

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k052662

B. Purpose for Submission:

New device

C. Measurand:

Follicle stimulating hormone

D. Type of Test:

Qualitative

E. Applicant:

IND Diagnostic Inc.

F. Proprietary and Established Names:

One Step FSH Menopausal Test

G. Regulatory Information:

1. Regulation section:

21 CFR§862.1300, Follicle-stimulating hormone test system

2. Classification:

Class I, meets the limitations of exemptions 862.9 (c), (9)

3. Product code:

CGJ

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use

2. Indication(s) for use:

The One Step FSH Menopausal Test is a rapid chromatographic immunoassay for the qualitative detection of follicle stimulating hormone (FSH) in urine to aid in the detection of the onset of menopause. The test utilizes a combination of antibodies including mouse monoclonal anti-FSH antibodies and goat polyclonal anti-mouse antibodies to selectively detect elevated levels of FSH. This device is intended for both professional and lay person use.

3. Special conditions for use statement(s):

This device is for professional and over-the-counter use.

4. Special instrument requirements:

Not applicable

I. Device Description:

The One Step FSH Menopausal Test is supplied in three formats and is a chromatographic immunoassay for the qualitative detection of follicle stimulating hormone (FSH) in urine. The devices contain membrane strips coated with mouse monoclonal anti-FSH antibody A in the test region, goat anti-mouse (IgG) polyclonal antibody in the control region and a non-woven cloth which contains colloidal gold conjugate of monoclonal anti-FSH antibody B. The devices are single-use and visually read. One is a dipstick device, one is a midstream device and the other is a cassette device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

FSH Menopause Predictor Test - Midstream

2. Predicate 510(k) number(s):

k046115

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Detection of FSH in urine	Detection of FSH in urine
Principle/Methodology	Uses colorimetric visual interpretation	Uses colorimetric visual interpretation
Sensitivity	25 mIU/mL	25 mIU/mL

Differences		
Item	Device	Predicate
Device type	Midstream, test strip and cassette	midstream
Test time	Read results after 10 minutes	Read results after 3 minutes

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

Two site immunoassay

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Five batches of normal human urine negative for FSH were spiked to levels of 0, 12.5, 25, 37.5 and 50 mIU/mL. Ten consumers blindly tested each of the 5 batches using all three test formats. The results are in the table below:

FSH Added mIU/mL		0	12.5	25	37.5	50
Number of samples tested		30	30	30	30	30
Negative	MS	10	10	1	0	0
	C	10	10	1	0	0
	S	10	10	1	0	0
Positive	MS	0	0	9	10	10
	C	0	0	9	10	10
	S	0	0	9	10	10
MS = Midstream, C = Cassette, S = Strip						

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable

d. *Detection limit:*

The sensitivity of the test is 25 mIU/mL. Seventy-five samples from known non-menopausal were pooled together and split. Each pool was then spiked to concentrations of 0, 12.5, 25, 37.5 and 50 mIU/mL. Two trained technicians performed 5 tests at each concentration for each test format over two days. The results are in the table below:

FSH Added (mIU/mL)	0	12.5	25	37.5	50
N	30	30	30	30	30
Negative	30	30	1	0	0
Positive	0	0	29	30	30

e. *Analytical specificity:*

The specificity of the One Step FSH Menopausal Test was tested with similar hormones and compounds found in normal human urine. Luteinizing hormones (1,000 mIU/mL), human chorionic gonadotropin (100,000 mIU/mL) and thyroid stimulation hormone (1,000 mIU/mL) were added to urine containing different levels of FSH concentration and did not interfere with the results.

Interference substances were added in urine containing the following FSH concentration 0, 25 and 50 mIU/mL. None of the substances in the table below at the concentrations tested interfered with the assay.

Substance	Concentration
Acetaminophen	20 mg/mL
Acetylicylic acid	20 mg/mL
Albumin	100 mg/mL
Ascorbic Acid	20 mg/mL
Atropine	20 mg/mL
Bilirubin	2 mg/mL
Caffeine	20 mg/mL
Gentestic Acid	20 mg/mL
Glucose	2g/dL
Hemoglobin	1 mg/dL

f. *Assay cut-off:*

See Detection limit section above.

2. Comparison studies:

a. *Method comparison with predicate device:*

The One Step FSH Menopausal Test was compared to the FSH Menopause Predictor Test – Midstream (k041165) using 75 women. 25 test were run for each format.

75 women, ages 40-60 tested their own urine at home using one of the three formats of One Step Menopausal Test and FSH Menopause Predictor Test. The women were instructed to record their results and to keep their urine for testing by the trained technician. The technician tested each sample using the One Step FSH Menopausal Test, all three formats and the FSH Menopause Predictor Test.

There was an accuracy of 94.7% between the One Step Menopausal Test-all formats and the FSN Menopause Predictor Test when performed by the lay user. There was a 98.7% agreement between the One Step Menopausal Test-all formats and the FSN Menopause Predictor Test when performed by the trained technician. There was a 98.7% agreement between the results of the lay person and the trained technician when using the One Step FSH Menopausal Test. The midstream test device when used by the lay user was done with midstream test method and the trained technician used the dip method.

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values are based on literature and in previous sensitivity studies that demonstrated adequate performance at the cutoff of 25 mIU.mL.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Other Supportive Device and Instrument Information:

Q. Administrative Information:

1. Applicant contact information:

a. *Name of applicant:*

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f. *Contact:*

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2. Review documentation:

R. Reviewer Name and Signature:

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