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QuickStick™ Pro HCG Test

Catalog # 9009-25

Test Instructions

Intended Use

The QuickStick™ Pro HCG Test is a sensitive immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.

Summary & Explanation

Urine tests for the confirmation of pregnancy are based on detecting elevated levels of human chorionic gonadotropin (hCG), a hormone produced by the placenta in increasing amounts about 10 days after fertilization.[1] Since hCG is present in the urine of pregnant women, it is an excellent marker for the confirmation of pregnancy. QuickStick™ Pro enhances the procedural convenience and sensitivity of qualitative testing for hCG. The device utilizes monoclonal antibody technology and an internal control to allow rapid, visually interpreted, qualitative hCG test results.

Principle of the Procedure

The QuickStick™ Pro employs the basic immunochemical sandwich assay principle, which relies on the recognition and formation of specific antibody / hCG / antibody complex. The membrane is pre-coated with mouse anti-hCG on the test band region and goat anti-mouse on the control band region.

During the test, urine is allowed to react with colored conjugate (mouse anti-hCG monoclonal antibody-colloidal gold conjugate) which is pre-dried on the test strip. As urine migrates chromatographically on the membrane it carries the colored conjugate with it. If hCG is present, a specific antibody / hCG / colored antibody complex is formed on the test band region of the membrane. The absence of this colored band suggests a negative result.

To serve as a procedural control, a different colored band will always appear in the control region. This control is a polyclonal antibody (goat anti-mouse), which is spotted on the membrane in the form of a line. Mouse IgG - Colloidal gold is coated in the sample path. As the urine migrates, mouse IgG - Colloidal gold is transported up the membrane. The conjugated mouse IgG binds to the goat anti-mouse that has been immobilized at the control region. This forms a colored band in the control region, regardless of the presence of hCG in the test specimen.

Reagents & Materials Provided

1. 25 Test Devices
2. 1 Directional Insert

Precautions

QuickStick™ Pro is intended for *IN VITRO* diagnostic use only. Do not use this device beyond its stated expiration date.

Storage & Stability

QuickStick™ Pro can be stored at room temperature (15 – 30 °C, 59 – 86 °F), and will remain stable at this temperature until the expiration date on the pouch.

Specimen Collection & Preparation

Any urine sample is appropriate for hCG testing, but the first morning urine is optimal because it will generally contain the highest concentration of hCG. Very turbid urine specimens may be centrifuged prior to analysis.

Specimens containing particulate matter, such as salts that may have precipitated out of solution, should not be shaken or disturbed; sample should be pipetted from the clear supernatant of such samples.

Urine may be collected in any suitable, clean glass or plastic container. If the specimen is not to be tested immediately, it may be stored at 2° – 8° C for up to 48 hours. Longer storage is not recommended.

Procedural Notes

The following procedural notes should be read carefully to ensure the best results with QuickStick™ Pro.

Transfer of Specimens – A clean pipette should be used to transfer the specimen to a test tube or sample cup.

Incubation Time & Temperature – The QuickStick™ Pro assay performs with the stated sensitivity and specificity at room temperature (15° – 30° C, 59° – 86° F). Temperatures lower than this will result in less color development at the end of the 5-minute incubation.

Specimens with high hCG levels may give positive results in less than 5 minutes. For such specimens it is not necessary to wait the full 5 minutes to obtain a valid result.

Batch Processing – If several specimens are to be analyzed at one time, perform each test step for all specimens at timed intervals before proceeding to the next test step. It is recommended that no more than five (5) devices be run in any one batch.

Turbid Specimens – Turbidity and particulates slow the rate of phoresis, the speed which liquid passes across the membrane. In certain cases, an extremely turbid specimen may cause the liquid transfer to stop. In such cases, centrifuge the sample and retest using a fresh device.

Reagent & Materials Preparation

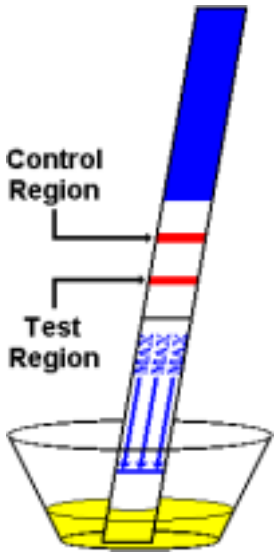
All devices and specimens should be at room temperature before the assay procedure is begun.

A new transfer pipette must be used for each specimen or control.

Test Procedure

The test procedure for QuickStick™ Pro is performed at room temperature. Before performing the test, read the section entitled "Procedural Notes." The assay procedure is as follows:

1. Set up a sufficient number of test strips and label appropriately.
2. Remove a QuickStick™ Pro from its protective pouch. Verify that the test strip is within expiration dating.
3. Place the reaction strip vertically in the urine sample. The urine level must not be higher than the "**MAX**" line at bottom of the strip.
4. Capillary action will draw the urine sample up the reaction strip. In 5 minutes a colored band will appear at the top of the test area to show that the test is complete.
5. Read test results immediately.

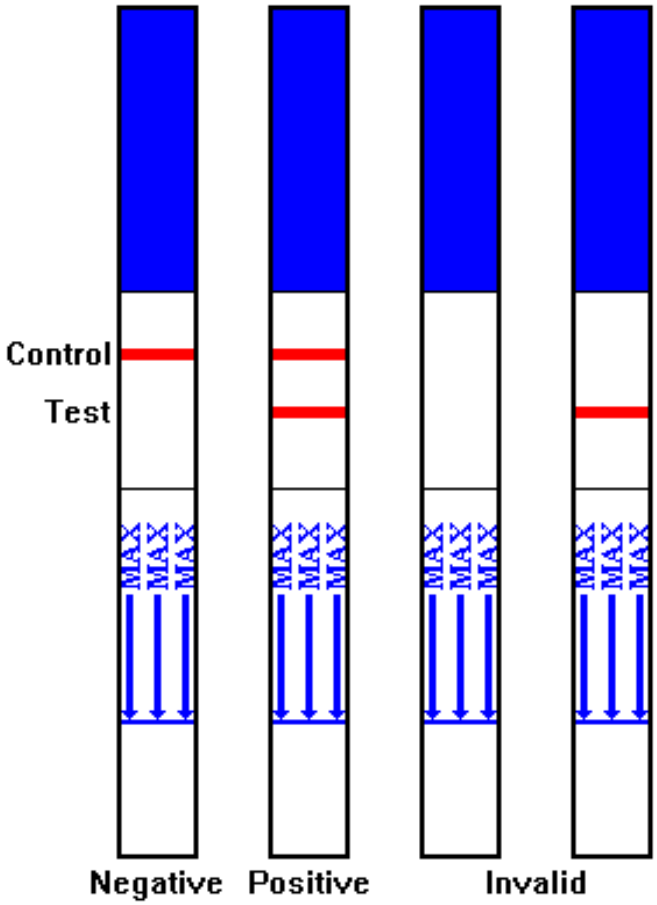


Interpretation of Results

Negative: The appearance of one (**1**) colored band in the test area.

Positive: The appearance of two (**2**) colored bands in the test area.

Invalid Result: If no control line appears, the test is invalid. The sample must be retested.



Quality Control

The QuickStick™ Pro assay contains a built in control feature. Development of a rose pink colored line at the top of the Control region (**C**) indicates a valid test result. The control confirms the device to be effectively absorbing sample which then transports mouse IgG - Colloidal gold. As the urine migrates, Mouse IgG - Colloidal gold is transported up the membrane. The conjugated mouse IgG binds to the goat anti-mouse that has been immobilized at the control region. This forms a colored band in the Control region.

For a positive result, a second colored band with the specific antibody - hCG - colored conjugate complex will form below the control line in the Test region (**T**). The absence of this second band in the Test band region suggests a negative result.

Good laboratory practice (GLP) recommends the use of external controls to assure proper assay performance. It is recommended that these controls be tested once every 25 tests or at the interval determined by your laboratory's standard quality control procedures.

Expected Results

HCG is not normally detected in the urine of healthy males or healthy non-pregnant females. During pregnancy, the urine hCG concentrations begin to rise within the first week of implantation. This concentration will increase until the latter part of the first trimester when it may reach a level in excess of 100,000 mIU/ml.[2] HCG levels decline after this point and remain lower throughout the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal levels within days of parturition. The QuickStick™ Pro is sufficiently sensitive to detect as low as 25 mIU/ml (calibrated against the WHO 3rd IS 75/537) hCG, as early as one week after implantation.

Limitations

The contents of this kit are only for use in the qualitative detection of hCG in urine. While pregnancy is the most likely reason for the presence of hCG in urine, conditions other than pregnancy may be associated with elevated urinary hCG levels. Such conditions include ectopic pregnancy and molar pregnancy.[3] Conditions unrelated to pregnancy, including nontrophoblastic malignancies and choriocarcinoma have been reported to cause elevated hCG levels in some patients.

Test results must always be evaluated in conjunction with other clinical and laboratory information available to the physician.

Performance Characteristics

Sensitivity, Specificity & Accuracy – The QuickStick™ Pro assay will give positive test results with samples containing hCG concentrations as low as 25 mIU/ml.

The QuickStick™ Pro assay was used to test urine samples from patients presenting for pregnancy testing. All assay results, positive and negative, were evaluated against results obtained from three commercially available, visually interpreted tests for hCG. A commercially available quantitative assay was used to resolve discrepant results.

Of the urine samples evaluated in this study, >99.9% (90/90 x 3) were positive and >99.9% (28/28 x 3) were negative. The QuickStick™ Pro test had a correlation of >99.9% to three other commercially available kits.

Combined Corrected Correlation
QuickStick™ Pro vs. 3 Commercially Available hCG Tests

Characteristic	Expected / Observed	% Correct
Sensitivity	270 / 270	100 %
Specificity	84 / 84	100 %
Accuracy	354 / 354	100 %

Interfering Substances – The QuickStick™ Pro was tested with urine containing the interfering substances listed in the following tables. No interference with the expected results was seen at the indicated concentrations.

Chemical Analyte	Concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
DMSO	5.0 %
EDTA	80 mg/dL
Ephedrine	20 mg/dL

Chemical Analyte	Concentration
Ethanol	1.0 %
Gentisic Acid	20 mg/dL
β-Hydroxybutyrate	2000 mg/dL
Methadone	10 mg/dL
Methanol	10.0 %
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic Acid	20 mg/dL
Uric Acid	20 mg/dL

Urine Analyte	Concentration
Albumin (serum)	2000 mg/dL
Bilirubin	1000 µg/dL
Glucose	2000 mg/dL

Urine Analyte	Concentration
Hemoglobin	1000 µg/dL
pH	5 to 9

Hormone	Concentration
LH	300 mIU/mL
FSH	1000 mIU/mL
TSH	1000 µIU/mL

Hormone	Concentration
Estriol 17-beta	1400 µg/mL
Pregnanediol	1500 µg/mL

Bibliography

1. Braunstein, G.D., Rasor J., Adler, D., Danzer, H., and Wade, M.E. "Serum Human Chorionic Gonadotropin Levels Throughout Normal Pregnancy." American Journal of Obstetrics and Gynecology, **126**:678 (1976)
2. Hussa R.O. "Human Chorionic Gonadotropin, A Clinical Marker: Review of its Biosynthesis" The Ligand Review, **3**:6 (1981)
3. Krieg A.F. In Clinical Diagnosis and Management by Laboratory Methods, 16th Ed., JB Henry, W.B. Saunders Co., **1**:680-692 (1979)

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FOR IN VITRO DIAGNOSTIC USE ONLY

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