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

A. 510(k) Number:
k083891

B. Purpose for Submission:
New device

C. Measurand:
Calibration verification materials for Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), Cortisol, and Free T4 (FT4).

D. Type of Test:
Calibration verification materials

E. Applicant:
Maine Standards Company

F. Proprietary and Established Names:
VALIDATE® THY Calibration Verification Test Set

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1660, Quality Control Material

2. Classification:
   Class I, reserved

3. Product Code:
   JJY

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for Use below

2. Indication(s) for use:
   VALIDATE THY Calibration Verification Test Set consists of two sets of bottles, a THY set and a FT4 Set. The THY set consists of five (5) levels of the following four analytes: Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating

Hormone (TSH), and Cortisol, and the FT4 set consists of five (5) levels containing Free Thyroxine (FT4).

VALIDATE THY 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.

3. Special condition for use statement(s):
   Prescription Use Only

4. Special instrument Requirements:
   Automated, semi-automated, and manual clinical chemistry systems

I. Device Description:

VALIDATE® THY Calibration Verification Test Sets are human serum based calibration verification / linearity materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. Each test set consists of one bottle each of Levels 1 through 5. One bottle of Base Matrix is also included. There exists a linear relationship among Levels 1 through. Human source material is considered a potentially biohazardous material. These materials were tested and found negative for HIV-1/2, HCV, HBV, and HBsAg. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   VALIDATE® Thyroid Calibration Verification/Linearity Test Set

2. Predicate K number(s):
   k062501

3. Comparison with predicate:

	Predicate	Device
Intended Use	For *in vitro* diagnostic use in quantitative determination of linearity, calibration verification and verification of reportable ranges in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitative determination of linearity, calibration verification and verification of reportable ranges in automated, semi-automated and manual chemistry systems.
Analytes	T3, T4, TSH, Cortisol	T3, T4, TSH, Cortisol, Free T4
Matrix	human serum	human serum
Number of	5	5

Levels	plus a base matrix	
Preparation	Liquid, ready to use	Liquid, ready to use
Packaging	3.0 mL each level	1.5 mL each level
Stability	Until Expiration	Until Expiration
Storage	-10 to -20°C	-10 to -20°C

VALIDATE® THY Calibration Verification Test Set differs from the current product in it includes a set for FT4.

K. Standard/**Guidance Document Referenced (if applicable):**
CLSI EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures

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 (controls, calibrators, or method):
VALIDATE THY Calibration Verification Test Set solutions are tested during manufacturing with standards traceable to National Institute for Standards and Technology (NIST) Standard Reference Material (SRM) where available. For analytes where NIST materials are not available, primary analytical standards are used.
Each lot of the VALIDATE THY Calibration Verification Test Set is manufactured such that a linear relationship exists among the Levels 1 through 5. The expected value of the Base Matrix is zero, however, in some instances a non-zero result may be obtained.
Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument/reagent system calibration. The degree of acceptable non-linearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Stability testing protocols and acceptance criteria were described 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 comparaison:
   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 satisfies the requirement of 21 CFR part 809.10

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.