VA Salt Lake City Health Care System, MC 113
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Document Title: Clinitek Status Clinitest HCG

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-beta 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 mlU/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.

Specimen:

Urine specimens must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used.

Urine samples may be stored 2°-8°C up to 72 hours. Samples stored refrigerated (2°-8°C) are to be brought to room temperature (20-30°C) before testing. This assay requires 200 μL of sample for a single determination. Specimens not tested within 1 hour room temperature should be refrigerated.

All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. The test cassette should be discarded in a proper biohazard container after testing.

NOTE: Hand hygiene should be observed before and after interacting with each patient. Gloves are to be worn when handling specimens and while completing all testing. Gloves should be changed between patients.

Reagents and Materials

- Test Cassettes
- Disposable sample droppers
- Package insert
- Specimen collection container

Storage and Stability:

Store as packaged in the sealed pouch at 2°-30°C. The test cassette is stable through the expiration date printed on the sealed pouch. Bring refrigerated cassette to room temperature before use. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE. Do not use tests beyond the manufacturer's expiration date.**

Quality Control:

External quality control will be performed every 28 days and with each new shipment of cassettes on the Clinitek Status+ Connect System. The Quality Control material is the MAS UA controls level 1 and 2. The controls once opened are valid for 90 days when stored at 2-8°C and 6 weeks stored at 20-30°C. To perform quality control:

1. At the Select Ready screen, select **QC Test Cassette test due.** The QC Test screen displays.
2. Select **QC Cassette Test Required**.
3. If the instrument is set to determine pass/fail, the Control Lot screen displays.
4. Enter the name of the control. Use the alpha keyboard to enter text. To enter numeric text, select **123.**
5. Select **Enter.** The *Control Lot* screen displays.
6. Enter the control lot. Use the alpha keyboard to enter text. To enter numeric text, select **123.**
7. Select **Enter.** The *Control Expiration* displays.
8. Use the arrow keys to indicate the control lot expiration date.
9. Select **Enter.** The *Cassette Lot* screen displays.
10. Use the alpha keyboard to enter text. To enter numeric text, select **123.**
11. The *Cassette Expiration* screen displays.
12. Use the arrow keys to indicate the cassette lot expiration date.
13. Select **Enter**. The *Prepare Test* screen displays.
14. Mix control and apply 4 drops to the cartridge.
15. Select **Start.** The *Results screen* displays.
16. To print the results, select **Print.**
17. Select **Done.** The *QC Test-Select PASS or FAIL* screen displays.

If Quality Control Fails, repeat with same bottle of controls. If the controls fail again, obtain fresh bottles of control and rerun. If the instrument continues to fail contact the Ancillary Testing Coordinator.

Calibration:
The CLINITEK Status Connect System 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.

Patient Testing:

1. At the main **Select** screen, touch **Cassette Test**. The **Operator ID** screen will appear.
2. Touch **Enter New Operator ID**. The **Enter Operator ID** screen will appear.
3. Scan ID badge.
4. Touch **Enter**. The **Patient Information** screen will appear.
5. Select **Enter New patient**.
6. Use the keypad to enter the patient's name using a maximum of 20 characters.
7. Touch **Enter**. The **Patient ID** screen will appear.
8. Use the keypad to enter the patient's ID, Full Social Security Number

   NOTE: You must enter in the FULL SOCIAL SECURITY NUMBER in correctly, without dashes otherwise the result will not cross into the patient chart.
9. Touch **Enter**. The **Test Type** screen will appear.

   WARNING: If refrigerated, bring the test cassette and patient sample to room temperature 20 to 30°C prior to testing.
10. Touch **Clinitest hCG Cassette**. A **Prepare Test** screen will appear displaying the following two steps:
    a. Make sure the test table insert is facing up and in position for a cassette test.
    b. Remove the test cassette from the foil package and place the cassette on the test table.
11. 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. Hold pipette at slight angle
    b. 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)
    c. 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.

       WARNING: Do not push or pull the test table.
    d. At the end of the eight-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 according to your standard laboratory procedures.
15. Touch **Done** to complete the test and return to the main **Select** screen.
16. Results should automatically upload into the patient chart. If there are any problems with resulting please contact the Ancillary Testing Coordinator.

Reference Interval for Healthy Men and Healthy Non-pregnant Women

- No detectable hCG level occurs when using the Clinitest hCG Pregnancy Test

Reference Interval for Pregnant Females

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

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).

Procedure Notes

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 confirm that the Control (C) and Reference (R) regions met minimum intensity specifications.

Borderline Results

The result is indeterminate, repeat in 48 – 72 hours or draw serum top tube and send to main laboratory for a serum hCG.

Negative Results

The instrument will automatically determine the Test (T) region is less intense than the 25 mIU/mL hCG concentration level that the device can detect, and confirms 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 assay.

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 Siemens Healthcare Technical Solutions Center if the problem persists.

NOTE: If the Clinitek Status is unable to perform pregnancy testing, send all samples to the lab for a qualitative urine hcg or collect serum and order a serum hcg.

Performance Characteristics:

Sensitivity and Specificity:

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 (see Summary and Explanation of the Test), 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, results should be confirmed by an alternative hCG method.

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.

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.

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

Revision History

Section	Change	Date	Requester	Approver
Header	Update header	02/02/2017	Hung Ho	E. Hart MD
Font, Size	New Time Roman, 12	02/02/2017	Hung Ho	E. Hart MD