



**CLINICAL
DIAGNOSTICS**

Product Brochure

Calibration Verification and/or Linearity
Test Products for Clinical Analyzers

Validate[®]
AccuTrak[™]



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

Market Leader in Calibration Verification

INSTALLATION

VALIDATE® and AccuTrak™ 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® and AccuTrak™ 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.

Easy

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



VALIDATE® levels 1 - 5 are prepared according to CLSI's EP06 guideline. AccuTrak™ is prepared as individual levels across the reportable range.



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

Efficient

Together with the MSDRx® Infinity software, VALIDATE® and AccuTrak™ 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.

AccuTrak™ and VALIDATE®

AccuTrak™

AccuTrak™ **Calibration Verification Panels** are designed to provide independent levels across the assay's reportable range. These panels are intended exclusively for **calibration verification** and are **not suitable for linearity assessments**.

VALIDATE®

In contrast, VALIDATE® **Calibration Verification and Linearity products** are manufactured using an **equal-delta format**, which creates a defined relationship between levels. This format supports both **calibration verification** and **linearity assessment**.

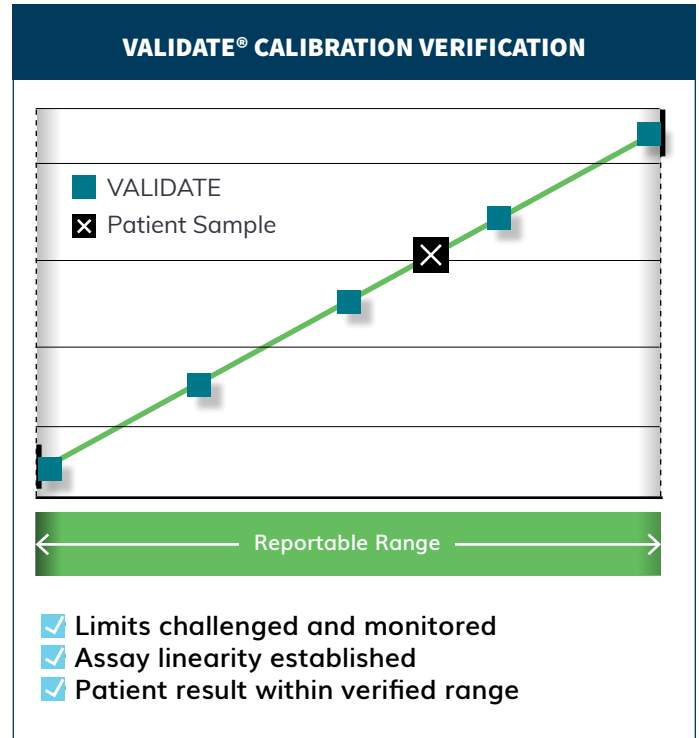
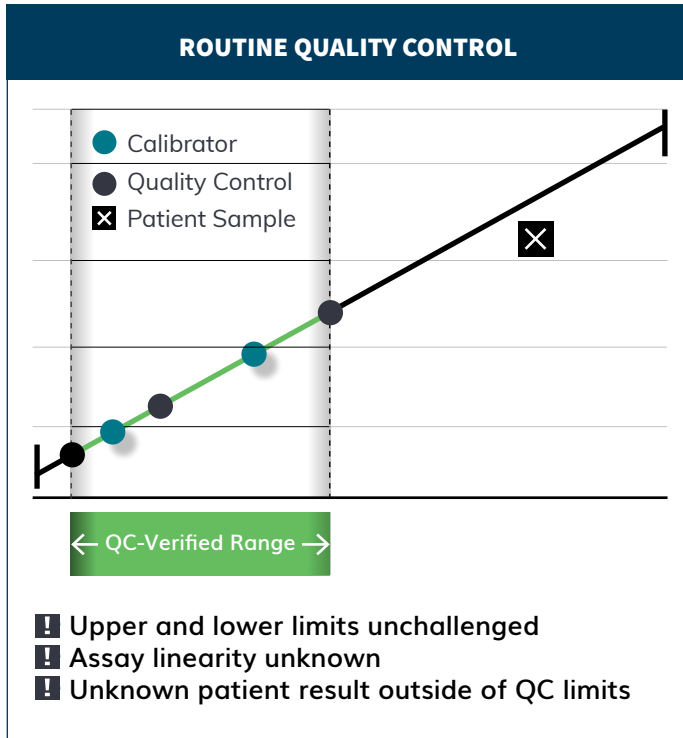
Both AccuTrak™ and VALIDATE® products are **liquid, ready-to-use**, and compatible with MSDRx Infinity® - LGC's cloud-based data reduction software that enables peer group analysis.



AccuTrak™	VALIDATE®
For calibration verification and reportable range verification	For linearity, calibration verification, and reportable range verification
Single analyte	Single or multi-analyte
Liquid, ready-to-use	Liquid, ready-to-use
Good for multiple uses and have extended open-vial stability	Good for multiple uses and have extended open-vial stability
Configurations tailor-made to analytical instrument platforms	Configurations tailor-made to analytical instrument platforms
Levels are prepared individually across the reportable range	Levels 1-5 are prepared according to CLSI's EP06-A guidelines
Data reduction software and peer group comparison through MSDRx Infinity	Data reduction software and peer group comparison through MSDRx Infinity

Comparison of Recovered Value vs. Concentration

Assaying materials in the same manner as patient samples, using VALIDATE® and AccuTrak™, 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 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 described in CLSI EP06, verifies a linear response. AccuTrak™ products are manufactured as individual levels across the reportable range to assist in calibration verification. Patient samples are reported with increased confidence.

*NOTE: AccuTrak™ Products are only intended for use in calibration verification and reportable range verification.

Configurations Tailor-Made to Analytical Instrument Platforms

CLINICAL CHEMISTRY & IMMUNOASSAY ANALYZERS

- Abbott Laboratories
- Beckman Coulter
- QuidelOrtho
- Polymedco
- Roche Diagnostics
- Siemens Healthineers
- Tosoh Bioscience

HEMOSTASIS ANALYZERS

- Diagnostica Stago
- Instrumentation Laboratory
- Siemens Healthineers

Calibration Verification Products

The following VALIDATE® and AccuTrak™ products offer in excess of 170+ analytes, formulated into standard groupings. Visit mainestandards.com website to see Typical Recovered Values (TRV) and lot-specific information in Product Inserts (PIs).

VALIDATE® PRODUCTS

AccuTrak™ PRODUCTS

GENERAL CHEMISTRY

GC1*

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

*1100ab and 1100ro are not CE-approved
**Uric Acid is only available for 1100vt

GC2

Ammonia
Carbon Dioxide
Ethyl Alcohol
Total Iron
Uric Acid**

**Uric Acid is not available for 1200vt

GC3*

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

*1300ab not CE-approved

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

Folate RBC*

Folate RBC
*Not CE-approved

BODY FLUIDS

Body Fluids

Albumin
Amylase
Cerebrospinal Fluid Total Protein
Cholesterol
Creatinine
Glucose
Lactate
Lactate Dehydrogenase
Total Protein
Triglycerides
Urea Nitrogen

Body Fluids 2

Calcium
Chloride
Potassium
Sodium
Total Bilirubin
Uric Acid

Body Fluids 3

Cancer Antigen 19-9
Carcinoembryonic Antigen

BONE

B-CTX*

Beta-CrossLaps
*Not CE-approved

OCN*

N-MID Osteocalcin
*Not CE-approved

PTH

Parathyroid Hormone

VIT D*

Vitamin D
*506ro not CE-approved

Calibration Verification Products (continued)

CARDIAC

CM1

Creatine Kinase-MB
Myoglobin

CM2*

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

*402pf, 402re, and 402vt are not CE-approved

CM3

Homocysteine
Lipoprotein (a)

HIGH SENSITIVE TROPONIN

High Sensitivity Troponin T
High Sensitivity Troponin I

DIABETES

Diabetes*

Cystatin C
Beta-Hydroxybutyrate
C-Peptide
Insulin
Fructosamine

*Not CE-approved

HbA1c

% Glycohemoglobin A1c

FERTILITY

Fertility 1

Follicle-stimulating Hormone
Human Chorionic Gonadotropin
Luteinizing Hormone
Prolactin
Testosterone

Fertility 2*

Alpha-fetoprotein
Androstenedione
Dehydroepiandrosterone Sulfate
Estradiol
Progesterone

*504re not CE-approved

Fertility 3

Anti-Müllerian Hormone
Sex Hormone-binding Globulin

Fertility 4*

Placental Growth Factor

*Not CE-approved

FERTILITY II

sFlt-1

Soluble fms-like Tyrosine Kinase-1

HORMONE

GH

Human Growth Hormone
Insulin-Like Growth Factor-1

GH2

Insulin-Like Growth Factor Binding
Protein-3

HEMOSTASIS

D-DIMER

D-Dimer

FIBRINOGEN

Fibrinogen

HEPARIN

Heparin Anti-Xa

IMMUNOSUPPRESSANTS

ISx

Cyclosporine
Sirolimus
Tacrolimus

OSMOLALITY

OSMO

Serum Osmolality
Urine Osmolality

POC

WBG

Glucose

RHEUMATOID ARTHRITIS

Anti-CCP

Cyclic Citrullinated Peptides IgG
Antibody

SARS-CoV-2 IgG

SARS-CoV-2 IgG

SARS-CoV-2 IgG Antibody

Calibration Verification Products (continued)

SEPSIS

IL-6

Interleukin-6

PCT

Procalcitonin

SEROLOGY

aHBs

Hepatitis B Surface IgG Antibody

Rubella IgG

Rubella IgG Antibody

Toxoplasma IgG

Toxoplasma gondii IgG Antibody

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

SP3

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

THERAPEUTIC DRUGS

MTX*

Methotrexate

*Not CE-approved

TDM1*

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

*301ab, 301au, and 301bc are not CE-approved

THYROID

THY*

Cortisol
Free Triiodothyronine
Free Thyroxine
Thyroid Stimulating Hormone
Total Triiodothyronine
Total Thyroxine

*901ab and 901re not CE-approved

THY2*

Thyroglobulin
T-Uptake

*Not CE-approved

CT*

Calcitonin

*Not CE-approved

THYROID II

aTG

Anti-Thyroglobulin

aTPO

Anti-Thyroid Peroxidase

TUMOR MARKERS

PSA*

Free Prostate-Specific Antigen
Total Free Prostate-Specific Antigen

*Not CE-approved

Tumor Markers

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

Tumor Markers 2*

Cytokeratin 19 Fragment
Human Epididymal Protein 4

*Not CE-approved

URINE CHEMISTRY

UC1*

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

*701re not CE-approved

UC4*

Calcium
Cortisol
Creatinine
Magnesium
Phosphorus

*704ro not CE-approved

UC5

Amylase
Micro-Albumin
Pancreatic Amylase

UC6

Micro-Albumin
Creatinine

Data Submission

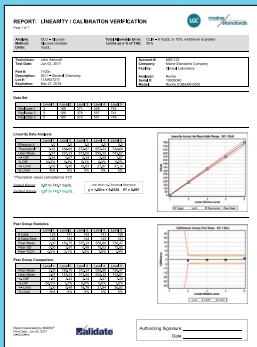
Maine Standards' Data Reduction Program puts the power of analysis at your fingertips. This free statistical software delivers real-time analysis of your calibration verification and linearity test results.

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®, AccuTrak™, and MSDRx® Infinity. Compare your data to Peer Means at each level across the entire range. Supplying vital information to troubleshoot your assay and evaluate specific methods as part of routine accreditation events with anytime, online access to peer recoveries.



Reports

MSDRx® Infinity 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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