POINT OF CARE PREGNANCY TESTING PROCEDURE

Materials and Equipment: McKesson MediLab Pregnancy Test (McKesson Medical-Surgical)
- Disposable pipettes (included in cassette pouch)
- KOVA Liqua-Trol Control System, Hycor Biomedical, Inc
- Urine container, sterile or non-sterile
- Timer

Specimen: **Handle patient specimens as potentially infectious.**

URINE—First morning specimen is preferable for testing (generally contains the highest concentration of hCG), however urine from any time of day may be used. Specimen must be collected in a clean, dry container. Specimens may be stored at 2-8°C for up to 48 hours. SPECIMEN MUST BE AT ROOM TEMPERATURE PRIOR TO TESTING. If sample is very cloudy and has visible precipitates, centrifuge, and test clear aliquot.

LABEL the specimen with a registration sticker and include the type of specimen (clean or dirty) and the time collected.

Principle: Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placenta shortly after conception. hCG can be detected as early as 7 to 10 days following conception. At the time of the first missed menstrual period, HCG concentration is about 100 mIU/ml.

McKesson MediLab hCG Combo Pregnancy Test is a chromatographic immunoassay utilizing monoclonal antibodies to detect the presence of hCG sensitive to 25 mIU/ml. The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the structurally related hormones hFSH, hLH, and hTSH at physiological levels.

Procedure: Urine

1. Allow urine specimen and test kit, in the original pouch, to warm to room temperature (20 -30°C).
2. Open test kit, remove test device and pipette immediately before testing. Label test device with patient or control identification.
3. Holding pipette in VERTICAL position, draw the urine sample into the pipette and dispense 3 full drops into the sample well. Use a separate test device and pipette for each patient or control.
4. Set timer for 3 minutes.
5. Observe color development of colored lines in test and control regions. Wait for the red line(s) to appear. Read the result at 3 minutes. The background must be clear(white) before the result is read. Do not read results after 10 minutes.
6. Log quality controls, SID#, and results on the appropriate log.
7. Enter results into drop down section “Pregnancy test UCSC-POC” area of PNC.

Interpretation of Results:

1. NEGATIVE: one red-colored band in the control(C) region and region; no band in the test(T) region.

DIRECTOR REVIEW / DATE
DIRECTOR REVIEW / DATE
DIRECTOR REVIEW / DATE
REVISED / DATE
REVISED / DATE

HC LAB (6/04)
pocthcg2 / poc
POCT PREGNANCY TESTING

Interpretation of Results (cont.)

2. POSITIVE: two red-colored bands in the test and control regions; a band in the test region may be any shade of red. The patient may re-tested 48 hours later with a first morning void or a serum specimen if the result is questionable.

3. INVALID RESULT: A total absence of red-colored bands in both regions is an indication of a procedural error or reagent deterioration. Repeat procedure using a new test device.

| NEGATIVE RESULT | POSITIVE RESULT | INVALID RESULT |

Quality Control: Urine: positive and negative controls (Kova Liqua-Trol system) should be performed with each new box of test devices; Kova Liqua-Trol Level II Normal with hCG should be used as the positive control and Kova Liqua-Trol Level I Abnormal should be used as the negative control.

A colored band appearing in the control region is considered an internal positive procedural control, indicating proper performance and reactive reagents. A clear to light pink background in the results window is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.

Limitations:

1. Test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.
2. A negative result may be due to a very dilute urine specimen (as indicated by a low specific gravity) or a specimen collected too early in the term of the pregnancy. If pregnancy is still suspected, repeat testing on first morning urine or serum specimen 48 hours later.
3. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Immunologically interfering substances such as those used in antibody therapy treatments may invalidate the test result.

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


HC LAB (6/04)
pocthcg2 / poct