RESZON

IVD

For use with human urine
For *in vitro* diagnostic use
For home self-testing

Reszon Pregnancy Rapid Test Midstream

REF RPT-RD0302-01

MDA Reg. No.:

INTENDED USE

Reszon Pregnancy Rapid Test Midstream (10 mIU/ml) is a rapid and one-step test for qualitative detection of Human Chorionic Gonadotropin (hCG) hormone in urine specimens. Reszon Pregnancy Rapid Test Midstream (10 mIU/ml) is able to detect equal or greater than 10 mIU/ml hCG in urine samples. It is intended for early detection of pregnancy and suitable for home self-testing.

SUMMARY AND EXPLANATION OF THE TEST

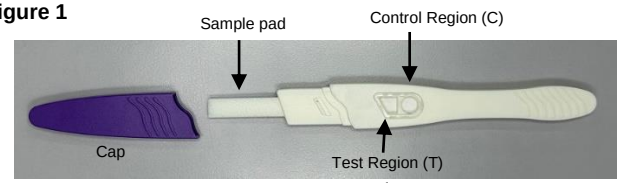
Human Chorionic Gonadotropin (hCG) is a hormone produced by the placental in early stage of pregnancy. In normal pregnancy, hCG can be detected in serum as early as 7 to 10 days following conception. The hormone level doubles every 1.3 to 2 days and may reach 100 mIU/ml at the first missed menstrual period. Appearance and sharp rising of the hCG hormone make it an excellent marker for the early detection of pregnancy. The hormone is also excreted in the urine, thus, allow non-invasive detection of it.

Reszon Pregnancy Rapid Test Midstream is a one-step pregnancy test, which is based on sandwich immunoassay for qualitative detection of human hCG in urine. The method employs a unique combination of dye conjugated monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity. In less than 5 minutes, elevated levels of hCG equal to or greater than 10 mIU/ml can be detected. This level of concentration may be found as early as on the first day of the first missed menses, therefore, allowing early detection of pregnancy.

PRINCIPLE OF THE TEST

As the test sample diffuses through the absorbent test strip, the dye-labeled antibody binds to the hCG in the sample, forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the Reaction Area (Figure 1) and produces a pink-purplish color band at Test Zone (T) on the midstream. In the absence of hCG, there is no "T" band in the Test Zone. Unbound dye conjugate binds to the reagents in the Reaction Area, producing a pink-purplish color at Control Zone (C) on the dipstick, demonstrating that the reagents and test strip are functioning correctly.

Figure 1



Reaction Area

REAGENTS AND MATERIALS SUPPLIED

1. **Reszon Pregnancy Rapid Test Midstream** sealed in individual foil pouch (1 pcs)
2. Instruction for Use (product insert) (1 pc)

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Clock or timer

STORAGE AND STABILITY

Store at 4-30 ºC, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat. Refer to the label for expiry date.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only and suitable for home self-testing.
2. This product insert must be strictly followed in order to produce accurate test results.
3. Avoid cross contamination of urine samples by using a new or clean dry urine collection container for each urine sample.
4. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
5. All test devices, reagents and specimens must be at room temperature (15-30°C) before running the assay.
6. Do not use device if the sealed pouch is visibly damaged.
7. Do not use the kit contents beyond the expiration date.
8. Do no reuse the test device.

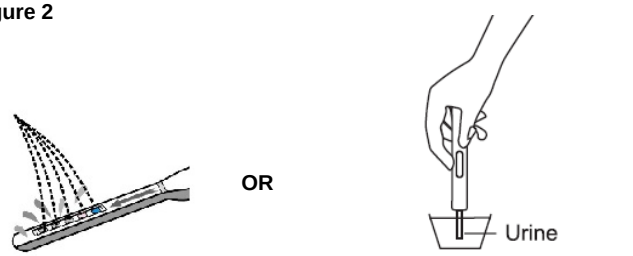
SAMPLE COLLECTION AND PREPARATION

Specimens collected at any time may be used. However, the first morning urine generally contains the highest concentration of hormone.

ASSAY PROCEDURE

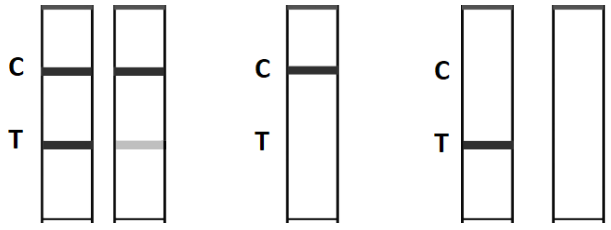
1. Open foil pouch only when ready to use. Tear the pouch at the notch and remove the midstream from the pouch.
2. Hold the midstream by the handle with the exposed tip pointing downward, directly into your urine stream for at least 15 seconds until it is thoroughly wet. Alternatively, you can collect your urine in a clean container and dip only the tip of the midstream into the urine for at least 15 seconds. See the illustration (Figure 2) below.
3. After removing the midstream test from your urine, immediately replace the cap over the tip and lay the midstream flatly on a non-absorptive clean surface.
4. Read results after three (3) minutes (see Interpretation of Results). ***NOTE***: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time. Do not interpret the result after 10 minutes.
5. Flush the remaining urine sample down the toilet. Discard remaining components in the waste.

Figure 2



Immerse for at least 15 seconds

INTERPRETATION OF RESULTS



Positive (Pregnant) | **Negative** | **Invalid**

1. Any intensity of band observed should be considered as present of the band.
2. In 3-5 minutes, a pink-purplish band will appear in the "C" control region of the dipstick, indicating that the test is completed.
3. **Positive (pregnant)**: pink-purplish band appears at the "C" region and "T" region.
4. **Negative (not pregnant)**: Only one pink-purplish colored band appears at the "C" region.
5. **Invalid**: Absence of band in both regions, or only band at the "T" region, is an indication of procedure error and/or the test device has deteriorated. Repeat the assay using a new test dipstick.

QUALITY CONTROL

Each test strip has its own built-in quality control indicator. If after performing the test and no line is visible in the Reaction Area, you may have added the urine sample in the wrong position or the test device may have deteriorated. Repeat the assay using a new test device.

LIMITATIONS OF THE TEST

1. This product is designed for use with human urine only.
2. The test is a qualitative screening assay and is not for determining quantitative concentration level of hCG.
3. In the early stages of pregnancy, hCG levels will be low. When a negative result is obtained and pregnancy is still suspected, first morning urine specimen should be collected 48 hours later and tested.
4. Trophoblastic diseases such as choriocarcinorma or hydatidiform mole secrete hCG and can give positive results in the absence of pregnancy.
5. Abnormal pregnancies, especially ectopic pregnancy may produce levels of hCG below the sensitivity of this assay in the early stages of pregnancy and give negative results.
6. 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.

WARRANTY AND LIMITED LIABILITY

The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

PERFORMANCE CHARACTERISTICS

Clinical performance

The Reszon Pregnancy Rapid Test Midstream (10 mIU/ml) is able to detect equal or greater than 10 mIU/ml hCG in urine as indicated by the development of two bands in the Reaction Area. Both sensitivity and specificity of the test is 100%.

Urine from healthy man and non-pregnant women will normally show undetectable levels of hCG when tested with Reszon Pregnancy Rapid Test. The test will yield a positive result on the first day of missed menstrual period.

Usability Study

A usability study was conducted with the enrolment of 120 lay users who were instructed to self-collect their urine samples. The sensitivity and specificity of the test were 98.89% and 100% respectively. The overall feedback from lay users was that the test was user-friendly and easy to use.

Menopausal Urines

A study was performed using urine specimens from 20 postmenopausal women. These specimens were chosen because urine from postmenopausal women frequently interferes with pregnancy tests due to cross reactivity with other gonadotropin hormones. All 20 urine specimens were negative when tested with the Reszon Pregnancy Rapid Test.

Cross-reactivity

No cross reactivity with Reszon Pregnancy Rapid Test was detected from 1000 mIU/ml of Follicle Stimulating Hormone (hFSH), 300 mIU/ml of Luteinizing Hormone (LH), and 1000 mIU/ml of Thyroid Stimulating Hormone (hTSH).

Interference Testing

The following potentially interfering substances were added in hCG free and 25 mIU/ml hCG spiked urine samples. None of the substances tested shows interference with the assay.

Analyte	Concentration	Analyte	Concentration
Acetaminophen	20 mg/dl	EDTA	20 mg/dl
Acetoacetic Acid	20 mg/dl	Ethanol	1%
Ascorbic Acid	20 mg/dl	Gentisic Acid	20 mg/dl
Atropine	20 mg/dl	Glucose	2000 mg/dl
Acetylsalicylic Acid	20 mg/dl	Hemoglobin	1 mg/dl
Albumin	2000 mg/dl	Methadone	10 mg/dl
Ampicillin	20 mg/dl	Methanol	10 %
Bilirubin	2 mg/dl	Phenylpropanolamine	20 mg/dl
Caffeine	20 mg/dl	Phenothiazine	20 mg/dl
Codeine	10 mg/dl	Salicylic Acid	20 mg/dl
Ephedrine	20 mg/dl	Tetracycline	20 mg/dl

FREQUENTLY ASKED QUESTIONS

1. How does the test work?
   The test detects the human chorionic gonadotropin hormone (hCG) in urine that the body produces during pregnancy.
2. Do I have to test with first morning urine?
   You can test at any time of the day, however, the first morning urine generally contains the highest concentration of hormone.
3. How accurate is the test?
   The test is more than 99% accurate in clinical tests when used from the day of expected period.
4. How do I know whether the test was run properly?
   The Control line should appear which shows that you have followed the test procedure properly and the proper amount of urine was absorbed.
5. Can any medication or medical conditions affect the result?
   Fertility drugs that contain hCG may cause misleading and false positive result.
6. What should I do if the test result shows that I am pregnant?
   You should consult your doctor for result confirmation and further steps.
7. What should I do if the test result shows that I am not pregnant?
   You may not be pregnant or the level of the hormone is too low to be detected or you may have miscalculated the day of expected period. If your period is overdue, test again in 3 days' time. If you still get negative result and still have not had period, consult your doctor.

REFERENCES

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EXPLANATION OF SYMBOLS

REF Catalogue number	IVD For *in vitro* diagnostic use	Contains sufficient for <n> tests	Single use	Manufacturer
LOT Batch code / Lot number	Manufacturing Date (yyyy/mm)	Expiry Date (yyyy/mm)	Consult instruction for use	Temperature limitation (4°C-30°C)

ORDER INFORMATION

Product Code	*Description*	*Packing Size*
RPT-RD0302-01	Reszon Pregnancy Rapid Test Midstream (10 mIU/ml)	1 test / kit

MANUFACTURER
Reszon Diagnostics International Sdn. Bhd.
No. 12A, Jalan TP5, Taman Perindustrian UEP, 47600 Subang Jaya, Selangor, Malaysia.
Tel: +603-8022 1162
Email: info@reszonics.com | Website: www.reszonics.com

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