Rapid Response™

Midstream Pregnancy Test
(Urine)
REF HCG-1M1 Product Insert

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

Intended Use

The Rapid Response™ Midstream Pregnancy Test is a rapid, qualitative immunoassay for the determination of human chorionic gonadotropin (hCG) in urine specimen at 20 mIU/mL or above. This kit is intended for use as an aid in the early detection of pregnancy.

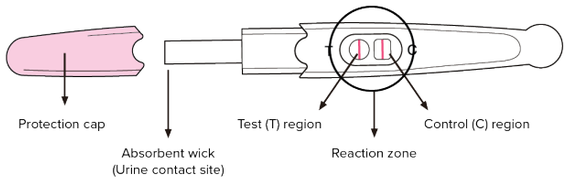
Introduction

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both serum and urine as early as 7 to 10 days after conception[1-4]. hCG level continues to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period[2-4], and peaking in the 30,000 – 100,000 mIU/mL range by 10-12 weeks into pregnancy.
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 neoplasm and hence these conditions should be considered before a diagnosis of pregnancy can be made.
The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the Midstream Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

Principle

The Rapid Response™ Midstream Pregnancy Test is a qualitative, solid phase, two-site sandwich immunoassay[5,6] for the detection of human chorionic gonadotropin (hCG) in urine. This test utilizes the principle of immuno-chromatography, a unique two-site immunoassay on a membrane. As the test sample flows through the membrane assembly within the test device, the colored anti-hCG-colloidal gold conjugate binds with the hCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-hCG coated on the membrane leading to formation of a pink colored line which confirms a positive test result. Absence of this colored line in the test region indicates a negative test result.
The unreacted conjugate and unbound complex form a pink line, if any move further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region. This control line serves to validate the test results.

Test Device



- The midstream test device has got at the left ending the absorbent wick (urine contact site) with a mark, which indicates the maximum immersion depth. Right next to it there is the Reaction zone with the test (T) and control (C) region. At the right ending there is the handle to hold the strip with your fingers.

Precautions

- For *in vitro* diagnostic use only.
- Do not immerse, soak or dip the test above the maximum depth mark.
- Use new specimen collection container for each urine sample.
- Do not touch the Absorbent Wick to avoid contamination.
- Urine specimens may be potentially infectious.
- Use test right after removed from foil pouch.
- Please take the specificity and the cross reactivity into account for evaluation.
- Humidity and high temperature can adversely affect results.
- Keep out of the reach of children.

Storage and Stability

- Store as packaged in the sealed pouch refrigerated (2-8°C; 36-46°F) or at room temperature (not above 30°C; 86°F).
- **DO NOT FREEZE** or use beyond the expiration date.

Materials

Materials provided

- Individually packed test midstream
- Package insert

Materials required but not provided

- Specimen collection container
- Timer
- Positive urine controls
- Negative urine controls

Collection and Storage of Specimens

- The urine specimen must be collected in a clean and dry plastic or glass container.
- The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine collected at any time of day may be used.
- Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain clear supernatant for testing.
- Urine containing excessive bacterial contamination should not be used, as may cause spurious results.

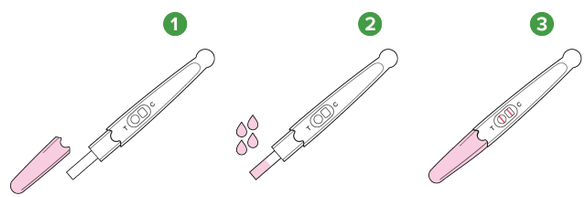
Test Procedure

IMPORTANT Test device, pre-collected urine sample, and controls should be brought to room temperature. (15-30°C; 59-86°F) prior to testing. Do not open pouches until ready to perform the assay.

- Read the Direction for Use carefully prior to performing tests.
- Remove the test device from the sealed pouch and use it as soon as possible.
- Remove the protection cap. (See illustration 1).

For Midstream:

1. Take the test at the assigned handle and hold the absorbent wick into the urine stream for 10-15 seconds. (See illustration 2).
2. Re-cap the protection cap. Place the test on a clean and level surface. (See illustration 3.)



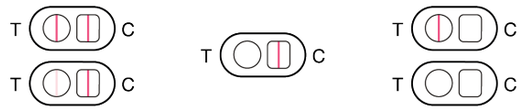
For Dipstick:

1. Dip the test into collected urine sample for 10-15 seconds.
2. Re-cap the protection cap. Place the test on a clean and level surface.

Reading Results:

3. Interpret the result at 3 minutes. Do not interpret test result after 10 minutes.

Results Interpretation



PREGNANT: Two red colored lines are visible; one line in the round test window (T) – Test region, and a second line in the square window (C) – Control region. The color intensity of the test line may be weaker or stronger than that of the control line.
NOT PREGNANT: Only one colored line appears in the square window. This line is just the control line (C).
INVALID: No line appears in the control region (C). Under no circumstances should a positive sample be identified until the control line forms.
NOTE:

1. If there are no colored line visible on both windows after 5 minutes, or if there is only a red colored line visible in the round window (T) – Test region, the test is invalid.
2. Both T and C lines' color intensity may be different, which is normal. If you are not sure about the result at 2-5 minutes because of a very faint line, read the result again at 10 minutes. In many cases, the line intensity increases after this additional period, which makes interpretation easier.

Reliability

- If the test line in the round window is very faint, patient may repeat the test after 3 days using a new device with first morning urine.
- If the test result is "not pregnant", and the period is not occurring, it is recommended to perform another test in 3 days later. In case of positive results, the patients should contact doctor for helpful advices regarding an ideal progress of pregnancy

Quality Control

The Rapid Response™ Midstream Pregnancy Test provide built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless of the presence of hCG in 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.

Limitations

1. Very dilute urine specimens as indicated by low specific gravity may not contain representative levels of hCG. If

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pregnancy is still suspected, a first morning urine sample should be obtained 48-72 hours later and be tested. 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[7], a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.

2. Several conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasm including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG[8-9]. Therefore, the presence of hCG in urine as determined by using the Rapid Response™ Midstream Pregnancy Test should not be used to diagnose pregnancy unless these conditions have been ruled out. 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.

Performance Characteristics

Sensitivity

The analytical sensitivity of the Rapid Response™ Midstream Pregnancy Test is 20 mIU/mL (based on the 4th IRP of HCG). The Rapid Response™ Midstream Pregnancy Test does not show a "high-dose Hook" or "Prozone Effect" up to the maximal observed physiological.

Specificity

The specificity of the Rapid Response™ Midstream Pregnancy Test was determined from cross-reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Negative results were obtained from all tests conducted with 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 mIU/mL hTSH.

Bibliography

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Glossary of Symbols

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

EC REP
MDSS GmbH
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CE

BTNX Inc.
722 Rosebank Road,
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