

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

A. 510(k) Number:

K110880

B. Purpose for Submission:

Modified Device – Adding Cholinesterase (CHE) to a previously cleared device (k091225)

C. Measurand:

Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) and Cholinesterase (CHE)

D. Type of Test:

Quality control material

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

VALIDATE[®] GC3 Calibration Verification / Linearity Test Kit

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	Class I, reserved	21 CFR 862.1660	Chemistry 75

H. Intended Use:

1. Intended use(s):

See Indications for Use below

2. Indication(s) for use:

VALIDATE[®] GC3 Calibration Verification / Linearity Test Kit is intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range. See the package insert for the list of all analytes claimed.

3. Special conditions for use statement(s):

For In Vitro Diagnostic Use. For prescription use only.

These tests are not intended for use as routine quality materials or as calibration materials.

4. Special instrument requirements:

The validation and stability studies were conducted using Beckman Coulter AU 680 analyzer.

I. Device Description:

Each VALIDATE[®] GC 3 Calibration Verification / Linearity Test Kit contains purified chemicals in a human serum albumin base. Five levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes.

Material of human origin used in the manufacture of this test set has been tested using FDA approved methods and found to be non-reactive for HBsAg and antibodies to HCV and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device

Maine Standards Company, VALIDATE[®] GC3 Calibration Verification / Linearity Test Kit

2. Predicate K number

k091225

3. Comparison with predicate

	New VALIDATE® GC3 Calibration Verification / Linearity Test Kit	Predicate VALIDATE® GC3 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, semi-automated and manual chemistry systems.	Same
Analytes	ALP, ALT, AMY, AST, CK, GGT, LD, LIP, CHE	ALP, ALT, AMY, AST, CK, GGT, LD, LIP
Matrix	Human serum albumin	Same
Number of Levels	6 including a base matrix	Same
Preparation	Liquid, ready to use	Same
Packaging	3.0 mL each level	Same
Stability	Until expiration	Same
Storage	-10 to -25°C	Same

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

NCCLS. *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. NCCLS document EP6-A [ISBN 1-56238-498-8]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2003.

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):*

Stability

The sponsor provided protocol, acceptance criteria and summary data for stability for up to 8 months that were reviewed and were accepted to be adequate. The real time stability study is ongoing.

Traceability:

Same as k091225, there are no traceable materials or methods available for the enzymes in GC3.

Value assignment

Value assignment for the following analytes in the predicate device have already been cleared under k091225

Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD) and Lipase (LIP) The data provided by the sponsor indicates that for these analytes, each level is within the claim range and the five levels are linear.

However, since Cholinesterase (CHE) had not been validated previously value assignment for this analyte was provided separately.

The following table lists the Target recovery, the Mean observed, as well as the absolute difference and % difference of the Mean / Target.

X	Target	Mean	+/- Diff	% Diff
1	0.97	0.94	0.03	3.1%
2	4.37	4.44	0.07	1.6%
3	7.78	7.74	0.04	0.5%
4	11.18	10.74	0.44	3.9%
5	14.58	13.41	1.17	8.0%

The results provided satisfied the acceptance criteria

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:

Calibration verification/linearity material is manufactured such that equal distance exists between each consecutive level. The expected values are provided in the labeling for each specific lot.

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.