510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k123127

B. Purpose for Submission:

New device

C. Measurand:

Multi-analyte control materials

D. Type of Test:

Quantitative, Immunoassay

E. Applicant:

Maine Standards Company LLC

F. Proprietary and Established Names:

VALIDATE® PSA Calibration Verification/ Linearity Test Kit

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:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   VALIDATE® PSA Calibration/ Verification/ Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analytes: Total prostrate-specific antigen (PSA) and free prostrate-specific antigen (fPSA) on automated systems.

2. Indication(s) for use:

   Same as Intended use.

3. Special conditions for use statement(s):

   For In Vitro Diagnostic Use. For prescription only.

   The kit is not intended for use as routine quality control material or as calibration materials.

4. Special instrument requirements:

   Automated analyzer systems

I. Device Description:

Each test kit consists of one bottle each of Levels 1 through 6 plus a Base matrix. Each bottle contains 2.5 mL each level, ready to use. There exists a linear relationship among Levels 1 through 6.

Material of human origin used in the manufacture of this test kit has been tested using FDA or CE approved methods and found to be non-reactive for HBV, HCV and HIV.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VALIDATE® Chem 6 Calibration Verification Test Set

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

   k013119 (for Uric Acid)

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test kit	Calibration Verification Test Kit	Same
Stability	Until expiration date	Same

Differences		
Item	Device	Predicate
Intended Use	VALIDATE PSA Calibration Verification/ Linearity Test Kit for automated systems	VALIDATE Chem 6 Calibration Verification Test Set for Uric Acid in automated, semi-automated and manual instrument systems
Analytes	Total PSA and Free PSA	Uric Acid
Matrix	Human serum based	Aqueous solution
Number of levels	6 Levels	5 Levels plus a level zero
Packaging	2.5 mL each level	5.0 mL each level
Storage	-10 to -25°C	2-8°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:

A total of six linear dilution levels of Total PSA and Free PSA were tested in triplicate ranging between 0.01 - 148.2 ng/mL for Total PSA and 0.008 - 62.6 ng/mL for Free PSA on representative automated analyzers. Linear regression analysis results are tabulated below. Criteria of acceptability with total allowable error of 0.3 ng/mL or 32% whichever is greater. Linearity claims for these products are: Total PSA: 0.008-150 ng/mL and Free PSA: 0.005-50 ng/mL.

Linearity was determined using CLSI EP6-A. Results for Total and Free PSA are summarized in the following tables:

Validate® Total PSA	
Automated analyzer	Mean vs Target Regression
Beckman-Coulter® Access II Immunochemistry Analyzer	y = 0.974x + 0.951
Roche® Cobas 6000 Chemistry Analyzer	y = 1.024x - 0.042
Siemens® Centaur Immunochemistry Analyzer	y = 1.009x - 0.127

Validate® Free PSA	
Automated analyzer	Mean vs Target Regression
Beckman-Coulter® Access II Immunochemistry Analyzer	y = 1.042x – 0.382
Roche® Cobas 6000 Chemistry Analyzer	y = 0.920x + 0.484

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability: Values of this product are linked to the WHO PSA standard based on the respective instrument calibration traceability.

Stability: The sponsor provided protocol, acceptance criteria, and line data with summary.

Real time stability study on the 6 level vials is on-going. Data from 3 lots support 3 months shelf life and 2 lots for 4 months for opened vial.

Open vial freeze-thaw study on 6 levels of Total PSA and Free PSA were performed for 6 freeze-thaw cycles. Data support maximum of 4 freeze/ thaw cycle.

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.