510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k091225

B. Purpose for Submission:
New device

C. Measurand:
VALIDATE GC1 Calibration Verification/Linearity Test Set: Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (CA), Chloride (CL), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Potassium (K), Lactate (LAC), Lithium (LITH), Magnesium (MG), Sodium (NA), Phosphorous (PHOS), Total Protein (TP), Triglycerides (TRIG), and Uric Acid (UA).

VALIDATE GC2 Calibration Verification/Linearity Test Set: Ammonia (NH3), Carbon Dioxide (CO2), Ethanol (ETOH), and Iron (FE).

VALIDATE GC3 Calibration Verification/Linearity Test Set: Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD), and Lipase (LIP).

VALIDATE GC4 Calibration Verification/Linearity Test Set: Direct Bilirubin (DBIL) and Total Bilirubin (TBIL).

D. Type of Test:
Control Material

E. Applicant:
Maine Standards Company

F. Proprietary and Established Names:
VALIDATE GC1 Calibration Verification/Linearity Test Set
VALIDATE GC2 Calibration Verification/Linearity Test Set
VALIDATE GC3 Calibration Verification/Linearity Test Set
VALIDATE GC4 Calibration Verification/Linearity Test Set

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, Multi-analyte controls, all kinds (assayed)

4. Panel:
   Clinical Chemistry (75)

H. Intended Use:

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

2. Indications(s) for use:
   VALIDATE GC1, GC2, GC3 and GC4 Calibration Verification/Linearity Test Sets 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. See attached Package insert labeling for all analytes claimed.

3. Special conditions for use statement(s):
   For In Vitro Diagnostic Use. For prescription use only.
   These test sets are not intended for use as routine quality control materials or as calibration materials.

4. Special instrument requirements:
   Automated, semi-automated, and manual chemistry systems as specified in the package insert.

I. Device Description:

VALIDATE GC1 Calibration Verification/Linearity Test Set is in a human serum matrix that is compatible with chemistry systems for measuring albumin (ALB), blood urea nitrogen (BUN), calcium (CA), cholesterol (CHOL), chloride (CL), creatinine (CREA), glucose (GLU), potassium (K), lactate (LAC), lithium (LITH), magnesium (MG), sodium (NA), phosphorous (PHOS), total protein (TP), triglycerides (TRIG), and uric acid (UA). This test set includes 5 levels that have a linear relationship. Each bottle contains 4.0 mL of solution.

VALIDATE GC2 Calibration Verification/Linearity Test Set solutions is in an aqueous matrix that is compatible with chemistry systems for measuring carbon dioxide (CO2), ethyl alcohol (ETOH), ammonia (NH3), and Iron (FE). This test set includes 5 levels that have a linear relationship and a base matrix. Each bottle contains 3.0 mL of solution.

VALIDATE GC3 Calibration Verification/Linearity Test Set is in a human serum matrix that is compatible with chemistry systems for measuring alkaline phosphatase (ALP), alanine aminotransferase (ALT), amylase (AMY), aspartate aminotransferase (AST), creatine kinase (CK), gamma-glutamyl transferase (GGT), lactate dehydrogenase (LD), and lipase (LIP). This test set includes 5 levels that have a linear relationship and a base matrix. Each bottle contains 3.0 mL of solution.

VALIDATE GC4 Calibration Verification/Linearity Test Set is in a human serum matrix

that is compatible with chemistry systems for measuring total bilirubin (TBIL) and direct bilirubin (DBIL). This test set includes 5 levels that have a linear relationship and a base matrix. Each bottle contains 3.0 mL of solution.

Each lot of the VALIDATE GC test set is manufactured such that a linear relationship exists among the Levels 1 through 5. Therefore, the actual recovered values are used to calculate the target values. The expected value of the Base Matrix is zero; however, in some instances a non-zero result may be obtained.

VALIDATE GC1, GC3 and GC4 Calibration Verification/Linearity Test Sets contain human source material and include the following warning in the insert: Human source material is considered potentially biohazardous. Material of human origin used in the manufacture of this test set was tested using FDA approved methods and found to be non-reactive for HBsAg and to antibodies to HCV and HIV-1/2. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

VALIDATE GC2 Calibration Verification/Linearity Test Set is in an aqueous matrix and contains no human source material.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Predicates for VALIDATE GC1 Calibration Verification/Linearity Test Set: VALIDATE CHEM 1 (k012117), VALIDATE CHEM 3 (k012119) VALIDATE CHEM 6 (k013119), and VALIDATE CHEM 7 (k013265) Calibration Verification Test Sets.

   Predicates for VALIDATE GC2 Calibration Verification/Linearity Test Set: VALIDATE CHEM 2 (k012118), and VALIDATE CHEM 7 (k013265) Calibration Verification Test Sets.

   Predicates for VALIDATE GC3 Calibration Verification/Linearity Test Set: VALIDATE CHEM 4 test set (k012120).

   Predicates for VALIDATE GC4 Calibration Verification/Linearity Test Set: VALIDATE CHEM 4 test set (k012120).

2. Predicate 510(k) number(s):
   k012117, k012118, k012119, k012120, k013119, k013265

3. Comparison with predicate:

Comparison for GC1:

	VALIDATE GC1 Calibration Verification/ Linearity	VALIDATE CHEM 1 Calibration Verification	VALIDATE CHEM 3 Calibration Verification	VALIDATE CHEM 6 Calibration Verification	VALIDATE CHEM 7 Calibration Verification

	Test Set	Test Set	Test Set	Test Set	Test Set
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.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.
Analytes	ALB, BUN, CA, CHOL, CL, CREA, GLU, K , LAC, LITH, MG, NA, PHOS, TP, TRIG, UA	BUN, CA, CL, GLU, K , LAC, LITH, MG, NA, PHOS, TRIG,	ALB, CHOL, TP	UA	CREA, ETOH, FE, NH3
Matrix	Human Serum	Aqueous	Human Serum	Aqueous	Aqueous
Number of Levels	5	6 including zero	6 including zero	6 including zero	6 including zero
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	4.0 mL each level	5.0 mL each level	5.0 mL each level	5.0 mL each level	5.0 mL each level
Storage	-10 to -20°C	2-8°C	2-8°C	2-8°C	2-8°C

Comparison for GC2:

	VALIDATE GC2 Calibration Verification/ Linearity Test Set	VALIDATE CHEM 2 Calibration Verification Test Set	VALIDATE CHEM 7 Calibration Verification Test Set
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.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.
Analytes	CO2, ETOH, FE, NH3	BUN, CO2, GLU	CREA, ETOH, FE, NH3
Matrix	Aqueous	Aqueous	Human Serum
Number of	6 including a base matrix	6 including zero	6 including zero

Levels			
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	3.0 mL each level	5.0 mL each level	5.0 mL each level
Storage	2-8°C	2-8°C	2-8°C

Comparison for GC3:

	VALIDATE GC3 Calibration Verification/ Linearity Test Set	VALIDATE CHEM 4 Calibration Verification Test Set
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.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.
Analytes	ALP, ALT, AMY, AST, CK, GGT, LD, LIP	ALP, ALT, AMY, AST, CK, GGT, LD, LIP, TBIL, DBIL
Matrix	Human Serum albumin	Bovine Serum Albumin stabilized with Ethylene Glycol
Number of Levels	6 including a base matrix	6 including zero
Preparation	Liquid, ready to use	Liquid, ready to use
Packaging	3.0 mL each level	5.0 mL each level
Storage	-10 to -20°C	-10 to -20°C

Comparison for GC4:

	VALIDATE GC4 Calibration Verification/ Linearity Test Set	VALIDATE CHEM 4 Calibration Verification Test Set	VALIDATE CHEM 5 Calibration Verification Test Set
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.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.
Analytes	DBIL, TBIL	ALP, ALT, AMY, AST, CK, GGT, LD, LIP, TBIL, DBIL	TBIL and DBIL as part of the TBIL component
Matrix	Human serum albumin	Bovine Serum Albumin stabilized with Ethylene Glycol	Bovine Serum Albumin
Number of Levels	6 including a base matrix	6 including zero	6 including zero
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use

Packaging	3.0 mL each level	5.0 mL each level	5.0 mL each level
Storage	-10 to -20°C	-10 to -20°C	-10 to -20°C

K. Standard/ Guidance Document Referenced (if applicable):
CLSI document EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

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:
For VALIDATE GC1, GC2, and GC4 Calibration Verification/Linearity Test Sets the sponsor states that 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.

VALIDATE GC3 Calibration Verification/Linearity Test Set**:** No traceability claims were made.

Stability:
Real-time, open bottle, stability testing protocols and acceptance criteria were reviewed and found to be acceptable. GC2 is held at 2 to 8°C whereas GC1, GC3 and GC4 were held at -10 to -20°C for up to 13 months (one month beyond the claimed shelf life). Test sets are stable until the expiration date printed on the bottle when stored according to instructions at -10 to -20°C for GC1, GC3, and GC4 and 2 to 8°C for GC2. A maximum of four (4) freeze-thaw cycles are recommended for GC1, GC3, and GC4 and it is recommended not to freeze GC2.

Value Assignment:
Levels 1 and 5 are spiked with the required raw materials and intermediate levels (2-4) are made by following EP6-A by equal part dilutions. For value assignment samples are tested, in triplicate, at three stages of manufacturing: in process (level 1 and 5), secondary (all levels) and final product in bottles (all levels). Each determination must fall within the cited acceptance range. Appropriate controls are run with each determination. The analyzer used for analysis depends on the

final product configuration. It is recommended that each laboratory establish its own values and acceptable non-linearity.

c. Detection limit:
Not Applicable.

d. Analytical specificity:
Not Applicable.

e. 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):
4. Clinical cut-off:
   Not Applicable.
5. Expected values/Reference range:
   Not Applicable.

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.