

Ovulation (LH) Tracking Kit

Instruction for use (English)

Thank you for choosing LittleBegin Ovulation (LH) Tracking Kit.

Own your wellness and healthy, let's start from here. In this IFU, you will know how to use the **Ovulation (LH) Tracking Kit** by yourself properly and safely.

LOD: 15/30 mIU/mL

REF 305003701 (10 Tests)

Intended use

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 "LH surge" usually takes place in the middle of the menstrual cycle.

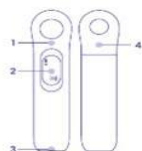
This Ovulation (LH) Tracking Kit is composed of the Ovulation Digital Reader and LH test stick. The LH test stick may detect specific marker in the urine and the Reader makes it simple and reliable to check the result. Together with the matching App, the results can be recorded and analyzed in your mobile phone. As to predicting the time of ovulation and peak fertility window period, it is intended to be used for the qualitative detection of luteinizing hormone (LH) in human urine. It detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24-36 hours. During this fertile time that pregnancy is most likely to occur.

Test principle

The LH test stick is a lateral flow sandwich immunoassay employing monoclonal antibodies that are specifically directed against the coating and labeling antibody. During the test procedure, collect a sample in a clean, dry container and dip the sample pad into the container until the screen prompts sample adding is complete which usually takes about 10-15 seconds.

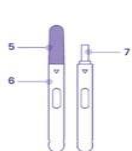
After the urine specimen is applied to the stick, the substance to be tested in the sample will react with the monoclonal antibody conjugate of the substance to be tested obtained by mouse immunization. Conjugated complexes migrate along the membrane to the test and control regions. The digital component integrated with the chromatographic strip displays the results of the immunochemical reaction on the screen of the equipment. After the equipment self-calibration procedure is completed, the screen displays the progress bar to indicate that the test is working. After the result is displayed on the screen, the test is completed. The test progress usually takes 5-10 minutes.

Product details



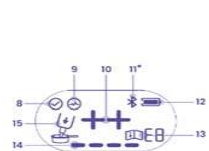
Ovulation Digital Reader

1. Ovulation Digital Reader
4. Battery cover
7. Sampling tip
10. Test results
13. Error code



Test Stick

2. Screen
5. Test stick cap
8. Test complete
11. Bluetooth connection status
14. Progress bar in test



Screen

3. Test insert position
6. Test stick
9. In testing
12. Battery status
15. Prompt to add sample

*Steady on indicates that the matching App is connected, blinking or off indicates that the App is not connected.

Package contents

Materials Provided

Ovulation Digital Reader	Test stick	Package insert
Urine cup	CR2032 battery	Screwdriver



Warning

Any measurement done by this product is for personal reference only. It is very dangerous for a patient to conduct self-diagnosis and self-treatment based on measurements only. Please be sure to follow your doctor's instructions.

Confirm testing day

Cycle length	Testing day	Cycle length	Testing day	Cycle length	Testing day
21 or less	5	28	11	35	18
22	5	29	12	36	19
23	6	30	13	37	20
24	7	31	14	38	21
25	8	32	15	39	22
26	9	33	16	40 or more	23
27	10	34	17		

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.

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.

Note: If uncertain about the length of the subject's menstrual cycle, use the shortest menstrual cycle length (21 days) when reading the chart.

Warnings and precautions

- For *in vitro* diagnostic use only.
- Do not put other items into the Ovulation Digital Reader except the test stick.
- Treat the used test stick as medical waste to avoid biological hazards.
- If the test sample is potentially infectious, please use protective gloves or other protective measures to avoid skin contact with the test stick and sample.
- Read through the IFU before you start the test.

Directions for use

Procedure of using the kit Install the CR2032 battery inside the package



- The Ovulation Digital Reader and test stick can work without App. In order to take historical records, it is recommended to use it with the matching app.
- To avoid wasting the test stick, please pair the App when you taking a test.
- Place the Ovulation Digital Reader as close as possible to your phone. If the pairing fails, please try again. or contact customer services for help.

Start the Ovulation Digital Reader

Take out a test stick from the foil wrapper, insert the test into the Reader.



Pair Ovulation Digital Reader: Click the pair button in your APP.

Do the test

- 1) Collect your urine sample using the clean dry cup included in the package.
 - First morning urine is not recommended and any other time of day is suitable.For best results, try to collect urine at approximately the same time each day.
 - Only fill sample cup to the line. Don't drink too much liquid before testing.
- 2) Allow the test stick to equilibrate to room temperature (20°C~30°C or 68°F~86°F). Take out the test stick from the foil wrapper, remove the test stick cap, and insert the

test into the Ovulation Digital Reader. Icon " " blinks prompt to add sample. (Please make sure that the test stick is inserted all the way to the bottom)



- 3) Dip the sampling tip of the test stick into the urine and hold the Reader until you hear one "beep" (usually takes 10-15 seconds to complete), a progress bar will appear at the bottom of the screen. Then pull out the Reader and put the test stick cap back on.

- Please finish adding samples within 10 minutes, otherwise the test will fail.
- Do not merge the urine pass over the plastic part of the test stick.
- Do not pull out the test stick while adding samples.



- 4) Place the Reader on a flat surface. Wait for about 5-10 minutes till you hear three "beeps" and a mark "√" shows on the screen, which indicate that the test is completed. The test result will be displayed on the screen.



- Do not pull out the test stick while testing.
- If the matching App is connected, the test results will also be uploaded to the App for historical records.

Interpretation of the test results

The instrument will automatically determine the test item based on the test strip.

Ovulation (LH) Test: The C-line is white.

* The measurement result will be displayed for 10 minutes. If the screen goes out after some time, pulling out the test stick, it will show again for 10 seconds.



Indicates a LOW result with a low probability of conception. Please test again after 24 hours. To ensure the accuracy of the tests, please test every day.



Indicates HIGH result, when the test detects the rise of LH, "+" will be displayed, which indicates a high probability of conception. Please test every 4-6 hours afterwards. Have intercourse today to increase your chance to pregnant.



Indicates a PEAK result which means an LH surge is detected. And you have the highest probability of conception. Please keep testing every 4-6 hours until it shows "+" or "-". which indicates that you have ovulated. Have intercourse within 24 hours to maximize your chance to pregnant.

*For fertility tests, a second positive result may indicate fertility problems.

Note: any positive results should be discussed with your physician and sought professional advice.

Error and troubleshooting

When a fault occurs during the test process, the instrument will beep for 10 seconds and display the error code on the screen. The meanings of the error code are shown in the following table.

Trouble	Reason	solution
The screen becomes unclear or doesn't show anything	Low battery	Replace battery
	An error occurs and the machine shuts down automatically	Replace the new test Stick and take a test again.
Inaccurate results	Incorrect test procedure	Test according to the user manual strictly
Error code: E0	Low battery	Replace battery
Error code: E1	Test fail	Replace test Stick and take a test again
Error code: E2	Add sample time out (more than 10 minutes without complete add sample)	Take out the test stick, wait 10 seconds after the Reader is off, then reinsert the test. Sample addition should be completed within 10 minutes
Error code: E3	stick pull out during test	Reinsert the stick within 10 seconds; otherwise, the test will fail

If the methods do not solve the problem, please contact customer services for help.

Maintenance

When the Reader starts to blink the low battery signal "  ", Replace a new battery for the Reader.

- Please keep the Reader clean.
- The internal hardware and software of the Ovulation Digital Reader can only be repaired, replaced or upgraded by manufacturer. Please contact customer services for support.

Maintenance Method and Plan

- The Reader does not require special maintenance or cleaning.
- External cleaning and maintenance method: A cloth dampened with 70% alcohol can be used to wipe the outside of the Reader.
- Do not use strong bleach ($\geq 0.5\%$ bleach solution), because oxidizing substances and solvents may damage the Reader's parts and touch screen.
- Take care to avoid getting liquids, dirt, blood or buffer into the Reader through the slot or data port.

Caution: Before cleaning, please make sure the Ovulation Digital Reader is turned off and the battery has been taken out.

Disclaimer

This IFU is written in accordance with available information and contents are subject to change without notice. The manufacturer has made the best effort to guarantee the manual's accuracy and reliability.

However, the company does not assume liability for loss or damage caused by omissions, inaccuracies or typographical errors in this IFU if there are discrepancies in this manual due to software upgrades, instructions and functions dictated by the software.

Dos and Don'ts

- For Over-the-Counter (OTC) Use. Do not use it after the expiration date.

- Do not eat, drink or smoke in the area where the samples or products are handled.
- Do not use a test if the pouch is damaged.
- Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for the proper disposal of samples.
- Humidity and temperature can adversely affect results.
- Keep out of the reach of children.
- The test stick in the bag should be used immediately after unpacking to avoid failure caused by dampness.
- Stop drinking water 2 hours before collecting the urine sample to prevent it from being diluted.
- There is a desiccant in the aluminum foil bag. Do not eat it.
- The urine cup can be reused.
- Test sticks are disposable and cannot be reused.
- The used test should be discarded according to local regulations.
- This product is for *in vitro* diagnostic use only.
- This product is an auxiliary diagnostic device only. It cannot determine the actual amount of hormone in a urine sample. The test results cannot serve as a basis for diagnosis.
- Used test stick, reader and the battery disposal must comply with the regulations of the national government and environmental protection agencies.
- When there are stains, it is recommended to wipe with alcohol cotton or damp cloth.
- Do not attempt to disassemble or repair the Reader. Doing so may result in inaccurate readings.
- Please check the delivery information of products, including unpacking, completeness and any damages during transport, and contact customer services if there are any damages.

Product specifications

Product name: LittleBegin Ovulation (LH) Tracking Kit

Dimension of Reader: 120*28.5*19mm

Weight of Reader: 30g

Operation condition Temperature: 20°C~30°C(68°F~86°F), RH: $\leq 85\%$,

Pressure: 86.0KPa -106.0KPa

Storage condition Temperature: -25°C~55°C(-13°F~131°F), RH: $\leq 95\%$,

Pressure: 86.0KPa -106.0KPa

Service life of Reader: 3 years

Battery: CR2032 battery (replaceable battery)

Test sticks: Contains 10 test sticks

Storage condition of test stick Temperature: 2°C~30°C(36°F~86°F)

FCC Warning

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

* RF warning for Portable device:

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

Basic Information

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Guide to Symbols

	Store between 2°C-30°C		For in vitro diagnostic use only
	Caution		Consult instructions for use
	Manufacturer		Waste electrical materials should be sent to a dedicated collection point for recycling.
	FCC Mark		Catalogue number