



**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**  

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**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™ provide comprehensive calibration verification assessments.



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**.

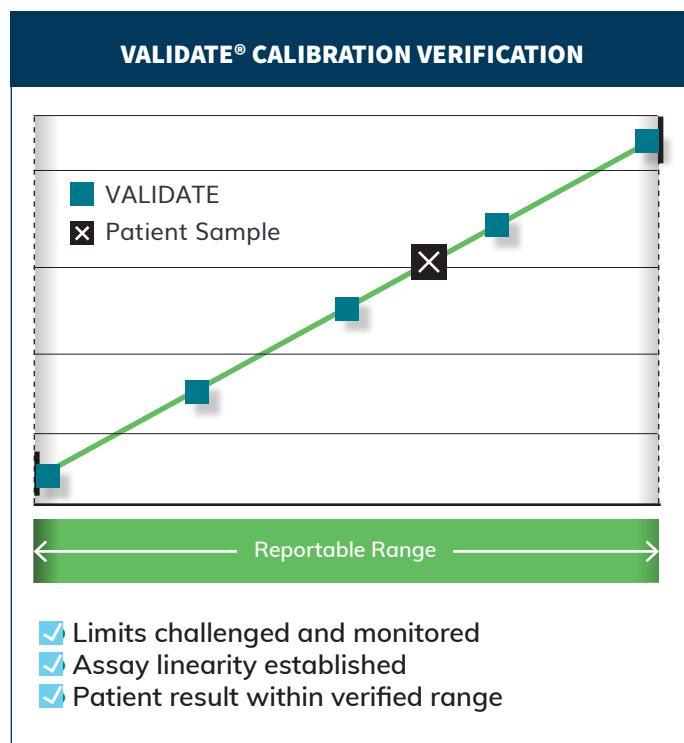
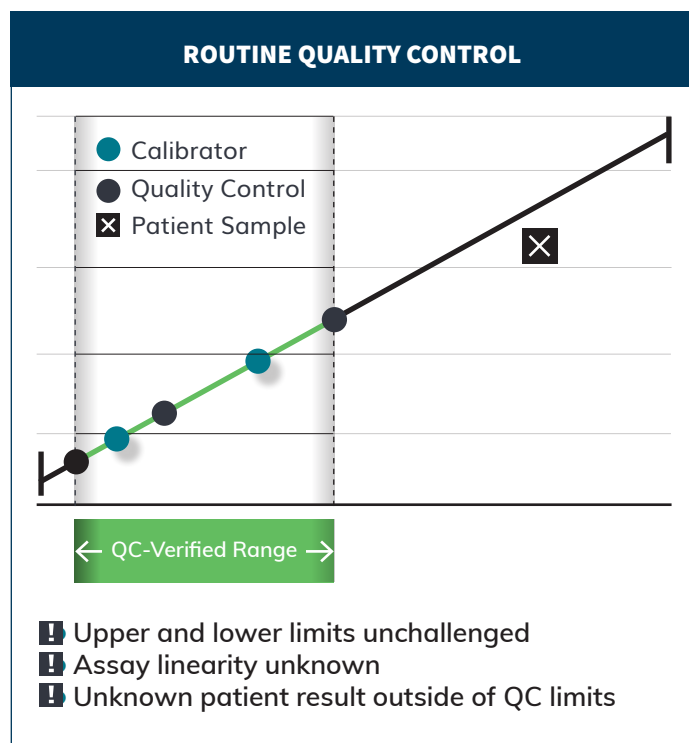
Both AccuTrak™ and VALIDATE® products are **liquid, ready-to-use**, and compatible with MSDRx Infinity® - LGC's cloud-based data reduction software that enables peer group analysis.



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 180+ analytes, formulated into standard groupings. Visit [mainstandards.com](http://mainstandards.com) website to see Typical Recovered Values (TRV) and lot-specific information in Product Inserts (PIs). Most VALIDATE® or AccuTrak™ products are registered in the EU. For availability within EU nations, check with your distributor or contact [cdx-sales@lgcgroup.com](mailto:cdx-sales@lgcgroup.com).

### 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\*\*

\*\*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

##### 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

#### ALZHEIMER'S DISEASE

##### tTau CSF

Total-Tau CSF

##### pTau181 CSF

Phospho-Tau (181P) CSF

##### pTau181 Plasma

Phospho-Tau (181P) Plasma

#### ALZHEIMER'S DISEASE II

##### Abeta42 CSF

Beta-Amyloid (1-42) CSF

#### ANEMIA

##### Anemia

Ferritin  
Folate  
Vitamin B12

##### Ferritin

Ferritin

##### Folate RBC

Folate RBC

#### 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

##### OCN

N-MID Osteocalcin

##### PTH

Parathyroid Hormone

##### VIT D

Vitamin D

## Calibration Verification Products (continued)

### CARDIAC

#### CM1

Creatine Kinase-MB  
Myoglobin

#### CM2

Brain Natriuretic Peptide  
High Sensitivity C-Reactive Protein  
N-Terminal pro B-type natriuretic peptide  
Troponin I

#### 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

#### 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

#### Fertility 3

Anti-Müllerian Hormone  
Sex Hormone-binding Globulin

#### Fertility 4

Placental Growth Factor

### FERTILITY II

#### sFlt-1

Soluble fms-like Tyrosine Kinase-1

### GROWTH 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

### SEPSIS

#### IL-6

Interleukin-6

#### PCT

Procalcitonin

## Calibration Verification Products (continued)

### 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

#### TDM1

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

### THYROID

#### THY

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

#### THY2

Thyroglobulin  
T-Uptake

#### CT

Calcitonin

### THYROID II

#### aTG

Anti-Thyroglobulin

#### aTPO

Anti-Thyroid Peroxidase

#### aTSHR

Anti-Thyroid Stimulating Hormone  
Receptor

#### T-Uptake

T-Uptake

### TUMOR MARKERS

#### PSA

Free Prostate-Specific Antigen  
Total Free Prostate-Specific Antigen

#### 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

### URINE CHEMISTRY

#### UC1

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

#### UC4

Calcium  
Cortisol  
Creatinine  
Magnesium  
Phosphorus

#### UC5

Amylase  
Micro-Albumin  
Pancreatic Amylase

#### UC6

Micro-Albumin  
Creatinine

## Data Submission

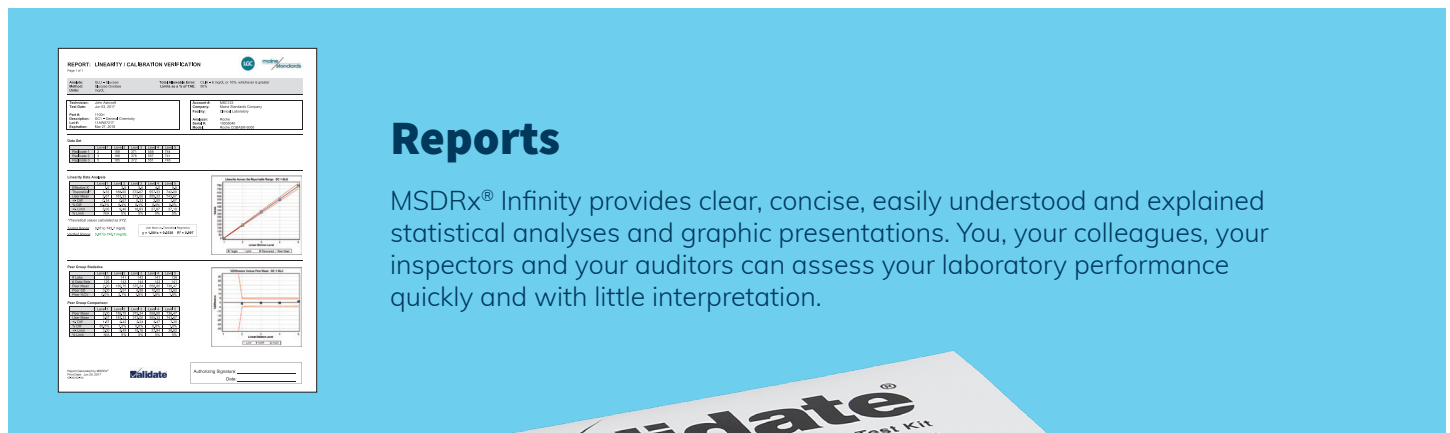
Maine Standards' Data Reduction Program puts the power of analysis at your fingertips. This free statistical software delivers real-time analysis of your calibration verification and linearity test results.

### LINEARITY ASSESSMENT

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





Most VALIDATE or AccuTrak products are registered in the EU. For availability within EU nations, check with your distributor or contact [cdx-sales@lgcgroup.com](mailto:cdx-sales@lgcgroup.com).



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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**AccuTrak™**

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