AUG 2 0 2001

MAINE STANDARDS COMPANY, LLC

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K012117."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Christine Beach, Mgr. RA/QA

Summary prepared on: June 29, 2001

Proprietary Name: VALIDATE Chem 1 Calibration Verification Test Set
Common Name: Calibration Verification
Classification Name: Calibrator, Multi-Analyte

Predicate Devices:

1. **DOCUMENT** Multi-Analyte CAL-VER, K870252, manufactured by CASCO NERL Diagnostics.
2. **DOCUMENT** Direct ISE CAL-VER, K881773, manufactured by CASCO NERL Diagnostics.
3. **DOCUMENT** Iron/Magnesium/Triglyceride CAL-VER, K893142, manufactured by CASCO NERL Diagnostics.
4. **DOCUMENT** Ammonia/Ethanol CAL-VER, K962629, manufactured by CASCO NERL Diagnostics.
5. **Precitrol** Ethyl Alcohol/Ammonia/Lactate Control, Roche Diagnostics.

Device description: VALIDATE Chem 1 Calibration Verification Test Set contains purified chemicals in an aqueous base. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains one bottle each of six (6) levels, including zero. Each bottle contains 5 milliliters.

Intended use: VALIDATE Chem 1 Calibration Verification Test Set is intended for *in vitro* diagnostic use for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the following analytes: sodium, potassium, chloride, calcium, phosphorus, lactate, glucose, urea nitrogen, creatinine, triglyceride, ammonia, ethanol, magnesium, and lithium.

K012117

Comparison of VALIDATE Chem 1 Calibration Verification Test Set to the predicate devices:

Table 1 compares characteristics of the VALIDATE Chem 1 Calibration Verification Test Set with those of the DOCUMENT Multi-Analyte CAL•VER, DOCUMENT Direct ISE CAL•VER, DOCUMENT Iron, Magnesium, Triglyceride CAL•VER, DOCUMENT Ammonia/Ethanol CAL•VER, and Roche Diagnostics Precitrol Ethyl Alcohol/Ammonia/Lactate Control.

TABLE 1. Comparison of Products

	VALIDATE CHEM 1 Calibration Verification Test Set	**DOCUMENT Multi-Analyte CAL•VER**	**DOCUMENT Direct ISE CAL•VER**	**DOCUMENT Iron, Magnesium, Triglyceride CAL•VER**
Catalog #	10001	M-100	M-101	M-103
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 *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.
Analytes	NA, K, CL, CA, PO_4, GLU, BUN, CRE, TRIG, MG, LAC, NH_3 ETOH, LI	GLU, BUN, NA, K, CL, CRE, CA, PO_4	NA, K, CL, LI	MG TRIG
Matrix	aqueous	aqueous	aqueous	aqueous
Number of Levels	6 including Zero	5	5	5
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	5.0 mL each level	15.0 mL each level	10.0 mL each level	10.0 mL each level
Stability	Until Expiration	Until Expiration	Until Expiration	Until Expiration
Storage	2-8°C	18-25°C	18-25°C	2-8°C

K012117

TABLE 1: continued

	VALIDATE CHEM 1 Calibration Verification Test Set	DOCUMENT Ammonia/ Ethanol CAL•VER	Roche Diagnostics Precitrol Ethyl Alcohol/Ammonia/ Lactate Controls Low and High
Catalog #	10001	M-100	1775812 / 1775782
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 *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For use as an assayed control material to aid in the assessment of day-to-day performance of automated, semi-automated or manual chemistry systems.
Analytes	NA, K, CL, CA, PO_4, GLU, BUN, CRE, TRIG, MG, LAC, NH_3 ETOH, LI	NH_3 ETOH	LAC
Matrix	aqueous	aqueous	aqueous
Number of Levels	6 including Zero	5	1 low and 1 high
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	5.0 mL each level	3.0 mL each level	4.0 mL each level
Stability	Until Expiration	Until Expiration	Until Expiration
Storage	2-8°C	2-8°C	2-8°C

The performance of VALIDATE Chem 1 Calibration Verification Test Set solutions on the Roche Diagnostics Hitachi 911 instrument system as compared to DOCUMENT Multi-Analyte CAL•VER, DOCUMENT Direct ISE CAL•VER, DOCUMENT Iron, Magnesium, Triglyceride CAL•VER, DOCUMENT Ammonia/Ethanol CAL•VER, and Roche Diagnostics Precitrol Ethyl Alcohol/Ammonia/Lactate Control has been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 1 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 1 Calibration Verification Test Set and the predicate devices are presented in Table 2.

K012117

TABLE 2. Linear Regression Statistical Comparison of VALIDATE Chem 1 Calibration Verification Test Set to the predicate devices.

	VALIDATE Chem 1 Calibration Verification Test Set		DOCUMENT Multi-Analyte CAL•VER		DOCUMENT Direct ISE CAL•VER		DOCUMENT Iron, Magnesium, Triglyceride CAL•VER	
Analyte	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regressio Equation Y=intercep + slope(X
NA	0.99993	-2.455 + 1.017	N/A	N/A	0.99976	3.02 + .966	N/A	N/A
K	0.99964	-.014 + 1.018	N/A	N/A	0.99983	-.014 + .98	N/A	N/A
CL	0.99998	-.175 + 1.002	N/A	N/A	0.99972	-3.751 + 1.017	N/A	N/A
CA	0.99992	-.017 + 1.007	0.99995	-.609 + 1.124	N/A	N/A	N/A	N/A
PO4	0.99999	-.048 + 1.011	0.99985	-.167 + 1.049	N/A	N/A	N/A	N/A
GLU	0.99998	-.486 + .998	0.99994	2.529 + 1.02	N/A	N/A	N/A	N/A
BUN	0.99998	-.729 + 1.016	0.99972	1.836 + .924	N/A	N/A	N/A	N/A
CRE	0.99999	-.066 + 1.005	0.99997	-.32 + 1.063	N/A	N/A	N/A	N/A
TRIG	0.99999	-3.002 + 1.004	N/A	N/A	0.99997	1.58 + 1.016	0.99997	1.58 + 1.016
MG	0.99984	.022 + .992	N/A	N/A	0.99913	.138 + 1.009	0.99913	.138 + 1.009
LI	0.99978	.074 + .982	0.99959	-.052 + .986	N/A	N/A	N/A	N/A

TABLE 2: continued

	VALIDATE Chem 1 Calibration Verification Test Set		DOCUMENT Ammonia/ Ethanol CAL•VER		Roche Diagnostics Precitrol Ethyl Alcohol/Ammonia/Lactat Control Low and High	
Analyte	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)
LAC	0.99995	.046 + .979	N/A	N/A	0.99990	-.049 + 1.001
NH_3	0.99498	29.859 + .905	0.99945	10.778 + .915	N/A	N/A
ETOH	0.99948	2.281 + .965	0.99992	1.609 + .971	N/A	N/A

Summary:

Linear regression analysis was carried out on recovered values for each analyte. Each analyte was tested in triplicate. The VALIDATE Chem 1 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Multi-Analyte CAL•VER, DOCUMENT Direct ISE CAL•VER, DOCUMENT Iron, Magnesium, Triglyceride CAL•VER, DOCUMENT Ammonia/Ethanol CAL•VER, and Roche Diagnostics Precitrol Ethyl Alcohol/ Ammonia/Lactate Control.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 0 2001

Ms. Christine V. Beach
Manager, RA/QA
Maine Standards Company, LLC
765 Roosevelt Trail
Windham, ME 04062

Re: 510(k) Number: K012117
Trade/Device Name: VALIDATE Chem 1 Calibration Verification Test Set
Regulation Number: 862.1660
Regulatory Class: Class I, Reserved
Product Code: JJY
Dated: July 3, 2001
Received: July 6, 2001

Dear Ms. Beach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K012117

Device Name: VALIDATE Chem 1 Calibration Verification Test Set

Indications for Use:

The VALIDATE Chem 1 Calibration Verification Test Set is 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 following analytes: sodium, potassium, chloride, calcium, phosphorus, lactate, glucose, urea nitrogen, creatinine, triglyceride, ammonia, ethanol, magnesium, and lithium.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

Nasia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012117