

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

A. 510(k) Number:

k133816

B. Purpose for Submission:

New device

C. Measurand:

Calibration Verification Material (CVM) for IMMULITE® 2000 Free PSA antigen

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

IMMULITE® 2000 Free PSA 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:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

The IMMULITE® 2000 Free PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative measurement of Free PSA antigen.

2. Indication(s) for use:

Same as Intended Use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

IMMULITE® 2000 Systems

I. Device Description:

The CVM kit contains one set of four vials (LPFCVM 1-4), 2 mL each. LPFCVM1 contains bovine protein/buffer matrix with preservatives. CVM2 – CVM4 contain low, intermediate and high levels of Free PSA respectively, in bovine protein/buffer matrix with preservatives matrix. The CVMs are supplied in lyophilized form.

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):

IMMULITE® 2000 PSA Calibration Verification Material (CVM), k131536

2. Comparison with predicate:

Similarities		
Item	Device IMMULITE® 2000 Free PSA CVM	Predicate IMMULITE® 2000 PSA CVM
Intended Use	The IMMULITE® 2000 Free PSA Calibration Verification Material (CVM) is intended for monitoring system performance of the IMMULITE Immunoassay system for the quantitative	Same

Similarities		
Item	Device	Predicate
	IMMULITE® 2000 Free PSA CVM	IMMULITE® 2000 PSA CVM
	measurement of Free PSA antigen.	
Function	Quality Control material	Same
Traceability	Internal reference preparation	Same
Levels	4 (zero, low, intermediate and high)	Same
Storage	<u>Unopened</u> : ≤20° C until the expiration date <u>Opened</u> : Use immediately after opening; discard any unused material	Same
Use	Single Use Only	Same

Differences		
Item	Device	Predicate
Analyte	Free PSA	PSA
Form	Lyophilized	Liquid
Matrix	Bovine Serum Albumin	Processed (pH-treated) Chicken Serum

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

GEN13640 Stability Testing of In Vitro Diagnostic Reagents (Version 2002)
 Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
 Guidance for Industry and FDA Staff– Assayed and Unassayed Quality Control Material

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 Free PSA CVMs are traceable to the WHO NIBSC 1st International Standard 96/668 through internal reference calibrators.

Value Assignment:

IMMULITE® CVMs are value assigned using approved reference calibrators lot manufactured with qualified materials and measurement procedures. Each level of CVM was tested in six runs, three replicates per run for a total of 18 replicates using two different kit lots on four instruments. The values are assigned using a curve of assigned reference calibrators. The CVM values are calculated based on the recovered values for each run on each instrument independently. CVM values are then averaged across all systems. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The values in the table below are example of the target range for each CVM level for the lot tested.

Level	Catalog number	Target Mean (ng/mL)	Guideline Target Mean \pm 2SD (ng/mL)	
1	LPTSCVM1	0.00	0.00	0.07
2	LPTSCVM2	0.20	0.17	0.22
3	LPTSCVM3	1.45	1.29	1.61
4	LPTSCVM4	24.40	22.00	26.80
Assay range 0.07 – 25.0 ng/mL				

Value assignment is lot specific. Each lot of CVM quality control is tested for verification by calculating the recovery of patient samples, spiked patient samples and normal male samples and controls using the assigned value. The controls must fall within their target ranges.

Stability:

The stability studies were conducted to validate shelf life claim for the IMMULITE® 2000 Free PSA CVM on IMMULITE 2000 platforms. The CVMs are run as part of the calibrator stability testing. The CVMs are run in duplicates and the concentration value is determined from the reference internal material. One lot was tested for 42 months. Two additional lots were tested for six months. For all studies there is percent recovery of more than 90%. The claimed CVM stability is 6 months when stored at -20°C prior to opening, and for 8 hours at ambient temperature (room temperature) after opening. Each CVM is for single use only. Real time stability is ongoing.

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.