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

A. 510(k) Number:

k090475

B. Purpose for Submission:

New device

C. Measurand:

Calibrator/Control material for Troponin-I (TnI), Troponin-T (TnT), BNP, the N-amino terminus of brain naturiuretic peptide (NT-proBNP), high sensitive C-reactive protein (hsCRP), and Myeloperoxidase (MPO).

D. Type of Test:

Control Material

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

VALIDATE CM2 Calibration Verification/Linearity Test Set

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1660, Quality Control Material (assayed and unassayed)
2. Classification:
   Class I, reserved
3. Product code:
   JJY, Multi-analyte controls, all kinds (assayed)
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below.

2. Indications(s) for use:

   VALIDATE CM2 Calibration Verification/Linearity Test Set solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated, and manual chemistry systems. Each VALIDATE CM2 Calibration Verification/Linearity Test Set consists of two sets of bottles. Set 1 contains BNP, hs-CRP, Troponin-I, and MPO. Set 2 contains NT-proBNP, hs-CRP, Troponin-T and MPO.

3. Special conditions for use statement(s):

   VALIDATE CM2 Calibration Verification/Linearity Test solutions are not intended for use as routine quality control materials or as calibration materials.

   These solutions are not intended for use on systems employing reflectance spectroscopy.

4. Special instrument requirements:

   Automated, semi-automated, and manual chemistry systems.

I. Device Description:

VALIDATE CM2 Calibration Verification/Linearity Test Set is in a human serum matrix that is compatible with chemistry systems for measuring Troponin-I (TnI), Troponin-T (TnT), BNP, the N-amino terminus of brain naturiuretic peptide (NT-proBNP), high sensitive C-reactive protein (hsCRP), and Myeloperoxidase (MPO). Each test set contains two sets of bottles. Set 1 contains TnI, BNP, hsCRP, and MPO; Set 2 contains TnT, NT-proBNP, hsCRP, and MPO. There is a bottle of base matrix included with each set. Each bottle contains 2.0 mL of solution. There exists a linear relationship among Levels 1 through 5.

Material of human origin used in the manufacture of this test set has been tested using FDA approved methods or methods cleared in compliance with the European Directive 98/79/EC, Annex I, III, or IV and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VALIDATE CM1 Calibration Verification/Linearity Test Set.

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

k053247

3. Comparison with predicate:

Similarities		
Item	Device: VALIDATE CM2	Predicate: VALIDATE CM1
Intended Use	VALIDATE CM2 Calibration Verification/Linearity Test Set solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated, and manual chemistry systems.	The Validate Cardiac Marker Calibration Verification Test Sets are used for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated, and manual chemistry analyzers.
Matrix	Human Serum	Human Serum
Preparation	Liquid, ready to use	Liquid, ready to use
Stability	Until expiration	Until expiration
Storage	-10 to -20°C	-10 to -20°C

Differences		
Item	Device	Predicate
Analytes	Set 1: BNP, hs-CRP, TnI, MPO Set2: NT-proBNP, hsCRP, TnT, MPO	CK-MB, MYO
Number of Levels	2 sets of 6 including base matrix	5 including a 0
Packaging	12 x 2.0 mL	5 x 3.0 mL

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

CLSI document EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

L. Test Principle:

Not Applicable.

M. Performance Characteristics (if/when applicable):
1. Analytical performance:

  a. *Precision/Reproducibility:*

   Not Applicable.

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b. *Linearity/assay reportable range:*

  Not Applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: No traceability claims were made.

Stability: Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Test sets are stable until the expiration date printed on the bottle when stored at -10° to -20°C and handled according to instructions. A maximum of four (4) freeze-thaw cycles are recommended.

Value Assignment: The raw materials are prepared at high concentration, analyzed, and are spiked into the human serum matrix. A linear relationship is achieved by mixing the low and high levels to produce five levels with equally spaced concentrations. For value assignment the high and low levels (1 and 5) are assayed in triplicate. Once all the levels are diluted all 5 levels are run again in triplicate, and then again in triplicate once bottled. Appropriate controls for a given system are run with each determination and must fall within the cited acceptance range. It is recommended that each laboratory establish its own values and acceptable non-linearity.

c. *Detection limit:*

  Not Applicable.

d. *Analytical specificity:*

  Not Applicable.

e. *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):

4. Clinical cut-off:

Not Applicable.

5. <u>Expected values/Reference range:</u>
   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.