Rapid Response™

Pregnancy Test Strip
(Urine)
REF HCG-1S50, HCG-1S100 Product Insert

A rapid test for the qualitative detection of Human Chorionic Gonadotropin (hCG) in human urine specimens.
For professional *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ Pregnancy Test Strip is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine specimens. This kit is intended for use as an aid in the early detection of pregnancy.

Introduction

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However, elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

Principle

The Rapid Response™ Pregnancy Test Strip detects human chorionic gonadotropin through visual interpretation of color development on the strip. Anti-hCG antibodies are immobilized on the test region of the membrane and anti-mouse antibodies on the control region. During testing, the specimen reacts with anti-hCG antibodies conjugated to colored particles and precoated onto the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient hCG in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Precautions

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Storage and Stability

- The kit should be stored at 2-30°C (36-86°F) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **DO NOT FREEZE**.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Materials

Materials provided

- Individually packed test strips
- Product insert

Materials required but not provided

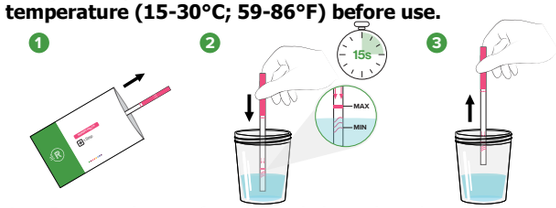
- Specimen collection container
- Timer
- Centrifuge

Collection and Storage of Specimens

- The Rapid Response™ Pregnancy Test Strip is intended for use with human urine specimens only.
- Although urine specimens from any time of day can be used, first morning urine specimens are preferable as they contain the highest concentration of hCG.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Urine specimens must be collected in clean, dry containers. Ensure that the volume of specimen collected is sufficient to submerge the dip region of the strip.
- Collected urine specimens must be put in clean, dry containers.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C (36-46°F) for up to 48 hours. For long term storage, specimens should be kept below -20°C (-4°F).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Test Procedure

Bring tests, specimens, and/or controls to room temperature (15-30°C; 59-86°F) before use.

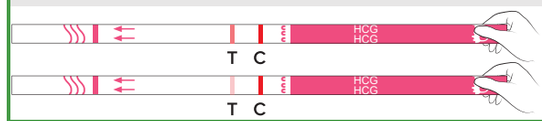


1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. As the test begins to work, color will migrate across the membrane.
5. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 3 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak test bands (T) after a prolonged period of time. Therefore, do not interpret the result after 10 minutes.

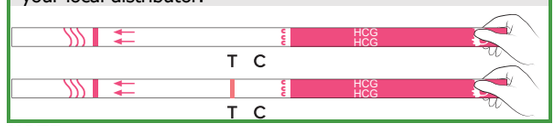
Results Interpretation

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.



NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The Rapid Response™ Pregnancy Test Strip is for professional *in vitro* diagnostic use and should only be used for the qualitative detection of human chorionic gonadotropin.
2. Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is suspected after a negative result, a first morning urine sample should be obtained 48-72 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.
4. 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 (>10 mIU/mL). Therefore, the presence of hCG in urine as determined by using the Rapid Response™ Pregnancy Test Strip should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. When hCG levels are below the minimum detection level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
6. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Expected Values

Urine hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 IU/mL about 2-3 months after the last menstrual period. The Rapid Response™ Pregnancy Test Strip has a sensitivity of 20 mIU/mL for urine.
Reportedly, a level of 20 mIU/mL or more is present 7-10 days after conception or 4-5 days prior to the first missed menses. Test results which appear as very light bands in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urine specimen be obtained after 48-72 hours and tested. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48-72 hours later.

Performance Characteristics

120 positive and negative clinical urine samples were analyzed at 3 sites (including 2 POL sites).

Table: Rapid Response™ Pregnancy Test Strip vs. QuickVue One-Step hCG Combo test

		QuickVue +	QuickVue -
Rapid Response	+	60	0
	-	0	60

The comparison agreements are >99.9%.

Sensitivity and Precision

The Rapid Response™ Pregnancy Test Strip will display positive results with specimens containing HCG at a level of 20mIU/ml or greater for urine. 3 lots devices were evaluated at 3 physician's offices by 9 operators.

Typical Urine format Data

hCG Concentration (mIU/mL)	Site 1		Site 2		Site 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0
5	50	0	50	0	50	0	150	0	100%	0
10	50	0	50	0	50	0	150	0	100%	0
12	50	0	50	0	50	0	150	0	100%	0
16	24	26	24	26	25	25	73	77	48.7%	51.3%
20	0	50	0	50	0	50	0	150	0	100%
24	0	50	0	50	0	50	0	150	0	100%
30	0	50	0	50	0	50	0	150	0	100%
50	0	50	0	50	0	50	0	150	0	100%
100	0	50	0	50	0	50	0	150	0	100%

Specificity

The specificity of the Rapid Response™ Pregnancy Test Strip was determined in cross reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all produced negative results. Tests were performed for samples with 0 and 20 mIU/mL hCG in urine. No interference was found for the following substances at the given concentrations.

Acetaminophen	20mg/dl	Codeine	6ug/gl
Acetoacetic Acid	2000mg/dl	Ethanol	1.0%
Ascorbic Acid	20mg/dl	Methanol	10%
B-hydroxybutyrate	2000mg/dl	Albumin	2000mg/dl
Caffeine	20mg/dl	Glucose	2000mg/dl
Ephedrine	20mg/dl	Bilirubin	2mg/dl
Gentisic Acid	20mg/dl	Atropine	20 mg/dl
Phenylpropanolamine	20mg/dl	Estriol-17-beta	1400ug/dl
Salicylic Acid	20mg/dl	Hemoglobin	500mg/dl
Phenothiazine	20mg/dl	Pregnanediol	1500ug/dl
EDTA	80mg/dl	Thiophene	20mg/dl
Acetylsalicylic Acid	20 mg/dl	Ampicillin	20mg/dl
Benzoylecgonine	10mg/dl	Tetracycline	20mg/dl
Cannabinol	10mg/dl	Ketone	20mg/dl

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Glossary of Symbols

	Consult instructions for use	Σ	Test per Kit	EC REP	Authorized Representative
86°F 30°C / 36°F 2°C	Store between 36°F to 86°F		Use by	REF	Catalogue #
LOT	Lot Number	IVD	For *in vitro* diagnostic use only		Do Not Reuse

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover, Germany

CE

BTNX Inc.
722 Rosebank Road,
Pickering, ON, L1W 4B2
Canada

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