



Linearity and Calibration Verification Test Kits for Clinical Analyzers

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



maine
standards

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 additional material for troubleshooting.

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.



Fulfill 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 calibrations.

Market Leader in Calibration Verification

INSTALLATION

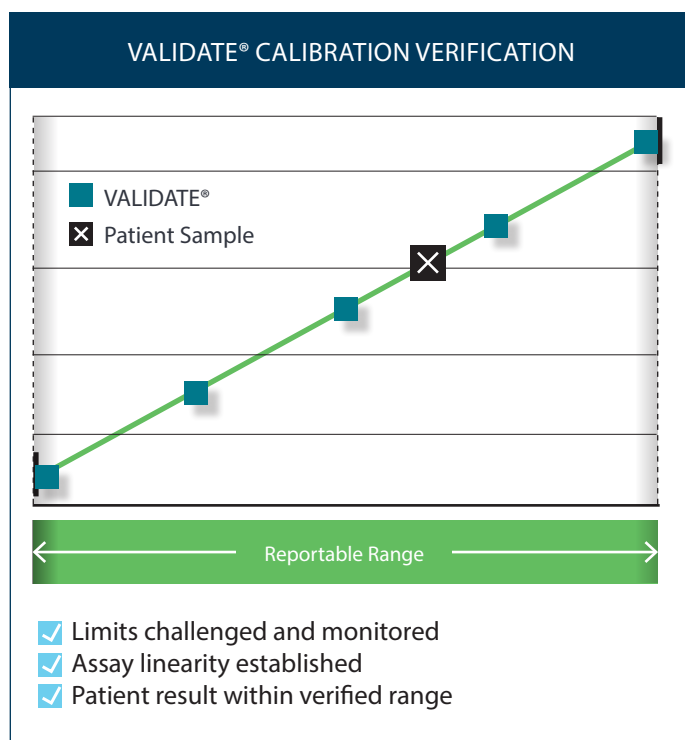
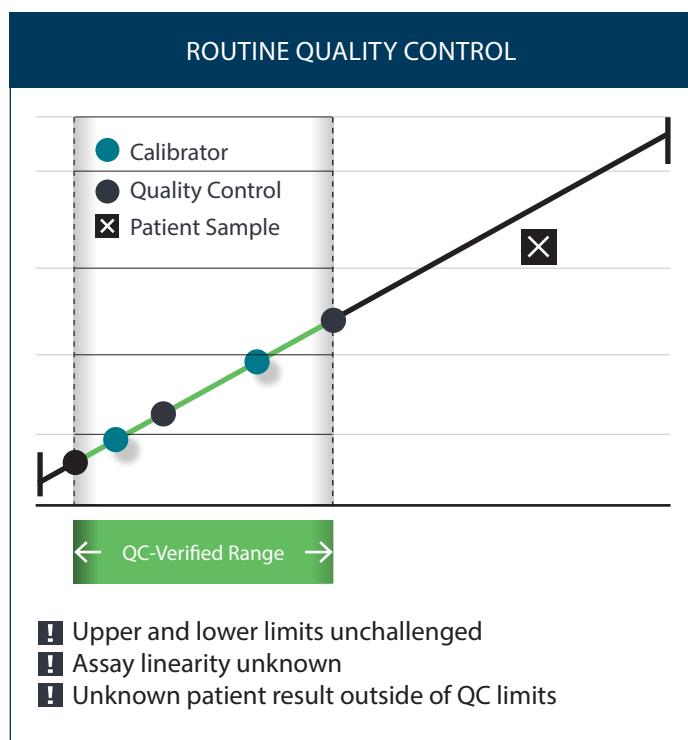
VALIDATE® products are used to perform verification of new instruments and assays. These instrument-specific kits are used by manufacturers and clinical laboratories to ensure instrument and assay specifications are being met, maintaining reliable and consistent patient results.

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.



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® 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
- Alfa Wassermann
- Beckman Coulter
- Ortho Clinical Diagnostics
- Roche Diagnostics
- Siemens Healthineers
- Tosoh Bioscience

HEMOSTASIS ANALYZERS

- Diagnostica Stago
- Instrumentation Laboratory
- Siemens Healthineers

VALIDATE® Products

VALIDATE® offers in excess of 150 analytes, formulated into standard groupings. Visit our website, 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 CHEMISTRY



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

LIPOPROTEINS



LP

High Density Lipoprotein
Low Density Lipoprotein

LP2

Apolipoprotein A1
Apolipoprotein B

ACTH



ACTH

Adrenocorticotrophic Hormone

ANEMIA



ANEMIA

Ferritin
Folate
Vitamin B12

FERRITIN

Ferritin

BODY FLUIDS



BF

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

BF2

Alkaline Phosphatase
Calcium
Chloride
Potassium
Sodium
Total Bilirubin
Uric Acid

BONE



PTH

Parathyroid Hormone

VIT D

Vitamin D

CARDIAC



CM1

Creatine Kinase-MB
Myoglobin

CM2

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

CM3

Homocysteine
Lipoprotein (a)

HIGH SENSITIVE TROPONIN

High Sensitivity Troponin T
High Sensitivity Troponin I

DIABETES



Diabetes

Beta-Hydroxybutyrate
C-Peptide
Glucose
Insulin
Fructosamine

HbA1c

% Glycohemoglobin A1c

VALIDATE® Products (continued)

FERTILITY



FERT 1

Follicle-stimulating Hormone
Human Chorionic Gonadotropin
Luteinizing Hormone
Prolactin
Testosterone

FERT 2

α 1-fetoprotein
Dehydroepiandrosterone Sulfate (DHEA SO4)
Estradiol
Progesterone

FERT 3*

anti-Müllerian Hormone
Sex Hormone-binding Globulin

*Not CE-approved

HEMOSTASIS



D-DIMER

D-Dim (D-Dimer)

FIBRINOGEN

FIBR (Fibrinogen)

HEPARIN

HP (Heparin Anti-Xa)

OSMOLALITY



OSMO

Serum Osmolality
Urine Osmolality

POC



WBG

GLU (Glucose)

SEPSIS



IL-6

Interleukin-6

PCT

Procalcitonin

SERUM PROTEINS



SP1

α 1-Antitrypsin
Complement C3
Complement C4
Immunoglobulin A
Immunoglobulin G
Immunoglobulin M
Transferrin

SP2

Albumin
C-Reactive Protein
Ceruloplasmin
Haptoglobin
Prealbumin
Rheumatoid Factor

SP3

α 1-Acid Glycoprotein
Antistreptolysin O
B2-Microglobulin
Immunoglobulin E

THERAPEUTIC DRUGS



TDM1

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

THYROID ANALYTES



THY

Cortisol
Free T3

Free T4

Thyroid Stimulating Hormone

Total T3

Total T4

TUMOR MARKERS



PSA*

Free Prostate-Specific Antigen
Total Free Prostate-Specific Antigen

*Not CE-approved

TM

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

URINE CHEMISTRY



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

Micro-Albumin
Creatinine

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.

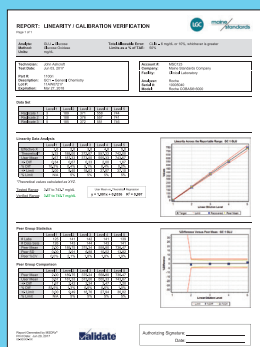


LINEARITY ASSESSMENT

Instant results. Easily and quickly perform linear regression analysis, including slope (proportional error), y-intercept (constant error), R2 and view an X-Y graph.

PEER GROUP ANALYSIS

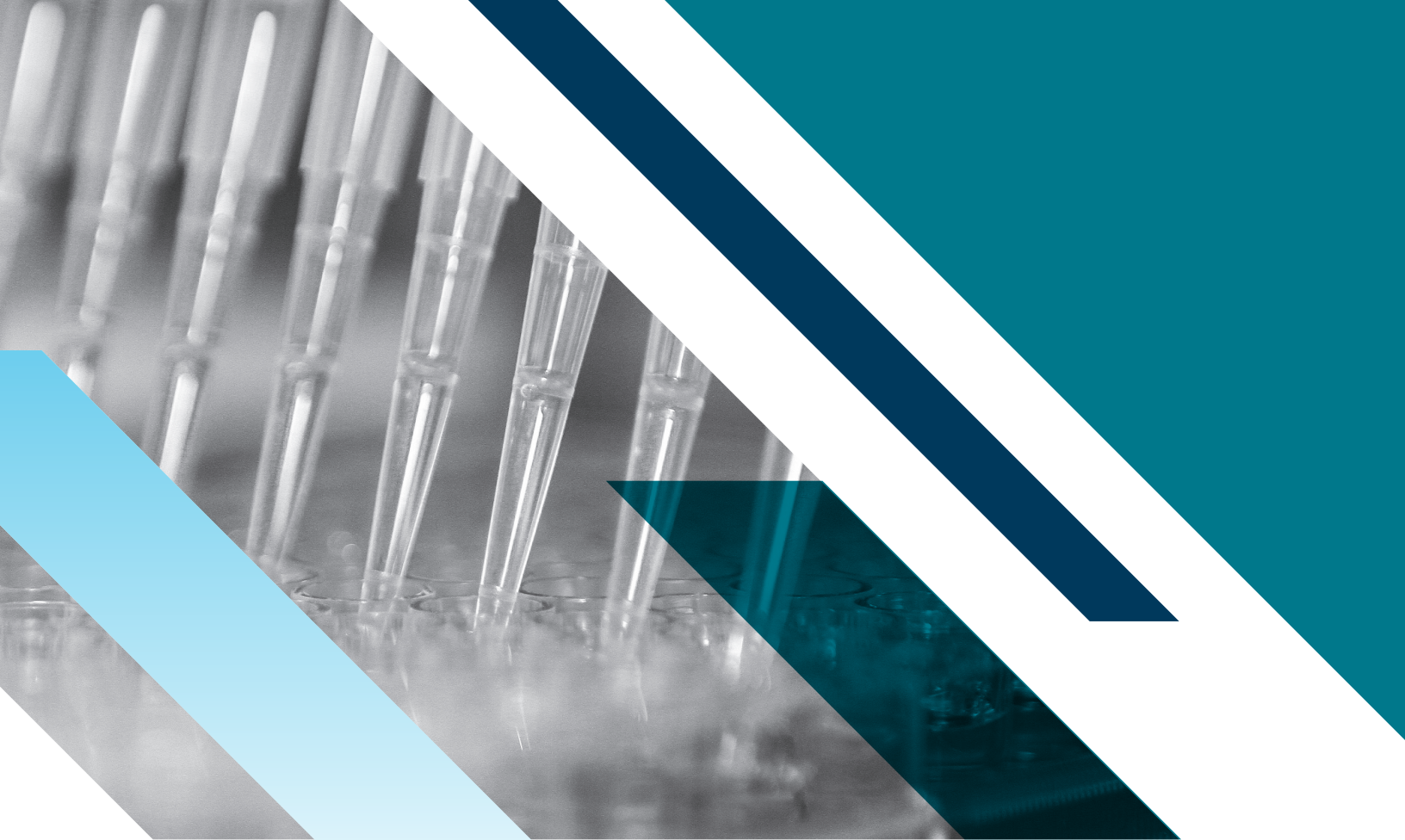
Take peer group analysis to a new level by using VALIDATE® and MSDRx®. Compare your data to Peer Means at each level across the entire range. Assess against Total Allowable Error Limits. If necessary, troubleshoot your assay. Evaluate specific methods in advance of Proficiency Testing (PT) events with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





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



DEA Registered Facility for the manufacture of controlled substances.



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



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



Maine Standards Company
221 US Route 1
Cumberland Foreside, ME 04110
1.800.377.9684 or 1.207.892.1300
www.mainestandards.com



MEDIMARK® Europe • 11, rue Émile Zola BP 2332 • 38033 Grenoble Cedex 2 – France
+ 33 (0) 4 76 86 43 22 • info@medimark-europe.com



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