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

A. 510(k) Number:

k142964

B. Purpose for Submission:

New device

C. Measurand:

Calibration Verification /Linearity test kit for Ferritin, Folate, and Vitamin B12

D. Type of Test:

Not Applicable

E. Applicant:

Maine Standards Company LLC

F. Proprietary and Established Names:

Validate Anemia Calibration Verification/ Linearity Test Kit

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

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   VALIDATE® Anemia 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 analytes: Ferritin Set: ferritin (FERR), Vitamin B12/ Folate Set: vitamin B12 (VIT B) and folate (FOL), on automated instrument systems. The product is intended for use with quantitative assays on the indicated analyzers specified in the labeling.

2. Indication(s) for use:

   Same as Intended use above

3. Special conditions for use statement(s):

   For In Vitro Diagnostic Use. For prescription use only.

4. Special instrument requirements:

   Roche Cobas, Beckman Access

I. Device Description:

Each VALIDATE® Anemia Calibration Verification/Linearity Test Kit contains two analyte sets of purified chemicals in a human serum base. The kit includes a ferritin set containing five liquid levels, 3.0 mL each, and a Vitamin B12 /Folate set containing five liquid levels, 4.0 mL each. Prior to use, users should remove the VALIDAE Anemia materials from storage and allow coming to room temperature. Invert gently several times before dispensing. To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10 to -25°C immediately after dispensing.

CAUTION POTENTIAL BIOHAZARD

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, HIV-1 and HIV-2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VALIDATE® Ferritin Calibration Verification/Linearity Test Kit

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

   k133550

3. Comparison with predicate:

Similarities		
Item	New Device VALIDATE® Anemia Calibration Verification/ Linearity Test Kit	Predicate (k133550) VALIDATE® Ferritin Calibration Verification/ Linearity Test Kit
Intended Use	For *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated instrument systems	Same
Preparation	Liquid, ready to use	Same
Stability	Until expiration date	Same
Storage	-10 to -25°C	Same
Matrix	Human serum base	Same
Number of levels	5 levels	Same

Differences		
Item	New Device VALIDATE® Anemia Calibration Verification/ Linearity Test Kit	Predicate (k133550) VALIDATE® Ferritin Calibration Verification/ Linearity Test Kit
Analytes	Ferritin, Vitamin B12 and Folate	Ferritin
Packaging	4.0 mL vial for each level of Vitamin B12 and Folate Set, 3.0 mL vial for each level Ferritin Set	3.0 mL vial for each level Ferritin Set

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

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

Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline (CLSI EP25-A)

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:

All the analytes contained in the Validate Anemia Calibration Verification/ Linearity Test Kit were obtained from commercially available sources.

Value Assignment:

The VALIDATE® Anemia Calibration Verification/Linearity Test Kits are manufactured such that an equal relationship exists among Levels 1 through 5; Level 1 being the lowest concentration and Level 5 being the highest. Levels 1 and 5 are prepared independently by the addition of specific amounts of ferritin, Vitamin B12 and folate chemicals (bought from a commercial source) to a human serum base. Intermediate Levels 2, 3, and 4 are subsequently prepared from Levels 1 and 5 by equal part dilutions following the CLSI EP6-A guidelines. The testing was performed on five separate days, six replicates per analyte to have five testing events and total of 30 replicates. A total mean value, total standard deviation and total percent coefficient of variation (CV %) for the high value level and low value level are calculated. All values assignment results met their pre-determined acceptance criteria. Typical mean values for each analyte for each specific instrument are provided in the package insert. Typical mean recovery values for all levels for one representative lot are presented in Table 1 below.

Table 1

Ferritin Set							
Instrument	Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
Beckman/Access	FERR	ng/mL	1.9	348	694	1040	1386
Roche/Cobas	FERR	ng/mL	3.0	465	926	1388	1820
Vitamin B12/Folate Set							
Instrument	Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
Beckman/Access	Vit B12	pg/mL	68	462	855	1248	N/A
Roche/Cobas	Vit B12	pg/mL	83	515	947	1380	1812
Instrument	Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
Beckman/Access	FOL	ng/mL	1.1	4.0	7	10	13
Roche/Cobas	FOL	ng/mL	2.4	6	10	13	17

Stability:

Real-Time stability studies were conducted to support the shelf-life and open-vial claims. The sponsor provided testing time points included date of manufacture (DOM), followed by testing at specific intervals of 1,2,3,6,9,12,and 13 months post manufacture. The last testing event is one month post-expiration. Acceptance criteria and studies protocols were reviewed and found to be acceptable to support the sponsor's following stability claims: VALIDATE Anemia materials are stable up to 12 months when stored between -10 to -25°C prior to opening. Open vial stability studies support a maximum of 4 freeze/thaw cycles when materials are stored between -10 to -25°C until the expiration date of the vials.

A freeze/thaw stability assessment was also conducted in support of the product package insert four (4) freeze/thaw events claim. Acceptance criteria and studies protocols were reviewed and found to be acceptable.

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:

   See package insert

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.