ENGLISH

RESZON

# PREGNANCY Rapid Test Midstream IVD

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

REF RPT-RD0302-01

MDA Reg. No.: IVDB3556123-155383

**Read this instruction carefully before taking a test.**

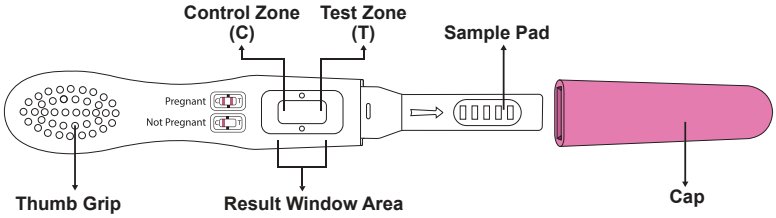
**ULTRA-SENSITIVE** for early detection of pregnancy

Use the **FIRST URINE** of the day if testing early

**CHECK** the expiration date and only open the pouch once ready to test

**DO NOT** drink a lot of fluids before testing

## KNOW YOUR MIDSTREAM TEST DEVICE

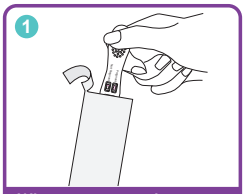



## BEFORE YOU BEGIN

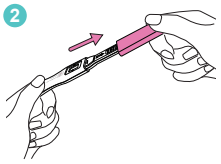
You may find it helpful to have a watch or clock with you when doing the test.

## TAKE THE TEST & DO IT RIGHT

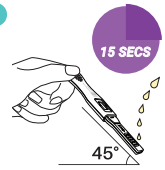
1. When you are ready to test, tear the foil pouch at the notch and remove the midstream device from the pouch.



2. Take the cap off.

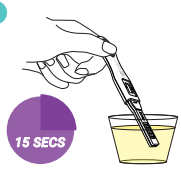


3. Hold the midstream device above the thumb grip at 45° angle / slanting position while peeing directly on it for 15 seconds.

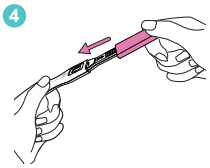



OR

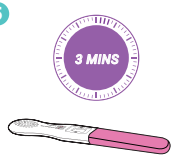
3. Alternatively, you could also collect urine in a clean, dry container / cup & dip the sample pad area in the cup for 15 seconds.




4. Remove the midstream device from urine. Put the cap on & keep the device on a clean,flat surface.



5. Read results after 3 minutes.




## READ YOUR RESULT

In 3-5 minutes, a pink-purplish band will appear in the "C" control zone of the midstream, indicating that the test is completed. Any intensity of band observed should be considered as presence of the band.

! 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.**

## DISPOSAL

Flush the remaining urine sample down the toilet. Discard remaining components in the waste.

## RESULT INTERPRETATION

| Positive (Pregnant) | Negative (Not Pregnant) | Invalid |
|---|---|---|
|  Pink-purplish band appears at the "C" region and "T" |  Only one pink-purplish colored band appears at the "C" region. |  Absence of band in both regions, or only one band at the "T" region is an indication of procedure error and/or the midstream test device has deteriorated. Repeat the assay using a new midstream test device. |

## 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 not 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.

## 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

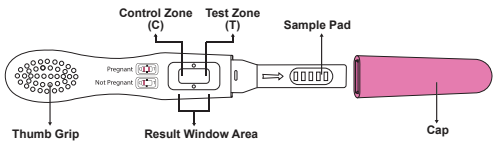
Human Chorionic Gonadotropin (hCG) is a hormone produced by the placental in early stage of pregnancy. In normal pregnancy, hCG can be detected in serum as early as 7 to 10 days following conception. The hormone level doubles every 1.3 to 2 days and may reach 100 mIU/ml at the first missed menstrual 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 (10 mIU/ml) 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 Result Window 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 Result Window 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**




## Reagents and Materials Supplied

1. Reszon Pregnancy Rapid Test Midstream (10 mIU/ml) sealed in individual foil pouch (1 pc)
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.

## 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 Result Window 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

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 Result Window 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 (10 mIU/ml). 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 postmenopasal 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 Reszon Pregnancy Rapid Test Midstream (10 mIU/ml).

### Cross-Reactivity

No cross reactivity with Reszon Pregnancy Rapid Test Midstream (10 mIU/ml) 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).

### Interfering Substances

The following potentially interfering substances were added in hCG free and 10 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 |

## References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2. Lenton, E.A., Neal, L.M., Sulaiman, R. (1982). Plasma concentrations of human chorionic gonadotropin from the time of implantation until the second week of pregnancy. Fertility & Sterility, 37: 773.
3. Batzer, F.R. (1980) Hormonal Evaluation of Early Pregnancy. Fertility & Sterility, 34: 1.
4. Engvall, E. (1980) Enzyme Immunoassay ELISA and EMIT. Method in Enzymology, 70: 419-439.
5. Uotila, M., Ruoslahti, E., and Engvall, E. (1981) Two-site sandwich enzyme immunoassay with monoclonal antibodies to human alpha-fetoprotein. J. Immunol. Methods., 42: 11-15.
6. Jovanovic, L., Dawood, M.Y., Saxena, B.B., and Landesman, R. (1978). Hormonal profile as a prognostic index of early threatened abortion. Am. J. Obstet. Gynecol., 130(3):274-8.
7. Larsen, J. et al. (2013) Human chorionic gonadotropin as a measure of pregnancy duration. Int. J. Gyn & Obstertrics.,123: 189-195.
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## Explanation of Symbols

| | | | | |
|---|---|---|---|---|
| REF Catalogue number | IVD For *in vitro* diagnostic use | Number of test | 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) |

## Ordering 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.**
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*Queries & Feedback*

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**www.reszonics.com**