

SALIVA - BASED FERTILITY TEST

Geratherm[®]
ovu control

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INSTRUCTION MANUAL

Geratherm[®] ovu control
GT-OVU04

CE 0197

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Please read these instructions carefully.

PURPOSE OF USE

Geratherm® ovu control is a saliva test for self-testing for determining the fertile and infertile days.

 This product is specifically not a contraceptive.

The reliability of the method is dependent on correct following of the instructions and correct evaluation of the results.

It is strongly recommended that you consult your doctor if you begin to plan a family.

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DESCRIPTION OF THE DEVICE

The Geratherm® ovu control consists of four components: the casing, the lighting system, the optical system (lens) and the lid.



TECHNICAL DATA

Magnification:	50-fold
Dioptré:	+/- 5
Batteries:	2 x LR44 1.5V
Light source:	LED diodes
Dimensions:	67 x 22 x 22 mm
Weight:	39 g

Operating and storage between uses conditions

Temperature:	+15 °C to +30 °C
Air humidity:	10 - 70%;
Atmospheric pressure:	50 - 106 kpa

Transport and storage conditions

Temperature:	0 °C to +70 °C
Air humidity:	10 - 95 %
Atmospheric pressure:	50 - 106 kpa

IP code (protection rating): IP22 (effective against bigger solid bodies; protected against dripping water)

Quality guarantee:

Geratherm® is certified in accordance with Council Directive 98/79/EG and EN ISO 13485 and is entitled to affix the CE mark C € 0197 (notified Body TÜV Rheinland LGA Products GmbH)



Note:

If the device is used outside of the specifications, proper function is no longer guaranteed! We reserve the right to make technical changes to improve and further develop the product. This device and its accessories comply with European standards EN60601-1 et seq. and is subject to special safety measures in terms of electromagnetic tolerance.

TECHNICAL DATA

Electromagnetic compatibility

The device complies with current specifications with regard to electromagnetic compatibility and is suitable for use in all premises, including those designated for private residential purposes. The radio frequency emissions of the device are extremely low and in all probability do not cause any interference with other devices in the proximity.

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GENERAL INFORMATION

A regular and stable menstrual cycle of a woman is about 28 days. Approximately 14 days after the beginning of the last-, and 15 days before the next menstrual period the rising blood estrogen levels lead to ovulation.

The biological properties of egg cells only permit fertilization within approximately 24 hours after ovulation.

Because the male sperm have a life span of up to 72 hours, in general, a conception in a time frame of approximately 2 days before and 1 day after the actual ovulation is possible.

Geratherm® ovu control was tested in a field study against a urine fertility rapid test, The Geratherm® ovu control possessed a high level of agreement in determining the fertile / infertile days.

Furthermore, in a medical study of patients the following was confirmed.

Geratherm® ovu control is capable of showing a positive test result at an LH concentration of about 4 mIU / ml (this concentration value is the minimum required for an ovulation trigger) .



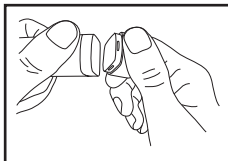
PRECAUTIONS

1. Certain medications or hormone treatments, as well as smoking, acute inflammations in the mouth or throat, and alcohol can temporarily alter the composition of saliva and thereby affect the result.
2. Before applying the saliva, check that the outer, smooth surface of the lens is clean.
3. For reasons of hygiene and health, it is recommended that the device be used by one individual only.
4. Do not expose your device to intense heat or cold.
5. Never immerse the device in water or other fluids.
6. Do not clean it under running water.
7. Do not drop the ovu control device and do not subject it to sudden impacts.
8. Protect it from dust, dampness and heat.
9. Do not modify or disassemble the device.
10. Keep out of the reach of unsupervised children. Consumables could be swallowed.
11. Damaged devices should not be used.

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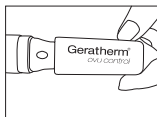
CHANGING THE BATTERIES

First remove the blue casing. You can change the batteries by pushing the white cover off by tipping it to the side.



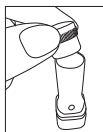
Replace the empty batteries (2 x LR44 1.5V) with new ones. Pay attention to correct polarity; the positive pole of both batteries must be in the correct position. Push the white cover back onto the device.

USE



Step 1

Remove the long blue protective cap from the Geratherm® ovu control.



Step 2

Carefully remove the lens by pulling it off the casing. Carefully clean the outer (smooth) surface of the glass with a dry dust-free cloth.

Step 3

Preferably in the morning, before eating breakfast, cleaning your teeth or smoking, place a drop of saliva on the middle of the lens using a clean and dry finger. Dab the saliva onto the lens from above, without smearing the drop.

Ensure that no air bubbles or foam are on the lens. Leave the saliva sample to dry at room temperature for about 10 to 15 minutes. To do this, lay the lens aside with the drop uppermost.

Note:

1. Apply the Geratherm® ovu control before eating, drinking, brushing teeth or smoking.
2. In the early morning hours, it may happen that the saliva is too thick. If this is the case, the result of the test may be false. Then run the test again later in the afternoon or when the saliva is liquefied. In this case, the test must be conducted no earlier than 3 hours after eating, drinking, brushing teeth or smoking.
3. Clean the lens with a dry cloth before and after each use.
4. To stimulate the flow of saliva, you can lightly bite your tongue.

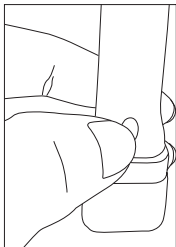
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USE

Step 4

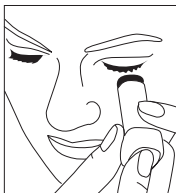
Place the lens with the completely dried drop of saliva inside the casing of the device.

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Step 5

Push the button to activate the light switch. If necessary, remove any visual aids. While pressing the light switch, look through the upper section of the device with the inserted lens so as to view your test result. Look closely and carefully at the sample in order to evaluate your result correctly.



Note:

Should no structure at all be visible when you examine the sample, remove the optical system from the casing and wait a few more minutes until the sample is completely dry before repeating the test.

Step 6

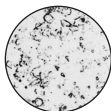
After each use, clean the lens. Use the supplied cleaning cloth or any other clean cloth. Do not immerse the Geratherm® ovu control in water. Place the blue cap back on after use.

INTERPRETATION OF RESULTS

It is scientifically proven that there is a direct correlation between the increase in oestrogen levels and the time of ovulation. Oestrogen can be detected in saliva, as well as elsewhere in the body. During a woman's fertile days, the salt content in the saliva rises owing to the increased oestrogen production. The salt crystals that form in dried saliva have a fern-like structure. This 'ferning pattern' can be seen most clearly directly before ovulation.

During the infertile days this 'ferning pattern' disappears owing to the increasing level of progesterone, and a gravel-like pattern is seen instead.

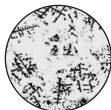
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INFERTILE

Conception is unlikely

You see a gravel-like pattern with dots and bubbles. You are most probably not fertile.



TRANSITION PHASE – LESS FERTILE

Conception is possible, but unlikely

A few crystals with a slight 'ferning pattern' are visible. You are 3-4 days before ovulation. This is the start of the fertile period.



FERTILE

Conception is highly probable

The 'ferning pattern' is clearly visible. Ovulation has begun. Fertility lasts about 3 days. During these fertile days sexual intercourse is recommended if you wish to conceive.

INTERPRETATION OF RESULTS



Changes to the 'ferning pattern' can be caused by the following:

- After removal of contraceptives and other hormonal contraceptive methods (eg, birth control pills)
- After birth, during and after lactation
- Eating, drinking, smoking, brushing your teeth before testing

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EVALUATION CALENDAR (Example for the month of January)

The values recorded in an evaluation calendar are important for determining the fertile phase.

Carefully filled in record sheets provide important diagnostic information and you should always take them with you when you visit your doctor.

Start recording on the first day of a menstrual period.

New evaluation calendars can be downloaded from the Geratherm® homepage by clicking on the following link:

<http://www.geratherm.com>

EVALUATION CALENDAR

(Example for the month of January)

Geratherm®
ovu control

My fertility calendar


Month/day	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
January	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺	☺
February																															
March																															
April																															
May																															
June																															
July																															
August																															
September																															
October																															
November																															
December																															

Fertile ☺
Less fertile ☺
Infertile ☺
Period ■
Intermenstrual bleeding ▣

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CLEANING

Clean the lens (glass substrate) with a dry lint-free cloth.











-  Do not clean the lens under running water.
Do not use soap or detergent to clean the lens.
Residues may disrupt the crystal formation!

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DURABILITY

The product can be used over 50000 hours with daily use, taking account of changing batteries.

SYMBOL INDEX

	Read Instructions		Lot Number
	Protect from moisture		Serial number
	Store at rel. Humidity between 10 % and 95 % R.H		Only for in vitro use, external use
	storage between 0 ° C and +70 ° C		Manufacturer
	Do not dispose in domestic household waste		Attention, consult accompanying documents in

INDEX (EXPLANATION OF TERMS)

Product for Personal Use

A „product for personal use“ refers to any product that can be applied to the purpose specified by the manufacturer by any amateur in the home environment.

Electromagnetic Compatibility

The electromagnetic compatibility refers to a usually desirable state that technical devices do not affect each other by disturbing and unwanted electrical or electromagnetic effects.

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Ovulation

The expulsion of the unfertilized egg from the ovary is called ovulation. Ovulation takes place in about the middle of the female menstrual cycle and is essential for the fertilization of the ovum by a sperm in the fallopian tube.

Progesterone content

Progesterone belongs to the group of sex hormones. This is mainly generated during the second phase of the menstrual cycle, and in much higher amounts during pregnancy.

Estrogen content

Estrogens are the primary female sex hormones. Estrogens promote the maturation of an egg capable of being fertilized. By estrogen, the endometrium is well supplied with blood. The cervix opens and the cervical secretion is permeable to sperm.

LH concentration

Luteinizing hormone (LH) is one of the hormones that regulate reproduction.

Women have a steep rise of LH concentration in blood and urine which can be detected before ovulation, which then again subsides quickly.

Under the influence of estrogen, LH is produced in greater quantities in the first half of the cycle. When the oocyte is mature; large amounts of LH are released into the blood by these ovulation is triggered.

INDEX (EXPLANATION OF TERMS)

Ferning Pattern

The ferning pattern phenomena is occurring under the influence of estrogen, very characteristic fern-like formations of salt crystals in the dried saliva. This phenomenon is particularly evident just before ovulation, but disappears under the influence of progesterone in the second half of the menstrual cycle.

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DISPOSAL

Observe the applicable regulations when disposing of the device and batteries. This product must not be disposed of together with domestic waste.

Please remove the batteries before disposing of the device/unit. Do not dispose of old batteries with your household waste, but at a battery collection station at a recycling site or in a shop.



WARRANTY

The Geratherm® ovu control is guaranteed against manufacturer's defect for one year from the date of purchase. This guarantee does not cover any damage to your product that is caused by improper handling.

The manufacturer is not responsible and cannot be held liable for improper use or the false interpretation of the result.

CERTIFICATE OF GUARANTEE

Geratherm® guarantees the ovu control against any manufacturing defect for one year from the date of purchase if it is returned to the dealer from whom it was purchased. During this period the unit will be repaired or replaced free of charge if the fault is due to defective design or assembly.

This guarantee does not cover any damage or defect caused by improper handling resulting from use that is not in compliance with these instructions, or caused by unauthorised attempts to repair it. Your local dealer cannot declare this manufacturer's guarantee invalid, but may expand it by additional guarantees at his discretion and at his own expense.

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Model No.:

Serial No.:

Date of purchase:

Dealer's signature:

Invoice No. / Receipt No.:



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FERTILITY TEST
Geratherm® ovu control
GT-OVU04