**Human Chorionic Gonadotropin**

**Rapid Detection Test**

**INSTRUCTIONS FOR USE**

Format: Cassette
Catalog Number: GNM

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**PLEAS READ INSTRUCTIONS BEFORE USE**

**INTENDED USE**

The Genomix Human Chorionic Gonadotropin Rapid Detection Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test provides a visual, qualitative result, and all positive specimens must be confirmed with other qualified assays. The test is intended for healthcare professional use only.

**SUMMARY AND PRINCIPLE OF THE ASSAY**

The Genomix Human Chorionic Gonadotropin Rapid Detection Test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. This assay is conducted by adding urine sample to the sample well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimen results with the specific antibody-hCG colored conjugate to form a colored line at the test region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control region if the test has been performed properly.

**PACKAGE CONTENT**

- Pouch content: Cassette, Dropper, Desiccant.
- Test instruction.

**MATERIAL REQUIRED BUT NOT PROVIDED**

- Sample collection container.
- Clock or timer.

**PRECAUTIONS**

- For professional in vitro diagnostic use only.
- Test device should remain sealed until use.
- Do not use after the expiration date printed on the pouch.
- Keep out of children's reach.
- All samples should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

**TEST PROCEDURES**

1. Remove the testing device from the foil pouch by tearing at the "notch". Then place the testing device on a level surface. DO NOT INTERPRET RESULTS AFTER 20 MINUTES.
2. Holding the Sample Dropper vertically, add two full drops (100 micro liters) of specimen without air bubbles into the sample well marked with an arrow on the testing device.
3. Wait for the pink coloured test band to appear then read the results. Positive results can be read as soon as it appears. Negative results may be confirmed in 20 minutes. Ensure that the background of the test window is white before interpreting the results.

**INTERPRETATION OF THE RESULTS**

- **Positive**
  - Distinct pink color bands appear at the control and test line regions.
- **Negative**
  - Only one pink color band appears on the control region. There is no apparent color band on the test region.
- **Invalid**
  - No visible band at control region. Repeat with a new test device. If test still fails, please contact the distributor with lot number.

**STORAGE AND STABILITY**

- Test device in the sealed pouch can be stored at 2-30°C up to the expiration date. Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

**SPECIMEN COLLECTION AND PREPARATION**

**Urine assay**:
A urine sample must be collected in a clean and dry container. A first morning urine sample is preferred since it generally contains the highest concentration of hCG; however, urine samples collected at any time of the day may be used. Urine samples exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample 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 samples when possible.

**Sample Storage**:
Urine or serum sample may be stored at 2 to 8°C for up to 48 hours prior to testing. For prolonged storage, samples may be frozen and stored below -20°C. Frozen samples should be thawed and mixed before testing.

**LIMITATIONS**

- Very dilute urine samples, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.
- False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine or serum sample should be collected 48 hours later and tested.
- Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum samples shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons (5), a test result that is weakly positive should be confirmed by retesting with first morning urine or serum sample collected 48 hours later.
- This test detects intact hCG only. This test does not reliably detect hCG degradation products, including free-beta subunits and beta-core fragment. Therefore, this test may show reduced reactivity in urine after 8 weeks gestation. This test should not be used to monitor trophoblastic disease or post-partum patients.
- Quantitative assays used to detect hCG may be detecting hCG degradation products, and therefore may disagree with the results of the ICONR25 hCG test.
- 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 (6-7). Therefore, the presence of hCG in urine or serum sample should not be used to diagnose pregnancy unless these conditions have been ruled out.
- 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.
- This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

**MANUFACTURER CONTACT INFORMATION**

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