AG- OVULATION (LH) RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene Ovulation (LH) Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of luteinizing hormone (LH) in urine to aid in the detection of ovulation.

PRINCIPLE

AstraGene Ovulation (LH) Rapid Test Kit is a rapid lateral flow immunoassay for the qualitative detection of hLH surges in urine, signaling that ovulation is likely to occur in the next 24-36 hours.

The test utilizes a combination of antibodies including a monoclonal hLH antibody to selectively detect elevated levels of hLH. The urine sample moves forward laterally on the test due to capillary forces. In the presence of hLH an immunological reaction between hLH and labeled anti-hLH antibodies takes place leading to a distinct red colored test line. Depending on the hLH concentration, the test line becomes lighter or darker. Other labeled antibodies from the control line. This reaction serves as a proof for the proper use and function of the test strip. This methodology is named immunochromatography.

PACKAGE CONTENTS

Kit content	**Cassette**	
Description	**1 test**	**10 tests**
Test Card with Desiccant	1	10
IFU	1	1

Catalogue Number	**10 tests**	**1 test**
Cassette Model	AG/RTK/LH/23/01	AG/RTK/LH/23/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Sample Collection Container
- Dropper
- Clock or timer.
- Latex gloves

STORAGE &STABILITY

Store as packaged in the sealed pouch at 2-30ºC. The test is stable until the expiration date marked on its sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- Determine the optimal time for urine collection. For best results, collect urine at about the same time each day. Some women have found that their best specimen is after 12 noon. Do not collect the first urine specimen after waking up.
- Reduce liquid intake approximately 2 hours prior to urine collection.
- Record the date, cycle day and time of urine collection. See the TEST RESULTS CHART at the end of this package insert.
- Urine can be stored at room temperature for up to 8 hours or at 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 refrigerated, let urine reach room temperature before testing. Do not shake the container. If a sediment forms at the bottom of the collection container, allow the sediment to settle. Use only urine from the top of the container.

WHEN TO START TESTING

- First, determine the subject's Menstrual Cycle Length. The Menstrual Cycle Length is the number of days from the first day of the subject's period (menstrual bleeding) to the last day before the next period starts.
- Next, determine the Days to Count Ahead after the period to start testing. Find the subject's Menstrual Cycle Length on the first row of the chart below, and read the corresponding Days to Count Ahead in the second row. This is the number of days after the period to begin testing.

Menstrual Cycle Length

21	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**
6	6	7	7	8	9	10	11	12
30	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**
13	14	15	16	17	18	19	20	21

Days to Count Ahead

- Finally, determine the day to start testing. Starting from and including the first day of the last period, count ahead the number of days indicated in the previous step. This is the day on which testing should begin. As a basic guideline, it is recommended to test once a day for five days.
- Note: If uncertain about the length of the subject's menstrual cycle, use the shortest menstrual cycle length (21 days) when reading the chart. In this case, it may be necessary to test for more than 5 days.

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- Example: The subject's usual menstrual cycle length is 28 days. The chart indicates to count ahead11 days from the subject's last period. The subject's last period started on the 3rd. Starting from and including the 3rd, count ahead 11 days to arrive at the 13th. Urine collection and testing should start on the 13th and proceed through the 17th. (See the Example Specimen Calendar below).

Example Specimen Calendar

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	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			

()—First day of the period
<>--Being test with the Ovulation (LH) Rapid Test (Urine)

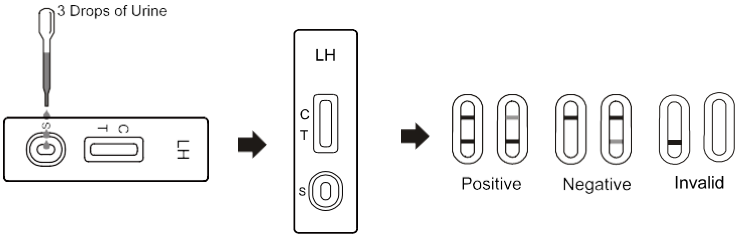
PROCEDURE

Allow the test, urine specimen and/or controls to reach room temperature (15-30°C) prior to testing.

- Determine the day to begin testing. (See the above section: "WHEN TO START TESTING").
- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour.
- Place the test cassette on a clean and level surface. Hold the sample dropper vertically and transfer 3 drops of urine to the specimen well of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration below.
- Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not interpret the result after 10 minutes.

RESULT INTERPRETATIONS

- **POSITIVE:** Two colored lines are visible, but the line in test line region (T) is the same as or darker than the one in the control line region (C). This indicates probable ovulation in 24-36 hours.
- **NEGATIVE:** Two colored lines are visible, but the line in the test line region (T) is lighter than the one in the control line region (C), or if there is no line in the test line region (T). This indicates that no LH surge has been detected.
- **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



PERFORMANCE CHARACTERISTIC

Laboratory studies show that the sensitivity of the AstraGene Ovulation (LH) Rapid Test Kit is 25 mIU/mL and the accuracy is 99.0%.

INTERFERENCE SUBSTANCE

AstraGene Ovulation (LH) Rapid Test Kit has been tested with commonly known drugs and hormones including FSH (1,000 mIU/mL), TSH (1,000µIU/mL). At the levels tested, none of these substances interfered with the expected test results.

LIMITATION OF THE PROCEDURE

- For professional in vitro diagnostic use only.
- This test may not be used as a form of birth control.
- 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 the Ovulation (LH) Rapid Test (Urine). In addition, the test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
- Keep out of the reach of children.

WARNING AND PRECAUTION

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- The test should remain in the sealed pouch until ready to use.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the

procedure and follow the standard procedures for proper disposal of specimens.

- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

SYMBOLS

 Do not use if package is damaged  Manufacturer  Batch Code

 CE mark of Conformity  Refer to the instructions  ISO  GMP

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