Read this Instructions For Use carefully before testing.

For in vitro diagnostic use only

MIZUHO MEDY Co., Ltd.

Self-test kit of Luteinizing Hormone

LH Quick CHECKER・S

[General precautions]

1)Do not use this product for other purpose than in virto diagnosis.
2)Determine the diagnosis comprehensively based on other relevant test results or clinical manifestations.
3) Others usage than instructions for use is not guaranteed.

[Contents]

Test stick - 10 tests
・Colloidal gold conjugated to mouse monoclonal anti-LH antibodies
・Mouse monoclonal anti-LH antibodies conjugated to haptens (mixture of three haptens)

[Intended use]

For detection of Luteinizing Hormone (LH) in urine (Detection of LH means the finding of an increase of HL concentration in urine.)

[Principle of the test]

After wetting absorbent tip with urine, LH in specimen migrate and react with colloidal gold conjugated to mouse monoclonal anti-LH antibodies and mouse monoclonal anti-LH antibodies conjugated to 3 different kinds of haptens, which results in forming three kinds of immunocomplexes differing only in hapten. Each of these immunocomplexes is distributed by reacting with the corresponding anti-Hapten antibodies on the membrane filter depending on its concentration. Therefore, the amount of immunocomplexes distributed to each anti-Hapten antibody will be different. As a result, red-purple lines will appear in the test line area, and its number will change depending on LH concentration in urine.

[Procedural precautions]

1) Notes on a collection of urine
・You can test urine anytime of the day (morning, afternoon or evening), but should be tested by use of the urine collected at about same time of every day.
・For about 4 hours before testing, do not urinate as much as possible.
・Avoid the excessive amount of liquid intake before testing.
・Avoid the exercise with heavy sweating before testing.
・When there is a severe cloudy urine or bloody urine, avoid using them.
2) Interfering substances and medications
Influences were not found to the following concentrations.

Hemoglobin	5mg/mL	Urea	1mg/mL
Glucose	100mg/mL	Ascorbic acid	5mg/mL
Albumin	10mg/mL	Acetaminophen	2mg/mL

3) Immunological cross reaction
Influences were not found to the following concentrations.

FSH	2,000mIU/mL
TSH	1mIU/mL
hCG	100mIU/mL

[Test procedure]

●Test starting date
Because test starting date is decided by a menstrual cycle on the test starting date, refer to the following table of the test starting date.

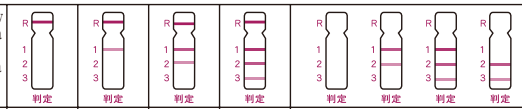
Menstrual cycle length (Days)	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40
Using the first day of your period as Day 1, count forward the following number of days to start testing	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23

●Test procedure
1) Preparation of reagent
Test stick: No special preparation is required for test stick
2) Test procedure
(1) Preparation of sample: No special preparation is required for urine.
(2) Test procedure
① Remove test stick from aluminum foil pouch.
② Remove cap and hold absorbent tip directly in urine stream for 5 seconds or more with facing interpretation window front and pointing absorbent tip downward. Or you may also collect your urine in a clean dry cup and immerse the entire absorbent tip in the urine for 10 seconds.
③ Replace cap over while facing interpretation window front and pointing wet absorbent tip downward and place the test stick on a flat surface for 10 minutes with facing interpretation window up.
④ Visually confirm the appearance of red-purple line at reference line area and the number of lines at test line area.

[Interpretation]

When a red-purple line is recognized at reference line area, interpret the result to be score 0, score 1, score 2, or score 3 by the number of lines at test line area.

《Interpretation example of score》

Interpretation window Reference line area Test line area					
Number of lines in test line area	0	1	2	3	Example of Retest When no line appears at reference area, test result becomes "Retest" regardless of number of test line.
Interpretation of score	Score 0	Score 1	Score 2	Score 3	

《Retest》

When a red-purple line does not appear on reference area, operational mistakes such as the lack of sample are thought. Retest with new test stick after checking the test procedure. If the same result comes out in the retest, use other procedure.

●Interpretation of LH surge
1) Implementation of the test
Implement a test based on the above-mentioned test procedure as a sample with urine of the about same time in succession every day from the test starting date.
2) Interpretation
Interpret the increase or not of the score level by contrast with the test starting date.
・Test every day until score level increases from a score level of the test starting day.
・Continue the testing and confirm the decrease of the score level to identify a peak of the LH surge.
・When the score level is increased, it is predicted to ovulate within 36 hours. It is likely thought to be most fertile time during this period.

3) Interpretational precautions

・This product is aimed for the detection of the LH increase and cannot use it for quantification of LH. Do not use it for quantification of LH by the number of lines.
・When score level decrease or do not increase as a result of testing, continue testing or test again in the next menstrual cycle.
・When it is interpreted to be score 3 on the test starting date, LH surge may have already taken place. Or it is thought that urinary LH concentration is possibly high due to some kind of reason such as pregnancy, childbirth delivery, miscarriage, artificial abortion, abnormal pregnancy, hCG-producing tumor, fertility treatment, endocrinopathy, menopause so continue the testing.
・When there is an irregular menstrual cycle or the secreted LH is in low concentration, or in case that LH surge is over in a short time, the number of lines may not increase.
・Plural lines may appear at menopause. The LH concentration of the woman after the mature phase tends to increase with age.
・Interpret the result at 10 minutes after the test implementation as the score level may change gradually as the time goes by. Do not interpret the result after waiting 20 minutes or more.

[Performance characteristics]

1) Sensitivity
When 10 mIU/mL of the control specimen is tested, score 1 is shown.
2) Accuracy
When 0 mIU/mL, 10 mIU/mL, 30 mIU/mL or 100 mIU/mL of the control specimen is tested respectively, score 0, score 1, score 2, and score 3 is shown respectively.
3) Reproductively
When 0 mIU/mL of control specimen are tested three times, score 0 are shown in all case. When 100 mIU/mL of control specimen are measured three times, score 3 are shown in all case.
※10 mIU/mL, 30 mIU/mL, and 100 mIU/mL control
They are prepared to become 10 mIU/mL, 30 mIU/mL and 100 mIU/mL based on LH International standard (WHO).
4) Detectability
The LH concentration showing score 1 is 10 mIU/mL.
5) Correlation
After testing the correlation between this product and Company A and Company B of the same method by use of urine specimen, the following correlation was obtained.

N=115

			This product				
	Interpretation		Negative		Positive		Total
		Score	0	1	2	3	
Company A	Negative	1	13	4	0	0	17
		2	5	39	2	0	46
	Positive	3	0	0	31	3	34
		4	0	0	5	13	18
Total			18	43	38	16	115

N=115

			This product				
	Interpretation		Negative		Positive		Total
		Score	0	1	2	3	
Company B	Negative	1	17	19	0	0	36
		2	1	23	0	0	24
	Positive	3	0	1	8	0	9
		4	0	0	30	16	46
Total			18	43	38	16	115

※Score 0 and score 1 in this product are interpreted as negative, and score 2 and score 3 of this product are interpreted as positive.
※Score of this product means number of line in test line area.
※Scores of product of Company A and Company B means result of comparing color intensities between test line and control line.
(Score of product of Company A and Company B)
Score 1: No test line appears
Score 2: Test line is lighter than control line.
Score 3: Test line and control line are same color intensity.
Score 4: Test line is darker than control line.

6) Standard substance for calibration
LH International Standard (WHO)

[Precautions for usage or handling]

1) Precautions for handing (for hazard prevention)
Specimen should be handled as potentially infectious material including HIV, HBV and HCV. You wear disposable gloves in order to avoid danger of the infection while you are testing, and do not pipette by the month.
2) Precautions for usage
①Do not freeze this product. Store in in accordance with description of instructions for use. Do not use frozen reagents because they could show false results by change of quality.
② Do not use reagent beyond expiration date.
③ Do not use this product for the purpose of contraception.
④ Do not put this product in direct sunlight or near heat source.
⑤ Perform a test in accordance with test procedure.
⑥ Open the aluminum foil pouch just before starting test, and use test stick immediately. If it is left in air for long time after the opening, it could be non-reactive due to getting moistened.
⑦ Do not wet interpretation window by urine.
⑧ Do not touch absorbent tip directly by hand.
⑨ Do not disassemble test stick.
⑩ Perform a test immediately after collection of urine.
3) Precautions for disposal
Dispose of used test stick and utensils as plastic trash.

[Storage and Expiry]

・Storage: Room temperature (1~30℃)
・Expiry: 36 months

[Reference]

・W.H.OTaskForce:Am.J.Obstet.Gynecol,138(4),383(1980)

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