The ICON® 25 hCG test (Urine/Serum) 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.

**INTENDED USE**

The ICON® 25 hCG test is a rapid test that qualitatively detects the presence of hCG in urine or serum sample at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, the ICON® 25 hCG test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

**SUMMARY AND EXPLANATION OF TEST**

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception (1-4). hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period (2-4), and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

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**PRINCIPLES OF THE PROCEDURE**

The ICON® 25 hCG 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. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine or serum sample to the sample well of the test device and observing the formation of colored lines. The sample migrates via capillary action along the membrane to react with the colored conjugate.

Positive samples react with the specific antibody-hCG-colored conjugate to 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**

**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
- Product Instructions

**Materials required but not provided**
- Sample collection container
- Timer

**PRECAUTIONS**

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test device should remain in the sealed pouch until use.
3. All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The test device should be discarded in a proper biohazard container after testing.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2 to 30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SAMPLE 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 samples 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 samples 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.

**TEST PROCEDURE**

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine or serum (approx. 100µl) to the sample well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the sample well (S). See the illustration below.
3. 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.

**INTERPRETATION OF TEST RESULTS**

(Please refer to illustration above)

**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 or 650-845-3526.

**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.

LIMITATIONS OF THE PROCEDURE

1. 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.
2. 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.
3. Very low levels of hCG (less than 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 (5), a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum sample collected 48 hours later.
4. This test reliably detects intact hCG up to 500,000 mIU/mL.
5. This test detects intact hCG only. This test does not reliably detect hCG degradation products, including free-beta subunits and beta-core fragment. Therefore, this test may show reduced reactivity in urine after 8 weeks gestation. This test should not be used to monitor trophoblastic disease or post-partum patients.
6. Quantitative assays used to detect hCG may be detecting hCG degradation products, including free-beta subunits and beta-core fragment. Therefore, this test may show reduced reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive samples.

- Acetaminophen 20 mg/mL
- Acetylsalicylic Acid 20 mg/mL
- Ascorbic Acid 20 mg/mL
- Atrazine 20 mg/mL
- Bilirubin (serum) 40 mg/dL
- Bilirubin (urine) 2 mg/dL
- Triglycerides (serum) 1200 mg/dL

None of the substances at the concentration tested interfered in the test.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum samples. The amount of hCG will vary greatly with gestational age and between individuals.

The ICON® 25 hCG test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the ICON® 25 hCG test and another commercially available urine/serum membrane hCG test. The urine study included 159 samples and both tests identified 88 negative and 71 positive results. The serum study included 73 samples and both assays identified 51 negative and 21 positive and 1 inconclusive result. The results demonstrated a 100% overall agreement (for an accuracy of > 99%) of the ICON® 25 hCG test when compared to the other urine/serum membrane hCG test.

Sensitivity and Specificity

The ICON® 25 hCG test detects hCG at concentrations of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) samples showed no cross-reactivity.

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BIBLIOGRAPHY


PRODUCT INFORMATION

Product Name

ICON® 25 hCG Urine/Serum

Product No.

43025

CLIA Category

• Urine
• Serum

PRODUCT INFORMATION

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