

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

A. 510(k) Number:

k051012

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Salimetrics LLC
Progesterone Calibrator and Control.

C. Measurand:

Progesterone Calibrator and Control

D. Type of Test:

Calibrator and Control

E. Applicant:

Salimetrics LLC

F. Proprietary and Established Names:

Proprietary Name – Salimetrics LLC Progesterone Calibrator and Control

Established Name - Calibrator and Control

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150 Calibrator

21 CFR 862.1660 Control

2. Classification:

Class II – Calibrator

Class I – Controls

3. Product code:

JIT
JJY

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The salivary progesterone calibrator is a device intended for medical purposes to use in the Salimetrics competitive enzyme immunoassay to establish points of reference that are used to determine values in the measurement of free progesterone in saliva.

The salivary progesterone controls are devices intended for use in monitoring the performance of the salivary immunoassay of free progesterone in saliva.

3. Special conditions for use statement(s):

4. Special instrument requirements:

For use with a Microplate reader capable of reading at 450nm.

I. Device Description:

The Salimetrics Saliva progesterone calibrator comes with the Salimetrics Saliva Progesterone Assay Kit and also may be sold separately. It is in a 1mL vial. The calibrator is derived from synthetic progesterone and is suspended in a saliva-like matrix with a non-mercury preservative.

The Salimetrics Saliva progesterone control is provided in 0.5 mL vials in two concentrations, a high control of 1000 pg/mL and a low control of 50.6 pg/mL. The control is derived from synthetic progesterone and is suspended in a saliva-like matrix with a non-mercury preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

IBL (Immuno Biological Laboratories) Progesterone LIA

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

k040923

3. Comparison with predicate:

Salimetrics Progesterone Calibrator to the predicate device

Device Characteristic	Salimetrics Progesterone Calibrator	Predicate Device
Concentration	2430 pg/mL	1000 pg/mL
Matrix	Saliva-like matrix	Buffer, BSA, 0.1%NaN ₃
Calibrator Range	10 – 2430 pg/mL	10 – 1000 pg/mL
Storage	2-8°C	2-8°C <-20°C
Stability	1.5 years	>4wks >6months

Salimetrics Progesterone Controls to the predicate device

Device Characteristic	Salimetrics Progesterone Controls	Predicate Device Controls
Concentration	1000 pg/mL, 50.6 pg/mL	200 pg/mL, 30 pg/mL
Matrix	Saliva-like matrix	Buffer, BSA, 0.1%NaN ₃
Storage	2-8°C	2-8°C <20 °C
Stability	2.0 years	>4wks >6months

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

FDA's Guidance for Industry, Abbreviated 510(k) Submission for In Vitro Diagnostic Calibrators; Final

FDA's Points to Consider Guidance Document on Assayed and Unassayed Quality Control Material; Draft

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

Based upon real time and accelerated stability studies, the Progesterone Calibrator is stable for 1.5 years.

The calibrator is prepared from starting progesterone standard (1000 ng/mL). The progesterone standard is of synthetic origin. The standard is prepared by accurately weighing on a balance calibrated by an independent company to standards traceable to international measurement standards. Salimetrics prepares the progesterone working calibrator (2430 pg/mL) via dilution with standard diluent, following GMP regulations. Pipettes and balances are independently validated to NIST standards. The calibrator performance is verified by immunoassay.

The controls are prepared from starting progesterone standard (1000 ng/mL). The progesterone standard is of synthetic origin. The standard is prepared by accurately weighing on a balance calibrated by an independent company to standards traceable to international measurement standards. Salimetrics prepares the progesterone high control (1000 pg/mL) via dilution with standard diluent, following GMP regulations. Salimetrics low control is prepared from the Salimetrics progesterone working calibrator (2430 pg/mL) via dilution with standard diluent, following GMP regulations. Pipettes and balances are independently validated to NIST standards. The control performance is verified by immunoassay.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable

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:

Not applicable

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.