DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MAINE STANDARDS COMPANY LLC
JAMES CHAMPLIN
MANAGER, QA & RA
221 US ROUTE 1
CUMBERLAND FORESIDE, ME 04110

April 30, 2015

Re: K142964
Trade/Device Name: VALIDATE® Anemia Calibration Verification/ Linearity Test Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: April 1, 2015
Received: April 2, 2015

Dear James Champlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k142964

Device Name
VALIDATE® Anemia Calibration Verification/Linearity Test Kit

Indications for Use *(Describe)*
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(VITB) and folate (FOL), on automated instrument systems. The product is intended for use with quantitative assays on the indicated analyzers specified in the labeling.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

The assigned 510(k) number is: k142964

**A. Submitter:**

Maine Standards Company LLC
221 US Route 1
Cumberland Foreside, ME 04110
Telephone: 207-892-1300
Fax: 207-892-2266

Contact Person:
James Champlin
Manager, Quality Assurance & Regulatory Affairs
jchamplin@mainestandards.com
Telephone: 207-892-1300 Ext. 29

Date of Summary Preparation:
April 24, 2015

**B. Device Classification:**

| | |
|---|---|
| Device classification name: | Quality control material (assayed and un-assayed)* |
| Common name: | Calibration Verification / Linearity Test Kit |
| Proprietary Name: | VALIDATE® Anemia Calibration Verification / Linearity Test Kit |
| Review Panel: | Clinical Chemistry 75 |
| Regulation Number: | 21 CFR 862.1660 |
| Product Code: | JJY |
| Regulatory Class: | Class I Reserved |

**C. Predicate Device Identification**:
VALIDATE® Ferritin Calibration Verification / Linearity Test Kit
Maine Standards Company LLC, Cumberland Foreside, ME 04110.
510(k) Number: k133550

**D. Candidate 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, 3.0mL each, and a Vitamin B12/Folate set containing five liquid levels, 4.0 mL each. The sets are provided to establish the relationship between theoretical and actual performance of the included analytes: Ferritin, Vitamin B12 and Folate. 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.

**E. Intended use**: **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.

**F. Summary of Performance Data:**

The performance of the new VALIDATE® Anemia Calibration Verification / Linearity Test Kit was compared to the predicate device k133550, VALIDATE® Ferritin Calibration Verification / Linearity Test Kit. Table 1 compares the technical characteristics of the new VALIDATE® Anemia Calibration Verification / Linearity Test Kit with those of the predicate VALIDATE® Ferritin Calibration Verification / Linearity Test Kit.

**Table 1 – Technical Comparison to Predicate**

| | **New Device** VALIDATE® Anemia Calibration Verification / Linearity Test Kit | **Predicate (k133550)** VALIDATE® Ferritin Calibration Verification / Linearity Test Kit |
|---|---|---|
| **Similarities** | | |
| Test Kit | Calibration Verification Test Kit | Same |
| 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** | | |
| Analytes | Ferritin, Vitamin B12 and Folate | Ferritin |
| Packaging | 3.0 mL each level Ferritin Set<br>4.0 mL each level Vitamin B12/ Folate Set | 3.0 mL each level |

Value Assignment

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 Ferritin, Vitamin B12 and Folate to a human serum base. The VALIDATE® Anemia Calibration Verification / Linearity Test Kit was tested on the Roche Cobas and Beckman Access analyzers to confirm adequate recovery across all levels. Levels 1 through 5 must meet specified Ferritin, Vitamin B12 and Folate target ranges at all stages of testing.

Specific recovery targets for Levels Levels 1 through 5 are determined by the upper and lower detection limits for each analyte. Intermediate 2, 3, and 4 are subsequently prepared from Levels 1 and 5 by equal part dilutions following EP6-A guidelines. Typical value ranges are provided in the package insert. All stated recovery values met internal pre-determined acceptance criteria.

Typical recovery values for Low Levels and High Levels, established via an internal protocol, are presented in Table 1. Typical values for Mid-Levels are calculated based on an equal distance (delta) between levels. Any level result showing no value is above the method's reportable range. Due to the analytical differences of immunoassays on different instrument systems, these ranges are to be used as a guide only. Expected target values may change depending on instrumentation and methodology.

**Table 1**

| **Ferritin Set** | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | **Levels** | | | | |
| **Instrument** | **Analyte** | **Units** | **1** | **2** | **3** | **4** | **5** |
| Beckman Access/DxI | FERR | ng/mL | 1.9 | 348 | 694 | 1,040 | 1,386 |
| Roche Cobas/Elecsys | FERR | ng/mL | 3.0 | 465 | 926 | 1,388 | 1,850 |
| **Vitamin B12 / Folate Set** | | | | | | | |
| | | | **Levels** | | | | |
| **Instrument** | **Analyte** | **Units** | **1** | **2** | **3** | **4** | **5** |
| Beckman Access/DxI | VIT B12 | pg/mL | 68 | 462 | 855 | 1,248 | N/A |
| Roche Cobas/Elecsys | VIT B12 | pg/mL | 83 | 515 | 947 | 1,380 | 1,812 |
| | | | | | | | |
| Beckman Access/DxI | FOL | ng/mL | 1.1 | 4 | 7 | 10 | 13 |
| Roche Cobas/Elecsys | FOL | ng/mL | 2.4 | 6 | 10 | 13 | 17 |

The quantitative determination of linearity, calibration verification, and verification of reportable range relies on the known relationship between each of the levels of the product (in this case equal deltas as outlined in the CLSI EP6A referenced standard) not on an expected value.

Traceability

This product is traceable to a reference standard based on the automated instrument platform it is used on. The traceability of our product will be established per the respective end user automated instrument calibrator traceability reference statement.

Stability

Stability testing was performed using the Beckman Coulter® Access II and Roche COBAS 6000 instrument systems. The study testing time points included date of manufacture (DOM), followed by testing at specific intervals post manufacture. The last testing event is one month post-expiration. Acceptance criteria are defined as 90 to 110% of DOM value for product levels 2-5.

A freeze/thaw stability assessment was also conducted in support of the product package insert four (4) freeze/thaw events claim. All product levels tested within the 90 to 110% of control acceptance criteria limits after 6 freeze/thaw events.

Shelf Life Claim: Stability of the VALIDATE® Anemia Calibration Verification / Linearity Test Kit was set at 12 months based on real-time open vial studies as a worst case scenario. The recommended storage temperature is -10 to -25°C. All supporting data is retained on file at Maine Standards Company LLC.

Linearity:
Linearity testing was carried out with the candidate device VALIDATE® Anemia Calibration Verification / Linearity Test Kits using a Roche® Cobas 6000 Chemistry Analyzer and Beckman-Coulter® Access II Immunochemistry Analyzer. Product linearity performance was demonstrated for both automated systems. All supporting data for all three analytes is retained on file at Maine Standards Company LLC.

**G. Conclusion:**
Based upon the purpose of the device, the descriptions and labeling of the predicate device, the VALIDATE® Anemia Calibration Verification / Linearity Test Kit behaves substantially equivalent to the predicate for the evaluation of calibration verification, verification of reportable range. The product is substantially equivalent to the predicate device k133550.