Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 927
VERSION: 5

SUBJECT: Pregnancy Testing: Use of the Clinitest hCG Pregnancy Test

PURPOSE:
The Clinitest hCG Pregnancy test is rapid chromatographic immunoassay using monoclonal antibodies intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine. It is for in vitro diagnostic use in the rapid determination of hCG in urine.

POLICY:
Urine pregnancy testing with the Clinitest hCG Pregnancy Test will be used for the presumptive diagnosis of pregnancy for the identified female patient population, per provider order or protocol order. A confirmed pregnancy diagnosis should only be made by a clinician after all clinical and laboratory findings have been evaluated.

Only designated authorized personnel will perform pregnancy testing. Competency must be demonstrated to and deemed satisfactory by the Clinical Instructor or designee.

SPECIMEN:
Urine is to be collected in a clean, dry, plastic container without preservatives. Specimens collected at random may be used; however, the first morning urine generally contains the highest concentration of hCG and is therefore the most suitable.

Refrigerate specimens at 2-8° for up to 72 hours if testing is not performed immediately. If refrigerated, bring samples to room temperature before testing. Do NOT freeze the urine sample.

EQUIPMENT AND MATERIALS:
Equipment:
- Clinitest hCG Pregnancy test cassette.
- Clinitek Status Plus meter
- Transfer pipette (inside of cassette package).
- 2 small disposable, plastic containers for QC solutions.
- Clean, dry plastic container for urine specimen.

Materials:
- Gloves
- Urine control level 1 and urine control level 2.

Reagent Storage Requirements:

1. The test kit is to be stored at room temperature (15-30° C or 59-86° F) and out of direct sunlight for the duration of the shelf-life.
2. The test kit must remain sealed in the foil pouch just prior to use.
3. Do not use kit contents after the manufacturer expiration date printed on the outside of the kit.
4. The urine control solutions are ready to use.
5. Open urine control solutions are kept at room temperature (15-25° C). The control solutions are stable for 30 days after opening, or the manufacturer's expiration date, whichever comes first.
6. Unopened control solution vials are stored at 2-8° and are stable until the expiration date on the label.
7. The open date and date of expiration are to be recorded on the bottles of control solution and box of kits, along with the initials of the person opening each.

PROCEDURE:

QUALITY CONTROL:

1. Must be performed each day the clinic is open to patients.
2. Must include two urine control levels, levels 1 and 2.
3. Must react as expected before patient testing can be performed.
4. Additional QC should be performed if a new lot of test strips are opened or if there is any question about instrument performance.
5. Each test includes 2 procedural controls, which indicate that sufficient sample was added and the correct technique was used. If the instrument detects a failure in either of these, an error is reported and the test must be repeated.

Quality Control Procedure:

1. Check expiration dates of solutions (once opened, stable for 30 days).
2. If the expiration date has passed, obtain fresh control solutions.
3. Check expiration date of Clinitek hCG pregnancy kit (shelf life is per manufacturer).
4. Remove test device from the pouch and lay on a clean and level surface.
5. Label the device with the control identification.
6. Wash hands and put on gloves (control solutions must be handled in the same manner as patient specimens).
7. Pour a small amount of urine control solution level 1 into a small clean plastic container.
8. Turn on the Clinitek Status and turn the table insert so the cassette holder is facing upwards.
9. Choose "QC Test Due" from the main Select screen. Touch the Cassette screen button. Place the cassette onto the test table. Touch the Clinitest hCG button. Then follow the prompts by entering or scanning "Operator ID" as the operator's employee ID number. Then enter or scan the lot numbers of the controls and strips as prompted.
10. Wash hands and put on gloves.
11. Touch START. You have 8 seconds to complete the next step.

12. Holding the supplied pipette at a slight angle, squeeze the upper bulb and draw enough sample to fill the stem completely with an overdrawn amount going into the reservoir (lower bulb). Then, discharge sample in the pipette stem into the sample well of the cassette by squeezing the upper bulb in one squeeze. All the fluid should express. Excess fluid will remain in the reservoir.
13. Do not push or pull the test table. Do not reuse the pipette. The test table will automatically be pulled into the instrument. When analysis is complete, results will be displayed.
14. Remove the cassette. It can be discarded in appropriate waste container.
15. Discard unused portion of solution and container in the appropriate waste container. •**DO NOT RETURN UNUSED PORTION TO ORIGINAL CONTAINER.**
16. Repeat steps 7 through 12 with urine control solution level 2.
17. Clean work area with approved disinfectant.
18. Remove gloves and wash hands.
19. If QC did not pass, you MUST add a note by pressing the QC Notes button. This is a free text field. Press PRINT as QC results will not automatically print. Corrective action must be taken and documented before patient testing can begin.
20. Both levels of QC must be run within 10 minutes of each other, or it will time out and QC will fail. The first QC will not count, even if it passed, and will have to be repeated.

Corrective Action for Quality Control Failure:

1. Confirm that both the cassettes and control solutions have not exceeded the expiration dates.
2. Repeat the procedure with the same control solution(s) and/or cassette a maximum of twice before trying a new action.
3. Repeat with new control solutions or a new cassette if needed.
4. Record all corrective action and follow-up by entering a QC note in the analyzer.
5. If proper results are still not obtained, consult the POCT Coordinator or laboratory personnel. No patients can be tested until QC is acceptable.

PATIENT TEST:

1. Must have a provider's order (either in ORCHID or as a written protocol order).
2. Identify patient with at least 2 acceptable identifiers.
3. Follow infection control guidelines, including universal precautions.
4. Explain the procedure to the patient and provide them with the necessary supplies, including a label with their full name and medical record number on the urine container.
5. Wash hands and put on gloves.
6. Obtain urine specimen from the patient in appropriate labeled container.

7. If the Clinitek Status Plus Urine Chemistry Analyzer is off, turn it on by pressing the on/off button located on the front of the instrument. Choose Cassette test from the main Select screen. Follow the prompts by entering or scanning “New Operator ID” as the operator’s employee ID number. Then enter “Patient ID” by scanning the patient’s FIN number. Never enter the FIN number manually. The next screen will be “Prepare Test.”
8. Remove the test device from the pouch and lay on a clean, level surface.
9. Label the device with the patient’s identifying information.
10. Touch START. You have 8 seconds to complete the next step.
11. Holding the supplied pipette at a slight angle, squeeze the upper bulb and draw enough sample to fill the stem completely with an overdrawn amount going into the reservoir (lower bulb). Then, discharge sample in the pipette stem into the sample well of the cassette by squeezing the upper bulb in one squeeze. All the fluid should express. Excess fluid will remain in the reservoir.
12. Do not push or pull the test table. Do not reuse the pipette. The test table will automatically be pulled into the instrument. When analysis is complete, results will be displayed.
13. Remove the cassette. It can be discarded in appropriate waste container.
14. After the test is complete, make sure to press DONE. If this is not done, it will not chart.
15. Results will then chart automatically. NEVER enter the result manually into Cerner. If this is done, TWO results will post to Cerner.
16. Remove gloves and wash hands.

Interpretation of the Results:

1. 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 half or less than half of the corresponding serum hCG concentrations. Thus, hCG can likely be detected in urine as early as 14 days after conception (about 28 days since the last menstrual cycle), doubling the concentration about every 2 days until it peaks around 8-10 weeks after the last menstrual cycle. Hormone levels >25 mIU/mL are reported as positive. Samples reported as borderline are considered intermediate and should be repeated in 48-72 hours.
2. POSITIVE: The instrument will automatically determine if 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 meet minimum intensity specifications
3. BORDERLINE: Result is indeterminate, repeat in 48-72 hours.
4. NEGATIVE: The instrument will automatically determine that the Test (T) region is less intense than the 25 mIU/mL hCG concentration level that the device can detect, and confirms that the Control (C) and Reference (R) regions meet minimum intensity specifications.
5. 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. If not, the user

will be advised to repeat the test and to contact the POC coordinator or designee.

6. If a negative result is obtained, but pregnancy is suspected, another sample should be collected after 48-72 hours and retested or by performing a quantitative assay.

Documentation:

1. Patient results are automatically printed on the tape from the instrument.
2. At the end of each day (or month if the clinic volume is low) remove the tape from the instrument and store the tape away from the sunlight or direct lighting until it can be picked up by the laboratory.

Limitations:

1. Test results must always be evaluated with other data available to the physician.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected and tested.
3. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone.
4. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning serum or urine specimen should be collected 48-72 hours later and retested.
5. Excretion of hCG is often decreased in extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can yield false negative results.
6. This test is not intended to detect conditions other than pregnancy. A number of conditions other than pregnancy, including chorionic epithelioma or hydatid mole, trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in serum or urine specimens should not be used to diagnose pregnancy unless these conditions have been ruled out.
7. Patients on antibody therapies may obtain invalid results due to the presence of interfering antibodies in the medications.
8. 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 detection method.

Expected Results:

Healthy men and non-pregnant women do not have hCG levels detectable by this test. In normal pregnancy, levels of 100 mIU/ml hCG can be reached on the first day of the missed menstrual period. Levels peak about 8-10 weeks after the last menstrual period and then decline to lower values during the remainder of the pregnancy. Following delivery, levels rapidly decrease and usually return to normal within days after parturition.

MAINTENANCE:

Cleaning the Test Table and Test Strip Insert:

1. The test strip insert must be cleaned each day of use. Remove the insert and rinse both sides of the insert under running water or in soapy water. Dry and replace the insert. If the analyzer is just being used for pregnancy testing and not UA's, then the insert only needs to be cleaned weekly.
2. The Test Table must be cleaned weekly. Fill a tall, narrow container (e.g. Empty Multistix bottle) to a depth of about 4 inches with Isopropyl Alcohol. Make sure that the solution does not dome in contact with the white calibration bar. Place the insert and/or test table into the solution for 2-10 minutes. Rinse the alcohol off of both sides of the table with running water. Check the white calibration bar for dirt or discoloration. If it is dirty or discolored, gently wipe and clean it with a new cotton-tipped stick or lint-free cloth wetted with water. Solvents of any kind must never be used. Take care not to scratch or discolor the white calibration bar. Dry the test table thoroughly with a soft cloth or lint-free tissue.
3. The outside of the analyzer shall be cleaned with facility approved disinfectant after each day of use.

Loading the Paper Roll:

1. Open the printer cover by pulling on the tab.
2. Open the paper roll compartment cover by pressing down on its tab and pulling out.
3. Lift the paper holding arm into theopen, upright position.
4. Place the new paper roll into the printer paper 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.

ERROR MESSAGES AND CORRECTIVE ACTION:

- Error messages will be displayed when the analyzer detects something that needs attention. Some errors disable the instrument completely and some only

warn of a problem. All errors must be taken care of before the error message will be removed.

- A Paper Roll Icon displays on the Print Help button on the Select Ready screen. This indicates that the printer is out of paper. Replace the paper.
- A profile picture of the unit with an X through it appears when the analyzer is not connected to the base. Check and tighten the cables on the analyzer. Call the lab if this cannot be corrected.
- Two computers with an X through them indicate a remote connection could not be established. Turn the unit off, then on again. If this does not correct, call the lab.
- If the test table movement is irregular or slow, it indicates a heavy buildup of dried urine on the test table. Clean the test table.
- If an error message appears, review the error messages listed below:

Error Message	Corrective Action
E01	Low battery power. Replace the batteries.
E02	Failure of calibration data. Contact Lab.
E03-E08, E21, E22, E90-E93	Failure of computer software. Contact Lab.
E10 or E48	Loss of test results. Power off, then on after 2 seconds. Repeat the test.
E11	Failure of test table. It is positioned improperly. Make sure it is in place. Move it in or out of the analyzer slightly to reposition the test table. If the error remains, with the analyzer powered on, disconnect the power cord from the back of the unit and connect it back in. Press the on/off button to power it back up. If the error remains, contact the lab.
E12	Failure of LED. An LED light source failed. Contact the lab.
E20	Failure of clock. Contact the lab.
E23	Low battery power. Contact the lab.
E24	No printer paper. Replace the paper.
E25, E64, E65	Failure of automatic calibration. Clean the calibration bar. If the error remains after cleaning, contact the lab.
E27	Setup failure. Power off the analyzer for 2 seconds. Then power it back up.
E28	Printer error. Lift the printer cover. Push the paper holding arm back into position.
E50	Incorrect strip type or tilted strip. Verify that you correctly placed the strip on the test table insert. If error remains, contact the lab.
E52	Invalid barcode. Repeat the test using the correct barcode.
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 with the correct test table.
E57	Missing strip or cassette. Repeat the test and ensure that you correctly position the strip or cassette on the test table.
E58	Misplaced strip. Repeat the test ensuring that you correctly position the strip on the test table. If the error remains, examine the test table insert to ensure that the small, white line located near the tip of the strip is present and not damaged. If the line is damaged, contact the lab.
E59	Inverted strip positioned on the test table. Repeat the test with a fresh strip and ensure that it is correctly positioned on the test table.
E60	Tilted strip. Repeat the test with a fresh strip and ensure that the strip is correctly positioned on the test table.
E61	Dry strip. Repeat the test with a fresh strip and ensure that it has been in contact with the sample.
E62	Light Ingress. Too much light is reflecting on the analyzer. Move the unit to a location with lower lighting.
E63	Failure to find end of strip. Repeat the test with a fresh strip and ensure that it is correctly positioned on the test table.
E67 or E68	Sampling error. A sample flow issue with the cassette test might have been detected.
E69	Strip quality problem. When the analyzer performed a QC check, the strip quality failed. This detects whether the strip was compromised due to humidity exposure. Also, some patient samples that are highly pigmented or have very high leukocyte levels might falsely cause this error. Remove the strip and discard. Repeat with a fresh strip that meets the quality requirements.

REFERENCES:

Clinitest hCG Pregnancy test product insert, Siemens Healthcare Diagnostics Inc., 2015
Clinitek Status Plus Analyzer Operator's Guide, Siemens Medical Solutions Diagnostics, Tarrytown, NY, Rev C, 2011-12
Clinitek Status Connect System Operator's Guide, Siemens Medical Solutions Diagnostics, Tarrytown, NY Rev B, 2011-06

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Date: 11/16/2018	**Original Date:** 10/01/2010
Reviewed: 11/16/2018	**Next Review Date:** 11/16/2020
Revised:	2/28/12 nurse changed to authorized personnel, 3/13/14 reformatted for PPM, 11/12/14 updated to QuickVue, 3/17/17 to better represent use in Cerner, 1/2018 –updated to reflect use of Clinitek Status analyzer with Clinitest hCG cassettes
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