BTNX INC.

Rapid Response®

LH Ovulation Test Strip
(Urine)

REF LH-1S-07 Product Insert

For professional use only.

Intended Use

The Rapid Response® LH Ovulation Test Strip is a rapid visual immunoassay for the qualitative, presumptive detection of luteinizing hormone in human urine specimens. This kit is intended for use as an aid in the detection of ovulation.

Introduction

While a woman's body always produces a small amount of human luteinizing hormone (LH), there is a sudden increase of this hormone during the middle of the menstrual cycle. This increase of the LH level, called the LH surge, promotes the release of a mature egg from the ovaries (ovulation). For most women, ovulation will occur within 24-36 hours after the peak of the LH surge. Immediately after ovulation, the egg is capable of being fertilized for a short time (approx. 12 hours). With the Rapid Response® LH Ovulation Test Strip, the LH surge will be detected in urine within 6 days. The fertile days of the menstrual period start after this LH surge.

Principle

The Rapid Response® LH Ovulation Test Strip detects human luteinizing hormone through visual interpretation of color development on the strip. Anti-LH 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-LH antibody 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 LH in the specimen, a colored line will form at the test region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result. The appearance of a colored line 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 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 any area where 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.

Materials

Materials provided

- Individually packed test strip
- Package insert

Materials required but not provided

- Specimen collection container
- Timer
- Centrifuge

Storage and Stability

- The kit should be stored at (35.6-86°F; 2-30°C) 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 in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Initial Testing Date

The initial testing date for a complete 6 day window depends on the length of the last normal menstrual cycle. The first day when bleeding begins in the menstrual period is counted as day 1. The chart below demonstrates the correlation between the starting day and a typical menstrual cycle.

Monthly Cycle (in Days)	Start on this day with the first test of the kit
26	10
27	10
28	11
29	11
30	12
31	12
32	13
33	13

If the menstrual cycle is shorter or longer than shown in the chart above, a physician should be consulted to determine the optimum day to start testing.

Example:

Mon	Tue	Wed	Thu	Fri	Sat	Sun
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Beginning of last period
The day you begin testing

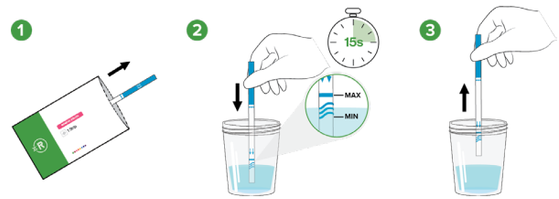
Collection and Storage of Specimens

- The Rapid Response® LH Ovulation Test Strip is intended for use with human urine specimens only.
- Choose a convenient time of the day to collect urine. Reduce liquid intake approximately 2 hours prior to urine collection. Try to collect urine at about the same time each day for the entire cycle.
- **Do not collect the first urine specimen after waking up.**
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Urine specimens must be collected in clean, dry containers. Ensure that the quantity of the specimen collected is sufficient to submerge the dip region of the test strip.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 35.6-46.4°F (2-8°C) for up to 24 hours. Do not freeze. For best results, test urine on the same day that it is collected.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

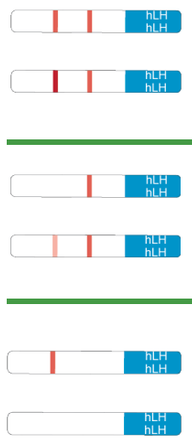
Test Procedure

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

1. Remove the test from its sealed pouch and use it as soon as possible. For best results, the assay should be performed within one hour.
2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane.
3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. As the test begins to work, color will migrate across the membrane.
   After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.



Results Interpretation



POSITIVE RESULT:
Two colored lines appear on the membrane. The color intensity of the test line (T) is the same as or stronger than that of the control line (C). This indicates probable ovulation within the next 24-36 hours.

NEGATIVE RESULT:
One colored line appears, in the control region (C). No test line appears, or the test line (T) is less intense than the control line (C). This indicates that no LH surge has been detected and daily testing should continue.

INVALID RESULT:
Control line fails to appear. Results from any test which has not produced a control line 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 LH present in the specimen. Therefore, in cases of weak T bands, indicating a negative result, LH has been detected by the test but it is below the level of an LH surge.
2. Not every woman ovulates mid-cycle, therefore, a positive result may not appear during the selected days of testing.
3. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. The appearance of a colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms 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

- Test results cannot be used as an aid for contraception.
- The test should not be used:
  - During pregnancy
  - After the onset of menopause
  - After and during hormone treatment
- The use of certain pain relievers, antibiotics and other common medicines can produce incorrect results.
- The menstrual cycle can be irregular after discontinuing the use of certain medicines containing LH or human chorionic gonadotropin (hCG). Therefore, two regular menstrual cycles should take place before testing.
- Some diseases (e.g. inflammation of the ovaries or hormonal imbalance) can produce false results. In such cases a physician should be consulted.

Performance Characteristics

Accuracy

Studies show that the Rapid Response® LH Ovulation Test Strip has a cut-off concentration of 30 mIU/mL LH in urine. The Rapid Response® LH Ovulation Test Strip shows 98.7% accuracy in detecting LH surges.

Cross Reactivity

The following hormones do not give positive results at the listed concentrations:

hCG	200 µIU/mL
hFSH	200 µIU/mL
hTSH	200 µIU/mL

None of the following substances interfered with the assay at the listed concentrations:

p-Acetaminophenol	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic acid	20 mg/dL

Bibliography

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6. Braunstein GD et al. Ann Inter Med. 78: 39-45
7. Engvall E. Methods Enzymol. 1980; 70: 419-439.
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Glossary of Symbols

Consult instructions for use

Test per Kit

Do Not Reuse

Store between 35.6°F to 86°F

Use by

REF Catalogue #

LOT Lot Number

IVD For *in vitro* diagnostic use only

EC REP Authorized Representative

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