TANNER scientific®

hCG Pregnancy Urine/Serum Combo Test

INTENDED USE

Tanner Scientific® hCG Pregnancy Urine/Serum Test is a rapid chromatographic immunoassay for the visual, qualitative detection of human chorionic gonadotropin (hCG), in serum or urine specimen, to help in the early determination of pregnancy.

The test kits are for health care professionals' use including professionals at physician's office labs (POLs). The test utilizes monoclonal antibody reagents to selectively detect elevated levels of hCG in serum or urine specimen at the sensitivity of 20mIU/mL.

SUMMARY & EXPLANATION OF TESTS

Human chorionic gonadotropin is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in serum as early as 7 days following conception (1-4), doubling every 1.3 to 2 days. At the time of the first missed menstrual period, hCG concentration is about 100 mIU/ml (2-5), and peak levels of 200,000mIU/ml or higher are seen in the end of the first trimester. The appearance of hCG soon after conception, and its subsequent rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

The hCG immunoassay kit is a rapid test to detect the presence of hCG in serum or urine specimens in a qualitative format sensitive to 20mIU/ml. The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in serum or urine. The immunological specificity of the test kit virtually eliminates cross reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

PRINCIPLE

The hCG test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of human chorionic gonadotropin in serum or urine specimens. The membrane was pre-coated with anti-Alpha hCG capture antibody on the test band region and goat anti-mouse on the control band region. During testing, the urine specimen is allowed to react with anti-beta hCG monoclonal antibody. The mixture then 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 in the test band region. The absence of a colored band in the test band region indicates a negative result. To serve as a procedural control, a colored band at the control region will always appear regardless of the presence of hCG.

REAGENTS & MATERIALS SUPPLIED

+ Directions for Use
+ Test Device: Each test device contains a reagent strip, strip is housed in a plastic housing for cassette device. Reagent strip contains anti-alpha hCG capture antibody coated membrane and colloidal gold particles coated with mouse anti-beta hCG monoclonal antibody.
+ Disposable Specimen Pipette: one per test (for cassette device only).

MATERIAL REQUIRED BUT NOT PROVIDED

+ Specimen collection tube or container
+ Timing device (i.e. timer, clock, watch, etc.)
+ Positive urine control
+ Negative urine control

STORAGE & STABILITY

The test kit is to be stored at refrigeration (2-8°C) or room temperature (up to 30°C) in the sealed pouch for the duration of the shelf life.

WARNING & PRECAUTIONS

+ **FOR IN VITRO DIAGNOSTIC USE ONLY**
+ For professional use (including Physician's Office Labs).
+ The pouch containing the test device should be sealed. Discard the test device if package is ripped or torn.
+ Do **NOT** use test kit beyond expiration date.
+ Serum and Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
+ Avoid cross-contamination of serum or urine samples by using a new specimen collection device and specimen pipette for each serum or urine sample.

SPECIMEN COLLECTION & HANDLING

URINE ASSAY

The urine specimen 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 specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear specimen 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 specimens when possible.

SPECIMEN STORAGE

Serum or urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below –20°C. Frozen specimens should be thawed and mixed before testing.

QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. Quality Control for waived testing of urine samples should be performed with each new kit lot, each shipment of test kits and once a month as a check for storage. Quality control specimens are available from commercial sources and are recommended to be used daily. Use the same assay procedure as with a serum or urine specimen.

Controls should be challenging to the assay cutoff concentration. If control values do not fall within established limits, assay results are invalid. Water should not be used as a control. Users should follow the appropriate federal, state, and local guidelines concerning the testing of external positive and negative controls.

Tanner Scientific® hCG Pregnancy Urine/Serum Test provides built-in process control with a different antigen/antibody reaction at the control region (C) in each strip. This control line should always appear regardless of the presence of hCG in serum or urine. If the control line does not appear, the test device should be discarded. The presence of this control band in the control region serves as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

TEST PROCEDURE

IMPORTANT

Test device, patient's sample, and controls should be brought to room temperature (15-30°C) prior to testing. Do **NOT** open pouches until ready to perform the assay.

1) **Remove** the test device from the sealed pouch and use it as soon as possible.

TESTING DEVICE

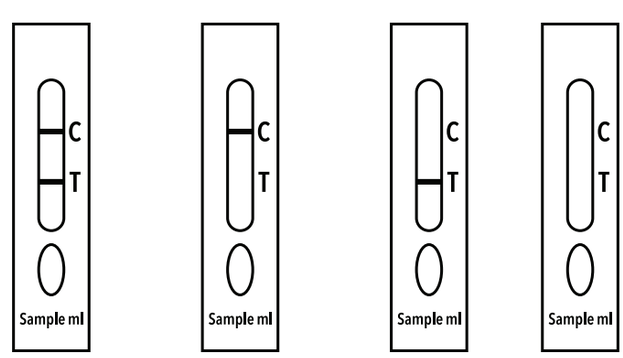
2) **Place** the device on a clean and level surface.
3) **Draw** the sample up the pipette and dispense 2-3 drops (approximately 0.1 to 0.12 ml) into sample well. Avoid adding drops that contain air since air bubbles in the well may cause uneven flow or prevent the flow of the sample onto the test strip.

READING RESULT

4) **Urine Specimen:** The result(s) should be read at 3-5 minutes. However, positive results may be read and reported as early as 1 minute, but negative results must be reported at 3 minutes only. Do **NOT** interpret the result(s) until 5 minutes after the addition of sample.
5) **Serum Specimen:** The result(s) should be read at 5-8 minutes. However, positive results may be read and reported as early as 3 minutes, but negative results must be reported at 5 minutes only. Do **NOT** interpret the result(s) until 8 minutes after the addition of sample.

INTERPRETATION OF RESULTS

1) **Negative:** Only one colored line appears in the control region (C). The missing of the test line indicates a negative result.
2) **Positive:** Two colored lines should be observed in the viewing window. The line in the test region (T) is the hCG probe line, and the line in the control region (C) is the control line.
3) **Invalid:** No line appears in the control region (C). Under no circumstances should a positive sample be identified until the control line (C) forms in the viewing area. If the control line (C) does not form, the test result is inconclusive and the assay should be repeated with a new device.



Positive Negative Invalid

NOTES ON THE INTERPRETATION OF RESULTS

+ Negative test results in patients suspected to be pregnant or if a faint line appears in the test region, the test should be repeated with a sample obtained 48 hours later, or to perform a quantitative assay. When testing with a urine specimen, the first morning specimen would contain the highest hCG concentration.
+ The shade of pink on the (T) test band region will vary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by a qualitative test.

LIMITATION OF PROCEDURE

+ 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 dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine should be obtained from the patient 48-72 hours later and tested.
+ As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
+ Immunologically interfering substances such as those used in antibody therapy treatments may invalidate the test results.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women. The amount of hCG will vary greatly with gestational age and between individuals.

PERFORMANCE CHARACTERISTICS

ACCURACY (POL SITES) 145 positive and negative clinical serum samples and 145 positive and negative clinical urine samples were analyzed at multiple POL sites. All tested clinical specimens were randomly selected and collected at any time during the day, no first morning urine is required. Clinical samples tested were collected from pregnant and non-pregnant women patients (include post menopausal person). Both ***Tanner Scientific® hCG Pregnancy Urine/Serum Test*** and predicate device were tested, the results were interpreted by the untrained nurse and clinical assistant. Of theses serum and urine specimens tested, all results are matched by both the new screening method and the predicate kit. The result demonstrates minimum of 98% agreement for the accuracy study.

(I) SERUM CLINICAL SAMPLES:

	Teco One Step hCG Urine/Serum Test			
Tanner Scientific® hCG Cassette Panel		+	-	Total
	+	58	0	58
	-	1	86	87
	Total	59	86	145

Sensitivity: 98.3%; Specificity: 100%

(II) URINE CLINICAL SAMPLES:

	Teco One Step hCG Urine/Serum Test			
Tanner Scientific® hCG Cassette Panel		+	-	Total
	+	59	0	59
	-	0	86	86
	Total	59	86	145

Sensitivity: 100%; Specificity: 100%

PRECISION (POL SITES) Lab spiked hCG urine and serum controls were used to evaluate the precision performance of ***Tanner Scientific® hCG Pregnancy Urine/Serum*** Cassette and Dipstick Tests. 3 lots of devices were evaluated at 3 point-of-care sites by 9 operators.

A) SERUM CONTROLS:

Levels (mIU/ml)	# of Negative	# of Positive	% Negative	% Positive
0	225	0	100%	0%
10	225	0	100%	0%
15	225	0	100%	0%
20	7	218	3.1%	96.9%
40	0	225	0%	100%
100	0	225	0%	100%

B) URINE CONTROLS:

Levels (mIU/ml)	# of Negative	# of Positive	% Negative	% Positive
0	225	0	100%	0%
10	225	0	100%	0%
15	225	0	100%	0%
20	7	218	3.1%	96.9%
40	0	225	0%	100%
100	0	225	0%	100%

SENSITIVITY & CROSS-REACTIVITY

The ***Tanner Scientific® hCG Pregnancy Urine/Serum Test*** detects serum or urinary hCG at a concentration of 20mIU/ml or greater. The test has been standardized to the WHO Fourth International Standard 75/589. Cross-reactivity (Specificity) evaluated at negative (0 mIU/ml) and positive (20 mIU/ml) hCG specimens showed no cross-reaction:

Compounds (Level)	% Non-Cross-Reactivity
hCG (20 mIU/ml)	100%
hLH (300 mIU/ml)	1,500%
hFSH (1,000 mIU/ml)	5,000%
hTSH (1,000 µIU/mL)	5%

INTERFERENCE

The performance of ***Tanner Scientific® hCG Pregnancy Urine/Serum Test*** at negative and cutoff points are not affected when the pH range of urine specimens is at 3.0 to 8.5 and the specific gravity range of urine specimens is at 1.00 to 1.03. The following substances were added to hCG free and 20mIU/ml hCG spiked serum and urine samples. None of the substances at the concentration tested interfered with the assay.

Substances	Con. in Serum	Con. in Urine
Acetaminophen	20 mg/dl	20 mg/dl
Acetylsalicylic Acid	20 mg/dl	20 mg/dl
Albumin	2000 mg/dl	2000 mg/dl
Ascorbic Acid	20 mg/dl	20 mg/dl
Atropine	20 mg/dl	20 mg/dl
Bilirubin	40 mg/dl	2 mg/dl
Caffeine	20 mg/dl	20 mg/dl
EDTA	80 mg/dl	80 mg/dl
Ethanol	1%	1%
Gentesic Acid	20 mg/dl	20 mg/dl
Glucose	2 g/dl	2 g/dl
Hemoglobin	125 mg/dl	1 mg/dl
Methanol	1 %	1 %
Salicylic Acid	20 mg/dl	20mg/dl
Triglyceride	1200 mg/dl	N/A

*: β-core hCG level up to 8.53 pmol/L does not interfere with the assay.

REFERENCES

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NOTES ON SYMBOLS & MARKS

+30°C +2°C	Store Between	LOT	Batch Code
	Use By Expiration Date	2	Do Not Reuse
i	Consult Instructions for Use	IVD	For In Vitro Diagnostic Use

Distributed By

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