped stick with **distilled water** and carefully clean test table (except for white calibration bar).
3. Dry the test table thoroughly (except for the white calibration bar) with a lint-free tissue or paper towel. Do not use cotton balls.

4. Reinsert the test table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

   Note: Do not push the test table fully into the analyzer as the test table may become jammed and prevent the use of the analyzer



Weekly Maintenance:

Disinfecting the Table and Insert:

Note: Acceptable Disinfectants: 70% Alcohol Prep Pad, 5% bleach wipes.
Do not wet white calibration bar with disinfectant.

1. Wipe test table and insert with the acceptable disinfectant and let it soak for 2 minutes.
2. Rinse the test table and insert thoroughly with **distilled water**.
3. Dry with a lint-free tissue or paper towel. Do not use cotton balls.
4. Replace the test table and insert in the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

As Needed Maintenance:

Cleaning the White Calibration Bar:

To enable for the analyzer to perform as intended and provide reliable results, it is recommended that you periodically check the white calibration bar on the test table. In normal use, the white calibration bar should not become dirty or discolored.

1. Remove the insert from the table.
2. Remove the test table by pulling it slowly out of the analyzer.
3. Check the white calibration bar on the test table for dirt or discoloration.
4. If the white calibration bar is clean and unmarked, replace the table into the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over half way into the analyzer.
5. Replace the test table insert.
6. If the white calibration bar is dirty or discolored, gently wipe and clean with a new cotton-tipped stick with **distilled water.**

Note: Care should be taken not to scratch the white calibration bar. Solvents of any kind must not be used to clean the bar.

7. Allow the calibration bar to air dry and then inspect the surface for dust, foreign material, scratches or scuffs. If the calibration bar cannot be cleaned or is still marked, obtain a new table.
8. Replace the test table and insert in the analyzer by holding the table at the end opposite the white calibration bar, with the white calibration bar facing upwards. Push the test table firmly but slowly, just over halfway into the analyzer.

Cleaning the Outside of the Analyzer:

Always keep the outside of the analyzer clean and free of dust.

1. Turn the analyzer OFF by pressing the ON/OFF button for 2 seconds.
2. Wipe the outside (including the display) with a damp (not wet) paper towel and a mild detergent.

Note: Do not use any type of solvent, oil, grease, silicone spray or lubrication on the analyzer. Do not spray the glass cleaner directly into the screen. Care should be taken to avoid liquid from entering the printer compartment.

3. Rinse with a dampened paper towel with water and dry with paper towel.
4. The display may be disinfected using 70% alcohol pred pad or 5% bleach wipe (remove excess). Wipe the solution on and allow to remain for 10 minutes. Wipe clean using a paper towel dampened with water, then dry. Perform procedure when 10 minutes will not affect work flow.

Specifications:

Ambient Operating Temperature Range: 18° C to 30° C (64° F to 86° F)
Optimum Operating Temperature Range: 22° C to 26° C (72° F to 79° F)
Ambient Operating Humidity Range: 18% to 80% Relative Humidity (non- condensing)
Optimum Operating Humidity Range: 35% to 55% Relative Humidity (non-condensing)

Loading the Printer Paper Roll:

1. Open the printer cover by pulling up the tab.
2. Open the paper roll compartment cove by pressing down on its tab and pulling out.
3. Lift the paper holding arm into the open, upright position.
4. Place the new paper roll into the printer compartment with the paper unrolling from underneath and toward the compartment wall.
5. Feed the paper up along wall and through the printer. Once you have approximately 4 inches of paper through the printer, then feed the edge of the paper through the printer cover.
6. Push the paper holding arm down into the closed position.
7. Close the printer and paper roll covers by clicking them into position.

Note: The analyzer is set up to automatically print the results. The analyzer uses both ordinary thermal paper or label stock. Lift the printer cover and the instrument's serial number will be visible. Thermal printouts will fade with time. It is a regulatory requirement that instrument printouts are kept for 3 years. It may be necessary to photocopy the log sheets to satisfy this requirement.

Setting the Time (Daylight Savings Time)**:**

1. Press **INSTRUMENT SET UP**
2. Enter **PASSWORD** (Call POCT for password).
3. Scroll down to **DATE AND TIME SETTINGS**. Touch **SELECT.**
4. **SET DATE & TIME:** Move arrow up or down to change hour. Touch **SET.**
5. Touch **DONE**.

TROUBLESHOOTING:

Error Code	Description	Action
E01	Low battery power	Replace the batteries.
E02	Failure of calibration data	Contact Technical Support at 1-877-229-3711
E03,E04, E05,E06, E07,E08, E21,E22, E90,E91, E92 or E93	Failure of computer software	Contact Technical Support at 1-877-229-3711
E10 or E48	Loss of test results	1. Switch the instrument off by pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button. 3. Repeat the test.
E11	Failure of test table	1. Make sure that the test table is in place. Move the test table in or out of the instrument slightly to reposition the test table. 2. If the error remains, with the instrument powered on, unplug the power cord from the rear of the instrument and plug back in. Turn the instrument on by pressing the gray button. 3. If the error remains with the test table in place, contact Technical Support at 1-877-229-3711
E12	Failure of LED	Contact Technical Support at 1-877-229-3711
E20	Failure of clock	Contact Technical Support at 1-877-229-3711
E23	Low battery power	Replace the batteries. If the battery level Becomes too low to power the instrument, Error Code E01 will be displayed.
E24	No printer paper	Replace the printer paper.
E25,E64 or E65	Failure of automatic calibration	Clean the calibration strip. If the error remains after cleaning, contact Technical Support at 1-877-229-3711
E27	Set up failure	1. Switch the instrument off pressing the on/off button for 2 seconds. 2. Switch the instrument on again by pressing the on/off button.
E28	Printer error	Lift the printer cover and push the paper

		holding arm back into position.
E52	Invalid barcode	Repeat the test using the correct Siemens Cassette.
E53	Strip Test selected but cassette detected	Repeat the test using the Cassette Test.
E54	Cassette Test selected but strip detected	Repeat the test using the Strip Test
E56	Incorrect size test table	Repeat the test using the correct test table.
E57	Missing strip or cassette	Repeat the test ensuring that the strip is positioned on the test table.
E62	Light Ingress	Too much light is reflecting on the analyzer. Move the analyzer to another location with lower lighting. Contact Technical Support at 1-877-229-3711.
E67 or E68	Insufficient sample	A sample flow issue with the cassette test may have been detected. One or more of the test indicator lines may be missing or indiscernible from the background, or not enough sample was applied to the cassette. Repeat the test ensuring the pipette is correctly filled and the correct volume sample is dispensed into the well of the cassette.

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 nontrophoblastic 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, to exclude pregnancy with the 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.

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, send a blood sample to the Olive View-UCLA Laboratory for serum B-hCG.

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.

High-Dose Hook Effect

High-dose hook effects are not seen with this product until the urine hCG level exceeds 600,000 mIU/mL, a level 2-3 times higher than the highest level seen for pregnant individuals.

References:

1. Siemens Healthcare Diagnostics Clinitest hCG Test Package Insert, 06878007, 2007-08
2. Siemens Healthcare Diagnostics CLINITEK Status Analyzer Operator's Manual, 132387, Rev. T, 2003-07
3. Siemens Healthcare Diagnostics CLINITEK STATUS Connect System Operator's Manual, 135055, Rev A, 2009-12
4. National Committee for Clinical Laboratory Standards (NCCLS). Clinical Laboratory Procedure Manuals, Third Edition (GP2-A3), 1996
5. Siemens Healthcare Diagnostics CLINITEK Status + Analyzer Operators Manual, 135057, Rev. A, 2009-11.
6. Biosys Plus Urine Control Package insert

*NCCLS is now known as: Clinical and Laboratory Standards Institute (CLSI).

Approved by: Armine Baltayan (Interim Laboratory Director), Deepthi Karunasiri (Co-Director of Clinical Pathology)	Date: 05/03/2019
Review Dates: 05/03/2019	Revision Date:
Next Review: 05/03/2021	
Distribution: Pathology & Laboratory Services	
Original Date: Not Set	