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

A. 510(k) Number:

K143636

B. Purpose for Submission:

New device

C. Measurand:

Calibration Verification Material (CVM) for IMMULITE® 2000 Androstenedione assay and Troponin I assay

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:
IMMULITE® 2000 Androstenedione Calibration Verification Material
IMMULITE® 2000 Troponin I 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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indication for use below

2. Indication(s) for use:

   Androstenedione: The IMMULITE® 2000 Androstenedione Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Androstenedione assay on the IMMULITE 2000 systems

   Troponin I: The IMMULITE® 2000 Troponin I Calibration Verification Material (CVM) is for in vitro diagnostic use in the verification of calibration of the IMMULITE Troponin I assay on the IMMULITE 2000 systems

3. Special conditions for use statement(s):

   For Prescription use only

4. Special instrument requirements:

   IMMULITE 2000 Systems

I. Device Description:

Androstenedione: The IMMULITE® 2000 Androstenedione Calibration Verification Material (CVM) contains one set of four vials, 2mL each in liquid form. CVM1 contains processed human serum with preservatives. CVM2, CVM3 and CVM4 contain Androstenedione in processed human serum matrix with preservative.

Androstendione Analyte Target Mean Levels

CVM Level	Target Mean(ng/mL)
LAOCVM1	0.00
LAOCVM2	1.31
LAOCVM3	5.00
LAOCVM4	10.0

Troponin I: The IMMULITE® 2000 Troponin I Calibration Verification Material (CVM) contains one set of four vials, 2mL each after reconstitution. CVM1 contains equine serum

with 0.88% sodium azide and preservative. CVM2, CVM3 and CVM4 contain human Troponin I and rabbit Troponin C in equine serum matrix with 0.88% sodium azide and preservative.

Troponin I Analyte Target Mean Levels

CVM Level	Target Mean (ng/mL)
LAOCVM1	0.00
LAOCVM2	0.575
LAOCVM3	14.2
LAOCVM4	159

The package insert has the following warning:
CAUTION POTENTIAL BIOHAZARD
Contains human source material. Each donation of human blood or blood component was tested by FDA-approved methods for the presence of antibodies to human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) as well as for hepatitis B surface antigen (HBsAg) and antibody to hepatitis C virus (HCV). The test results were negative (not repeatedly reactive.). No test offers complete assurance that these or other infectious agents are absent; this material should be handled using good laboratory practices and universal precautions.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Androstenedione: IMMULITE® 2000 Cortisol Calibration Verification Material (CVM)

   Troponin I: IMMULITE® 2000 Prolactin Calibration Verification Material (CVM)

2. Predicate 510(k) number(s):
   Androstenedione: k141444
   Troponin I: k140818

3. Comparison with predicate:

Androstendione:

Similarities		
Item	Candidate Device IMMULITE 2000 Androstenedione CVM	Predicate Device IMMULITE 2000 Cortisol CVM, k141444
Intended Use	Calibration Verification Material (CVM) is for the verification of calibration of the chemistry assay.	Same
Storage	≤-20°C	Same
Form	Liquid	Same
Stability	Stable unopened until the expiration date	Same
Levels	4	Same
Matrix	Human Serum with preservatives	Same
Use	Single Use Only	Same

Differences		
Item	Candidate Device IMMULITE 2000 Androstenedione CVM	Predicate Device IMMULITE 2000 Cortisol CVM, k141444
Analyte	Androstenedione	Cortisol

Troponin I:

Similarities		
Item	Candidate Device IMMULITE 2000 Troponin I CVM	Predicate Device IMMULITE 2000 Prolactin CVM, k140818
Intended Use	Calibration Verification Material (CVM) is for the verification of calibration of the chemistry assay.	Same
Form	Lyophilized	Same
Matrix	Equine serum with preservatives	Same
Levels	4	Same
Stability	Stable unopened until the expiration date	Same
Use	Single Use Only	Same

Differences		
Item	Candidate Device IMMULITE 2000 Troponin I CVM	Predicate Device IMMULITE 2000 Prolactin CVM, k140818
Storage	≤-20°C	2-8°C
Analyte	Troponin I	Prolactin

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

CEN 13640 Stability Testing of In Vitro Diagnostic Reagents

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 Androstenedione CVMs are 4 level materials which are a subset of 7 level Androstenedione calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Androstenedione reagents and two point adjustors. The assigned reference calibrators are prepared using Androstenedione antigen stock and are traceable to an internal material which has been gravimetrically prepared.

The IMMULITE Troponin I CVMs are 4 level materials which are a subset of 10 level Troponin I calibrators. Calibrators are not commercialized but are used internally during manufacture and release testing of Troponin I reagents and two point adjustors. The assigned reference calibrators are prepared using Troponin I

antigen stock and are traceable to an internal standard which have been gravimetrically prepared.

Value Assignments:

Androstenedione: The CVMs dose values are generated using curve generated by 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. Quality control is performed by calculating the recovery of patient samples and controls using the assigned CVM values. The CVMs were tested on 27 replicates in total comprised of 9 runs, 3 replicates per run, 8 IMMULITE 2000 systems, and 3 different reagent kit lots.

Troponin I: The CVMs dose values are generated using curve generated by 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. Quality control is performed by calculating the recovery of normal patient samples, spiked samples and controls using the assigned CVM values. The assay controls must fall within their target ranges. The CVMs were tested on 15 replicates in total comprised of 5 runs, 3 replicates per run, on 4 IMMULITE 2000 systems and 2 different reagent kit lots.

Expected Values/Target Values/Reference Range:
Androstenedione: The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD). The target values are provided in the IMMULITE® 2000 CVM Calibration verification Material lot-specific value card.

Androstendione Analyte Target Range Levels

CVM Level	Target Mean (ng/mL)	SD	Guideline+/- 2SD Range (ng/mL)	
LAOCVM1	0.00	-	0.00	0.30
LAOCVM2	1.31	0.10	1.11	1.51
LAOCVM3	5.00	0.25	4.50	5.50
LAOCVM4	10.0	0.65	8.70	11.3

Troponin I: The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD).

Troponin I Analyte Target Range Levels

CVM Level	Target Mean (ng/mL)	SD	Guideline+/- 2SD Range (ng/mL)	
LAOCVM1	0.00	-	0.00	0.30
LAOCVM2	0.575	0.092	0.391	0.759
LAOCVM3	14.2	0.90	12.4	16.0
LAOCVM4	159	15.0	129	189

Stability:

Androstenedione Stability Summary:

A stability study was performed to validate the real-time shelf life and open vial stability claims for the IMMULITE 2000 Androstenedione Calibration Verification Material (CVM). The stability study protocols and acceptance criteria were reviewed and were found to be adequate to support the sponsor's following stability claims: The Calibration Verification Materials are stable up to 3 years when stored at -20°C prior to opening. Open vial stability studies support 8 hours of stability at room temperature (15-25°C).

Troponin I Stability Summary:

A stability study was performed to validate the real-time shelf life and open vial stability claims for the IMMULITE 2000 Troponin I Calibration Verification Material (CVM). The stability study protocols and acceptance criteria were reviewed and were found to be adequate to support the sponsor's following stability claims: The Calibration Verification Materials are stable up to 10 months when stored at -20°C prior to opening, and for 2 hours at room temperature (15-25°C) after reconstitution.

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.