

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

A. 510(k) Number:

k113373

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator materials for progesterone

D. Type of Test:

Calibrator material

E. Applicant:

Siemens Healthcare Diagnostics, Inc.

F. Proprietary and Established Names:

Dimension Vista® LOCI 9 Calibrator

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1150; Calibrator
2. Classification:
Class II
3. Product code:
JIT; Calibrator, Secondary
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
The LOCI 9 CAL is an *in vitro* diagnostic product for the calibration of the progesterone (PROG) method on the Dimension Vista® System.
2. Indication(s) for use:
See Intended Use section above
3. Special conditions for use statement(s):
For prescription use only

4. Special instrument requirements:
Dimension Vista® System

Stability and value assignment studies were performed on the Dimension Vista® 1500 Intelligent Lab System.

I. Device Description:

The LOCI 9 Calibrator is a liquid, frozen bovine serum albumin based product containing progesterone packaged as ten vials to a carton, with two vials at each of the 5 levels (A through E), 1.5 mL per vial. The LOCI 9 Calibrator includes progesterone, testosterone, buffers and preservatives. This calibrator will only be used with the Dimension Vista® Progesterone (PROG) method.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Siemens Dimension Vista® N-terminal Pro-Brain Natriuretic Peptide Calibrator

2. Predicate K number(s):
k080578

3. Comparison with predicate:

	<u>Candidate Device</u> Dimension Vista® LOCI 9 Progesterone Calibrator	<u>Predicate Device</u> Dimension Vista® PBNP CAL (k080578)
Intended use	Same	<i>In vitro</i> diagnostic product for the calibration of analytical methods on the Dimension Vista® System
Analyte	Progesterone	Synthetic PBNP
Matrix	Same	Bovine serum albumin-based
Form	Same	Liquid, frozen
# Levels	Ten vials, 2 vials/level, 5 levels (0, 1.0, 8.0, 20.0 and 44.0 ng/mL)	Ten vials, 2 vials/level, 5 levels (0, 250, 1,500, 12,000 and 36, 750 pg/mL)
Stability	Unopened-Same Opened—7 days	Unopened-until expiration date on the vial label Opened—30 days
Fill Volume	1.5 mL/vial	1.0 mL/vial

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

- Guidance for Industry – Abbreviated 510(k) Submissions for *In Vitro* Diagnostic Calibrators; Final

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 assigned values for the commercial LOCI 9 calibrator Levels B-E are assigned from the following master pool levels:

Analyte	Reference assignment of Master pools	Master pool Levels
Progesterone	Progesterone GC-IDMS*	0.97, 8.97, 17.2 and 43.8 ng/mL

*Gas chromatographic isotope dilution mass spectrometry

The zero calibrator for the progesterone master pool is fatty acid free bovine serum albumin calibrator base.

Stability:

Real Time/Closed Vial Stability: Target shelf-life for the Dimension Vista® LOCI 9 calibrators is 12 months when frozen (-15°C to -25°C). Shelf life is determined by comparing results of the calibrator levels stored at -15°C and -25°C with control calibrators stored at -70°C on intervals ranging from 0 to 395 days. Five replicates per level are tested. Three production (test) and control (reference) lots of calibrator were tested for stability.

Thawed 2-8°C Closed Vial Stability: 7 days at 2-8°C.

Punctured/Open Vial Stability: Punctured vials are stable for 7 days when stored on board the Dimension Vista® System. Once the cap is removed, the product is stable for 7 days when recapped and stored at 2-8°C.

Acceptance Criteria: The reference material (control calibrator) is stored at -70°C. The method is calibrated from this stored material. The -15°C and -25°C calibrator levels are recovered from the control calibration. Recoveries vs. time are monitored and allowable drift (% change in control vs. test calibrators) was ≤ 5% deviation from reference concentration for levels B-E.

Value Assignment:

The values of the LOCI 9 Calibrators are assigned by creating anchor pools from individual serum patient samples covering the assay range for progesterone that are assayed by GC-IDMS. The four level Master Pools are prepared by spiking commercially purified progesterone in bovine serum albumin (BSA) and assigning values on the Dimension Vista® 1500 Intelligent Lab System prior to storing at -70°C. A progesterone stock solution is made by spiking commercially available progesterone material gravimetrically into a BSA calibrator base at appropriate concentrations for levels B-E. The concentration of the bulk commercial calibrator is verified by measuring recovery on a Dimension Vista® instrument calibrated with Progesterone Master Pools. The final bottle values for commercial lots are assigned against the master pool curves using multiple instruments and reagent lots, where values must be within acceptable ranges of the target for levels B-E. The bottle value for each level is the mean of 45 replicates.

The attached table outlines the target range at each level as well as the acceptable range and precision around the target.

LOCI 9 Calibrator KC647			
Progesterone Method Range 0 to 40 ng/mL			
Level	Target	Range ng/mL	Level Precision
A	0	< 0.2 ng/mL	< 0.2 ng/mL
B	1.0	0.9 to 1.1	≤ 3%
C	8.0	7.2 to 8.8	≤ 3%
D	20.0	18.0 to 22.0	≤ 3%
E	44.0	39.6 – 48.4	≤ 3%

- 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.