

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

A. 510(k) Number:

k113524

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for total 25 (OH) vitamin D (VIT D)

D. Type of Test:

Not applicable

E. Applicant:

Maine Standards Company, LLC

F. Proprietary and Established Names:

VALIDATE® VIT D Calibration Verification / Linearity Test Kit

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	862.1660	Clinical Chemistry

H. Intended Use:

1. Intended use(s):

VALIDATE VIT D Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte: total 25(OH) Vitamin D (VIT D). The product is intended for use with quantitative assays on the indicated analyzer provided in the labeling.

2. Indication(s) for use:

Refer to intended use above

3. Special conditions for use statement(s):

For in vitro diagnostic use

For prescription use

4. Special instrument requirements:

DiaSorin Liaison® Analyzer

I. Device Description:

Each VALDIDATE® VIT D Calibration Verification / Linearity Test Kit contains purified chemicals in a human serum base. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The test kit assists in the documentation of linearity, calibration verification and verification of linear range. The solutions will also provide assistance when troubleshooting instrument systems, reagent problems and calibration anomalies.

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
25(OH) Vit D	ng/mL	5	39	73	106	140

Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA approved methods and was found to be non-reactive for HBsAG and to antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit

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

k013119

3. Comparison with predicate

	Candidate Device	Predicate (K013119)
	VALIDATE VIT D Calibration Verification / Linearity Test Kit	VALIDATE Chem 6 Calibration Verification / Linearity Test Kit
Indications for Use	Test Kit solutions are intended for <i>in vitro</i> diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the given analyte.	Same
Analytes	25 (OH) vitamin D (VIT D)	Uric acid
Matrix	Human serum base	Aqueous
Number of levels per set	6 including a base matrix	6 including zero
Preparation	Liquid, ready to use	Same
Fill volume	1.5 mL each level	5.0 mL each level
Storage and stability	Until expiration at -10 to -25 °C	Until expiration at 2 to 8 °C

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

CLSI EP06-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

b. *Linearity/assay reportable range:*

Not applicable

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

Traceability

Not applicable

Value Assignment

VIT D Calibration Verification / Linearity Test Kits are manufactured such that a linear relationship exists among Levels 1 through 5 and to provide an equal distance between Levels 1 to 5; Level 1 being the lowest concentration and Level 5 being the highest. A base matrix containing an analyte value of zero is also provided with the kit. The base matrix can be used to make dilutions of Level 1 to obtain a result lower than Level 1, if needed. The dilution scheme is achieved by calculating the delta between two consecutive levels (2, 3) and applying it to subsequent levels. Additionally, using recovered values for Levels 1 and 5 using a percentage calculation can give the required levels (CLSI EP06 Appendix A).

Target values for the linearity set were determined using the 25-Hydroxyvitamin D (25-OH-D) assay on the DiaSorin Liaison analyzer. Actual recovered values were used to calculate target values for each level of the linearity set using a linear regression technique. Appropriate equal distance values were entered as the ‘x’ values and recovered values from the levels were used as ‘y’ values to calculate a regression equation. The resulting ‘y’ values were used as target values for each of the five levels. Expected target values may change depending on instrumentation, methodology, and assay temperature. Typical value ranges are provided in the package insert. Typical value ranges for each level of the linearity set are summarized in the table below.

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
25(OH) Vit D	ng/mL	5	39	73	106	140

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Closed vial stability of the VALIDATE VIT D Calibration Verification / Linearity Test Kit was determined using real-time open vial studies as a worst case scenario and is on-going. The sponsor recommended storage temperature is -10 to -25°C.

d. Detection limit:

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.