1155009702

Product Instructions

ICON®25 hCG

IMMUNOCHEMICAL TEST FOR hCG IN URINE AND SERUM

For in vitro diagnostic use only

INTENDED USE

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.

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.

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.

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 mouse monoclonal anti-hCG antibodies and goat polyclonal anti-hCG antibodies 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
- Procedure Card

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.

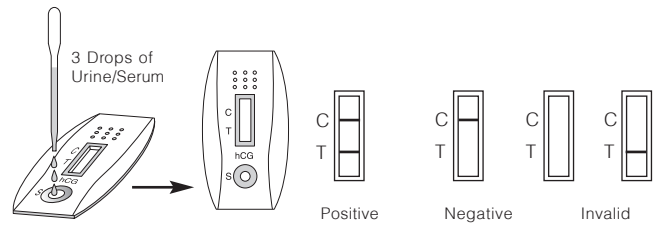
TEST PROCEDURE

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.



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 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.

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 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, and therefore may disagree with the results of the ICON®25 hCG test.
7. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG (6-7). Therefore, the presence of hCG in urine or serum sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
8. 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.
9. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

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 results. 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.

Interfering Substances
The following potentially interfering substances were added to hCG negative and positive samples.
All substances listed in mg/dL unless otherwise noted.

Acetaminophen	20	Ethanol	1%
Acetone	1,000	Estriol	2
Acetylsalicylic Acid	20	Estrone 3-Sulfate	10
Acetoacetic Acid	2,000	Gentisic Acid	20
Ampicillin	20	Glucose	2,000
Ascorbic Acid	20	Hemoglobin	1,000
Atropine	20	Heroin	1
Albumin	2,000	Ibuprofen	20
β-Hydroxybutyrate salt	2,000	Methadone	10
Benzoylecgonine	10	Methamphetamine	10
Bilirubin	20	Methanol	10%
Brompheniramine	20	Morphine	0.6
Caffeine	20	Oxalic Acid	40
Cannabinol	10	Phenothiazine	20
Clomiphene	100	Phenylpropanolamine	20
Cocaine	10	Pregnanediol	2
Codeine	10	Salicylic Acid	20
Cholesterol	500	Tetracycline	20
Creatine	20	Triglycerides	1,200
Dextromethorphan	20	Theophylline	20
DMSO	5%	Urea	2,000
EDTA	80	Uric Acid	20
Ephedrine	20		

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

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PRODUCT INFORMATION

Product Name	Product No.
ICON® 25 hCG Urine/Serum	**43025**
• 25 Determinations	

CLIA Category

• Urine	**WAIVED**
• Serum	**Moderately Complex**

For technical assistance call Technical Marketing at 800-877-6242 or e-mail askpcd@beckman.com

To order product, contact your medical supply distributor.

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