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

**A. 510(k) Number:**
k143373

**B. Purpose for Submission:**
New device

**C. Measurand:**
Calibration Verification Materials for Calcitonin and Prostatic Acid Phosphatase (PAP)

**D. Type of Test:**
Not applicable

**E. Applicant:**
Siemens Healthcare Diagnostics, Inc.

**F. Proprietary and Established Names:**

IMMULITE® 2000 Calcitonin Calibration Verification Material
IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material

**G. Regulatory Information:**

1. Regulation section:
   862.1660, Quality control material

2. Classification:
   Class I, reserved

3. Product code:
   JJX

4. Panel:
   Chemistry (75)

**H. Intended Use:**

1. Intended use(s):
   See indications for use statements below.

2. Indication(s) for use:
   IMMULITE® 2000 Calcitonin Calibration Verification Material:
   The IMMULITE® 2000 Calcitonin Calibration Verification Material (CVM) is for *in*

*vitro* diagnostic use in the verification of calibration of the IMMULITE Calcitonin assay on the IMMULITE 2000 systems.

IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material: The IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material (CVM) is for *in vitro* diagnostic use in the verification of calibration of the IMMULITE PAP assay on the IMMULITE 2000 systems.

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   IMMULITE® 2000

## I. Device Description:

The IMMULITE® 2000 Calcitonin Calibration Verification Material (CVM) contains one set of four vials, 3mL each after reconstitution. CVM1 contains bovine protein buffer matrix with preservatives and CVM2, CVM3, and CVM4 contain calcitonin in bovine protein buffer matrix with preservative.

The IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material (CVM) contains one set of four vials, 2mL each after reconstitution. CVM1 contains a bovine protein/buffer with 0.27% sodium azide and preservative. CVM2, CVM3, and CVM4 contain human prostatic acid phosphatase in a bovine protein/buffer matrix with 0.27% sodium azide and preservative.

Sponsor has the following caution statement in their labeling:
"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.).

## J. Substantial Equivalence Information:

1. Predicate device name(s):
   IMMULITE® 2000 Intact PTH Calibration Verification Material (CVM)
   IMMULITE® 2000 SHGB Calibration Verification Material (CVM)

2. Predicate 510(k) number(s):
   k140258
   k140541

3. Comparison with predicate:

IMMULITE® 2000 Calcitonin Calibration Verification Material:

| **Similarities** | | |
|---|---|---|
| Item | Candidate Device: IMMULITE® 2000 Calcitonin Calibration Verification Material: | Predicate: IMMULITE® 2000 Intact PTH Calibration Verification Material (k140258) |
| Intended Use | Calibration Verification Material (CVM) is for the verification of calibration of the chemistry assay. | Same |
| Storage | ≤-20°C | Same |
| Form | Lyophilized | Same |
| Levels | 4 | Same |
| Matrix | Bovine protein buffer with preservatives | Same |

| **Differences** | | |
|---|---|---|
| Item | Candidate Device | Predicate Device (k140258) |
| Analyte | Calcitonin | PTH |

IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material:

| **Similarities** | | |
|---|---|---|
| Item | Candidate Device: IMMULITE® 2000 Prostatic Acid Phosphatase (PAP) Calibration Verification Material: | Predicate: IMMULITE® 2000 SHGB Calibration Verification Material (k140541) |
| Intended Use | Calibration Verification Material (CVM) is for the verification of calibration of the chemistry assay. | Same |
| Storage | 2 – 8 °C | Same |
| Form | Lyophilized | Same |
| Levels | 4 | Same |

| **Differences** | | |
|---|---|---|
| Item | Candidate Device | Predicate Device (k140541) |
| Analyte | Prostatic Acid Phosphatase | SHBG |
| Matrix | Bovine protein/buffer matrix with 0.27% Sodium Azide and preservatives | Buffered bovine/protein with preservatives |

**K. Standard/Guidance Document Referenced (if applicable):**
Not applicable

**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):*

Value assignment and stability studies were performed on the IMMULITE 2000 analyzer.

Value assignment:

Value Assignment for the IMMULITE 2000 Calcitonin CVM was based on using assigned reference calibrators. The assigned reference calibrators were prepared using Calcitonin antigen stock traceable to WHO 2nd IRP 89/620. The CVM was tested on 27 replicates (in total comprised of 9 runs, 3 replicates per run) on 8 IMMULITE 2000 systems, using 3 reagent kit lots. 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. The expected assay range is 2 to 2000 pg/mL. The target values in table below can be considered as guidelines.

| CVM Level | Target Mean (ng/mL) | Standard Deviation (SD) | Guideline ±2SD Range (ng/mL) | |
|---|---|---|---|---|
| CVM1 | 0.00 | - | 0.00 | 0.02 |
| CVM2 | 18.9 | 2.95 | 13 | 24.8 |
| CVM3 | 316 | 16 | 284 | 348 |
| CVM4 | 2082 | 125 | 1832 | 2332 |

Value Assignment for the IMMULITE 2000 Prostatic Acid Phosphatase (PAP) CVM was based on using PAP antigen stock traceable to an internal standard which was gravimetrically prepared. The CVM was tested on 15 replicates (in total comprised of 5 runs, 3 replicates per run) on 4 IMMULITE 2000 systems, using 3 reagent kit lots. The Guideline Range (95% confidence interval) for each CVM level was established based on the Target Mean and ± 2 Standard Deviation (SD), except CVM4 needs to be diluted with CVM1 before assaying. The expected assay range is 0.2 to 100 mg/L. The target values in table below can be considered as guidelines.

| **CVM Level** | **Target Mean (ng/mL)** | **Standard Deviation (SD)** | **Guideline ±2SD Range (ng/mL)** | |
|---|---|---|---|---|
| CVM1 | 0.00 | - | 0.00 | 0.05 |
| CVM2 | 1.05 | 0.105 | 0.84 | 1.26 |
| CVM3 | 5.40 | 0.54 | 4.32 | 6.48 |
| CVM4<br>75% CVM4 + 25% CVM1 | 142<br>107 | -<br>12.84 | -<br>81.3 | -<br>133 |

Stability:

Shelf-Life and Open Vial Stability testing protocols and acceptance criteria for the IMMULITE 2000 Calcitonin CVM were described and found to be adequate. The real time stability study shows study results up to 5 years when stored at -20°C, supporting the claim of 5 years shelf life and up to 9 hours at ambient or room temperature (15-25°C) supporting the claim of 8 hours after reconstitution. The study results were within 90% to 110% recovery.

Shelf-Life and Open Vial Stability testing protocols and acceptance criteria for the IMMULITE 2000 Prostatic Acid Phosphatase (PAP) CVM were described and found to be adequate. The real time stability study shows study results up to 5 years when stored at -20°C, supporting the claim of 5 years shelf life and up to 9 hours at ambient or room temperature (15-25°C) supporting the claim of 8 hours after reconstitution. The study results were within 90% to 110% recovery

*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.