

PATHKITS

Product Code: **PKRK019**

Kit Contents: **5, 10, 15, 25, 50, 100 kits**

Shelf Life: **24 months**

Kit Components	Quantity
Aluminum pouches containing 1 Test and 1 Desiccant	5, 10, 15, 25, 50, 100
IFU	1

Introduction

Luteinizing hormone (LH) is a hormone produced by gonadotropic cells in the anterior pituitary gland. Presence of LH dramatically increases in the urine of normal women in the middle of the menstrual cycle. The elevated level of LH triggers ovulation which is when the egg is released periodically from Normal fertile women. Ovulation will occur after 24-48 hours following a positive test.

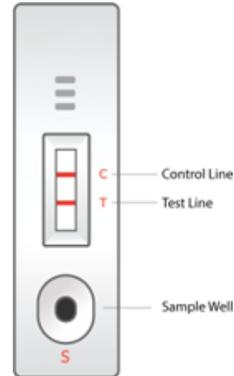
Intended Use

PregAtHome Ovulation Kit 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.

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, sperm must fertilize the egg 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" usually takes place in the middle of the menstrual cycle. It is during this fertile time that pregnancy is most likely to occur. Ovulation test detects LH surge in urine, signaling that ovulation is likely to occur in the next 24-48 hours. This period is considered to be the most fertile time. It is important to note that an LH surge and ovulation may not occur in all cycles.

PregAtHome Ovulation Kit



Precautions

- Please read all the information in this leaflet before performing the test.
- If the package is not completely sealed do not use the test
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test window. This could affect results and may also impose personal hazards.
- Do not use it after the expiration date printed on the foil pouch.
- Do not freeze.
- Keep out of the reach of children.
- For in vitro diagnostic and self-testing use. Not to be taken internally.
- Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
- The pouch contains a Silica Gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
- At the end of the test, wrap everything you have used in a plastic bag and throw away in the bin. Do not forget to wash your hands properly.

Storage and Stability

The kit can be stored at room temperature or refrigerated (2-40°C). Stable until the expiration date stated on the label when stored in an unopened vacuum package at 2-8°C. Opening the vacuum package may affect the test performance. DO NOT FREEZE!

When to Test

When to start testing chart

Length of your cycle (Days)	Start testing this many days after your period began
21	5
22	5
23	6
24	7
25	8
26	9
27	9
28	9
29	9
30	10
31	10
32	10
33	12
34	13
35	14
36	15
37	16
38	17
39	18
40	19

Simple Ovulation test midstream allows you to test over several days to find your most fertile time. Calculate when to start testing using the chart to the left as follows:-

1. First, calculate the length of your average menstrual cycle. Your menstrual cycle length is the number of days from the first day of your period

(menstrual bleeding) to the last day before your next period starts.

2. Circle your usual cycle length on the When to start testing chart. Note: if your cycle is irregular, you may want to use your shortest cycle length when reading the chart.
3. Count ahead days on the calendar according to the length of your cycle as specified in the "Start testing this many days after your period began" column in the "When to start testing" chart.
4. Start counting on the calendar beginning with the first day of your period.
5. Repeat the test on a daily basis (at the same time) until a surge is observed (test positive).
6. First morning urine should not be used when testing for LH. For best results, you should test around the same time each day for example, between 10:00AM and 8:00PM. You should reduce your liquid intake approximately 2 hours prior to testing.

Example: My usual cycle length is 28 days. My last period started on the 3rd. The "When to Start testing Chart" shows that I will count ahead 9 days beginning with the 3rd. When I count 9 days ahead on the calendar, I find that I will collect and test my urine starting on the 11th".

Sample Calendar

S	M	T	W	T	F	S
	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			

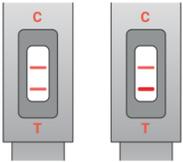
	First day of your period
	Begin testing with the test

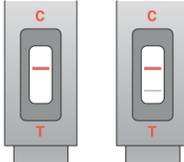
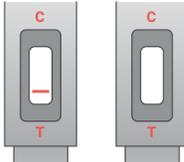
Test Procedure

1. Read instructions carefully before use.
2. Determine the day you will begin testing. (See the above section: "When to test").
3. Check that the test is completely sealed and bring the pouch to room temperature before opening it.
4. Remove the midstream test from the foil pouch and familiarize yourself with the product. See the illustration above.
5. Remove the Cap and hold the midstream test by the handle with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.
Note: Do not urinate on the Result Window. If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream test into the urine for at least 10 seconds.
6. After removing the midstream test from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream test on a flat surface with the Result Window facing upward, and then begin timing.

As the test begins to work, you may notice a light red flow moving across the Result Window. Wait for the red line(s) to appear. **Read results in 1 - 5 minutes.** It is important that the background is clear before the result is read. Positive results may be observed in 1 to 5 minutes depending on the concentration of LH. Do not read the result after 10 minutes.

Test Results

	<p>Positive <u>Positive results: 2 lines with (T) line is the same or darker than (C) line.</u> Two lines are visible and the test line (T) is the same as or darker than the control line (C). This indicates that you will probably ovulate in 24-36 hours.</p>
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	<p>Negative <u>Negative results: 2 lines with (T) line are lighter than (C) line or one line in the (C) area.</u> Two lines are visible, but the test line (T) is lighter than the control line (C), OR test line (T) does not appear. This indicates that no LH surge has been detected and daily testing should be continued.</p>
	<p>Nvalid <u>Invalid results = no lines or 1 line in the (T) area.</u> The result is invalid if the control line (C) fails to develop, even if the test line (T) appears in the result window. 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 midstream test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.</p>

Technical Assistance

For customer support, please contact our Technical Support:
*PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
Gurgaon -122015, India*
Customer care No.: +91-7303429198
Email: info@pathkits.com

From

State Drugs Controller-cum-Licensing Authority
Food and Drugs Administration, Haryana,
SCO-94, Sector-5, Panchkula.

To

M/s Pathkits Healthcare Pvt. Ltd.,
Plot no. 28-29, Electronic City, Sec-18,
District- Gurgaon-122001 (Haryana)

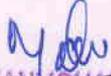
Dated: 30-12-2021

Subject: Regarding additional items.

With reference to your application no. MFG/MD/2021/48941
dated 26.10.2021 on the subject cited above.

Find enclosed herewith copy of Form MD-5 Endorsement -2.

Enclosed:- As above.


State Drugs Controller
State Drugs Controller-cum-Controlling &
Food & Drugs Administration, Haryana
Licensing Authority
Food & Drugs Administration, Haryana



FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000069

Endorsement No. 2

1. M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Plot No-28-29, Sector-18Gurgaon, Gurgaon, Haryana (India) - 122001 Telephone No.: 8802872273 FAX: 8802872273 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s PATHKITS HEALTHCARE PRIVATE LIMITED, 28, 29 Electronic City, Sector -18, Gurgaon, Haryana (India) - 122001 Telephone No.: 8588869343 FAX: 8588869343

2. Details of medical device(s) [Annexed]

3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	Generic Name:Human Chorionic Gonadotropin (hCG) test kit Model No.:PKRK0016 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Pregnancy Kit; PregAtHome Pregnancy Mini Kit
2	Generic Name:Human Chorionic Gonadotropin (hCG) Strip Model No.:PKUR001 - NA Intended Use:It determines the presence of hCG (Human Chorionic Gonadotropin) in urine samples. Class of medical device:Class B Material of construction:NA Dimension(if any):NA Shelflife:24 Months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Pregnancy Strip

3	<p>Generic Name:Luteinizing Hormone (LH) Test kit</p> <p>Model No.:PKRK019 - NA</p> <p>Intended Use:It is a rapid visual immunoassay for the qualitative, presumptive detection of luteinizing hormone in human urine specimens. This kit is for use as an aid in the detection of ovulation.</p> <p>Class of medical device:Class B</p> <p>Material of construction:NA</p> <p>Dimension(if any):NA</p> <p>Shelflife:24 Months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):PregAtHome Ovulation Kit</p>
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Place:

Date 30-Dec-21

Approved *M* No. to
 State Licensing Authority
 Except S. No.

(Manmohan Taneja)
 State Drugs Controller-cum-Controlling &
 Licensing Authority
 Food & Drugs Administration, Haryana

