

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

A. 510(k) Number:

k103683

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for the IMMULITE®/IMMULITE 1000 Progesterone assay (LKPW)

D. Type of Test:

Not Applicable

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

IMMULITE®/IMMULITE 1000 Progesterone Calibration Verification Material (CVM)

G. Regulatory Information:

1. Regulation section:

21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I, Reserved

3. Product code:

JJX – Single (Specified) Analyte Controls (Assayed and Unassayed)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

For in vitro diagnostic use, for the calibration verification of the IMMULITE®/IMMULITE 1000 Progesterone assay (LKPW).

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

IMMULITE®/IMMULITE 1000 system

I. Device Description:

The Calibration Verification Material (CVM) contains one set of four vials, 2 mL each, spiked with low, intermediate and high levels of progesterone in processed human serum, with preservative, and a progesterone-free sample. The Calibration Verifiers are supplied in liquid form, ready to use. Store unopened materials refrigerated at 2–8°C until expiration date. The product is labeled as stable at 2–8°C for 30 days after opening.

Warnings and Precautions: For in vitro diagnostic use. Follow universal precautions, and handle all components as if capable of transmitting infectious agents. Individual source materials derived from human blood were tested by FDA approved/cleared methods and found nonreactive for syphilis; for antibodies to HIV 1 and 2; for hepatitis B surface antigen; and for antibodies to hepatitis C. Sodium azide, at concentrations less than 0.1 g/dL, has been added as a preservative. On disposal, flush with large volumes of water to prevent the buildup of potentially explosive metal azides in lead and copper plumbing.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ADVIA Centaur® Enhanced Estradiol (eE2) Master Curve Material (MCM)

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

K102904

3. Comparison with predicate:

Reagent Similarities and Differences		
	Candidate Device IMMULITE/IMMULITE 1000 Progesterone CVM (k103683)	Predicate Device ADVIA Centaur Master Curve Material (k102904)
Intended/Indications for Use	is for <i>in vitro</i> diagnostic use in the verification of calibration	Same
Specimen Matrix	Human serum	Same
Form	Liquid	Lyophilized
Analytes	Progesterone	Estradiol
Storage	2 to 8°C	Same
Stability	Unopened-until expiration date on the vial label Opened- 30 days	Unopened-Same Opened- 14 days

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

- Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final
- Points to Consider for Review of Calibration and Quality Control Labeling for In Vitro Diagnostic Devices/Cover Letter dated 3/14/1996
- Format for Traditional and Abbreviated 510(k)s - Guidance for Industry and FDA Staff
- Indications for Use Statement
- Premarket Notification - Consistency of Reviews #K89-1 (blue Book memo)

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):*

Traceability:

The IMMULITE Progesterone CVMs are traceable to an internal standard manufactured using qualified materials and measurement procedures. Internal reference standards are prepared using Progesterone stock solution which had its concentration defined by optical density.

Stability:

Stability studies are being conducted on two lots under the following conditions: real time (2-8 °C) for 2 years, room temperature (15-28°C) for seven days, and accelerated (35-39°C) for three days. Current testing supports a seven month storage claim at 2-8°C, and real time studies are ongoing to support a 2 year stability claim.

Open vial studies are being performed for >90 days at 2-8°C. Vials are opened and tested at day zero and at each time point. Percent recovery is calculated using the average dose from triplicate results compared to the day 0 testing and the acceptance criteria is that the open vial must be within 10% from day 0 material for progesterone ≥ 2 ng/mL, and within 15% for progesterone ≥ 0.5 ng/mL and < 2.0 ng/mL. The sponsor will claim that it is stable for 14 day once reconstituted and stored at 2-8 °C.

Value Assignment

The IMMULITE[®] calibrators and CVMs are value assigned using purified Progesterone stock solution whose concentration was defined by optical density. The calibrators and CVMs are tested on minimum of 9 runs comprised of minimum 3 systems and 3 different kit lots. The calibrator values are calculated based on the recovered values for each run independently. The average analyte recovered for each CVM assigns their value. Quality control is performed by calculating the recovery of patient sample panels and controls using the assigned calibrator and CVM values. Three levels of commercially available controls and four levels of human serum based pools are used to validate the CVM value assignment. The target specifications for production lots are:

CVM (ng/mL)	Target (ng/mL)	Range (ng/mL)	Precision (% CV)
0	0	0.0-0.20	NA
0.47	0.47	0.26-0.68	<25
10	10	7.9-12.1	<10
40	40	32.4-47.6	<10

Matrix Effects

The Sponsor spiked three concentrations of progesterone CVM into a reference lot, evaluation lot, and male and female human serum lots. The progesterone values of the reference lot were compared to the evaluation and human serum lots. The acceptance criteria were $100\% \pm 15\%$ with an overall average of $\pm 10\%$. Each of the samples met the acceptance criteria, and the Sponsor concluded that there were no matrix effects.

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

The expected values are provided in the IMMULITE/IMMULITE 1000 Progesterone Calibration Verification Material lot-specific value sheet. The expected assay range is 0.2-40 ng/mL. The values below can be considered as guidelines:

Level	Units	Target Mean	Guideline \pm 2 SD range	
1	ng/mL	0.00	0.00	\leq 0.20
2	ng/mL	0.47	0.42	0.52
3	ng/mL	10.00	9.00	11.0
4	ng/mL	40.0	36.0	44.0

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.