PreventID® **Ovulation**

Manual (FOR PROFESSIONAL USE)

REF KST12110G7
KST12110GP

Intended Use

The **PreventID® Ovulation** (test strips) is a rapid test for the detection of luteinising hormone (LH) in urine. An increase in LH triggers ovulation and therefore marks a woman's most fertile day of the month. Because the ovule can be fertilised only 6 to 24 hours after ovulation, the **PreventID® Ovulation** is an important aid to pregnancy planning. For professional use only.

Materials

Materials Provided:

- test strips, individually packed TEST
- manual

Materials Required but not Provided: Timer or stop watch, sample container

Storage and Stability

Store the test between 4 °C and 30 °C; do not freeze. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the pouch. Do not use it beyond the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not use beyond the expiry date.
3. Read the manual carefully before performing the test.
4. Perform the test immediately after removing the test strip from the pouch.
5. During performing the test do not eat or smoke.
6. Wear protective gear such as disposable gloves, lab coat etc. and avoid spilling of sample material. If sample material has been spilled, clean the site thoroughly with disinfectant.
7. Clean all contaminated surfaces carefully. Dispose all test com ponents and samples in conventional garbage.
8. If the pouch has been damaged, do not use the test strip.
9. If you have any questions please contact Preventis GmbH.

When to begin testing?

- You may do this test at any time of the day, but you should test at approximately the same time each day. Reduce your liquid intake for 2 hours before testing.
- To decide when to begin testing, determine the length of your normal menstrual cycle. The length of your cycle is from the beginning of one period to the beginning of the next (count the first day of bleeding or spotting as day 1).
- If your cycle length is irregular, that is, if it varies by more than a few days each month, take the average number of days for the last 3 months. Use the chart to work out the day you should begin testing. The day you begin testing is listed opposite the number of days in your normal cycle *(Table 1)*.
- For example, if your period normally begins every 28 days, you should begin testing 11 days after the first day of your last period.
- For example: If the 2nd day of the month is the first day of menstrual bleeding (day 1), then the 12th day of the month is day 11 of your cycle. This is the day to begin testing *(Table 2)*.

Lenght of normal cycle (number of days)	Start testing after this number of days in current menstrual cycle
21	5
22	5
23	6
24	7
25	8
26	9
27	10
28	11
29	12
30	13
31	14
32	15
33	16
34	17
35	18
36	19
37	20
38	21
39	22
40	23

Table 1: Test begin in relation to cycle length

Sun	Mon	Tue	Wed	Thu	Fri	Sat
1	2 **1st day of cycle**	3	4	5	6	7
8	9	10	11	12 **11th day of cycle**	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Table 2: Example of how to calculate test begin in the calendar

Test Procedure

1. Collect urine in a sample container.
2. Shake test strip from the pouch. Hold test strip at the upper end.
3. Dip the test strip up to the maximum-line into the urine sample *(Fig. 1)*.
4. Remove the test strip from the urine sample as soon as the purple color line runs through the result area (after a few seconds).
5. Place test strip on a dry surface.
6. Interpret test result after **5 minutes**.

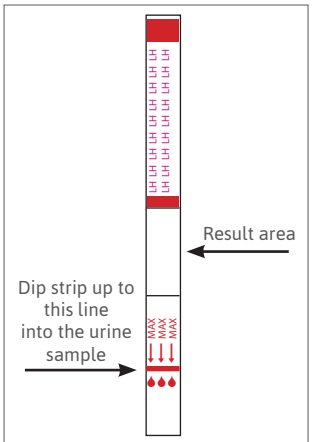

Fig. 1: **PreventID® Ovulation** Test strip

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Test Interpretation *(Fig. 2)*

For test interpretation place the test strip as shown in *Fig. 2* (sample area at the bottom). A coloured line appears in the upper part of the result area to indicate that the test is working properly **(C= control line)**.
The control line (C) is used as a reference.
The test result appears in the lower part of the result area. If a coloured line appears here, it is the **test line (T)**.

Depending on the coloured lines, the following results are possible:

Positive: If two lines with similar colour intensity appear in the result area, independent of which one appears first, an elevated LH-level has been detected. In this case, the test line (T)may appear more intensive than the control line.

Negative: If an intensive control line (C) and a weak test line (T) appear, an elevated LH-level has not been detected. If only the control line (C) is visible in the result area, an elevated LH-level has also not been detected.

Invalid: The test is considered invalid if no line or only the test line (T) appears in the result area. For example, the control line (C) does not appear if the strip membrane has not soaked enough sample fluid. The test should be repeated using a new test strip.

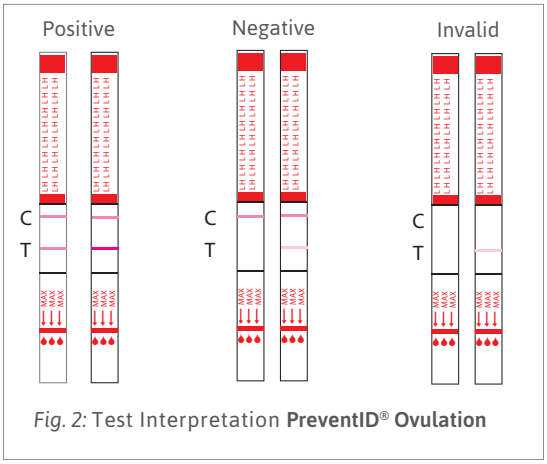

Fig. 2: Test Interpretation **PreventID® Ovulation**

Test characteristics

Clinical sensitivity

Clinical sensitivity for **PreventID® Ovulation** (test strips) was tested against the reference test Ultimed LH test, which is considered to be the gold standard for this parameter.
The **PreventID® Ovulation** (test strips) is in 100 % agreement with Ultimed LH test.

- Clinical Sensitivity = 100 %
- Clinical Specifity = 100 %

Analytical sensitivity

To determine the precise sensitivity of the **PreventID® Ovulation** test, urine sample devoid of LH are used together with Bio-Rad fertility controls to pre-set LH concentration levels. Specimens are prepared into 4 groups, LH-negative, 15 mIU/mL, 25 mIU/mL and 50 mIU/mL.
The summarised data showed the sensitivity of **PreventID® Ovulation** test (test strips) is determined to be at 25 mIU/mL (50 tests were used for each LH concentration level for each of the LOT tested).

Interference tests

Potentially interfering chemical substances such as pain medication, lipids, hemoglobin, bilirubin and glucose were supplemented to clinically defined negative normal urine and clinically defined positive urine specimens. These samples were tested using the **PreventID® Ovulation** test (test strips) by a replicate of 10. A sample was classified negative, when no purple colour band was visible for the LH test line but the purple colour "C" control line being visible within 5 minutes. A sample was classified positive, when both the control and test line were visible within 5 minutes. Tests were done with the following substances: Acetamiophen, 20 mg/dL, Acetyl salicylic Acid, 20 mg/dL, Ascorbic Acid, 20 mg/dL, Atropine, 20 mg/dL, Bilirubin, 60 mg/dL, Caffeine, 20 mg/dL, Creatinine, 20 mg/dL, Gentesic Acid, 20 mg/dL, Glucose, 2000 mg/dL, Hemoglobin, 500 mg/dL, Ketones, 40 mg/dL, Lithium Heparin, 3 mg/dL, Mestranol, 3 mg/dL, Nitrite, 20 mg/dL, Penicillin, 40,000 U/dL, Sodium Heparin, 3 mg/dL, Tetracycline, 20 mg/dL as well as Fatty acids, 300 mg/dL, Triglyceride, 250 mg/dL, Sterol esters, 300 mg/dL, Monoacylglycerols, 300 mg/dL, Diacylglycerols, 300mg/dL, Glycerophospholipids, 300mg/dL, Glyceroglycolipids, 300mg/dL, Sphingomyelin, 3020mg/dL, Glycosphingolipids, 300mg/dL. In conclusion, none of the above tested substances showed any interference with neither a clinically defined negative nor a positive specimen. Negative urine samples with supplementation of potentially interfering substances gave consistently negative test results, whereas urine samples positive to LH scored consistently positive.

Cross reactivity

Urine specimens devoid of LH were spiked with hCG (up to 10,000 mIU/mL), FSH (up to 1000 mIU/mL) and TSH (up to1000µIU/mL) , these samples were then tested with **PreventID® Ovulation** tests. At the levels tested, none of the hormones/substances cross reacted with the **PreventID® Ovulation** test (test strips).

Test Limitations

Use the test strip only once. Test results are only reliable if you follow the instructions for use carefully. Although the **PreventID® Ovulation** is highly accurate in detecting ovulation, a low incidence of false results (positive when no ovulation exists or negative when ovulation is present) can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory indings have been evaluated. The **PreventID® Ovulation** should not be used for contraception.

References

1. Apter D, Cacciatore B, Alfthan H, et al, „ Serum Luteinizing Hormone Concentrations Increase 100-Fold in Females From 7 Years to Adulthood, as measured by Tim-Resolved Immunofluorometric Assay" J Clin Endocrinol Metab, 1989, 68 (1):53-7.
2. Nippoldt TB, Reame NE, Reich RP, et al, „ The Roles of Estradiol and Progesterone in Decreasing Luteinizing Hormone Pulse Frequency in the Luteal Phase of the Menstrual Cycle." J Clin Endocrinol Metab, 1989, 69 (1): 67-76.

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Status: 2018-12-03

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
To be used with	Do not reuse
Read user instructions	Contains sufficient for <n> tests
Keep away from sunlight	

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