

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

A. 510(k) Number:

k050504

B. Purpose for Submission:

Notification of intent to manufacture and market the device: VALIDATE[®] Urine Chemistry Calibration Verification Test Sets.

C. Measurand:

UC1:

Set 1 - Uric Acid

Set 2 - Ethyl Alcohol, Sodium, Potassium, Chloride, Glucose, Bun/Urea, and Urine Protein

UC2:

Set 1 – Calcium, Magnesium, Phosphorus, and Creatinine

Set 2 - Amylase, Pancreatic Amylase, and Microalbumin

OSMO:

Set 1 – Serum osmolality

Set 2 – Urine osmolality

D. Type of Test:

Calibration Verification Material

E. Applicant:

Maine Standards Company

F. Proprietary and Established Names:

Proprietary – VALIDATE[®] Urine Chemistry Calibration Verification Test Sets.

Established Name – Quality Control Material

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1660

2. Classification:

Class I (reserved)

3. Product code:

JJY

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The VALIDATE[®] Urine Chemistry Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert.

3. Special conditions for use statement(s):

The VALIDATE[®] Urine Chemistry Calibration Verification Test Sets are used by trained laboratory professionals. They are not intended for use as routine quality control materials or as calibration materials. They are not intended for use with systems employing reflectance spectroscopy.

4. Special instrument requirements:

Clinical chemistry analyzers

I. Device Description:

The VALIDATE[®] Urine Chemistry Calibration Verification Test Sets are

comprised of three separate kits designated as UC1, UC2, and OSMO. Each kit of UC1, UC2 consists of two bottles each of six levels including zero. The OSMO set consists of two bottles each of five levels. All sets are in a human or serum matrix compatible with chemistry systems.

Human source material from which this product has been derived has been tested at the donor level for the Human Immunodeficient Virus (HIV1, HIV2) antibody, Hepatitis B Surface Antigen (HbsAg) and Hepatitis C Virus (HCV) and found to be non-reactive. FDA approved methods have been used to conduct these tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

VALIDATE[®] Chemistry 1 Calibration Verification Test Set

Bio-Rad Liquichek[™] Urine Chemistry Controls

2. Predicate 510(k) number(s):

k012117, k934357

3. Comparison with predicate:

	VALIDATE[®] Urine Chemistry Calibration Verification Test Sets	VALIDATE[®] Chemistry 1 Calibration Verification Test Set	Bio-Rad Liquichek[™] Urine Chemistry Controls
Catalog#	701/702/703	101	398
Intended Use	For in vitro diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert.	For in vitro diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert.	For in vitro use as assayed quality control urine to monitor the precision of laboratory testing procedures for the listed analytes.

Analytes	<p>701 – UC1 Uric Acid, Alcohol, Sodium, Potassium, Chloride, Glucose, Urea nitrogen/urea, Total protein</p> <hr/> <p>702 – UC2 Calcium, Magnesium, Phosphorous, Creatinine, Amylase, Pancreatic amylase, Microalbumin</p> <hr/> <p>703 – Osmo serum osmolality, urine osmolality</p>	Sodium, Potassium, Chloride, Calcium, Phosphorous, Glucose, BUN, Creatinine, Triglyceride, Magnesium, Lactate, Lithium	Amylase, Calcium, Chloride, Cortisol, Creatinine, Glucose, Magnesium, Microalbumin, Osmolality, Phosphorous, Potassium, Urine Total Protein, Sodium, BUN, UUN, Uric Acid
Matrix	Human urine, Human serum (osmo)	Aqueous	Human urine
Number of Levels	<p>701/702 6 including zero</p> <hr/> <p>703 5 levels</p>	6 including zero	1 level
Preparation	Liquid ready to use	Liquid ready to use	Liquid ready to use
Packaging	3.0 mL each level	5.0 mL each level	10 mL
Stability	Until Expiration	Until Expiration	30 days after opening
Storage	2 to 8 ⁰ C	2 to 8 ⁰ C	2 to 8 ⁰ C

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

None stated

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)*

The test sets, Cat # 701 / 702 / 703, are prepared in a human urine matrix to which analytes of a chemical or biological (human or animal) nature are added along with preservatives, stabilizers, and other excipients. The concentration of the added chemicals or biologicals are subsequently measured on various clinical chemistry analyzer systems using methods designed for measurement of these analytes in human urine. Levels 1 and 5 are prepared so that Level 1 meets the lower limit of the instrument manufacturer's claimed linearity and Level 5 the upper limit. Levels 1 and 5 are assayed in triplicate on the applicable instrument system. When the recovered values meet the acceptance tolerance, admixtures of Levels 1 and 5 are made to create Levels 2, 3 and 4. Levels 2, 3 and 4 are then tested, again in triplicate, to validate that recovery meets the required tolerance. After this testing event, all levels are labeled and filled after which final in process testing (FIPT) is performed, again in triplicate, for all analytes in each level. Each testing event requires each level be assayed in triplicate on the system for which the product is designed.

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 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.