Validate®

Body Fluids Calibration Verification / Linearity Test Kit

INTENDED USE
VALIDATE BODY FLUIDS Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the determination of linearity, calibration verification and verification of reportable range on automated instrument systems for the following analytes: Set 1: albumin (ALB), amylase (AMY), cholesterol (CHOL), creatinine (CREA), glucose (GLU), lactate (LAC), lactate dehydrogenase (LD), total protein (TP), triglycerides (TRIG) and urea nitrogen (UN).
Set 2: CSF Total Protein (CSF-TP).

Each test kit consists of two sets of one bottle each of Levels 1 through 5. Set 1 contains 4.0 milliliters. Set 2 contains 2.0 milliliters. For each set, there exists a linear relationship among Levels 1 through 5.

SUMMARY
The **VALIDATE** BODY FLUIDS Calibration Verification / Linearity Test Kit contains purified albumin, amylase, cholesterol, creatinine, glucose, lactate, lactate dehydrogenase, total protein, triglycerides and urea nitrogen in a simulated body fluid matrix. Multiple levels are provided to establish the relationship between theoretical and actual performance of each of the included analytes. The **VALIDATE** BODY FLUIDS Calibration Verification / Linearity Test Kit will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. The solutions will also provide assistance when troubleshooting instrument systems, reagent problems and calibration anomalies.

REAGENTS
Reactive Ingredients:
Purified albumin, amylase, cholesterol, creatinine, glucose, lactate, lactate dehydrogenase, total protein, triglycerides and urea nitrogen in a synthetic matrix designed to simulate cerebrospinal, peritoneal ascites, pleural and pericardial fluids[1,2,3,4,5].

Nonreactive Ingredients:
Preservatives and stabilizers.

Precautions and Warnings:
For In Vitro Diagnostic Use
Disposal of all waste materials should be in accordance with local guidelines.

WARNING: Potentially Biohazardous
Human source material is considered potentially biohazardous. Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA or CE approved methods and found to be non-reactive for HBV, HCV and HIV. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

STORAGE AND STABILITY
VALIDATE BODY FLUIDS Calibration Verification / Linearity Test Kits are stored at -10° to -25°C. ***Do NOT store in a frost-free freezer.*** Test kits are stable until the expiration date printed on the storage container when handled according to instructions. ***A maximum of four (4) freeze-thaw cycles is recommended.***

PREPARATION
Prior to use, remove the **VALIDATE** BODY FLUIDS Calibration Verification / Linearity Test Kit from storage and allow to come to room temperature (18° to 25ºC). Invert gently several times before dispensing.

To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10° to -25ºC immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** Calibration Verification / Linearity Test Kit should be treated in the same manner as patient samples. If dilutions or pre-treatment are required as part of the testing procedure, follow the manufacturer's instructions.

ASSAY
Analyze each level in replicates. If following the CLSI EP6 guidelines for linearity, use a random analytical sequence to assay each level.

CALCULATION OF RESULTS
VALIDATE Calibration Verification / Linearity material is prepared in a manner such that an equal distance (delta) exists between each consecutive level. This dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets.

Two examples for calculating the theoretical values of Levels 1 through 5 are provided below.

Example 1:
Choose two consecutive levels and calculate the delta between the recovered values. The following example demonstrates the use of the delta between Levels 2 and 3 to calculate the theoretical value for Levels 1, 4 and 5:

Level 3 - Level 2 = Delta

Level 1 Theoretical = Level 2 Recovered - Delta
Level 4 Theoretical = Level 3 Recovered + Delta
Level 5 Theoretical = Level 4 Theoretical + Delta

NOTE: The user can select the calculated delta between any two consecutive levels to calculate the theoretical values. Typically, the user should choose an area of recovery known to be linear for the method being studied.

Example 2:
Theoretical values can be determined using the recovered values for Levels 1 and 5. Using this method, the following formulas apply:

Level 2 Theoretical = 0.75 * (Level 1) + 0.25 * (Level 5)
Level 3 Theoretical = 0.5 * (Level 1) + 0.5 * (Level 5)
Level 4 Theoretical = 0.25 * (Level 1) + 0.75 * (Level 5)

After theoretical values are calculated, for each analyte plot the expected (Theoretical) value on the x-axis versus the Recovered value on the y-axis using standard linear graph paper. If the system is linear, the plot should approximate a straight line. The point at which the line is no longer straight can be used to determine the limit of linearity or the reportable range.

Data reduction is available from LGC Maine Standards. Commercially available linear regression software may also be used. The software should provide data point display and x-y graphical presentation. Linear regression should be interpreted using standard statistical analysis and the results should be compared with the instrument manufacturer's claims for linearity or with individual laboratory performance requirements. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

LIMITATIONS
VALIDATE Calibration Verification / Linearity Test Kit is not intended for use as routine quality control materials or calibration materials.

EXPECTED VALUES
VALIDATE Calibration Verification / Linearity Test Kits are manufactured such that an equal distance (delta) exists between levels as recommended by CLSI EP6 for assessing linearity. As the distance between levels is equal, any two levels can be held to be 'true' when assayed and the theoretical values for each of the other three levels can be calculated allowing this test kit to be used on multiple automated instrument systems.

Typical VALUES
Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument / reagent system calibration. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical recovered values for Level 1 and Level 5 are presented in the table below. Typical values for mid-levels are based on an equal distance (delta) between levels.

205bf
Lot#: 25AH066190

Typical Recovered Values on Roche COBAS®

Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/dL	0.4	1.8	3.3	4.7	6.1
AMY	U/L	9	304	599	894	1189
CHOL	mg/dL	8	205	402	598	795
CREAT	mg/dL	0.4	5.9	11.4	16.8	22.3
GLU	mg/dL	5	189	372	556	739
LAC	mg/dL	4	37	71	104	137
LD	U/L	10	248	485	723	960
TP	g/dL	0.5	3.2	6.0	8.7	11.4
TRIG	mg/dL	11	223	436	648	860
UN	mg/dL	4	32	59	87	114
CSF-TP	mg/dL	5	51	98	144	190

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Lot#: 25AH066190

Analyte	SI Units	Level 1	Level 2	Level 3	Level 4	Level 5
ALB	g/L	4	18	33	47	61
AMY	U/L	9	304	599	894	1189
CHOL	mmol/L	0.207	5.303	10.399	15.495	20.591
CREAT	µmol/L	35.2	517.6	999.9	1482.3	1964.6
GLU	mmol/L	0.278	10.462	20.647	30.831	41.015
LAC	mmol/L	0.444	4.135	7.826	11.516	15.207
LD	U/L	10	248	485	723	960
TP	g/L	5	32	60	87	114
TRIG	mmol/L	0.124	2.523	4.921	7.320	9.718
UN	mmol/L	1.428	11.246	21.063	30.881	40.698
CSF-TP	g/L	0.1	0.6	1.0	1.5	1.9

ORDERING INFORMATION
ORDER NO.: 205bf

VALIDATE BODY FLUIDS
Calibration Verification / Linearity Test Kit:
Set 1: 5 x 4 mL
Set 2: 5 x 2 mL

Contact Information:
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CE Symbols – This product fulfills the requirements of the European Directive 98/79/EC for *in vitro* medical devices. The following symbols may be used where applicable in labeling for LGC Maine Standards products:

Lot Number

Expiration Date

Manufacturer

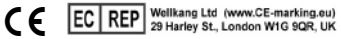
Storage Temperature

***In Vitro* Diagnostic Medical Device**

Catalog Number

Insert

Biological Risk



For a list of countries in which VALIDATE® is registered see:
http://www.mainestandards.com/Products/ce_reg.php

A worksheet to assist with manually calculating theoretical values can be found at www.mainestandards.com/Products or by calling Customer Support at 1-800-377-9684

Rx Only

Maine Standards Company, LLC., 221 US Route 1, Cumberland Foreside, ME 04110 USA

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