

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

A. 510(k) Number:

k062501

B. Purpose for Submission:

New device

C. Measurand:

Calibration verification solutions for Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol.

D. Type of Test:

Calibration verification

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

VALIDATE Thyroid Calibration Verification Test Set

G. Regulatory Information:

1. Regulation section:
21 CFR §862. 1660, Quality Control Material
2. Classification:
Class I
3. Product Code:
JJX
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for Use
2. Indication(s) for use:
VALIDATE Thyroid Calibration Verification Test Set solutions are for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in chemistry systems for the

following analytes: Triiodothyronine (T3), Thyroxine (T4), human Thyroid Stimulating Hormone (TSH), and Cortisol.

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 Thyroid Calibration Verification Test Set contains T3, T4, human TSH, and Cortisol in human serum matrix. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. Each test set consists of one bottle each of six (6) levels including zero. Each bottle of Levels 0 through 5 contains 3.0 milliliters. This material is stable until the date printed on the label when stored as directed.

All human source material was tested and found to be negative for HIV 1/2, HBsAg, and RPR by FDA approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Thyroid CAL•VER
2. Predicate K number(s):
k992034
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	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	<u>For in vitro diagnostic use in the quantitative determination of linearity, calibration verification, verification of Analytical Measurement Range (AMR), and verification of reportable ranges in automated semi-automated and manual chemistry systems</u>
Matrix	Human serum	Human serum
Storage	-10 to -20°C	-10 to -20°C

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

Not applicable

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 Thyroid 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.

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 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 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.