Linearity and Calibration Verification
Test Kits for Clinical Analyzers

Calibration Verification, performed at regular intervals, ensures that your clinical analyzer is performing to the manufacturer's claims, ensuring reliable and consistent patient test results.

Validate®
DELIVERS MORE

EASY.

VALIDATE® test kits use human-sourced raw materials, where available, and require no reconstitution.

- Liquid, ready-to-use solutions are supplied in multi-use dropper bottles for easy dispensing.
- Order once per year with extended open-vial stability and sufficient volume for 2+ verification cycles.

FAST.

VALIDATE® test kits increase productivity, reducing the need for sample preparation and manual dilutions.

- Levels 1 - 5 are prepared according to CLSI's EP06-A guideline.
- Fufill CLIA '88, CAP, ISO 15189, COLA, JCAHO, JCI and other accreditation and regulatory requirements.

EFFICIENT.

Together with our MSDRx® software, VALIDATE® provides a comprehensive calibration verification assessment.

- Instrument-specific configurations maximize range coverage and minimize dilutions.
- Use for installation, preventative maintenance and troubleshooting of reagents, QC and calibration.

MARKET LEADER IN CALIBRATION VERIFICATION

INSTALLATION

VALIDATE® products are used to perform validation of new instruments and assays, and to verify calibration. These instrument-specific kits are used by manufacturers and clinical laboratories to ensure instrument and assay specifications are being met, ensuring reliable and consistent patient results.

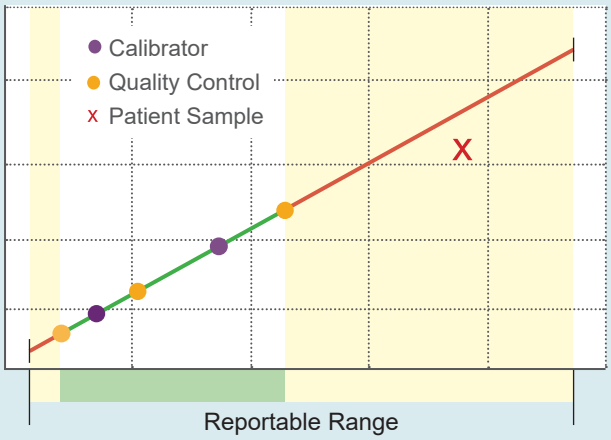
MAINTENANCE & TROUBLESHOOTING

VALIDATE® products are multi-use with extended open-vial stability. Having the same solutions available over several months and multiple uses affords the laboratory an invaluable tool when verifying and monitoring a method's performance.

COMPARISON OF RECOVERED VALUE VS. CONCENTRATION

Assaying materials in the same manner as patient samples, using VALIDATE®, confirms that an instrument, kit or test system has remained stable throughout the reportable range. Therefore, laboratories can expand beyond the routine quality control range, with confidence.

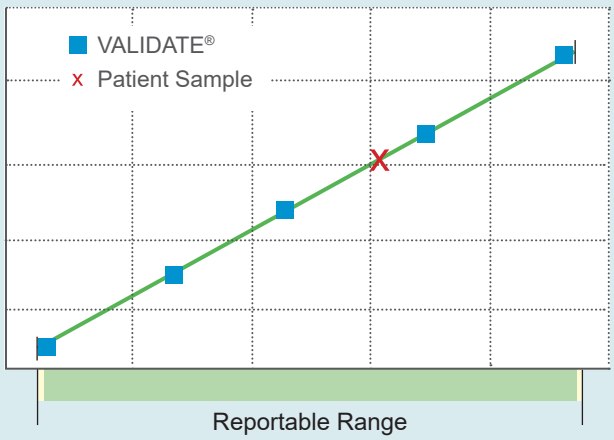
ROUTINE QUALITY CONTROL



- ! Upper and lower limits unchallenged
- ! Assay linearity unknown
- ! Unknown patient result outside of QC limits

The laboratory can not ensure that the response curve is linear beyond the limits of the calibrator and controls. When a patient sample result falls outside this range, there is reduced confidence that the result is valid.

VALIDATE® CALIBRATION VERIFICATION



- ✓ Limits challenged and monitored
- ✓ Assay linearity established
- ✓ Patient result within verified range

VALIDATE® challenges the extremes of the reportable range. Assaying five levels, using the equal-delta protocol prescribed by CLSI EP06-A, verifies a linear response. Patient samples are reported with increased confidence.

CONFIGURATIONS TAILOR-MADE TO ANALYTICAL INSTRUMENT PLATFORMS.

Clinical Chemistry & Immunoassay Analyzers

- Abbott Laboratories
- Beckman Coulter
- Ortho Clinical Diagnostics
- Roche Diagnostics
- Siemens Healthineers
- Tosoh Bioscience

Hemostasis Analyzers

- Diagnostica Stago
- Instrumentation Laboratory
- Siemens Healthineers

Validate® PRODUCTS

LGC Maine Standards offers in excess of 140 analytes, formulated into standard groupings. Visit our website, www.mainestandards.com, to view the multiple range coverages for each analyte and use the Analyzer Search Tool to identify the recommended products for your specific analyzers.

GENERAL CHEMISTRIES

GC1
- Albumin
- Blood Urea Nitrogen
- Calcium
- Chloride
- Cholesterol
- Creatinine
- Glucose
- Lactate
- Lithium
- Magnesium
- Phosphorus
- Potassium
- Sodium
- Total Protein
- Triglycerides
- Uric Acid

GC2
- Ammonia
- Carbon Dioxide
- Ethyl Alcohol
- Total Iron
- Uric Acid

GC3
- Alanine Aminotransferase
- Alkaline Phosphatase
- Amylase
- Aspartate Aminotransferase
- Creatine Kinase
- Gamma-Glutamyltransferase
- Lactate Dehydrogenase
- Lipase

GC4
- Conjugated Bilirubin
- Direct Bilirubin
- Total Bilirubin

IRON BINDING CAPACITY

IBC
- Total Iron Binding Capacity
- Unsaturated Iron Binding Capacity

LIPOPROTEIN

LP
- Apolipoprotein A
- Apolipoprotein B
- High Density Lipoprotein
- Low Density Lipoprotein

THERAPEUTIC DRUGS

TDM1
- Acetaminophen
- Amikacin
- Carbamazepine
- Digoxin
- Gentamicin
- Lidocaine
- N-Acetylprocainamide
- Phenobarbital
- Phenytoin
- Primidone
- Procainamide
- Quinidine
- Salicylate
- Theophylline
- Tobramycin
- Valproic Acid
- Vancomycin

URINE CHEMISTRIES

UC1
- Chloride
- Ethyl Alcohol
- Glucose
- Potassium
- Sodium
- Total Protein
- Urea Nitrogen
- Uric Acid

UC4
- Calcium
- Creatinine
- Magnesium
- Phosphorus

UC5
- Amylase
- Micro-Albumin
- Pancreatic Amylase

UC6
- Albumin
- Creatinine

OSMOLALITY

OSMO
- Serum Osmolality
- Urine Osmolality

CARDIAC MARKERS

CM1
- Creatine Kinase-MB
- Myoglobin

CM2
- Brain Natriuretic Peptide
- High Sensitivity C-Reactive Protein
- N-terminal Prohormone of BNP
- Troponin I
- Troponin T

HIGH SENSITIVE TROPONIN
- High Sensitivity Troponin I
- High Sensitivity Troponin T

THYROID ANALYTES

THY
- Cortisol
- Free T3
- Free T4
- Thyroid Stimulating Hormone
- Total T3
- Total T4

VITAMIN D

VIT D
- Vitamin D

SERUM PROTEINS

SP1
- α1-Antitrypsin
- Complement C3
- Complement C4
- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- Transferrin

SP2
- Albumin
- C-reactive Protein
- Ceruloplasmin
- Haptoglobin
- Prealbumin
- Rheumatoid Factor

SP3
- α1-Acid Glycoprotein
- Antistreptolysin O
- B2-Microglobulin
- Immunoglobulin E

TUMOR MARKERS

PSA*
- free Prostate-Specific Antigen
- total Prostate-Specific Antigen

*Not CE Approved.

TUMOR MARKERS
- Cancer Antigen 15-3
- Cancer Antigen 19-9
- Cancer Antigen 125
- Carcinoembryonic Antigen

ANEMIA

ANEMIA
- Ferritin
- Folate
- Vitamin B12

FERRITIN
- Ferritin

FERTILITY

FERTILITY 1
- Follicle-Stimulating Hormone
- Human Chorionic Gonadotropin
- Luteinizing Hormone
- Prolactin
- Testosterone

FERTILITY 2
- α1-fetoprotein
- Dehydroepiandrosterone Sulfate
- Estradiol
- Progesterone

GLYCOHEMOGLOBIN

HbA1c
- % Glycohemoglobin A1c

PROCALCITONIN

PCT
- Procalcitonin

BODY FLUIDS

BODY FLUIDS
- Albumin
- Amylase
- Cancer Antigen 19-9
- Carcinoembryonic Antigen
- Cerebrospinal Fluid Total Protein
- Cholesterol
- Creatinine
- Glucose
- Lactate
- Lactate Dehydrogenase
- Total Protein
- Triglycerides
- Urea Nitrogen

WHOLE BLOOD GLUCOSE

WBG
- Glucose

HEMOSTASIS

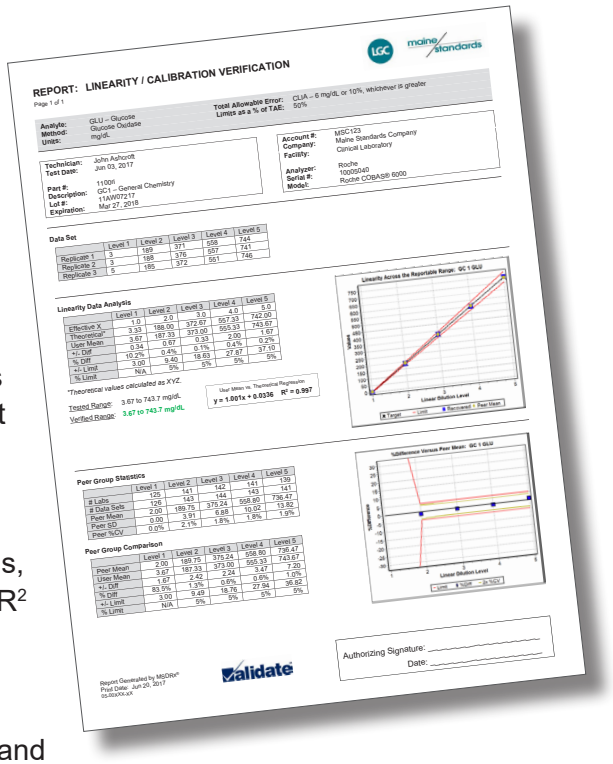
D-DIMER
- D-Dimer

HEPARIN
- Heparin Anti-Xa

FIBRINOGEN
- Fibrinogen

www.mainestandards.com

MSDRx®


REPORT: LINEARITY / CALIBRATION VERIFICATION

maine standards

Page 1 of 1

Analyte: GLU – Glucose
Method: Glucose Oxidase
Units: mg/dL

Total Allowable Error: CLIA – 6 mg/dL or 10%, whichever is greater
Limits as a % of TAE: 50%

Technician: John Ashcroft
Test Date: Jan 03, 2017

Peer #: 1100/5
Description: GC1 – General Chemistry
Lot #: 11W07217
Expiration: Mar 27, 2018

Account #: MSC123
Company: Maine Standards Company
Facility: Clinical Laboratory

Analyzer: Roche
Serial #: 10000540
Model: Roche COBAS® 6000

Data Set

	Level 1	Level 2	Level 3	Level 4	Level 5
Replicate 1	3	189	371	559	741
Replicate 2	3	188	376	557	741
Replicate 3	5	185	372	551	746

Linearity Data Analysis

	Level 1	Level 2	Level 3	Level 4	Level 5
Effective X	1.0	2.0	3.0	4.0	5.0
Theoretical*	3.33	187.33	373.00	557.33	742.00
User Mean	3.67	187.33	373.00	553.33	743.67
+/- Diff	0.34	0.67	0.1%	0.4%	1.67
% Diff	10.2%	0.4%	18.63	27.87	0.2%
+/- Limit	3.00	9.40	5%	5%	37.10
% Limit	N/A	5%			5%

*Theoretical values calculated as XYZ

Tested Range: 3.67 to 743.7 mg/dL
Verified Range: 3.67 to 743.7 mg/dL

User Mean vs. Theoretical Regression
y = 1.001x + 0.0336 R² = 0.997

Linearity Across the Reportable Range: GC 1 GLU

Peer Group Statistics

	Level 1	Level 2	Level 3	Level 4	Level 5
# Labs	125	141	142	141	139
# Data Sets	126	143	144	143	141
Peer Mean	2.00	189.75	375.24	558.80	736.47
Peer SD	0.00	3.91	6.88	10.02	13.82
Peer %CV	0.0%	2.1%	1.8%	1.8%	1.9%

Peer Group Comparison

	Level 1	Level 2	Level 3	Level 4	Level 5
Peer Mean	2.00	189.75	375.24	558.80	736.47
User Mean	3.67	187.33	373.00	555.33	743.67
+/- Diff	1.67	2.42	2.24	3.47	7.20
% Diff	83.5%	1.3%	0.6%	0.6%	1.0%
+/- Limit	3.00	9.48	18.75	27.94	36.82
% Limit	N/A	5%	5%	5%	5%

Tolerance Versus Peer Mean: GC 1 GLU

Authorizing Signature: _____
Date: _____

Report Generated by MSDRx®
Prod Date: Jun 20, 2017
05-002XX-xx

validate

DATA SUBMISSION

LGC Maine Standards' Data Reduction Program puts the power of analysis at your fingertips. This free statistical software delivers real-time analysis of your linearity and calibration verification test results.

LINEARITY ASSESMENT

Instant results. Easily and quickly perform linear regression analysis, including slope (proportional error), y-intercept (constant error), R^2 and view an X-Y graph.

PEER GROUP ANALYSIS

Take peer group analysis to a new level by using VALIDATE® and MSDRx®. Compare your data to Peer Means at each level across the entire range. Assess against Total Allowable Error Limits. If necessary, troubleshoot your assay. Evaluate specific methods in advance of Proficiency Testing (PT) events with anytime, on-line access to peer recoveries.

REPORTS

MSDRx® provides clear, concise, easily understood and explained statistical analyses and graphic presentations. You, your colleagues, your inspectors and your auditors can assess your laboratory performance quickly and with little interpretation.

Maine Standards Company
221 US Route 1
Cumberland Foreside, ME 04110
1.800.377.9684 or 1.207.892.1300

CE marked kits. Check with international distributors for specific product availability.

DEA REGISTERED — DEA Registered Facility for the manufacture of controlled substances.

FDA REGISTERED — US FDA Registered Facility. Complies with Quality System Regulation (QSR).

ISO CERTIFIED — ISO 13485:2016 Accredited Quality Management System (QMS).

CE EC REP
Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK