Urinalysis: CLINITEK Status Connect System with Siemens Clinitest Human Chorionic Gonadotropin (hCG) Pregnancy Test

Principle of the Test
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 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 Connect System and is intended for near-patient (point-of-care) and centralized laboratory locations.

Specimen Collection and Handling

Specimen Collection

⚠️ BIOHAZARD
All products or objects that come in contact with human or animal body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

Urine is the recommended sample type for this assay.
• This assay requires 200 μL of sample for a single determination.
• Collect urine into a clean, dry container.
• Specimens collected at any time of day may be used.

Specimen Rejection Criteria
1. Unlabeled specimen
2. Mislabeled specimen
3. Specimen tested after 72 hours from collection
Reagents

Storage and Stability

- Store Clinitest hCG Cassettes at room temperature (59-86°F; 15-30°C).
- 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.

Instrument Operation and System Description

The CLINITEK Status connector is intended for use with the CLINITEK Status Analyzer. Together, the two units comprise the CLINITEK Status Connect System. The connector also supports importing certain information using an optional bar code scanner. 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 (LED), a light guide, a mirror, a lens and a detector. Light from the LEDs travels 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 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.

System Start-up

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 Select Ready screen displays after system initialization.
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.

Maintenance

Cleaning the instrument:
1. Turn the analyzer off
2. Use a damp cloth with a mild detergent
3. Wipe the outside, including the display area

Routine Cleaning of Test Table Insert:
1. Remove the insert
2. Rinse both sides of the table insert under running water
3. Dry and replace insert

Periodic Cleaning of Test Table Insert:
1. Remove the test table by pulling slowly out of the analyzer
2. Drain the drip tray if necessary
3. Wet a cotton-tipped swab with water and carefully clean the test table (except for the white calibration bar)
4. Dry the test table thoroughly with a soft cloth or lint-free tissue
5. Replace the test table insert

Disinfecting the Test Table and Insert:
1. Prepare appropriate solution per laboratory procedure
2. Place the insert and/or test table into the solution
   - Make sure the white calibration bar remains above the solution
3. Soak table and insert
   - Minimum of 2 minutes to a maximum of 10 minutes
   - Do not exceed 10 minutes
4. Rinse the test table and insert thoroughly with water
5. Dry with a soft cloth and replace test table and insert

Cleaning the Calibration Bar:
1. Remove the insert from the test table by slowly pulling
2. Check the white calibration bar for dirt or discoloration
   - If clean and unmarked – replace table into analyzer
3. If the calibration bar is dirty or discolored, gently wipe it with a new cotton-tipped swab or lint-free cloth with distilled water
4. Allow calibration bar to air dry
5. Inspect the surface for dust, foreign material, scratches or scuffs
   - Replace entire test table if any marks are visible
6. Reinsert test table into analyzer
Quality Control (QC) and Frequency

- 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.
- It is recommended that quality control specimens be tested:
  1. Daily
  2. With each new lot of reagents
  3. New shipment of reagents
  4. Monthly for reagents that have been stored for more than 30 days.

QC Materials

Use a recommended quality control material (Quantimetrix). Water should not be used as a negative control.

Quantimetrix urine UCG control is good until the expiration date printed on each control vials. Please note that when using Quantimetrix urine Control for U/A, it is only good for 20 dips.

Troubleshooting Out-of-Range QC Values

A QC run is acceptable when all values fall within the expected results.

If the hCG QC results do not fall within the defined ranges then the run is rejected, and you must take the following corrective action:

- Review these instructions to ensure that the assay was performed according to the procedures recommended by Siemens Healthcare Diagnostics
- Verify that the cassettes and control materials are not expired
- If necessary, rerun the quality control samples or contact the Point of Care Testing Technologist at x6629.

Procedure:

A. Running a QC Strip Test

1. Remove solutions from the refrigerator and allow them to come to room temperature (20-25°C) for about 15-20 minutes. Verify the open date and expiration date. Check integrity of solutions.
2. Verify test kit manufacturer’s expiration date,
3. Put on clean gloves. Invert the vial several times to ensure homogeneity and avoid foaming.
4. At the Select Ready screen, select QC Test Due. The QC Test screen displays.
5. Select QC Cassette Test Required.
6. Select Enter New Operator Name
7. Scan Operator ID and select Enter
8. Select Enter lot and expiration date
9. The Control Lot screen displays.
10. Enter the control lot using the number key pad on the screen.
11. Select Enter. The Control Expiration screen displays.
12. Use the arrow keys to indicate the control lot expiration date.
13. Select **Enter**. The Cassette Lot screen displays.
14. Scan test strip lot number on the cassette package.
15. Select **Enter**. The Prepare Test screen displays.
16. Select **Start**.
17. Add quality control material to the test kit.
18. Repeat steps 8-17 for level 2 control

**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.

1. Hold pipette at a slight angle
2. 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)
3. 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.

4. At the end of the eight second countdown the test table and cassette will automatically be pulled into the instrument.
5. 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.

6. When analysis is complete the **Results** screen will be displayed.
7. Remove the used cassette and dispose of it according to hospital policy and procedure.
8. Touch **Done** to complete the test and return to the main Select screen.

**Troubleshooting Out-of-Range QC Values**
A QC run is acceptable when all values fall within the expected ranges. If the QC results do not fall within the defined ranges then the run is rejected, and you must take the following corrective actions:
• Review instructions to ensure that the test was performed according to the established hospital procedures.
• Verify that the cassette kits and control materials are not expired;
• If necessary, re-run the quality control samples or contact the Point of Care Testing Technologist at x6629.

**B. Running a Patient Test:**
In the Test mode, you are prompted to enter an Operator ID and Patient ID prior to running a test.
1. At the main **Select** screen, touch **Cassette Test**. The **Operator ID** screen will appear.
2. If you are a new operator, touch **Enter New Operator ID**. The **Enter Operator ID** screen will appear.
3. Scan employee ID.
4. Touch Enter
5. **Enter New Patient.** The **Enter Patient Name** screen will appear.
6. The **Patient ID** screen will appear.
7. Use the keypad to enter the patient’s ID using a maximum of 13 characters.
8. Touch Enter. A **Prepare Test** screen will appear.
9. Follow these steps to continuing preparing the test:
   a. Make sure the test table insert has the cassette holder facing upward.
   b. Have the cassette, urine sample and paper towel ready.
10. Touch **START**. Another **Prepare Test** screen will appear displaying the next 4 steps:
    **WARNING:** Once you touch the **START** button, you have eight seconds to add the urine sample.

1. Hold pipette at a slight angle
2. Squeeze the upper bulb and draw enough sample into the pipette to fill the stem completely, with a overdrawn amount going into the reservoir (lower bulb)
3. 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.
4. At the end of the eight second countdown the test table and cassette will automatically be pulled into the instrument.
5. 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.
6. When analysis is complete the Results screen will be displayed.
7. Remove the used cassette and dispose of it according to hospital policy and procedure.
8. Touch Done to complete the test and return to the main Select screen.

**Note:** *There is no need to order the POCT hCG in EPIC; such action will create a duplicate order.*

**Reference Interval for Non-pregnant Women**
- Negative - 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).

Acceptable Results
Patient test results are acceptable and may be reported when:
• Pre-analytic phase requirements are followed
• Analytical phase testing procedure is followed, including confirmation that the Control (C) and Reference (R)

Corrective Action
Patient test results must be repeated and corrective action taken when:
• Borderline or Indeterminate results are obtained
• Invalid results are obtained

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

Borderline Results
If the result is indeterminate, repeat in 48 – 72 hours as per manufacturer’s recommendation or send to the laboratory for 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 as per clinician’s discretion.

Invalid Results
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 to contact the Siemens Healthcare Technical Solutions Center if the problem persists.
Disposal

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. 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 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. Clinicians may submit a serum sample to the laboratory at their own discretion.

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 may 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 performed with 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH levels.

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

Equipment and Supplies

- Clinitest hCG Cassette with disposable pipette
- CLINITEK Status Plus Connect System
- Specimen collection container

References

1. Siemens Healthcare Diagnostics Clinitest hCG Test Package Insert, 06878007, 2007-08

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

Trademark Information

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