

# Ovulation Test

## Package Insert

REF SFLH 103-5 (5 Tests) English  
For Self Testing

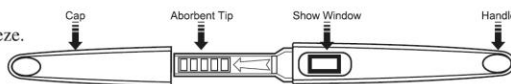
### PRINCIPLE

Ovulation is the release of an egg from the ovary. The egg then 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) which triggers the release of a ripened egg from the ovary. This is known as an "LH Surge", and usually takes place in the middle of the menstrual cycle. It is during this fertile time that pregnancy is most likely to occur. It is important to note that an LH surge and ovulation may not occur in all cycles. The Ovulation Test is a rapid, one-step lateral flow immunoassay for the qualitative detection of LH surges in urine, signalling that ovulation is likely to occur in approximately 30 hours. The test utilises a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH. The test is conducted by urinating on the absorbent tip and obtaining the result from the coloured lines.

### PRECAUTIONS

Please read all the information in this package insert before performing the test. Pay particular attention to the position of the C and T lines

- Do not use after the expiration date printed on the foil pouch
- Store in the sealed pouch in a dry place at 4-30°C. Do not freeze.
- Do not use if pouch is torn or damaged.
- Do not open the foil pouch until you are ready to start the test.
- Do not reuse the test device. Dispose of hygienically in domestic waste.
- Do not touch the membrane located in the windows.
- Treat urine samples and used devices as potentially infectious. Avoid contact with skin.
- Keep out of the reach of children.
- For *in vitro* diagnostic use. Not to be taken internally. Do not eat the desiccant in the package.



### KIT CONTENTS

- 5 Midstream Tests (each in foil pouch)
- Package insert

### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Disposable gloves

### WHEN TO START TESTING

This kit contains 5 tests allowing you to test over several days to find your most fertile time. Calculate when to start testing using the chart below. Determine the length of your menstrual cycle by counting the number of days from the first day of your period (menstrual bleeding) to the last day before your next period starts. Think back over the last few months to decide what your usual cycle length has been. On the chart below, read the day to start testing corresponding to your cycle length.

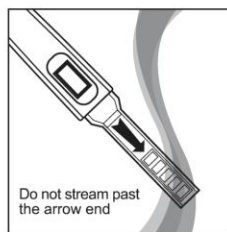
When to Start Testing Chart

| Menstrual cycle length | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 |
|------------------------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| Start test on day      | 5  | 6  | 7  | 7  | 8  | 9  | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 |

**Note:** If you are unsure about your cycle length, you may want to use your shortest cycle length when reading the chart. However, if you do this, you may need to test for more than 5 days.

### INSTRUCTIONS

- Allow the Ovulation Test to reach room temperature (15-30°C) before opening the foil pouch
- Remove the Ovulation Test from the pouch and use it as soon as possible.
- Remove the cap to expose the absorbent tip.
- Hold the test by the thumb grip with the exposed absorbent tip pointing downwards. Urinate on the absorbent tip until it is thoroughly wet (about 2-3 seconds). See illustration at right.  
**NOTE: Do not allow urine to come into contact with the Result window.**
- Lay the test down on a flat surface with the window on top and wait for the red line(s) to appear.
- Read the result after 10 minutes. Do **not** read the result after 15 minutes.



### READING THE RESULTS

#### POSITIVE

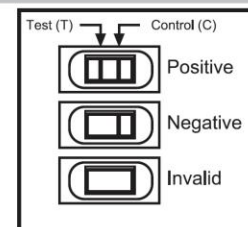
Two lines are visible and the Test Line (T) is the same as or darker than the Control Line (C). This indicates that the urine sample has been taken within 24-36 hours of the LH surge.

#### NEGATIVE

Two lines may be visible but the Test Line (T) is lighter than the Control Line (C). Alternatively, the Test Line is not visible. This indicates that the LH surge has not been detected. You should continue daily testing.

#### INVALID

The result is invalid if the Control Line (C) fails to appear. Insufficient volume of urine or incorrect procedure is the most likely reason for an invalid result. Review the procedure and repeat the test with a new test kit. If the problem persists, discontinue using the test kit and contact the Customer Care Line below.



### QUALITY CONTROL

A red-purple line appearing in the control region (C) confirms that the test is performing properly. It indicates that sufficient urine has been applied to the absorbent tip and that the correct procedure has been carried out.

### LIMITATIONS

- The reagents used in the test cross-react with human chorionic gonadotropin (hCG). The test is only intended for the detection of LH in hCG-free samples.
- The test will not work properly if you are pregnant, menopausal, or taking birth control pills.
- Women suffering from polycystic ovary syndrome may have elevated LH concentrations.
- Test results should not be affected by common pain relief medication.
- Antibiotics containing hCG or LH may affect the test results.
- Do **NOT** take any medical decision based on the results of this test without consulting your doctor.
- The Ovulation Test is not reusable.

### QUESTIONS & ANSWERS (Call our Customer Care Line 0800 0430318)

#### 1. Q: Can I use the Ovulation Test to avoid pregnancy?

A: No, the test should not be used as a form of birth control.

#### 2. Q: How accurate is the Ovulation Test?

A: The accuracy of the test is 99%

#### 3. Q: How sensitive is the Ovulation Test?

A: The test detects LH in urine at concentrations of 35mIU/mL or higher. Addition of the hormones FSH (200mIU/mL) and TSH (200KIU/mL) to urine samples did not interfere with the expected test results.

#### 4. Q: Do common medications affect the test?

A: No, but you should consult your doctor if you are taking any hormonal medication. Also, recent oral contraceptive use or pregnancy can affect the test results. At the concentrations shown, none of the following substances affected the test results: Acetaminophen (Paracetamol 20mg/dL), Acetylsalicylic acid (Aspirin 20mg/dL), Ascorbic acid (Vitamin C 20mg/dL), Atropine (20mg/dL), Caffeine (20mg/dL), Genticic acid (20mg/dL), Glucose (2g/dL) and Haemoglobin (1mg/dL).

#### 5. Q: What time of day should I perform the test?

A: Test at about the same time each day for the entire cycle.

#### 6. Q: How long will the lines remain visible?

A: You should read the results after 10 minutes. Do not read the results after 15 minutes as they may give you false information.

#### 7. Q: Once I see a positive result, when is the best time to have intercourse?

A: Ovulation is likely to occur within approximately 30 hours. This is your most fertile time and intercourse is advised within this time frame.

|  |                                     |
|--|-------------------------------------|
|  | Attention, see instructions for use |
|  | For <i>in vitro</i> use only        |
|  | Store between 4 - 30°C              |

|  |               |
|--|---------------|
|  | Tests per kit |
|  | Use by        |
|  | Lot Number    |

|  |               |
|--|---------------|
|  | Manufacturer  |
|  | Do not re-use |
|  | Catalogue #   |



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