

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k072246

B. Purpose for Submission:

New device

C. Measurand:

Quality controls for IgA, IgG, IgM; C3, C4, α 1-Antitrypsin and Transferin

D. Type of Test:

Quantitative determination in automated, semi-automated, manual chemistry systems

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

VALIDATE® SP1 Calibration Verification Test Set

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

Class I

3. Product codes:

JJY, Multi-analyte controls, All kinds (Assayed and Unassayed)

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

VALIDATE® SP1 Calibration Verification 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 for the following analytes: Immunoglobulin A (IgA), Immunoglobulin G, IgG), Immunoglobulin M (IgM), Complement C3 (C3), Complement C4 (C4), α 1-Antitrypsin (AAT), and Transferrin (TRF).

2. Indication(s) for use:

Same as Intended use.

3. Special conditions for use statement(s):

For prescription only.

4. Special instrument requirements:

None

I. Device Description:

VALIDATE® SP1 Calibration Verification Test Sets are human serum materials containing 5 levels of each of the seven analytes. Each test set consists of one bottle (1.0 mL) each of Level 1 to Level 5.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Cliniqa LiniCAL® Calibration Verifier Protein 1

Cliniqa LiniCAL® Calibration Verifier Protein 2

2. Predicate K number(s):
k031575 (IgA, IgG, IgM, C3, C4, TRF)
k031577 (AAT)
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	VALIDATE® SP1 Calibration Verification Test Set	Cliniqa LiniCAL® Calibration Verifier Protein 1 and Protein 2
Intended Use	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual chemistry systems	For <i>in vitro</i> diagnostic use in the clinical laboratory to verify calibration and/ or assess linearity. Five assayed levels are provided to allow monitoring of the reportable range
Matrix	Human serum	Same
Number of Levels	5 Levels	Same
Packaging	1.0 mL each level	Same
Format	Liquid	Same

Differences			
Item	New Device	Predicate Devices	
	VALIDATE® SP1 Calibration Verification Test Set	Cliniqa LiniCAL® Calibration Verifier Protein 1	Cliniqa LiniCAL® Calibration Verifier Protein 2
Analytes	IgA, IgG, IgM, C3, C4, AAT, and TRF	IgA, IgG, IgM, C3, C4, and TRF	AAT, AAG, AMG, AT3, B2M, CER
Stability	One year	Opened vial: 14 days	Opened vial: 14 days
Storage	-10°C to -20°C	2 - 8°C	2 - 8°C

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

CLSI EP6: Evaluation of linearity

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):*
Stability studies were performed with the acceptance criteria of >90% recovery from date of manufacture. Stability data showed shelf life of 2.5 years for -10°C and 5 years for -20°C. The expiration date claim is one year for -10 to -20°C.
- 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.