

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

A. 510(k) Number:

k053247

B. Purpose for Submission:

New Device

C. Measurand:

CK-MB, Myoglobin

D. Type of Test:

Calibration Verification Material

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

Proprietary Name - VALIDATE[®] Cardiac Marker Calibration Verification Test Sets

Established Name – Quality Control Material

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1660

2. Classification:

Class I (reserved)

3. Product code:

JJY

4. Panel:

75 Clinical Chemistry

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

The VALIDATE[®] Cardiac Marker Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for CK-MB and Myoglobin.

3. Special conditions for use statement(s):

The VALIDATE[®] Cardiac Marker Calibration Verification Test Sets are used by trained laboratory professionals. They are not intended for use as routine quality control materials or as calibration materials. They are not intended for use with systems employing reflectance spectroscopy

4. Special instrument requirements:

Automated, semi-automated and manual chemistry systems.

I. Device Description:

The VALIDATE[®] Cardiac Marker Calibration (CM1) Verification Test Set contains CK-MB and myoglobin in a human serum matrix. It is comprised of one bottle each of six (6) levels including zero. The sponsor states that for both analytes the contents of Level 0 and Level 1 are identical and should recover the same value. Each bottle contains 3mL and is shipped frozen.

The CM1 Test Set was tested and found negative for HIV-1/2, HCV, HBV, and HBsAg by FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Liquichek Cardiac Markers Control LT

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

k040277

3. Comparison with predicate:

Similarities		
Item	Device	Predicate (Bio-Rad)
Matrix	Same	Human Serum
Preparation	Same	Liquid, ready to use
Storage	Same	-10 to -20° C

Differences		
Item	Device	Predicate (Bio-Rad)
Intended Use	For in vitro diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated, and manual chemistry analyzers.	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures.
Number of Levels	6 including zero	3
Analytes	CK-MB, Myoglobin	CK-MB, Myoglobin, Digitoxin, Homocysteine, NT-ProBNP, Troponin-I, Troponin-T
Stability	Until expiration	10 days after opening

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

CLSI EP-6A: Evaluation of the Linearity of Quantitative Measurement Procedures:
A Statistical Approach; Approved Guideline

Guidance for Industry: Points to Consider Guidance Document on 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):

The raw materials (purified human CK-MB and myoglobin) are processed into a stock solution, analyzed, and spiked into the human serum base matrix. The product also includes stabilizers and preservatives. The sponsor states that for value assignment, levels 0, 1, and 5 are assayed in triplicate in three analytical runs while levels 2, 3, and 4 are assayed in triplicate in two analytical runs. Two levels of control material are run with each determination and must fall within the cited acceptance range for the run to be accepted.

Stability is assessed by measuring recoveries in both real-time and accelerated studies.

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):

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.