**LOURDES HOSPITAL**

**169 Riverside Drive**

**Binghamton, New York 13905**

**LAB MANUAL**

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**SUBJECT: Urine Qualitative Pregnancy ORIGIN DATE: 01/99**

**REVIEWED: 6/11/2021 REVISED: 2/02, 8/04,9/16/2014,6/6/2017**

**REGULATORY REFERENCES:**

**NYS, CAP, JCAHO CROSS REFERENCES:LAB-25-028**

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**POLICY**

The OSOM hCG combo Test can be used as a rapid screening for the qualitative detection of human chorionic gonadotropin(hCG) in the urine as an aid in the early determination of pregnancy.

Contrast hCG test is a solid phase, sandwich format immunochromatographic assay for the qualitative detection of hCG. Urine is added to the sample well of the test device using the pipette provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the result window, where labeled hCG complex is captured at a test line region containing immobilized rabbit ant-hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate with or without hCG complexed to it.

The appearance of two black bands in the result window – one at the “T: Test” and the other at the “C: Control” – indicates the presence of hCG in the sample. If a detectable level of hCG is not present, only the control band will appear in the result window.

**PROCEDURE:**

REAGENTS, MATERIALS, AND STORAGE REQUIREMENTS

OSOM hCG Combo Test kit

1. Osom hCG test devices individually packaged along with a disposable pipette
2. Membrane coated with rabbit polyclonal anti-alpha hCG.
3. Conjugate pad containing mouse monoclonal anti beta hCG.

**Storage:**

Store Contrast hCG test cartridges at room temperature (15 to 30°C) out of direct sunlight. Test devices are stable until the expiration date printed on the kit or foil pouch. DO NOT FREEZE. Outdated cartridges are discarded

SPECIMEN TYPE- A freshly collected urine sample

COLLECTION-

Urine samples may be collected in any clean, dry, plastic or glass container. For early determination of pregnancy, the first morning specimen of urine is recommended since it contains the highest concentration of hCG. Urine may be stored at room temperature (18-25°C) for up to 8 hours, or at 2-8°C for up to 72 hours. The sample must be brought to room temperature before testing.

IDENTIFICATION and LABELING: the patient will be identified using 2 identifiers, patient full name and date of birth. The urine cup will be labeled with these identifiers prior to giving to the patient

TEST PERFORMANCE

1. Remove the Test Device and pipette from the pouch and place on a flat surface.
2. Squeeze the bulb of the pipette and insert the barrel into the patient sample. Release the bulb and draw up enough sample to fill the barrel to the line indicated on the pipette. Do not overfill.
3. Expel the entire contents of the barrel (135 μl) into the sample well of the test device. No drop counting required. Discard of the pipette after one patient use
4. Read the results at 3 minutes for urine samples. Strong positive results may be observed sooner.
5. **Results are invalid after the stated read time.**

RESULT INTERPRETATION

**Positive**: Two black or gray bands (one at “T”, one at “C”) are visible in the results window, indicating that the specimen contains elevated levels of hCG. 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.

**Negative**: Only a black band appears at the “C” region of the test device, indicating that a detectable level of hCG is not present.

**Invalid**: If no band appears at the “C” region or incomplete or beaded bands appear at either the “C” or “T” region, the test is invalid. The test should be repeated using another test device.

**Expected Values** HCG is normally not detected in the urine or serum of healthy men and non-pregnant women. In normal pregnancy, 20 mIU/mL hCG is reported to be present in both urine and serum 2 to 3 days prior to the first missed menstrual period. Levels of hCG continue to increase up to 200,000 mIU/mL at the end of the first trimester.

*Contrast* hCG test devices will detect concentrations of 20 mIU/mL or more.

RESULT REPORTING

Patient results are not reported unless the quality control is acceptable.

The patient’s results must be recorded in the patients chart as well as the accession log with patient’s name, date of birth, the date and time of the test, and signature of the person performing the test. The accession record must also have the OSOM kit lot number and expiration date.

QUALITY CONTROL

Several controls are incorporated into each Contrast hCG test cartridge for routine quality checks and must be documented on the test log each day of testing. The same labeled conjugate antibody results in the appearance of both the test and control bands. The appearance of the control band in the results window is an internal positive control which validates the proper function of the test system, the environment and the operator.

Test system: The appearance of the control band assures that the detection component of both the test line and the control line has retained functional activity, that adequate volume was added and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the device.

Operator: The appearance of the control band indicates that an adequate volume of sample 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.

The clearing of the background 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 formation of a distinct

control band.

External Quality Control

Quantimetrix controls Level 1 and Level 2 are to be run following the same procedure as patient testing and recorded on the log sheet each day of testing.

If any external or internal QC are not within the expected range, the test should be repeated. If the problem persists, notify POC Coordinator at 798-5802 for further assistance.

All Quality Control must be within expected values before any patient testing can begin

FOLLOW UP RECOMMENDATIONS

If negative results occur and pregnancy is still suspected, it is good practice to resample and retest in 48 hours.

If it is not possible to wait the 48 hours a serum Quantitative HCG should be done.

If the test band appears very faint it is recommended that a new sample be collected 48 hours later and the test repeated or if unable to wait 48 hours a serum Quantitative HCG should be done.

Results should be confirmed using a quantitative HCG assay prior to the performance of any critical medical procedure.

LIMITATIONS

The Contrast hCG test detects the presence of hCG. If detectable levels of hCG are found under certain pathological conditions, such as trophoblastic disease, the test will a give positive result. The results of this test should be used as a supplement to other clinical information.

Dilute urine samples may not contain representative levels of hCG.

Some antipsychotic agents/drugs may cause false positive results.

References; Osom HCG-Combo package insert

**Electronic Authorizations:**

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