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Owner	Jeanna Begay
Area	Administrative - Waived Testing
Applicability	Hopi Health Center
References	WT.01.01.01, WT.04.01.01, WT.05.01.01

Urine Pregnancy Testing (hCG)

Policy

1. Urine pregnancy test will be done utilizing the Consult Diagnostics hCG Urine Cassette test kit.
2. Nursing and medical staff who have documented and demonstrated competency assessment for the point of care testing locations will perform urine pregnancy testing.
3. Urine pregnancy testing is for screening purposes only.

Intended Use

Consult Diagnostics hCG Urine Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine as an aid in the early detection of pregnancy. This is a CLIA waived test.

Summary

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG levels continue to rise as early as 7 to 10 days after conception. hCG levels continue to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mIU/mL range about 10 – 12 weeks into pregnancy. The appearance of hCG in urine soon after conception and its subsequent rapid rise in concentration during early gestational growth make it an excellent marker for early detection of pregnancy.

The Consult Diagnostics hCG Urine Cassette is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 20 mIU/mL in urine. The test utilizes a combination of monoclonal and polyclonal

antibodies to selectively detect elevated levels of hCG in urine.

At the level of claimed sensitivity, the Consult Diagnostics hCG Urine Cassette shows no cross-reactivity interference from the structurally related glycoprotein hormone hFSH, hLH and hTSH at high physiological levels.

Principle

The test utilizes a combination of antibodies including mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies to selectively detect elevated levels of hCG. The assay is conducted by adding urine specimen to the specimen well of the test cassette and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific colored antibody conjugates and form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Materials Required

1. Consult Diagnostics hCG Urine Cassette – test cassette contains anti-hCG gold conjugate and anti-hCG coated on the membrane
2. Disposable pipette (contained in kit)
3. Clock or Timer
4. Collection Cup
5. Quantimetrix Level 1 and 2 Controls
6. Procedure card

Reagent Stability & Storage

A.

Materials	Storage	Stability
Test Device	Store at room temperature (15°-30°C) in the sealed pouch. DO NOT FREEZE.	Expiration date printed on the sealed pouch. Must remain in sealed pouch until use. Do not use beyond expiration date.
Quantimetrix Quality Control Solutions	**Unopened**: Refrigerated at 2 to 8°C. **Opened**: Room Temperature (not to exceed 30°C) or Refrigerated (2 to 8°C). (Quantimetrix Dropper Plus)	**Unopened**: Expiration date printed on the bottle. **Opened**: Stored at room temperature, stable for one month. Stored refrigerated, stable until the expiration date on the bottle. (Quantimetrix Dropper Plus)

Note: Write on all control solutions the date opened and expiration date when stored at room temperature. Do not use any test device or control solution beyond its expiration date.

1. Quantimetrix Dropper Plus Urine Dipstick Controls:
    a. Contains human urine and human chorionic gonadotropin (hCG) from pregnancy urine.
    b. There is no known test method that can assure that a product derived from human material does not contain the Hepatitis or HIV virus. It is recommended that such samples be handled using the Standard Precautions.

Specimen Collection

A. Patient Preparation
    1. Follow department policy for patient preparation for urine collection.

B. Specimen Type
    1. Urine specimen collected in a clean and dry container without preservatives.
    2. The first morning specimen of urine is recommended since it usually contains the highest concentration of hCG. However, urine specimens collected at any time of the day may be used.
    3. Urine specimen may be stored at room temperature (15°-30°C) for up to 2 hours or refrigerated (2°-8°C) for up to 48 hours.
    4. If specimen has been stored refrigerated, allow it to warm to room temperature (15-30°C) before use.
    5. The test requires 3 drops of urine.

C. Handling Conditions
    1. Follow Standard Precaution guidelines in the collection, handling, storage, and disposable of controls, patient specimens, and all items exposed to specimens.

Quality Control

Internal Quality Control

The appearance of the control band in the results window is an internal positive procedural control which validates the following:

1. Test System: The appearance of the red control band assures that the detection component of both the test line and control line is intact, adequate sample volume was added, adequate capillary migration of the sample has occurred, and verifies proper assembly of the Test Device.
2. Operator: The appearance of the control band indicates that an adequate volume of fluid was added to the sample well for capillary migration to occur. If the control band does not appear

at the read time, the test is invalid.

3. The clearing of the background in the results area may be documented as an internal negative procedural control and also serves as an additional capillary flow control. At the read time, the background should appear white to light gray and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the observation of a distinct control band.
4. Results of the internal quality control for each test will be recorded in the patient and quality control logs.

External Quality Control

1. Two levels of quality control need to be tested, negative and positive.
    a. Quantimetrix - Level 1: Negative Control
    b. Quantimetrix - Level 2: Positive Control
2. The frequency of external negative and positive controls to be tested are:
    a. Each new lot number, each new shipment
    b. Monthly as a check on storage
    c. When test is questionable
    d. Each new untrained operator
3. The following control results must be obtained before reporting patient results:
    a. Level 1 Negative Control: No red band in the test window (T) and one red band in the control window (C).
    b. Level 2 Positive Control: One red band in the test window (T) and one red band line in the control window (C).
    c. Internal Positive Control: A red band in the control window (C) confirms that a sufficient sample volume was delivered and that the correct procedure was used.
    d. Internal Negative Control: A white to light gray background area indicates that the test is working properly.
4. Results of the quality control must be recorded in the QC logbook.

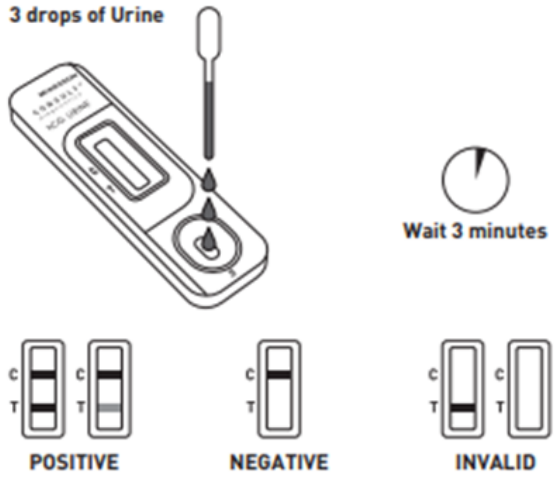
Procedure

Allow the test cassette, urine and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Follow hospital policy for the proper identification of the patient to be tested and proper specimen labeling. (Specimen accession labels contain the first and last name of the patient, medical record number, date of birth, date and time of specimen collection)
2. Remove the test cassette from the sealed pouch and the pipette from the pouch. Use as soon as possible.

3. Place the device on a flat surface. Squeeze the bulb of the pipette and insert the barrel into the patient sample. Release the bulb and draw up enough sample to dispense 3 drops of urine.
4. Hold pipette vertically and transfer 3 full drops of urine (approx. 100 µL) to the specimen well (S) of the test cassette and then start timer. Avoid trapping air bubbles in the specimen well.
    A. For Quality Control:
        i. Add 3 drops of the Level 1 control to the test device labeled (-).
        ii. Add 3 drops of the Level 2 control to the test device labeled (+).
5. Discard the pipette in a biohazardous waste container.
6. Read results at 3 minutes.

Note: Results should be read between 3 to 5 minutes only. A result seen after these times could be indicative of a low hCG level in the sample. It is recommended that the test be repeated with a new sample 48-72 hours or that an alternate confirmation method is used.



Interpretation of Results

1. **Positive Result**: **Two distinct red lines appear**. One line should in the control region (C) and another line should be in the test region (T). While the intensity of the test band may vary with different specimens, the appearance of 2 distinct bands should be interpreted as a positive result.
2. **Negative Result**: **One red line appears in the control region (C)**. No apparent red or pink line appears at the (T).
3. **Invalid Result**: **Control line fails to appear**. Insufficient specimen volume or incorrect procedural techniques are the most likely reason for control line failure. Review the procedure and repeat the test with a new test cassette. If problem persists, discontinue the test kit immediately, and contact Technical Support at (866) 216-0094 or contact the POCT Coordinator at (928) 737-6389.

Result Reporting

1. Reference Range: Negative results are expected in healthy non-pregnant women and healthy men.
2. Do not report patient results unless quality controls (internal and external) are acceptable.
3. Note: The Consult Diagnostics hCG Urine Cassette has a sensitivity of 20 mIU/mL in urine and is capable of detecting pregnancy as early as 1 day after the first missed menses.

Documentation of Patient and Quality Control Results

Results must be documented along with the initials of personnel performing the test and the date the test was performed. A functional audit trail must be maintained that allows retrieval of results.

1. Results and internal QC are to be recorded on the patient and/or QC log.
    - Must document the results of the Internal Quality Control (i.e. "Acceptable" or "Invalid").
    - **Do not report patient results unless quality control is acceptable.**
2. Document date and time the test was performed, clinical sign or symptom, provider, and two patient identifiers.
3. The initials of point of care testing personnel performing patient testing must be documented on log.
4. Results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

Limitations

1. 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 48 hours later and tested.
2. False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/Ml) are present in urine shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, can cause elevated levels of hCG. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.

5. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative test results.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by the medical provider after all clinical and laboratory findings have been evaluated.

References

A. *Consult* Diagnostics hCG Urine Tests Cassette Insert, McKesson Medical-Surgical Inc. Rev. 00, 12/15.

B. The Joint Commission Laboratory Accreditation Requirements.

C. Quantimetrix Corporation. *QC Dropper Plus Point-of-Care Urine Dipstick Control.* Redondo Beach, CA. M044731A-06/25.

Approval Signatures

Step Description	Approver	Date
Acting Lab Director	Carl Minami: Chief of Pathology	02/2026
Acting Chief Nurse Executive	Carletta Ami: Acting CNE	02/2026
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	01/2026
	Jeanna Begay	12/2025

Applicability

Hopi Health Center