



# 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.



## 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.



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 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.

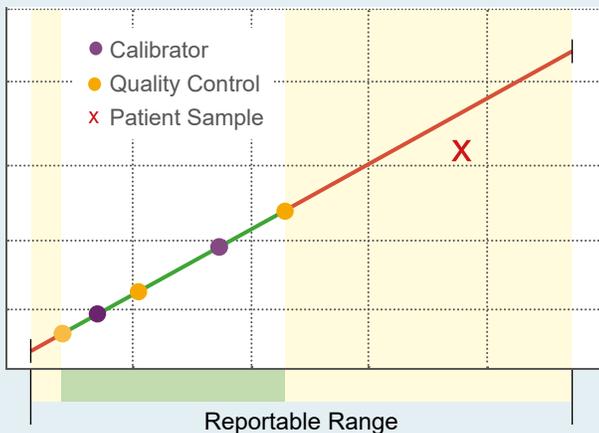
## MAINTENANCE & TROUBLESHOOTING

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.

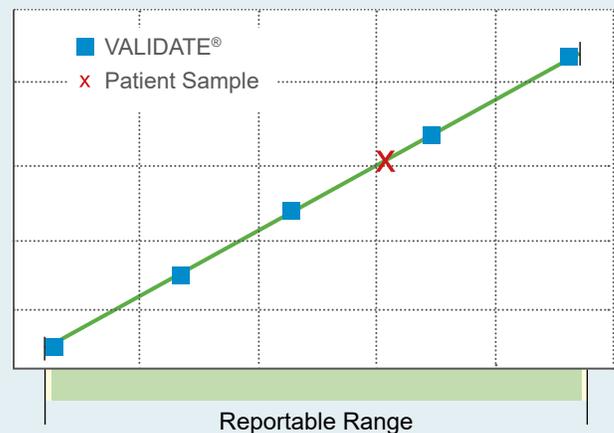
### ROUTINE QUALITY CONTROL



- ❗ 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



LGC Maine Standards offers in excess of 130 analytes, formulated into standard groupings. Visit our website, [www.mainstandards.com](http://www.mainstandards.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 DRUG MONITORING

### 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

## THYROID ANALYTES

### THY

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

## VITAMIN D

### VIT D

Vitamin D

## SERUM PROTEINS

### SP1

$\alpha$ 1-Antitrypsin  
Complement C3  
Complement C4  
Immunoglobulin A  
Immunoglobulin G  
Immunoglobulin M  
Transferrin

### SP2

Albumin  
C-reactive Protein  
Ceruloplasmin  
Haptoglobin  
Prealbumin  
Rheumatoid Factor

## 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

$\alpha$ 1-fetoprotein  
Dehydroepiandrosterone Sulfate  
Estradiol  
Progesterone

## GLYCOSYLATED HEMOGLOBIN

### HbA1c

% Glycohemoglobin A1c

## PROCALCITONIN

### PCT

Procalcitonin

## BODY FLUIDS

### BODY FLUIDS

Albumin  
Amylase  
Cancer Antigen 19-9  
Carcinoembryonic Antigen  
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



## 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

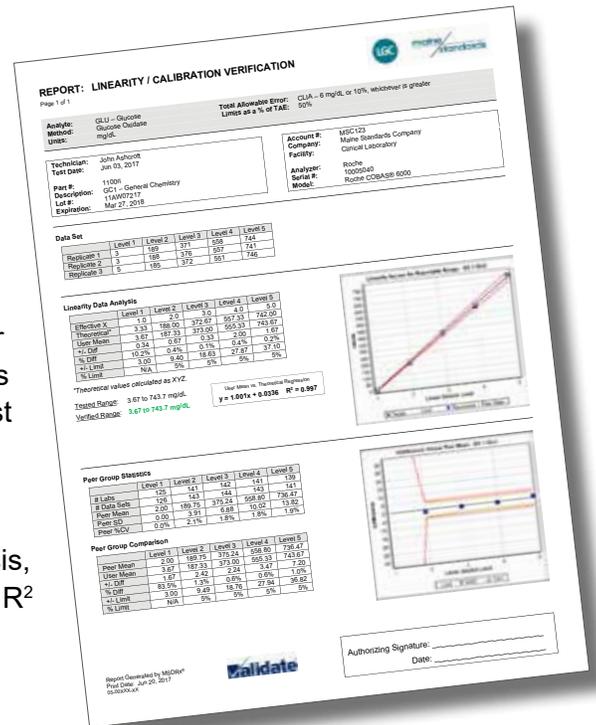
Instant results. Easily and quickly perform linear regression analysis, including slope (proportional error), y-intercept (constant error), R<sup>2</sup> and view an X-Y graph.

## 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 13485:2003 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



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