

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

A. 510(k) Number:

K030058

B. Analyte:

Follicle stimulating hormone

C. Type of Test:

Qualitative

D. Applicant:

Early Detect Inc.

E. Proprietary and Established Names:

EarlyDETECT® Menopause Test

F. Regulatory Information:

1. Regulation section:

21 CFR 862.1300

2. Classification:

Class I

3. Product Code:

CGJ

4. Panel:

75

G. Intended Use:

1. Intended use(s):

The *EarlyDETECT*® Menopause Test is a rapid *in vitro diagnostic* immunoassay designed for the qualitative determination of human follicle stimulating hormone (FSH) in urine for the confirmation of hormone changes related to the symptoms associated with the stages of menopause.

2. Indication(s) for use:

EarlyDETECT® Menopause Test is a qualitative rapid membrane immunoassay for the *in vitro diagnostic* detection of follicle stimulating hormone (FSH) in human urine as a confirmation of hormone changes related to the symptoms associated with the stages of menopause. This device is intended for professional and over the counter (OTC) use.

3. Special condition for use statement(s):
This is intended for clinical laboratory, physician's office laboratory, and over the counter use.
4. Special instrument Requirements:
Not applicable

H. Device Description:

The *EarlyDETECT*® Menopause Test is supplied in two formats: wand and cassette. The test wand and test cassette kits each consist of two test devices, each containing mouse monoclonal antibody-colloidal gold conjugate and mouse monoclonal antibodies on the test region, and a package insert. The test cassette kit also includes two disposable pipettes.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Abbott AXSYM FSH
2. Predicate K number(s):
K935612
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	<ul style="list-style-type: none"> • Detection of FSH 	<ul style="list-style-type: none"> • Determination of FSH
Differences		
Item	Device	Predicate
Intended Use	<ul style="list-style-type: none"> • Qualitative test for use with urine 	<ul style="list-style-type: none"> • Quantitative test for use with serum or plasma
Principle/Methodology	<ul style="list-style-type: none"> • Membrane immunoassay using colloidal gold conjugated antibody • Uses antibody stripped membrane for capture • Uses a colorimetric visual interpretation of bound colloidal gold antibody • Requires addition of urine to the device 	<ul style="list-style-type: none"> • Microparticle enzyme immunoassay using enzyme conjugated antibody • Uses antibody coated microparticles for capture • Uses instrumentation to read the final reaction

Sensitivity	and observing for colored lines • 25 mIU/mL	• Requires multiple pipetting and incubation steps • 0.2 mIU/mL
-------------	--	--

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

Not applicable

K. Test Principle:

The device is a two site sandwich immunoassay.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Within-Lot: Three batches of normal human urine demonstrated to be negative for FSH was spiked with FSH to levels of 0, 10, 25, 50, and 100 mIU/mL. Five devices in each of three batches (for a total of fifteen devices from one lot) were tested per concentration. The results showed excellent repeatability for all positive and negative urine samples.

Inter-Lot: Normal human urine known to be negative for FSH was spiked with FSH to levels of 0, 10, 25, 50, and 100 mIU/mL. The samples were blinded/coded and were used to test three (3) lots of test devices, each over a period of four weeks. Sixty (60) vials of each concentration were coded. Twenty (20) devices per concentration for each lot were tested. The results of these tests demonstrated no inter-lot variation when testing both positive and negative spiked samples across three (3) different lots of test devices.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Not applicable

d. *Detection limit:*

The sensitivity of the test is 25 mIU/mL.

A panel of FSH was prepared by spiking fresh normal human pooled urine specimens with FSH standard to concentrations of 0, 5, 10, 15, 20, 25, 50, and 100 mIU/mL. Fifty (50) devices per standard level were tested. Samples with concentrations of FSH equal to or lower than 20 mIU/mL were identified as negative for all samples. Samples

with concentrations of FSH equal to or higher than 25 mIU/mL were identified as positive for all samples.

e. Analytical specificity:

The specificity was tested with similar hormones and compounds commonly found in normal human urine. Luteinizing hormone (500 mIU/mL), human chorionic gonadotropin (250 IU/mL), and thyroid stimulating hormone (1000 mIU/mL) were added to positive and negative urine and showed no affect on the results.

Various prescription and OTC drugs and chemical and biological analytes were added to two urines, one with a 0 mIU/mL FSH level and the other with a 50 mIU/mL FSH level. None of the substances tested interfered with the test results.

f. Assay cut-off:

See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:

The *EarlyDETECT*® Menopause Test was compared to the Abbott AxSYM FSH using a total of 416 patient samples.

One hundred (100) women, age 19 to 80 years, tested their own urine at home using the test wand format, followed by the technician re-reading the test result at the visit later the same day. Blood was drawn on the same day and sent to the laboratory for analysis by the comparative method.

One hundred forty-seven (147) general practice male and female patients, age 18 to 83, collected their urine at home and brought it to their office visit. Each patient performed testing using both the cassette and wand (by dipping it in a cup of urine), followed by the technician or nurse also performing testing on both the cassette and wand.

An additional study was performed in the company's lab using 169 urines (with known concentrations of FSH) that were obtained from local hospitals over time. These urines were run using both the wand and cassette to evaluate performance of these devices against the reference FSH values.

For the study using 100 women, there was 99% agreement between the consumer and professional results. All the samples with concentrations of 24.9 mIU/mL and above were identified as positive by both the consumer and the professional.

The results from the 147 general practice patients showed 100% agreement between test formats and between the consumer and professional results. All samples with FSH at 24.8 mIU/mL and above were identified as positive on the *EarlyDETECT*® device.

Of the 169 urines evaluated in-house, two samples yielded discrepant results between the cassette and wand versions. One of the discrepant samples contained 24 mIU/mL FSH and the other contained 25 mIU/mL FSH. All other samples at 24 mIU/mL FSH and above tested positive on the *EarlyDETECT*® device.

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):*
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:

The expected values are based on literature and a study performed with the *EarlyDETECT*® Menopause Test. Women between the ages of 13 to 80 years were evaluated. Positive FSH levels were identified in women as early as 39 - 41 years, while negative FSH levels were found in women as late as 51 - 53 years.

M. Conclusion:

The *EarlyDETECT*® Menopause Test is similar to the AxSYM FSH test in that both devices immunologically capture follicle stimulating hormone in human specimens using specific double monoclonal and/or polyclonal antibodies for detection. The differences noted above do not raise new issues of safety or effectiveness. The new device uses well-established chemical principles, methodology, and components. To further demonstrate equivalence, method comparison, sensitivity, specificity, interfering substances, and reproducibility data were provided and found to be adequate. The *EarlyDETECT*® device demonstrated similar performance to other commercially available devices of this type. Additionally, the revised labeling is

adequate and conforms to 21 CFR 809.10. Therefore, I recommend a substantial equivalence determination for the *EarlyDETECT*® Menopause Test.