

Director Approval _____ Date _____

UCSF Medical Center Clinical Laboratories	Point of Care Testing
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IM Confirms® II Pregnancy Test

PURPOSE

IM Confirms® II Pregnancy Test is a rapid test for the detection of the presence of human chorionic gonadotropin (hCG) in a patient urine sample.

SCOPE

The hormone hCG is released by the placenta, present in maternal serum and subsequently excreted in urine during pregnancy. The appearance of hCG in urine soon after conception is a marker for the early detection of pregnancy. The test may be used in the ambulatory, inpatient, and home care settings.

PRINCIPLE

IM Confirms® II Pregnancy Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of human chorionic gonadotropin (hCG) in urine specimens.

During the test, the patient urine sample moves upward on the membrane chromatographically by capillary action. For a positive result, a colored band with a specific antibody-hCG-antibody-colloidal gold particle complex will form on the membrane. Absence of this colored band in the test region indicates a negative result. (To serve as a procedural control, a colored band in the control region will always appear regardless of the presence of hCG.)

IM Confirms® II is a qualitative visual test that can detect the presence of hCG in urine as early as 7 days after conception.

PERSONNEL

Intended for use by clinical personnel who have been trained and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, and Physicians. In the ambulatory setting, this includes Hospital Assistants, Licensed Vocational Nurses, Registered Nurses, Nurse Practitioners, Physician Assistants, and Physicians. Individuals who are color blind must demonstrate their ability to read the test results.

REAGENTS, EQUIPMENT, AND MATERIALS

- Patient Urine
- Test Device
 - Each test device is sealed in an individual pouch with a dessicator. Store devices at room temperature (up to 86° F or 30°C), away from direct sunlight or heat sources. Do not use test kits beyond expiration date.
- Disposable dropper pipettes supplied with each box
- Negative and Positive controls from IM Diagnostics hCG Accuracy Check
 - After opening, the controls are stable at refrigerated storage temperatures 36°–46°F (2° – 8°C) for 90 days from the date of opening or until the expiration date, whichever comes first.
 - Unopened controls are stable until the expiration date when stored refrigerated at 36°–46°F (2° – 8°C).
 - Do not use reagents beyond expiration date.
- Gloves

SPECIMEN REQUIREMENTS

Urine specimens must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at anytime of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen. Five drops of urine are needed to perform this test.

If testing is not done by the person obtaining the sample and/or if testing is delayed, then the specimen container (not the lid) must be labeled with two forms of patient identification, in the presence of the patient.

As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling specimens. Gloves should be worn while testing the specimen.

CONTROLS

The IM Confirms® II Pregnancy Test provides a built-in process control at the control region (C) in each device. A pink colored band at the control region must always appear regardless of the presence of hCG in urine. If the pink band at the control

region (C) does not appear, the test device should be discarded. The presence of this pink band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

IM Diagnostics hCG Accuracy Check includes one bottle (5.0 mL) of Urine Negative Control containing 0 mIU hCG/mL in a human based urine matrix, and one bottle (5.0 mL) of Urine Positive Control containing 50mIU hCG/mL in a human based urine matrix. Controls are stored at 2° - 8°C (36 - 46°F) and must be brought to room temperature before use.

Both positive and negative controls must be performed each time a box of 25 IM Confirms® II Pregnancy tests is opened.

QUALITY CONTROL PROCEDURE

- Bring IM Diagnostics hCG quality control set to room temperature.
- Check expiration dates on device pouches and control reagents.
- If new bottles of control are opened, record open date, expiration date and initials on bottles.
- Remove 2 test devices from their sealed pouches.
- Thoroughly mix contents of each bottle by gently swirling.
- Add 5 drops of IM Diagnostics hCG Urine Positive Control into the sample well of one device.
- Wait 4 minutes for the colored bands to appear.
- A Positive reading (two bands) should appear on the Positive Control device. In addition to the control band (C), a distinct colored band should also appear on the test (T) region.
- Dispense 5 drops of IM Diagnostics hCG Urine Negative Control into the sample well of the second device.
- Wait 4 minutes to confirm a negative outcome.
- A Negative reading is confirmed when only one colored band appears, located in the control (C) region. No band will appear in the test (T) region.
- Record result in QC log.
- Write the date and “QC performed” on the box

URINE TESTING PROCEDURE

- Verify patient identification using two patient identifiers and explain procedure to patient and/or family.
- If sample is not obtained from the patient by the person who will perform the test, and the test is not performed immediately, then the specimen container (not the lid) must be labeled with two forms of patient identification, in the presence of the patient.
- Check expiration date of pouch. Remove device from sealed pouch.

- Holding a clean pipette in a straight up and down position, **not at an angle**. **Draw the urine sample up the pipette and** dispense 5 drops of urine into the sample well of the device.
- A positive result may be read when 2 colored bands appear. In addition to the control band (C) a distinct colored band also appears on the test (T) region.
- A negative result should only be read after 4 minutes. Readings before this time may be false negatives due to low concentration of hCG in the specimen. Only one colored band appears on the control (C) region. No band appears in the test (T) region.
- Record result in patient's medical record.
- Report result to provider.

INTERPRETING RESULTS

C	T	Interpretation
Pink	Pink	Positive
Pink	No color	Negative
No color	No color	Do not report; Repeat with new device and pipette
No color	Pink	Do not report; Repeat with new device and pipette

LIMITATIONS

A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasm cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.

If a urine specimen is too diluted (low specific gravity), it may not contain representative levels of hCG. If pregnancy is suspected, ask the patient to collect first morning urine 48 to 72 hours later and repeat the test.

Because of the high sensitivity of the assay, specimens tested as positive during the initial days after conception may later be negative due to natural termination of the pregnancy.

A definitive clinical diagnosis should not be based on the result of a single test, but should be made by the physician after evaluation. Blood specimens may be sent to the Clinical Laboratories for confirmatory testing.

DOCUMENTATION

Lot numbers and expiration dates of all reagents and [devices](#) should be recorded on QC logs.

RECORD MAINTENANCE

Retired records containing laboratory worksheets and logs are kept in an accessible area for three years as required by law.

REFERENCES

- [IM Confirms® II Pregnancy Test 8/08](#)
- [IM Diagnostics hCG Accuracy Check 9/08](#)
- [IM Isbell Marthe Diagnostics, Inc.](#)
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