Background

The ICON® 25 hCG (urine/serum) test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum to aid in the early detection of pregnancy.

Specimen Collection and Handling

- **Urine Assay**

A urine sample must be collected in a clean and dry container. A first morning urine sample is preferred since it generally contains the highest concentration of hCG; however, urine sample collected at any time of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

- **Serum Assay**

Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed sample when possible.

- **Sample Storage**

Urine or serum sample may be stored at 2 to 8°C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below –20°C. Frozen samples should be thawed and mixed before testing.

Materials Provided

- Test devices – containing anti-hCG particles and anti-hCG coated on the membrane
- Disposable sample droppers
- Zip lock bag with 2 extra sample droppers
- Procedure Card
- Product instructions

Materials Required (but not provided)

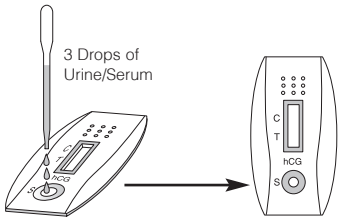
- Sample collection container
- Timer

Reagent Storage & Stability

- Store all test components in the sealed test pouch at 2 to 30°C until ready to use – **DO NOT FREEZE.**
- Expiration date is printed on the sealed pouch – Do not use beyond the labeled expiration date.

Procedure

- Bring the test device (kept sealed in pouch), urine or serum sample, and/or controls (if applicable) to room temperature (15 to 30°C) prior to testing.
- Remove the test device from the sealed pouch and use it as soon as possible.
- Place the test device on a clean and level surface.
- Hold sample dropper vertically and transfer 3 full drops of urine or serum (approx. 100uL) to the sample well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the sample well (S). Refer to illustration below:

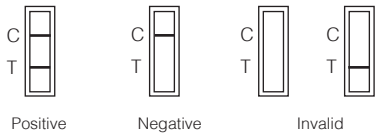


- Wait for the red line(s) to appear. Read the result at 3 minutes when testing a urine sample, or at 5 minutes when testing a serum sample. It is important that the background is clear before the result is read.
- Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 3 minutes when testing a urine sample, or after 5 minutes when testing a serum sample.

Interpretation

(Please refer to illustration below)

- **POSITIVE: Two distinct red lines appear.** One line should be in the control region (C) and another line should be in the test region (T).
- **NEGATIVE: One red line appears in the control region (C).** No apparent red or pink line appears in the test region (T).
- **INVALID: Control line fails to appear.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact Technical Marketing: 800-877-6242.



NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the sample.

However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

Quality Control

- Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal positive procedural control. It confirms sufficient sample volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly,the background in the result area should be white to light pink and not interfere with the ability to read the test result.
- It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing "0"mIU/mL hCG) be evaluated to verify proper test performance. It is recommended that federal, state and local guidelines be followed.

Precautions

Handle all patient samples, controls, and test components as biohazardous. Proper disposal methods should be followed.

Limitations

- Very dilute urine samples,as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.
- 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 urine or serum sample should be collected 48 hours later and tested.
- Very low levels of hCG (less that 50 mIU/mL) are present in urine and serum samples 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 or serum sample collected 48 hours later.
- A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms, such as testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG. Therefore, the presence of hCG in urine or serum sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
- 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 results.
- This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory finding have been evaluated.

Helpful Hints

Refer to Manufacturer's Instructions for additional interpretation help.
Technical assistance may be obtained by calling 800-877-6242 or by e-mailing us at askpcd@beckman.com.

References

Refer to Manufacturer's Instructions.

Review and Update

A. Reviewed By: _____

B. Title: _____

C. Review Date: _____

Manufactured for:

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