Rapid Response™

Pregnancy Combo Test Cassette
(Urine/Serum)

REF HCG-3C25, HCG-3C50 Product Insert

A rapid test for the qualitative detection of Human Chorionic Gonadotropin (hCG) in human urine or serum specimens.

For professional in vitro diagnostic use only.

Intended Use

The Rapid Response™ Pregnancy Combo Test Cassette is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine or serum 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 Combo Test Cassette detects human chorionic gonadotropin through visual interpretation of color development in the internal strip. Anti-hCG antibodies are immobilized on the test region of the membrane, and anti-mouse antibodies immobilized 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 by 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 precautions against microbiological hazards throughout the procedure 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 equipments, containers or reagents can lead to false results.

Materials

Materials provided

- Individually packed test devices
- Disposable pipettes
- Product insert

Materials required but not provided

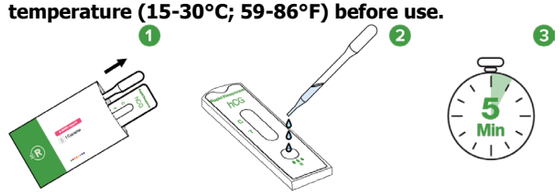
- Specimen collection container
- Centrifuge
- Timer

Collection and Storage of Specimens

- The Rapid Response™ Pregnancy Combo Test Cassette is intended for use with human urine or serum 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.
- Only clear specimens are recommended for use with this test. Serum should be separated as soon as possible to avoid hemolysis.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Collected urine/serum 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.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results

Test Procedure

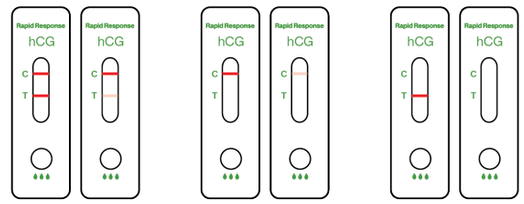
Bring tests, specimens, and/or controls to room temperature (15-30°C; 59-86°F) before use.



1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour. (See illustration 1).
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer. **Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.** As the test begins to work, color will migrate across the result area in the center of the device. (See illustration 2).
3. Wait for the colored band(s) to appear. The result should be read at 3 minutes when testing a urine specimen or at 5 minutes when testing a serum specimen. Do not interpret the result after 10 minutes. (See illustration 3).

NOTE: Low hCG concentrations may produce very weak T lines 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.
3. Negative results are expected in healthy, non-pregnant women. The amount of hCG in a sample can vary greatly with gestational age and between individuals.

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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

Limitations

1. The Rapid Response™ Pregnancy Combo Test Cassette 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/serum as determined by using the Rapid Response™ Pregnancy Combo Test Cassette 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 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.
7. As 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

hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200IU/mL about 2-3 months after the last menstrual period. The Rapid Response™ Pregnancy Combo Test Cassette has a sensitivity of 10 mIU/ml for serum and 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/serum specimen be obtained after 48-72 hours and tested again. 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 serum samples and 120 positive and negative clinical urine samples were analyzed at 3 sites (including 2 POL sites).

Rapid Response™ Pregnancy Combo Test Cassette vs. QuickVue One-Step hCG Combo test

Urine

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

Serum

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

The comparison agreements are >99.9%.

Sensitivity and Precision

The Rapid Response™ Pregnancy Combo Test Cassette will display positive results with specimens containing HCG at levels of 10 and 20mIU/ml or greater for serum and urine, respectively. 3 lots devices were evaluated at 3 physician's offices by 9 operators.

Typical Serum 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
4	50	0	50	0	50	0	150	0	100%	0
6	50	0	50	0	50	0	150	0	100%	0
8	24	26	25	25	25	25	74	76	49.3%	50.7%
10	0	50	0	50	0	50	0	150	0	100%
12	0	50	0	50	0	50	0	150	0	100%
14	0	50	0	50	0	50	0	150	0	100%
16	0	50	0	50	0	50	0	150	0	100%
20	0	50	0	50	0	50	0	150	0	100%
50	0	50	0	50	0	50	0	150	0	100%

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	25	25	24	26	22	28	71	79	47.3%	52.7%
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 Combo Test Cassette 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 gave negative results. Tests were performed for samples with 0 and 20 mIU/mL hCG in urine, and 0 and 10 mIU/mL hCG in serum. No interference was found for the following substances at the giving 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

Bibliography

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Glossary of Symbols

Consult instructions for use	Test per Kit	EC REP	Authorized Representative
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