

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

A. 510(k) Number:

k110061

B. Purpose for Submission:

New device

C. Measurand:

Quality control material for unconjugated estriol assay

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics

F. Proprietary and Established Names:

IMMULITE unconjugated Estriol (uE3) Calibration Verification Material

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:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

Refer to indications for use below

2. Indication(s) for use:

For in vitro diagnostic use as a control for calibration verification of the IMMULITE Unconjugated Estriol (uE3) assays on the IMMULITE/IMMULITE 1000 and 2000 systems.

The calibration verification material is assayed control with four levels. The analyte levels for IMMULITE 1000 are 0.00, 0.016, 2.70, and 11.2 ng/mL and 0.00, 0.19, 2.90, and 12.0 ng/mL for IMMULITE 2000 systems. The matrix is estriol in processed horse serum.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use. For prescription use only.

4. Special instrument requirements:

The IMMULITE Unconjugated Estriol (uE3) Calibration Verification Material (CVM) is intended for use with the IMMULITE/IMMULITE 1000 and 2000 systems.

I. Device Description:

The IMMULITE uE3 CVM consists of one set of four vials, 2 mL each, containing low, intermediate, and high levels of unconjugated estriol in processed horse serum, with preservative. The first level is an unconjugated estriol-free sample. The IMMULITE uE3 CVM levels are supplied in liquid form, ready to use.

IMMULITE uE3 CVM	Target Value (ng/mL)	
	IMMULITE/IMMULITE 1000	IMMULITE 2000
Level 1	0.00	0.00
Level 2	0.16	0.19
Level 3	2.70	2.90
Level 4	11.2	12.0

J. Substantial Equivalence Information:

1. Predicate device name(s):

ADVIA Centaur Enhanced Estradiol (eE2) Master Curve Material

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

k102904

3. Comparison with predicate:

Item	Device (k110061)	Predicate (k102904)
Indications for use	For use in calibration verification of the assay.	Same
Format	Liquid, ready for use	Lyophilized
Matrix	Horse serum	Human serum
Analyte	Estriol	Estradiol
Instrument	IMMULITE/IMMULITE 1000, and 2000 systems	ADVIA Centaur XP systems
Stability	<u>Unopened</u> Store at 2-8°C until expiration date <u>Opened</u> Use immediately after opening, discard after use	<u>Unopened</u> Store at 2-8°C until expiration date <u>Opened</u> 2-8°C for 14 days <u>On-board</u> 6 hours
Levels	4	6

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

1. Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrator; Final Guidance for Industry.
2. CLSI EP14-A2. Evaluation of Matrix Effects; Approved Guideline.

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 Unconjugated Estriol (uE3) Calibration Verification Material is traceable to an internal reference calibrator. Reference calibrators are traceable to individual human samples assigned with GC-MS values.

Expected Values and Value Ranges

Expected values for the IMMULITE uE3 CVM are determined by analyses of 40 replicates at each control level using three kit lots and three systems (IMMULITE/IMMULITE 1000 or IMMULITE 2000 systems). Pre-determined acceptance criteria for analyte recovery must be met for each calibrator lot. Calibrator assigned values are lot dependent as specified in the product labeling.

Stability

Stability testing protocols and acceptance criteria for the IMMULITE uE3 CVM were reviewed and found acceptable. The manufacturer claims a shelf life stability of 6 months at the recommended storage temperatures of 2-8°C.

- 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 labeling for each specific lot.

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.