Product Instructions

ICON 20 hCG

RAPID IMMUNOASSAY FOR THE QUALITATIVE DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN SERUM OR URINE

One Step Pregnancy Test For the Early Detection of Pregnancy

IVD

395127.FC
P-5027-D

INTENDED USE

ICON 20 hCG Serum/Urine Test is a simple immunoassay for the Qualitative Detection of Human Chorionic Gonadotropin (hCG) in Serum or Urine for the early detection of pregnancy.

SUMMARY AND EXPLANATION OF TEST

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placental trophoblastic cells shortly after the fertilized ovum is implanted in the uterine wall.[1-4] The primary function of hCG is to maintain the corpus luteum during early pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its rapid rise in concentration make it an excellent marker for confirmation of pregnancy. The hormone may become detectable in both urine and serum as early as 7 to 10 days after conception.[1-4] The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 30,000-100,000 mIU range by 10 to 12 weeks into pregnancy. The hormone is comprised of two non-covalently bound dissimilar subunits containing approximately 30% carbohydrate by weight.[5] The alpha subunit is structurally similar to other human pituitary glycoprotein hormones, whereas the beta (ß) subunit confers unique biological and immunological specificity to the molecule.[6,7]

PRINCIPLES OF THE PROCEDURE

The ICON 20 hCG Serum/Urine Test is a rapid test for detecting hCG qualitatively. The test employs a solid-phase chromatographic immunoassay technology to selectively detect elevated levels of hCG in serum or urine with a high degree of sensitivity. A fixed volume of sample is applied to the sample well. If hCG is present in the sample above or at the detection level, pinkish purple lines will appear at Test position (T) and Control position (C). If hCG is present below the detection level or not present in the sample, only one line at the Control position (C) will appear. Therefore, the presence of two colored lines, one at the Test position and the other at the Control position indicates a positive result, while the absence of the line at the Test position indicates a negative result.

REAGENTS

The ICON 20 hCG Serum/Urine Test kit contains complete reagent components and materials to perform all the tests.

MATERIALS

Materials Provided

- ICON 20 hCG Serum/Urine Test: Each device contains mouse monoclonal anti-hCG antibodies
- Disposable droppers
- Procedure Card
- Product Instructions

Materials Required But Not Provided

- Specimen cup

Materials May Be Required But Not Provided

- Timer
- External positive and negative controls

PRECAUTIONS

- For *in vitro* diagnostic use only.
- The ICON 20 hCG device should remain in its sealed pouch until ready for use.

STORAGE AND STABILITY

ICON 20 hCG Serum/Urine Test kit is to be stored at 2°C to 30°C in the sealed pouch.

SPECIMEN COLLECTION AND PREPARATION

- Approximately 110 µl of sample is required for each test.
- Specimens containing particulate matter may give inconsistent test results. Such specimens should be clarified by centrifugation prior to assaying.
- Frozen specimens must be completely thawed, thoroughly mixed, and brought to room temperature prior to testing by allowing the specimens to stand at room temperature for at least 30 minutes.

Serum sample

- Remove serum from the clot as soon as possible to avoid hemolysis. When possible, clear, non-hemolyzed specimens should be used.

Urine sample

- For optimal early detection of pregnancy, a first morning urine specimen is preferred since it generally contains the highest concentration of hCG. However, randomly collected urine specimens may be used.
- Collect the urine specimen in a clean glass or plastic cup.
- Urine containing excessive bacterial contamination should not be used since spurious results may occur with such specimens.

SPECIMEN STORAGE

- If testing will not be performed immediately, the specimens may be refrigerated (2°C to 8°C) for up to 48 hours prior to assay.
- For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens must be completely thawed and thoroughly mixed before using. Avoid repeated freezing and thawing.
- If specimens are to be shipped, they should be packed in compliance with Federal regulations covering the transportation of etiologic agents. For urine samples, add sodium azide to a concentration of 0.1% as a preservative. Ship sample by the quickest means possible, in a cold pack or frozen.

PROCEDURE

Test Procedure Summary

The procedure consists of adding the specimen to the sample well in the device and watching for the appearance of colored lines in the result window.

Procedural Notes

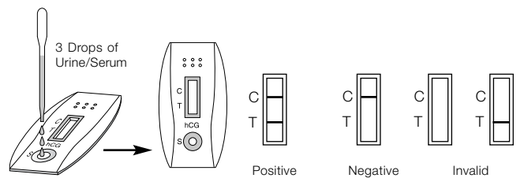
The instructions below must be followed to achieve optimal test results.

- Allow the dropper to fill with sample without air bubbles.
- Handle all specimens as if capable of transmitting disease.
- After testing, dispose of the ICON 20 hCG device and the disposable dropper following good laboratory practices. Consider each material that comes in contact with specimen to be potentially infectious.

Test Protocol

1. For each test, open one ICON 20 hCG Serum/Urine Test pouch, and label the ICON 20 hCG device with the patient ID.
2. Holding the dropper in a vertical position, add 3 drops (110 µl) of sample into the sample well (S).
3. Read the result at 3-5 minutes.*

*Confirm the negative results at 5 minutes.



RESULTS

HOW TO READ THE TEST

Positive: Two pinkish-purple lines, one each at the Test position (T) and at the Control position (C). One of the following indicates a positive test result:

a. Two strong pinkish-purple lines, one each in the Test (T) and Control (C) positions.
b. One strong pinkish-purple line at the Test position (T) and one light pinkish-purple line at the Control position (C).
c. One light pinkish-purple line at the Test position (T) and one strong pinkish-purple colored line at the Control position (C).

Negative: Only one pinkish-purple line, at the Control position (C).

NOTES ON RESULTS

Positive

A specimen containing a detectable level of hCG will generate a pinkish-purple line at the Test position (T) and Control position (C) within 3 minutes. The time required to generate the line is dependent on the hCG concentration in the sample. Positive results may be detected in as early as one (1) minute, depending on the hCG concentration. To be interpreted as positive, the pinkish-purple line at the Test position should be clearly distinguishable from the background color of the membrane. In strong positive tests, the color intensity of the control line (C) may be much lighter than that of the test line (T). *Note: The high dose hook effect has been found to occur at approximately 500,000 mIU/mL. For samples with extremely high concentrations of hCG, the higher the hCG concentration, the lighter the color band at the Test position may become.*

Negative

In the absence of hCG, or if the hCG concentration is below the detection limit of the test, there will be no apparent line at the Test position. The line at the Control position should be clearly readable.

Inconclusive or Invalid Results

If there is no distinct pinkish-purple line visible at the Control position, the test is inconclusive. If there is a suspected procedural error made by the user, the result should be considered inconclusive. It is recommended that in this case the test be repeated or a fresh specimen be obtained and tested. A control line should always appear. The absence of a pinkish-purple line at the Control position means the test is invalid and should be repeated.

Limitations

- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. Similarly, specimens from patients who have been routinely exposed to animals or to animal serum products may contain heterophile antibodies which may cause erroneous results.
- An extremely low concentration of hCG during the early stage of pregnancy can give a negative result. In this case, testing of another specimen obtained at least 48 hours later is recommended.
- The hCG level may remain detectable for several weeks after normal delivery, delivery by caesarean section, spontaneous abortion, or therapeutic abortion.[11]
- The hCG level in the case of spontaneous abortion may be very low and eventually decrease. The test is highly sensitive, and specimens which test positive during the initial days after conception may later be negative due to natural termination of the pregnancy. Natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of pregnancies overall.[12] Subsequent testing of a new urine sample after an additional 48 hours is recommended in order to confirm that the hCG level is rising as indicated in a normal pregnancy.
- The concentration of hCG may be very low in the case of ectopic pregnancy. A suspected ectopic pregnancy may be further evaluated using a serial, quantitative serum ß-hCG measurement.[13]
- Elevated hCG levels have been reported in patients with both gestational and nongestational trophoblastic diseases.[8,9,10] The hCG of trophoblastic neoplasms is similar to that found in pregnancy, so these conditions, including choriocarcinoma and hydatidiform mole, should be ruled out before pregnancy is diagnosed.
- Very high levels of hCG may exist in certain pregnancies and pathological conditions (e.g., choriocarcinoma and hydatidiform mole). This may weaken the intensity of the test line.
- The physician should evaluate data obtained with this kit in light of other clinical information.
- Samples which contain excessive bacterial contamination or which have been subjected to repeated freezing and thawing should not be used because such specimens can give spurious results.
- Urine samples collected after consumption of a large amount of fluids may contain a lower hCG concentration. If such a sample is negative, a first morning specimen should be obtained and retested.
- Degradation of hCG in serum samples may occur by a certain protease during prolonged storage even at 4°C and give a negative test result.

USER QUALITY CONTROL

Internal Control: Each ICON 20 hCG Serum/Urine Test device has a built-in control. The Control line is an internal positive procedural control. A distinct pinkish-purple Control line should appear at the C position indicating an adequate sample volume was used, the sample and reagent are wicking on the membrane, and the test reagents at the Control line and the conjugate-color indicator are reactive. In addition, the clearing background in the Result window is considered as an additional procedural control by providing a distinct readable result. This may be considered an internal negative procedural control. If background color appears in the Result window, interfering with your ability to read the test result and obscuring the formation of the Control band, your result may be invalid. If the problem persists, contact Beckman Coulter's Technical Marketing at 800-877-6242 or email askpcd@beckman.com.

External Control: External controls may also be used to assure that the test devices are working properly and that the assay procedure was followed correctly. It is recommended that a control be tested before using a new lot or a new shipment of kits as good laboratory testing practice and that users follow federal, state, and local guidelines for quality control requirements. For information on how to obtain controls, contact Beckman Coulter's Technical Marketing at 800-877-6242 or email askpcd@beckman.com.

EXPECTED VALUES

ICON 20 hCG Serum/Urine Test is capable of detecting hCG levels of 10 mIU/mL (serum) or 20 mIU/mL (urine) (calibrated against the WHO 3rd International Standard). HCG levels in normal early pregnant women vary and hCG levels often exceed 100 mIU/mL by the first day of the missed menstrual period.[1] The test is usually capable of detecting hCG by the first day of the missed menstrual period.

PERFORMANCE CHARACTERISTICS

Comparison Study

A total of 100 clinical serum samples and clinical urine samples were studied. These specimens were assayed with the ICON 20 hCG Serum/Urine Test and a predicate device according to the product instructions. The summary of the results is shown below (Table 1, Table 2).

Table 1. ICON 20 vs. Predicate Device with Serum Specimens

		ICON 20 hCG Serum/Urine		
		Positive	**Negative**	**Total**
Predicate device	**Positive**	50	0	50
	Negative	0	50	50
Total		**50**	**50**	**100**

Table 2. ICON 20 vs. Predicate Device with Urine Specimens

		ICON 20 hCG Serum/Urine		
		Positive	**Negative**	**Total**
Predicate device	**Positive**	50	0	50
	Negative	0	50	50
Total		**50**	**50**	**100**

The data demonstrates the excellent correlation with 100% agreement between the ICON 20 hCG Serum/Urine test and the predicate device in both serum and urine samples.

Physicians' Office Laboratory Evaluation

Reproducibility of ICON 20 test results was evaluated at three physicians office laboratories using a total of 120 blind control samples. The control panels were prepared in serum or urine. Each panel consisted of 5 negative (-), 5 low positive (25 mIU/mL hCG), 5 moderate positive (200 mIU/mL hCG), and 5 high positive (500 mIU/mL hCG) samples. The results obtained at each site agreed 100% with expected results.

Sensitivity

Standard controls (calibrated to the WHO 3rd International Standard) ranging from 5 mIU/mL to 80 mIU/mL in serum or urine were tested in 20 replicates. The results confirm sensitivity of 10 mIU/mL for serum and 20 mIU/mL for urine in 3 minutes assay time.

Specificity

The assay is free from interference with other commonly known homologous hormones when tested at the levels specified below.

Homologous Hormones	**Urine**	**Serum**
hFSH	1000 mIU/mL	1000 mIU/mL
hLH	500 mIU/mL	500 mIU/mL
hTSH	1000 µIU/mL	1000 µIU/mL

Other Interfering Substances

Potentially interfering substances were prepared at the following concentrations in serum which contained either 0 or 10 mIU/mL hCG and urine which contained either 0 or 20 mIU/mL hCG. These samples were tested with the ICON 20 hCG Serum/Urine Test. No interference was found (Table 3).

Table 3. Interfering Substances and Concentrations Tested

SUBSTANCE ADDED	CONCENTRATION ADDED	
	in Urine	**in Serum**
Acetaminophen	20 mg/dL	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	20 mg/dL
Ampicillin	20 mg/dL	20 mg/dL
Ascorbic Acid	20 mg/dL	20 mg/dL
Atropine	20 mg/dL	20 mg/dL
Caffeine	20 mg/dL	20 mg/dL
Gentisic Acid	20 mg/dL	20 mg/dL
Phenothiazine	20 mg/dL	20 mg/dL
Phenylpropanolamine	20 mg/dL	20 mg/dL
Salicylic Acid	20 mg/dL	20 mg/dL
Tetracycline	20 mg/dL	20 mg/dL
URINARY ANALYTES:		
Bilirubin	2 mg/dL	30 mg/dL
Glucose	2000 mg/dL	2000 mg/dL
Hemoglobin	25 mg/dL	250 mg/dL
Ketones	100 mg/dL	-
Albumin	2000 mg/dL	14000 mg/dL
Triglyceride	-	2000 mg/dL

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PRODUCT INFORMATION

Product Name
ICON 20 hCG Serum/Urine
- 25 test Kits

CLIA Category
- **Urine** — **WAIVED**
- **Serum** — **Moderately Complex**

REF **395097**

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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