

Kontrollen zur Verifizierung der **Linearität** und **Kalibrierung**

Klinische Chemie | Immunoassay | Hämostase

validate
AccuTrak™



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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AccuTrak™

validate

maine
standards

MKT-00618 Rev. 33



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.

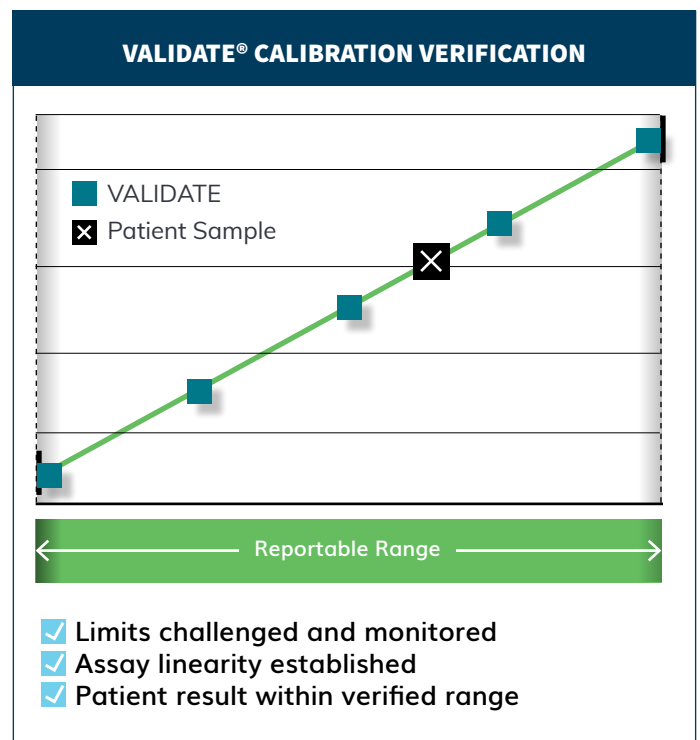
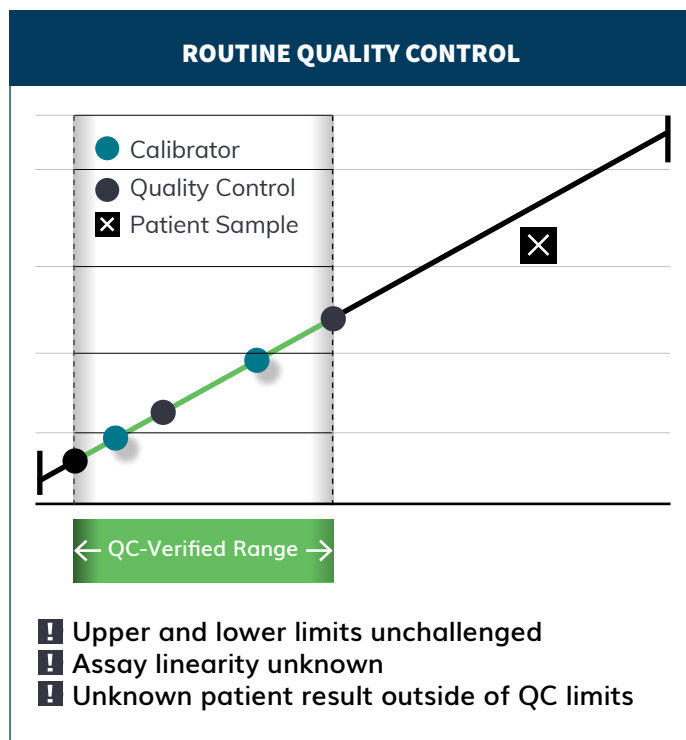


AccuTrak™	VALIDATE®
For calibration verification and reportable range verification	For linearity, calibration verification, and reportable range verification
Single analyte	Single or multi-analyte
Liquid, ready-to-use	Liquid, ready-to-use
Good for multiple uses and have extended open-vial stability	Good 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](https://www.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 <small>*402pf, 402re, and 402vt are not CE-approved</small> CM3 Homocysteine Lipoprotein (a) HIGH SENSITIVE TROPONIN High Sensitivity Troponin T High Sensitivity Troponin I	FERTILITY  Fertility 1 Follicle-stimulating Hormone Human Chorionic Gonadotropin Luteinizing Hormone Prolactin Testosterone Fertility 2* Alpha-fetoprotein Androstenedione Dehydroepiandrosterone Sulfate Estradiol Progesterone <small>*504re not CE-approved</small> Fertility 3 Anti-Müllerian Hormone Sex Hormone-binding Globulin Fertility 4* Placental Growth Factor <small>*Not CE-approved</small>	HEMOSTASIS  D-DIMER D-Dimer FIBRINOGEN Fibrinogen HEPARIN Heparin Anti-Xa
DIABETES  Diabetes* Cystatin C Beta-Hydroxybutyrate C-Peptide Insulin Fructosamine <small>*Not CE-approved</small> HbA1c % Glycohemoglobin A1c	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	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	CE	THERAPEUTIC DRUGS	CE	TUMOR MARKERS	CE
IL-6		MTX*		PSA*	
Interleukin-6		Methotrexate		Free Prostate-Specific Antigen	
PCT		*Not CE-approved		Total Free Prostate-Specific Antigen	
Procalcitonin		TDM1*		*Not CE-approved	
SEROLOGY		Acetaminophen		Tumor Markers	
aHBs		Amikacin		Cancer Antigen 15-3	
Hepatitis B Surface IgG Antibody		Carbamazepine		Cancer Antigen 19-9	
Rubella IgG		Digoxin		Cancer Antigen 125	
Rubella IgG Antibody		Gentamicin		Carcinoembryonic Antigen	
Toxoplasma IgG		Lidocaine		Tumor Markers 2*	
Toxoplasma gondii IgG Antibody		N-Acetylprocainamide		Cytokeratin 19 Fragment	
SERUM PROTEINS	CE	Phenobarbital		Human Epididymal Protein 4	
SP1		Phenytoin		*Not CE-approved	
Alpha-1 Antitrypsin		Primidone			
Complement C3		Procainamide			
Complement C4		Quinidine			
Immunoglobulin A		Salicylate			
Immunoglobulin G		Theophylline			
Immunoglobulin M		Tobramycin			
Transferrin		Valproic Acid			
SP2		Vancomycin			
Albumin		*301ab, 301au, and 301bc are not CE-approved			
C-Reactive Protein		THYROID	CE		
Ceruloplasmin		THY*		UC1*	
Haptoglobin		Cortisol		Chloride	
Prealbumin		Free Triiodothyronine		Ethyl Alcohol	
Rheumatoid Factor		Free Thyroxine		Glucose	
SP3		Thyroid Stimulating Hormone		Potassium	
Alpha-1-Acid Glycoprotein		Total Triiodothyronine		Sodium	
Antistreptolysin O		Total Thyroxine		Total Protein	
B2-Microglobulin		*901ab and 901re not CE-approved		Urea Nitrogen	
Immunoglobulin E		THY2*		Uric Acid	
		Thyroglobulin		*701re not CE-approved	
		T-Uptake		UC4*	
		*Not CE-approved		Calcium	
		CT*		Cortisol	
		Calcitonin		Creatinine	
		*Not CE-approved		Magnesium	
		THYROID II		Phosphorus	
		aTG		*704ro not CE-approved	
		Anti-Thyroglobulin		UC5	
		aTPO		Amylase	
		Anti-Thyroid Peroxidase		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.

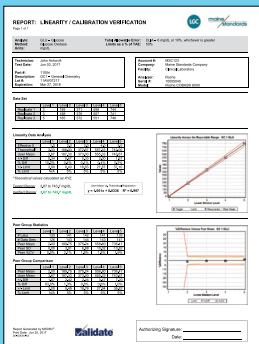


LINEARITY ASSESSMENT

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.

Ordering Information

HiSS Diagnostics GmbH ist Ihr offizieller Vertriebspartner für die Produkte von LGC SeraCare & Maine Standards. Wir unterstützen Sie bei der Etablierung individueller Workflows und beraten Sie persönlich zu Produktspezifikationen und Anwendungsbereichen.



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