Product Data

for

viola Menopause Test

- an immunochromatographic assay for the semiquantitative determination of hFSH in urine

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References

Introduction:

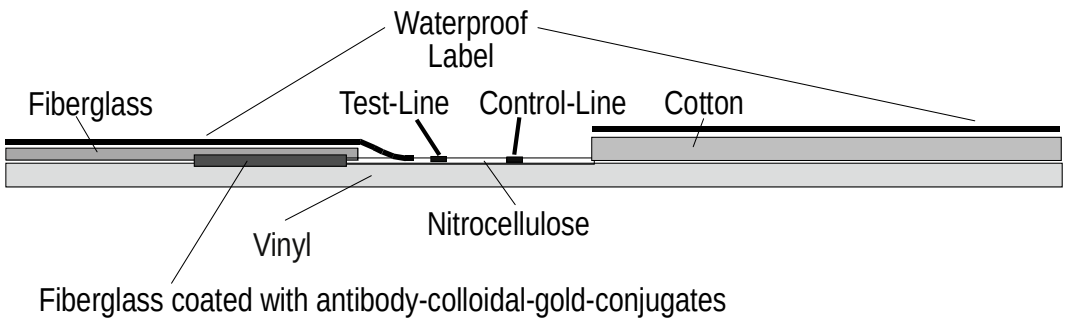
FSH in the female stimulates the growth of ovarian follicles and promotes follicular steroidogenesis. This stimulates LH production and leads to an LH surge, which in turn is the trigger for ovulation.
Therefore LH and FSH (among others) play important roles in regulating ovarian functions and menstrual cycle.
The hormone levels are used to assess menstrual cycle, ovulation or the determination of menopause.
Responsible for menopause is a change in the hormone production (leading to various symptoms like hot flashes, mood changes, insomnia, vaginal dryness and itching, reduced sex drive, …).
FSH levels usually (before Menopause) are between 2 and 20 IU/L (International Units per Liter), but rise and remain elevated (>25 IU/L) in Postmenopause.

PRINCIPLES OF THE PROCEDURE

The viola Menopause Test incorporates a monoclonal antibody-colloidal gold conjugate specific to β-hFSH to bind to FSH and a surface coated with monoclonal antibodies specific to α-hFSH to capture the complex. As the test strip in the test cassette is in contact with the urine, the antibody coated surface captures intact FSH bound to the antibody-colloidal gold conjugate forming a complex and giving a colored test line. As an independent control and as a reference for the intensity of a line of ~25 IU/L, at the gold-conjugate membrane an independent Antibody-gold-conjugate is mobilized to migrate to another antibody immobilized at the membrane; as a result a control line forms showing the intensity of a line of ~25 UI FSH / L urine and confirming the correct test performance.

Detection: </> 25 IU FSH / L urine
Incubation time: RESULTS 10 MINUTES AFTER APPLICATION OF SPECIMEN

Active Ingredients: Bovine Serum Albumin
Goat Anti-(Rabbit IgG) Polyclonal Antibody
Anti-α-FSH Monoclonal Antibody
Rabbit IgG Colloidal Gold Conjugate
Anti-β-FSH Monoclonal Antibody-Colloidal Gold Conjugate



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ASSAY PROCEDURE:
Given in instructions for use.

INTERPRETATION OF RESULTS:
The test should be considered positive, if 2 purple lines appear in the reaction field of the strip within 10 minutes, and the line in the lower part of the reaction field is as intense or more intense than the line in the upper part of the reaction field.
If only 1 purple line in the upper part of the reaction field appears or this line is clearly stronger than the one in the lower part of the reaction field, the test should be considered negative, meaning that there is no elevated FSH concentration this time. In the event of no purple line in the reaction field or if the whole reaction field turns purple, the test should be considered invalid.
Before and after more than 10 minutes the test results cannot be interpreted correctly anymore.
A positive result must be confirmed after 1 week (7 days), because only permanently elevated (>25 IU/L) FSH levels confirm, that Menopause was passed (Postmenopause was entered).

LIMITATIONS:
This test measures FSH in urine. If FSH levels are elevated (>25 IU/L), it is very likely that postmenopause was entered.
Factors affecting normal synthesis and secretion of FSH will alter results. In addition medication or urine containing FSH, hLH or hCG have a falsifying influence on the results. Conditions with decreased levels of FSH-values (amongst others: Progesterone-negative amenorrhea, hyperprolactinemy, anorexia nervosa, Kallmann syndrome (olfacto-genitale syndrome), trauma, tumor, empty sella at β-thalassemia) will influence the test results.
Conditions with increased levels of FSH-values (amongst others: Gonadal dysgenesia at 45X0 (Turner syndrome), gonadal dysgenesia at 45X0, 46XY-mosaic, gonadal dysgenesia at 46XY (Swyer syndrome), early menopause, resistant ovary syndrome (intermittent ovarian failure), condition after therapy with cystostatics or radiation, menopause or post-menopause) will influence the test results.

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Performance Study

SENSITIVITY

A) Addition and Measurement of added FSH:

FSH standards were added to pooled urine that contained no endogenous FSH to give final concentrations of 0, 10, 25, 50, 100 mIU/ml (WHO 2nd IRP 78/549). Each sample was then assayed according to the instructions as described in the package insert. The experiments were conducted in duplicate. The following data was obtained:

Final LH Concentration in mIU/ml	Expected Result	Observed Result
0	Negative	Negative
10	Negative	Negative
25	Positive	Positive
50	Positive	Positive
100	Positive	Positive

Furthermore FSH Standards (WHO standards) were added to a urine matrix to produce FSH concentrations of 10 mIU/ml, 25 mIU/ml and 50 mIU/ml.
The final concentrations were confirmed by using a microtiter EIA for FSH as a reference.
Each concentration was separated into 30 aliquots and each aliquot was assayed for FSH concentration.

Results:

In 30 of 30 samples with an FSH concentration of 50 mIU/ml, the color of the test line was darker than that of the control line (visual assay).
In 30 of 30 samples with an FSH concentration of 25 mIU/ml, the color of the test line was equal to that of the control line (visual assay).
In 30 of 30 samples with an FSH concentration of 10 mIU/ml, the color of the test line was lighter than that of the control line (visual assay).

B) Dilution:

Urine samples containing 200 mIU FSH /ml urine obtained from normal female volunteers were serially diluted with standards that contained no detectable FSH.

Results:

Dilution	FSH mIU/ml	Expected	Observed
1:1	200	Positive	Positive
1:2	100	Positive	Positive
1:4	50	Positive	Positive
1:8	25	Positive	Positive
1:16	12,5	Negative	Negative
1:32	6,25	Negative	Negative
1:64	3,125	Negative	Negative

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Specificity

The following substances were tested in specimens both positive (30 mIU/ml) and negative (10 mIU/ml) for FSH and were found to have no effect on the results up to the listed concentration.

Substance added	Final Concentration	10 mIU/ml Expected	10 mIU/ml Observed	30 mIU/ml Expected	30 mIU/ml Observed
Homologous Hormones:					
HCG (3rd IS, 75/537)	1000 mIU/ml	Negative	Negative	Positive	Positive
HLH (2nd IS, 78/549)	1000 mIU/ml	Negative	Negative	Positive	Positive
TSH (WHO 68/38)	1000 µIU/ml	Negative	Negative	Positive	Positive
Drugs:					
Acetaminophen	20 mg/dl	Negative	Negative	Positive	Positive
Acetylsalicylic A	20 mg/dl	Negative	Negative	Positive	Positive
Ascorbic A.	20 mg/dl	Negative	Negative	Positive	Positive
Atropine	20 mg/dl	Negative	Negative	Positive	Positive
Caffeine	20 mg/dl	Negative	Negative	Positive	Positive
Gentisic A.	20 mg/dl	Negative	Negative	Positive	Positive
Urinary Analytes:					
Glucose	2 g/dl	Negative	Negative	Positive	Positive
Hemoglobin	1 mg/dl	Negative	Negative	Positive	Positive
Ampicillin	20 mg/dl	Negative	Negative	Positive	Positive
Tetracycline	20 mg/dl	Negative	Negative	Positive	Positive

(A. = Acid)

CORRELATION:

The comparative study with quantitative EIA includes 84 female patients, who used the viola Menopausetest.
Each participant conducted the testing at home according to insert instructions. The urine samples obtained in the home testing were further tested in the laboratory using a conventional enzyme immunoassay for the quantitative determination of FSH.
The data obtained from the two testing methods was as follows:

Patient	Age	Ovulation Test	EIA Quantitative, hLH (mIU/ml)
1	57	+	96,9
2	31	-	8,2
3	50	-	16,2
4	41	-	8,2
5	49	-	4,3
6	36	-	2,5
7	38	-	13,3
8	46	±	23,0

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9	50	+	56,2
10	54	-	15,0
11	48	-	12,7
12	42	-	8,5
13	33	-	10,2
14	52	+	79,6
15	35	-	5,4
16	29	-	7,4
17	36	-	8,5
18	40	-	13,5
19	43	-	16,5
20	27	-	7,2
21	36	-	4,7
22	57	+	115,4
23	52	+	81,6
24	24	-	5,9
25	29	-	3,5
26	42	-	15,4
27	36	-	8,5
28	55	+	68,2
29	51	+	46,5
30	40	-	11,2
31	26	-	2,5
32	34	-	4,2
33	41	-	12,3
34	55	+	147,8
35	57	-	15,0
36	58	+	99,4
37	49	-	12,5
38	27	-	1,9
39	36	-	5,2
40	46	+	43,4
41	51	+	56,7
42	55	+	82,5
43	24	-	6,2
44	30	-	1,5
45	39	-	9,8
46	32	-	3,2
47	57	+	72,4
48	54	+	46,7
49	49	-	11,3
50	55	+	72,5
51	25	-	5,6
52	49	-	14,3
53	37	-	7,2
54	49	+	52,3
55	54	+	76,9
56	27	-	3,8
57	35	-	10,2
58	59	+	145,3
59	50	+	47,0
60	39	-	1,9
61	52	+	35,0
62	29	-	10,9
63	27	-	3,5
64	46	+	46,0

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65	36	-	5,0
66	46	+	75,0
67	40	-	10,7
68	56	+	44,0
69	26	-	12,7
70	30	-	3,7
71	55	+	150,7
72	27	-	8,5
73	43	-	12,4
74	33	-	3,7
75	37	-	2,4
76	56	+	176,4
77	38	-	5,5
78	25	-	4,5
79	30	-	5,6
80	29	-	11,0
81	24	-	2,4
82	42	-	17,0
83	34	-	4,5
84	29	-	3,9

The results obtained by females using the Menopause test showed a 100% correlation with results obtained by the laboratory working with the quantitative EIA. The results from the EIA indicate that FSH concentration equal or greater than 25 mIU/ml exhibits Postmeno-pause.

REAL TIME STABILITY TEST RESULTS FOR VIOLA-EARLY, STORED AT 15°C – 28°C

Tested over a period of 24 months, visual assay

LOT 1:

Sample	No	Real Time (Months)																							
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Neg. control	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10 mIU/ml	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25 mIU/ml	1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

LOT2

Sample	No	Real Time (Months)																							
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Neg. control	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10 mIU/ml	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25 mIU/ml	1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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LOT3

Sample	No	Real Time (Months)																							
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Neg. control	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10 mIU/ml	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25 mIU/ml	1	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
	2	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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