



**CLINICAL
DIAGNOSTICS**

Product Brochure

Linearity and Calibration Verification
Test Products for Clinical Analyzers

 **validate**



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 guideline.



Fulfill CLIA '88, CAP, ISO 15189, COLA, JCAHO, JCI and other accreditation and regulatory requirements.

Efficient

Together with the 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

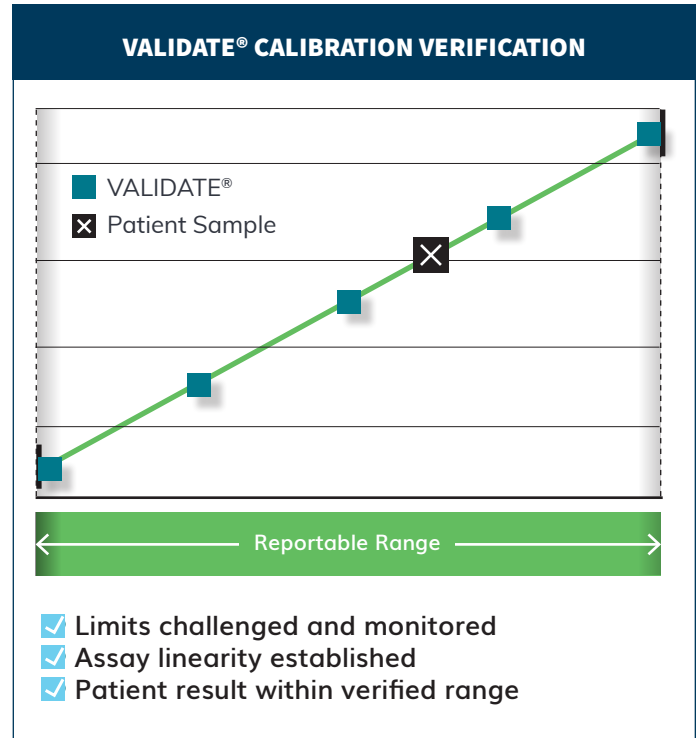
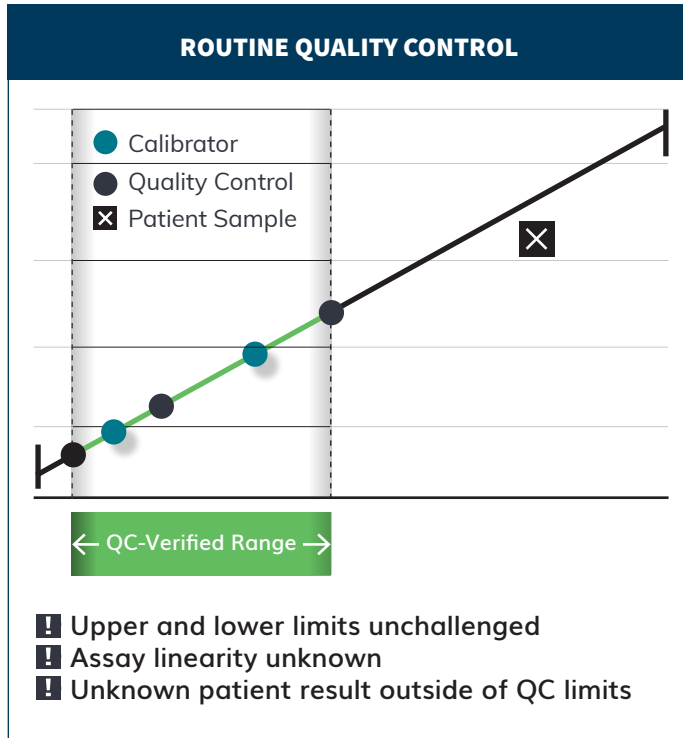
VALIDATE® products are used to perform verification of new instruments and assays. These instrument-specific kits are used by clinical laboratories to ensure instrument and assay specifications are being met, maintaining reliable and consistent patient results.

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 cannot ensure that the response curve is linear beyond the limits of the calibrator and controls. When a patient 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 described in CLSI EP06, 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

The following VALIDATE® products offer in excess of 170+ analytes, formulated into standard groupings. Visit mainestandards.com website to see TRVs and lot-specific information (PIs).

<p>GENERAL CHEMISTRY </p> <p>GC1*</p> <ul style="list-style-type: none"> Albumin Blood Urea Nitrogen Calcium Chloride Cholesterol Creatinine Glucose Lactate Lithium Magnesium Phosphorus Potassium Sodium Total Protein Triglycerides Uric Acid <p><small>*1100ab not CE-approved</small></p>	<p>LP2</p> <ul style="list-style-type: none"> Apolipoprotein A1 Apolipoprotein B 	<p>CARDIAC </p> <p>CM1</p> <ul style="list-style-type: none"> Creatine Kinase-MB Myoglobin
<p>GC2</p> <ul style="list-style-type: none"> Ammonia Carbon Dioxide Ethyl Alcohol Total Iron Uric Acid 	<p>ACTH </p> <p>ACTH</p> <ul style="list-style-type: none"> Adrenocorticotrophic Hormone 	<p>CM2*</p> <ul style="list-style-type: none"> Brain Natriuretic Peptide High Sensitivity C-Reactive Protein N-Terminal Prohormone of BNP Troponin I Troponin T <p><small>*402pf and 402re are not CE-approved</small></p>
<p>GC3</p> <ul style="list-style-type: none"> Alanine Aminotransferase Alkaline Phosphatase Amylase Aspartate Aminotransferase Creatine Kinase Gamma-Glutamyltransferase Lactate Dehydrogenase Lipase 	<p>ANEMIA </p> <p>ANEMIA</p> <ul style="list-style-type: none"> Ferritin Folate Vitamin B12 <p>FERRITIN</p> <ul style="list-style-type: none"> Ferritin 	<p>CM3</p> <ul style="list-style-type: none"> Homocysteine Lipoprotein (a) <p>HIGH SENSITIVE TROPONIN</p> <ul style="list-style-type: none"> High Sensitivity Troponin T High Sensitivity Troponin I
<p>GC4</p> <ul style="list-style-type: none"> Conjugated Bilirubin Direct Bilirubin Total Bilirubin 	<p>BODY FLUIDS </p> <p>BF</p> <ul style="list-style-type: none"> Albumin Amylase Cerebrospinal Fluid Total Protein Cholesterol Creatinine Glucose Lactate Lactate Dehydrogenase Total Protein Triglycerides Urea Nitrogen <p>BF2</p> <ul style="list-style-type: none"> Calcium Chloride Potassium Sodium Total Bilirubin Uric Acid 	<p>DIABETES </p> <p>Diabetes*</p> <ul style="list-style-type: none"> Cystatin C Beta-Hydroxybutyrate C-Peptide Insulin Fructosamine <p><small>*Not CE-approved</small></p>
<p>IRON BINDING CAPACITY </p> <p>IBC</p> <ul style="list-style-type: none"> Total Iron Binding Capacity Unsaturated Iron Binding Capacity 	<p>BF3</p> <ul style="list-style-type: none"> Cancer Antigen 19-9 Carcinoembryonic Antigen 	<p>HbA1c</p> <ul style="list-style-type: none"> % Glycohemoglobin A1c
<p>LIPOPROTEINS </p> <p>LP</p> <ul style="list-style-type: none"> High Density Lipoprotein Low Density Lipoprotein 	<p>BONE </p> <p>PTH</p> <ul style="list-style-type: none"> Parathyroid Hormone 	<p>FERTILITY </p> <p>FERT 1</p> <ul style="list-style-type: none"> Follicle-stimulating Hormone Human Chorionic Gonadotropin Luteinizing Hormone Prolactin Testosterone <p>FERT 2</p> <ul style="list-style-type: none"> α1-fetoprotein Dehydroepiandrosterone Sulfate (DHEA SO4) Estradiol Progesterone
<p>VIT D*</p> <ul style="list-style-type: none"> Vitamin D <p><small>*506ro not CE-approved</small></p>	<p>FERT 3</p> <ul style="list-style-type: none"> anti-Müllerian Hormone Sex Hormone-binding Globulin 	

VALIDATE® Products (continued)

HORMONE	SEROLOGY	THYROID ANALYTES 
GH Human Growth Hormone	aHBs anti-HBs	THY* Cortisol
HEMOSTASIS 	Rubella IgG anti-Rubella IgG	Free T3 Free T4 Thyroid Stimulating Hormone Total T3 Total T4 <small>*90Ire not CE-approved</small>
D-DIMER D-Dimer	Toxoplasma IgG <i>Toxoplasma gondii</i> IgG Antibody	THY2* Thyroglobulin T-Uptake <small>*Not CE-approved</small>
FIBRINOGEN Fibrinogen	SERUM PROTEINS 	TUMOR MARKERS 
HEPARIN Heparin Anti-Xa	SP1 α1-Antitrypsin Complement C3 Complement C4 Immunoglobulin A Immunoglobulin G Immunoglobulin M Transferrin	PSA* Free Prostate-Specific Antigen Total Free Prostate-Specific Antigen <small>*Not CE-approved</small>
IMMUNOSUPPRESSANTS 	SP2 Albumin C-Reactive Protein Ceruloplasmin Haptoglobin Prealbumin Rheumatoid Factor	TM Cancer Antigen 15-3 Cancer Antigen 19-9 Cancer Antigen 125 Carcinoembryonic Antigen
ISx Cyclosporine Sirolimus Tacrolimus	SP3 α1-Acid Glycoprotein Antistreptolysin O B2-Microglobulin Immunoglobulin E	URINE CHEMISTRY 
OSMOLALITY 	THERAPEUTIC DRUGS 	UC1* Chloride Ethyl Alcohol Glucose Potassium Sodium Total Protein Urea Nitrogen Uric Acid <small>*70Ire not CE-approved</small>
OSMO Serum Osmolality Urine Osmolality	TDM1* Acetaminophen Amikacin Carbamazepine Digoxin Gentamicin Lidocaine N-Acetylprocainamide Phenobarbital Phenytoin Primidone Procainamide Quinidine Salicylate Theophylline Tobramycin Valproic Acid Vancomycin <small>*30Ibc not CE-approved</small>	UC4 Calcium Creatinine Magnesium Phosphorus
POC 	UC5 Amylase Micro-Albumin Pancreatic Amylase	UC6 Micro-Albumin Creatinine
WBG GLU (Glucose)		
RHEUMATOID ARTHRITIS		
Anti-CCP αCCP		
SARS-CoV-2 IgG 		
SARS-CoV-2 IgG SARS-CoV-2 IgG		
SEPSIS 		
IL-6 Interleukin-6		
PCT Procalcitonin		

Data Submission

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.

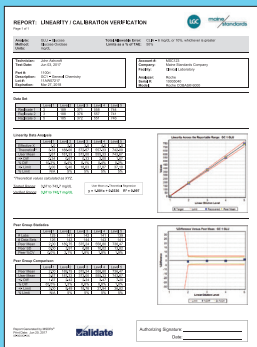


LINEARITY ASSESSMENT

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

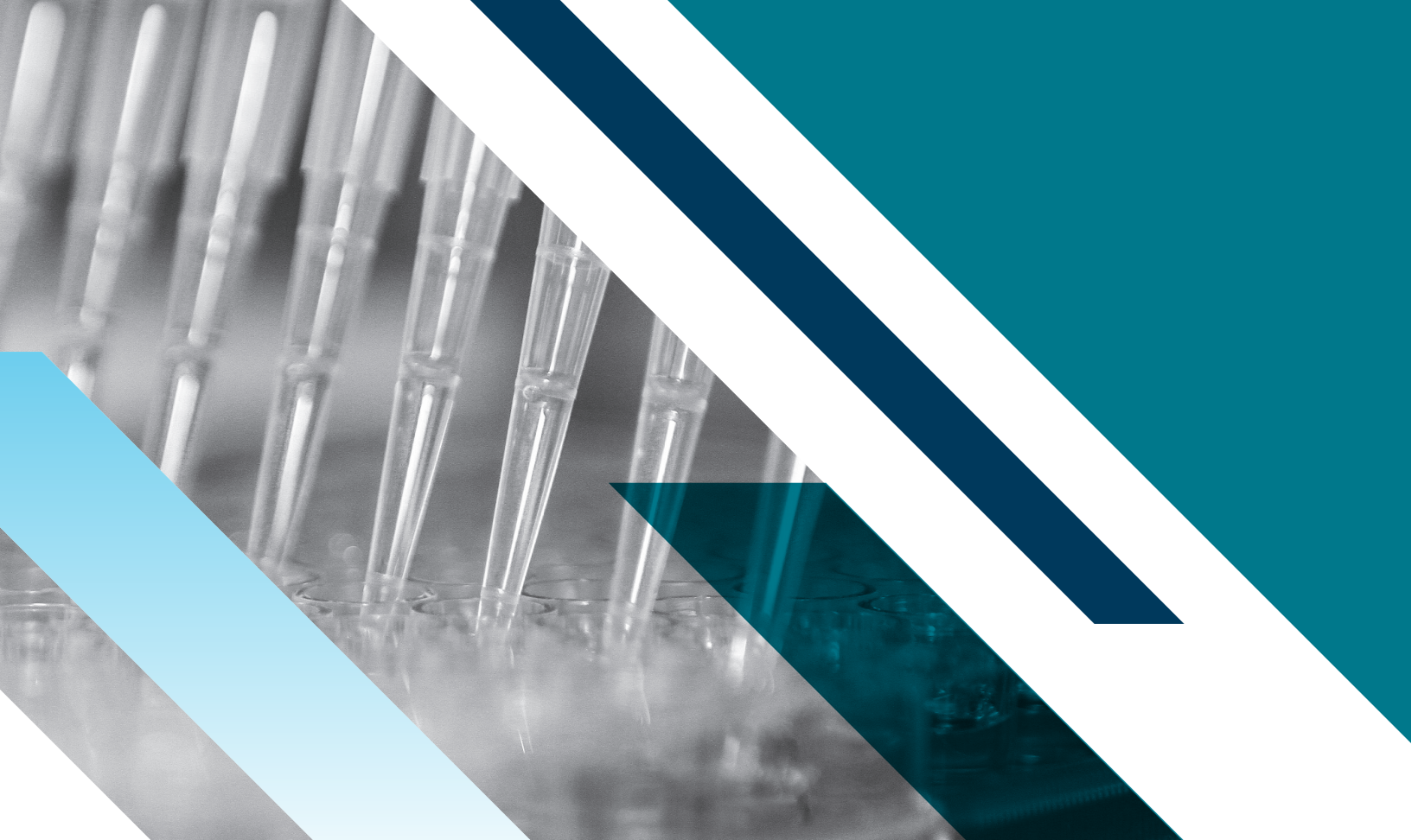
Take peer group analysis to a new level by using VALIDATE® and MSDRx®. Compare your data to Peer Means at each level across the entire range. Assess against Total Allowable Error Limits. If necessary, troubleshoot your assay. Evaluate specific methods in advance of Proficiency Testing (PT) events with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



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