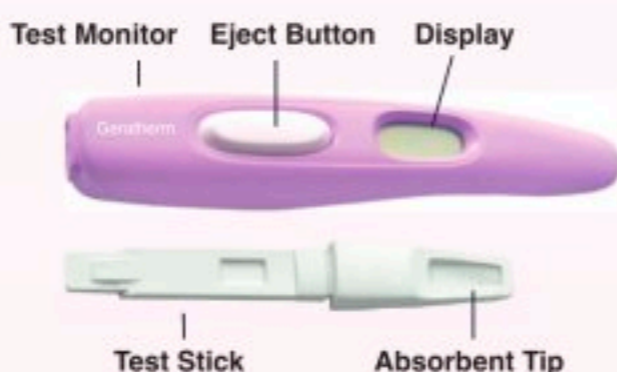


# Geratherm® digital duo

## Pregnancy & Ovulation Test



foil wrapper LH Ovulation Test

foil wrapper HCG Pregnancy Test

### Pregnancy Test

Geratherm® digital duo home pregnancy test is designed as an over-the-counter integrated digital self-testing device to qualitatively detect human chorionic gonadotropin (hCG) in a woman's urine for pregnancy determination. This device can test as early as 4 days before your missed period. But if you test before your missed period, you should keep 1 test for the day you have your missed period. It's essential to note that a confirmed pregnancy diagnosis should be made by a physician after evaluating all clinical and laboratory findings.

Before conducting the test, kindly read this leaflet attentively.

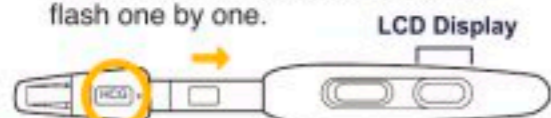
#### Attentions for the pregnancy test:

- Medications containing the pregnancy hormone hCG can affect the results.
- Before applying urine for testing, the test stick **must** be inserted into the test monitor correctly.
- Avoid holding the test with the absorbent tip facing upwards.
- Refrain from consuming excessive liquids before testing. See Q4.
- If testing before your expected period, use the first urine of the day. See Q3.

### 1 Prepare the test

**a** Take HCG test stick and remove it from the foil wrapper. Use the test stick straight away. Before applying urine for testing, the test stick **must** be inserted into the test monitor correctly. Follow the steps below.

**b** Make sure HCG symbol on test stick faces up and aligns with the monitor display. Find an arrow on test stick near HCG symbol. Insert the HCG test stick into the monitor until fully locked and you will feel a „click“ and hear a beep sound. All symbols will briefly flash one by one.



**c** Before doing the test wait for a steady HCG symbol on the display accompanied by a beep sound.



### 2 Choose testing method

With steady HCG symbol showing on the display place the absorbent tip:



in your urine stream for at least 10 seconds.

Take care not to get test monitor wet.

or



in a collected urine sample for at least 20 seconds. Collect your urine in a clean, dry container.

Throughout testing never hold the test with the absorbent tip pointing upwards.

### 3 Wait

After the absorbent tip of test stick is saturated with urine, lay the monitor on a flat surface with the display facing up. The monitor will beep, and the HCG symbol will flash to show the test is working.



#### Tips:

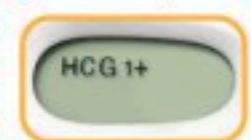
1. After the absorbent tip of test stick is saturated with urine, it may take few seconds for the HCG symbol to start flashing.
2. Do not eject the test stick while waiting for the result or move the monitor.

### 4 Read your result

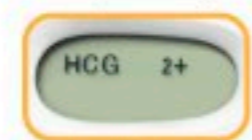
In 5 minutes, the display will show your result accompanied by a beep sound.



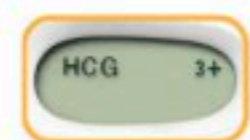
HCG - : Not Pregnant  
See Q7 for more information



HCG 1+: 1-2 Weeks



HCG 2+: 2-3 Weeks  
See Q6 for more information



HCG 3+: 3+ Weeks

### 5 Eject the Test Stick

After you have read the result, press the eject button on the monitor to remove the test stick.



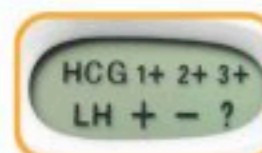
#### Tips:

1. The test result will be shown on the LCD display for about 60 minutes after test.
2. The result of your test can only be read on the LCD display, you cannot determine your result from any lines that you see on the test stick.
3. Once you have read your result, please eject the test stick and store the monitor for next test.
4. The test stick is not reusable. Do not re-insert a used test stick.
5. Dispose of the used test stick acc. to local regulations.

### 6 Test Stick Refill Pack

As soon as your test sticks have been used up, then you can buy Geratherm® digital duo Refill Pack Pregnancy Test and test with the same monitor.

### ! Test errors



Display:  
HCG1+2+3+LH+?

#### What it means:

Error occurs during testing.

#### Action:

All the symbols keep flashing. The reason could be the application of too much or too little urine. You should repeat the test with a new test stick. Following the instructions strictly will help you to avoid the errors.

### ? Questions and answers

#### 1. How does Geratherm® digital duo pregnancy test work?

It detects the pregnancy hormone hCG (human Chorionic Gonadotrophin) in urine.

#### 2. How early can I test?

You can test as early as 4 days before your missed period. But if you test before your missed period, you should keep 1 test for the day of your missed period. Reduce the liquid intake before taking the test. If testing before your expected period, use the first urine of the day.

#### 3. What time of day can I test?

If testing before you expect your period, always use the first urine of the day. If testing from the day you expect your period, you can test with urine collected from any time of the day.

#### 4. Does drinking liquid affect the test?

You should not drink too much liquid, including water, before testing. As it can dilute the level of any pregnancy hormone present in your urine and may affect the result.

#### 5. How accurate is Geratherm® digital duo pregnancy test?

It has over 99% accuracy in laboratory tests from the expected period day.

#### 6. My result is Pregnant. What should I do?

Please consult your doctor promptly for confirmation of your pregnancy, after evaluating all clinical and laboratory findings.

#### 7. My result is Not Pregnant. What should I do?

Possible reasons for a „Not Pregnant“ result could be that you are not pregnant, or the pregnancy hormone level may not be detectable yet. If you tested before your expected period, it's recommended to test again when your period is due. If you receive a „Not Pregnant“ result on or after the day you expect your period but still suspect pregnancy, please consult your doctor.

#### 8. Can medications or conditions affect results?

Please note that medications containing hCG can influence the test result. However, hormone therapies containing Clomiphene citrate, common painkillers, alcohol, antibiotics, or the contraceptive pill should NOT affect the test results. If you encounter any unexpected results, it's important to discuss them with your doctor.

Dispose of according to local regulations.

**Caution:** Device contains batteries, do not disassemble device, recharge or dispose of batteries in fire. Contains small parts. Do not eat any component of this device. If accidentally swallowed, seek medical attention.

### ★ Performance Characteristics

#### Accuracy:

A multi-center clinical evaluation was conducted comparing the Geratherm® digital duo pregnancy test with another commercially available urine membrane hCG test. The urine study included 100 specimens and both assays identified 60 negative and 40 positive results. The results demonstrated a 100% overall agreement (for an accuracy of >99%) of the Geratherm® digital duo pregnancy test when compared to the other urine membrane hCG test.

#### How Geratherm® digital duo pregnancy test works:

When you are pregnant, your body produces the pregnancy hormone hCG (human Chorionic Gonadotrophin). The secretion of this hormone by the developing placenta begins soon after conception and increases rapidly throughout the first trimester. The test can detect tiny amounts of hCG in your urine. Based on Third Edition of National Code of practice for Clinical Laboratory Practice, the relationship between hCG level and Pregnancy weeks is as table below. By using the table below and detecting hCG level in urine, the test can tell you for how many weeks from the conception you have been pregnant by showing "HCG1+", "HCG2+", "HCG3+" on its LCD display. If you are not pregnant, the test will show "HCG-" accordingly.

Pregnancy week	HCG (mIU/ml)
2 days - 1 week	5-50
1-2 week	50-500
2-3 week	100-5000
3-4 week	500-10000

#### Sensitivity and Specificity:

Geratherm® digital duo pregnancy test which complies with the WHO Third International Standard detects hCG at concentrations of 25 mIU/ml or greater. The addition of LH (500 mIU/ml), FSH (1000 mIU/ml), and TSH (1000 µIU/ml) showed no cross-reactivity to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) specimens.

#### Interfering Substances

The following potentially interfering substances were added to hCG negative and positive specimens.

Acetaminophen	20mg/ml
Ampicillin	20mg/ml
Acetylsalicylic Acid	20mg/ml
Gentisic Acid	20mg/ml
Ascorbic Acid	20mg/ml
Glucose	2g/dl
Atropine	20mg/ml
Caffeine	20mg/ml
Cortisol	200ng/ml
Albumin	2000mg/ml
DHEAS	500ng/ml
Estradiol(E-2)	25ng/ml
Estradiol(E-3)	25ng/ml
Tetracycline	20mg/dl
Uric Acid	10mg/dl

None of the substances at the concentration test interfered in the assay.

#### Important Note for Negative Results:

Some pregnant women may not detect hCG in their urine up to 4 days before the expected period. If you get a negative result (not pregnant) before your period is missed but suspect pregnancy, retest after your period is missed.

#### Important Note for Positive Results:

This test can detect low hCG levels, so it's possible to get positive results even if you're not pregnant. If you have doubts after a positive test, consult a doctor.

#### Index of Symbols

	Consult instructions for use		Batch code		Manufacturer
	In vitro diagnostic medical device		Use by date		Authorized representative in EU
	Store between 4-30°C		Keep dry		Importer
	Do not use if package is damaged		Do not reuse		Caution
	Date of manufacture		WEEE Directive Marking		Recycling

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