



K623410

JAN 06 2003

## 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: \_\_\_\_\_."

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

Summary prepared on: October 7, 2002

Proprietary Name: VALIDATE Chem 10 Calibration Verification Test Set  
Common Name: Calibration Verification  
Classification Name: Calibrator, Multi-Analyte

### Predicate Device:

1. **DOCUMENT** Reflectance II Test Set, K910440, manufactured by CASCO NERL Diagnostics.
2. Ortho-Clinical Diagnostics VITROS Calibrator Kit 4

**Device description:** VALIDATE Chem 10 Calibration Verification Test Set contains purified enzymes in a solution of bovine albumin. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains five (5) levels. Each bottle contains 5.0 milliliters.

**Intended use:** VALIDATE Chem 10 Calibration Verification Test Set is intended for *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity for automated and manual chemistry systems for the following analytes: alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, creatine kinase, gamma-glutamyl transferase, lactate dehydrogenase, lipase, and total bilirubin. The materials may also be utilized on Ortho-Clinical Diagnostic's Vitros analyzers for determining linearity of the Bu/Bc methods.

**Comparison to Predicate Devices:**

	<b>VALIDATE CHEM 10 Calibration Verification Test Set</b>	<b>DOCUMENT Reflectance II Test Set</b>	<b>Ortho-Clinical Diagnostics VITROS Calibrator Kit 4</b>
<b>Catalog #</b>	110	R-102	1204668
<b>Intended Use</b>	For <i>in vitro</i> diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For use in the calibration of VITROS chemistry systems for the quantitative measurement of total and direct bilirubin.
<b>Analytes</b>	ALT, AST, CK, LD, ALP, AMY, LIP, GGT, TBIL, Bu/Bc	ALT, AST, CK, LD, ALP, AMY, GGT	TBIL, Bu/Bc
<b>Matrix</b>	Bovine Serum Albumin	Human Serum	Bovine Serum Albumin
<b>Number of Levels</b>	5	5	3 (TBIL) 4 (Bu/Bc)
<b>Preparation</b>	Liquid, ready to use	Liquid, ready to use	Lyophilized
<b>Packaging</b>	5.0 mL each level	2 x 2.0 mL each level	3 mL each level
<b>Stability</b>	9 months	9 months	24 hours after reconstitution
<b>Storage</b>	-10 to -20° C.	-10 to -20° C.	-10 to -20° C.

The performance of VALIDATE Chem 10 Calibration Verification Test Set solutions on the Ortho-Clinical Diagnostics VITROS instrument system as compared to DOCUMENT Reflectance II Test Set and Ortho-Clinical Diagnostics Calibrator Kit 4 has been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 10 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 10 Calibration Verification Test Set and the predicate devices are presented in Table 2.

Table 2. Linear Regression Statistical Comparison between VALIDATE Chem 10 Calibration Verification Test Set and the predicate devices.

Analyte	VALIDATE Chem 10 Calibration Verification Test Set		DOCUMENT Reflectance II Test Set	
	Correlation Coefficient (r)	Regression Equation Y = slope(X) + intercept	Correlation Coefficient (r)	Regression Equation Y = slope(X) + intercept
ALP	0.9973	0.8898x + 42.375	0.994	0.978x - 35.071
ALT	0.9995	0.9722x - 0.0781	0.999	1.029x - 9.414
AMY	0.9983	0.9189x + 26.206	0.999	1.002x - 16.822
AST	0.9990	1.0521x - 11.729	0.998	0.982x - 4.709
CK	0.9932	0.814x + 59.839	0.999	0.974x + 8.122
GGT	0.9975	1.0994x - 17.786	0.999	0.987x + 4.625
LD	0.9997	1.0462x - 26.754	0.998	0.914x + 65.613
LIP	0.9999	0.9779x + 10.265	0.998	1.019x - 51.514

Analyte	VALIDATE Chem 10 Calibration Verification Test Set		Ortho-Clinical Diagnostics VITROS Calibrator Kit 4	
	Correlation Coefficient (r)	Regression Equation Y = slope(X) + intercept	Correlation Coefficient (r)	Regression Equation Y = slope(X) + intercept
TBIL	0.9999	0.9887x + 0.0423	<b>0.9999</b>	<b>0.9537x + 0.1719</b>
Bu	0.999	0.9463x + 0.0471	<b>0.9999</b>	<b>0.9765x + 0.0402</b>
Bc	0.9995	0.9662x + 0.1465	<b>0.9996</b>	<b>0.9899x - 0.0115</b>

**Summary:**

Linear regression analysis was carried out on recovered values for each analyte and the VALIDATE Chem 10 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Reflectance II Test Set and Ortho-Clinical Diagnostics Calibrator Kit 4.



JAN 06 2003

Ms. Christine Beach  
Manager, QA/RA  
Maine Standards Company  
765 Roosevelt Trail – Suite 9A  
Windham, ME 04062

Re: k023410  
Trade/Device Name: Validate Chem 10 Calibration Verification Test Set  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality control material (assayed and unassayed)  
Regulatory Class: Class I  
Product Code: JJY  
Dated: October 8, 2002  
Received: October 10, 2002

Dear Ms. Beach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

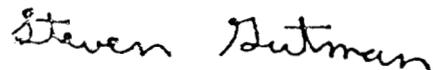
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

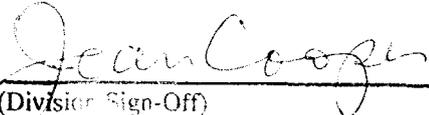
**INDICATIONS FOR USE STATEMENT**

510(k) Number: \_\_\_\_\_

Device Name: Validate Chem 10 Calibration Verification Test Set

**Indications for Use:**

The VALIDATE Chem 10 Calibration Verification Test Set is used by trained laboratory professionals for the determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual clinical chemistry systems for the following analytes: alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transferase, creatine kinase, lactate dehydrogenase, alkaline phosphatase, amylase, lipase, and total bilirubin. The materials may also be utilized on Ortho-Clinical Diagnostic's Vitros analyzers for determining linearity of the Bu/Bc methods.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number: K023410

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use