## INTENDED USE

The SHD LH Ovulation Test is a rapid visual immunoassay for the qualitative, presumptive detection of Human Luteinizing hormone (LH) in urine to predict time of ovulation. For self testing and in vitro diagnostic use only.

## SUMMARY

Ovulation is the release of an egg from the ovary. The egg passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH). This is known as the "LH surge" and usually takes place in the middle of the menstrual cycle. LH triggers the release of an egg from the ovary.

SHD LH Ovulation Test is a complete system to help you predict the time of ovulation and peak fertility. It is during this fertile time that pregnancy is most likely to occur. SHD LH Ovulation Test detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24 – 36 hours.

**Important:** the LH surge and ovulation may not occur in all cycles.

## PRINCIPLE

SHD LH Ovulation Test is a rapid chromatographic immunoassay for the qualitative detection of Luteinizing Hormone (LH) in urine to aid in the detection of the onset of ovulation. The test utilizes a combination of antibodies including mouse monoclonal anti-LH antibodies and goat polyclonal anti-mouse antibodies to selectively detect elevated levels of LH. The assay is conducted by adding urine specimen to 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 specimens react with the specific colored antibody conjugates and form a darker or equal dark colored line at the test line region of the membrane compared to the control region. Absence of this colored line or the colored line lighter than the control line suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

## PRECAUTIONS

- For in vitro diagnostic use only.
- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labelled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Region.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test strip. Discard it in the dustbin after testing.
- All urine specimens and used strip should be considered potentially infectious and avoided contact with skin.

## STORAGE & STABILITY

- The kit should be stored at 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 of the 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.

## SPECIMEN COLLECTION and PREPARATION

A fresh urine specimen should be used, no special pre-treatment is necessary. Specimens should be collected in a clean glass or plastic container.

Once you have identified what day you should begin testing you should then begin to collect your urine on a daily basis.

1. Do not use first morning urine samples as LH is synthesized in your body early in the morning. It will not show up in your urine until later in the day.
2. The best time to collect your urine is between 10am - 8pm. Pick a regular time that suits you best.
3. Collect urine at about the same time each day. Reduce liquid intake about 2 hours before collecting your urine as a diluted urine sample can prevent the test from detecting LH surge.

Urine samples may be stored for later testing within the same day. Urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze. For the best result, test the urine sample on the same day of collection. If sample has been previously refrigerated, let it equilibrate to room temperature before testing (about 30 minutes). Do not shake the collection container. If sediment forms at the bottom of the collection container, allow the sediment to settle. Only test urine from the top of the container.

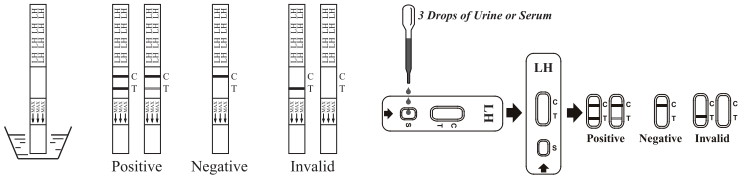
## LIMITATIONS

1. The test works only when the test procedures are precisely followed from the test insert.
2. Do not reuse the test kit. It is strictly for one time use.
3. This test is not be used as a form of birth control.
4. The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using this one step ovulation test. In addition, the test will not work properly if the urine sample is from a person who is pregnant, menopausal, or taking birth control pills.

## DIRECTIONS for USE

Allow the test and the specimen to equilibrate to room temperature (15-30°C) prior to testing

1. Determine the day to begin testing.
2. Collect urine sample in a clean and dry container.
3. To begin testing, open the sealed pouch and remove the test cassette and Pipette. Do not remove the cassette until you are ready to begin testing.
4. Place the test Cassette laterally on a flat and clean surface. Draw 0.2ml (about 4 drops) sample into the pipette, and dispense it into the sample well on the cassette.
5. Wait for coloured bands to appear. Depending on the concentration of LH in the urine specimen, positive results may be observed in as short as 40 seconds. However, to confirm negative results, the complete reaction time of 10 minutes is required. Do not read results after 30 minutes.




## INTERPRETATION of RESULTS

After each test, you must decide if you are having a L.H. surge. To determine your result, you must compare the colour intensity of the test band to the control band. The control band is used to compare the test band against and also confirms that you have completed the test correctly.

**Positive for L.H. surge:** If two colour bands are visible and the test band is of almost equal or greater colour intensity (darker) than the control band, this is a positive result and a good indication that the L.H. surge is occurring. You should ovulate within the next 24-36 hours. Sexual intercourse is advised at any time after the first positive test.

**Negative for L.H. surge:** If two bands are visible but the test band is of a less intense colour (paler) than the control band or cannot be seen, this means the L.H. level is at or near its normal level and that the surge is not in progress. You should continue with daily testing.

**Invalid result:** If no control band appears within 5 minutes, the result is invalid and should be ignored. A visible control line is needed in all cases to confirm a proper test result. Repeat test with a new test kit.

## Index or Symbols

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| | Attention, see instructions for use | Σ 1 | Tests per Kit | | Manufacturer |
| IVD | For *in vitro* | | Use by | 2 | Do not reuse |
| | Store between 2 - 30°C | LOT | Lot Number | REF | Catalogue Number |

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