

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).

 EC REP

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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.

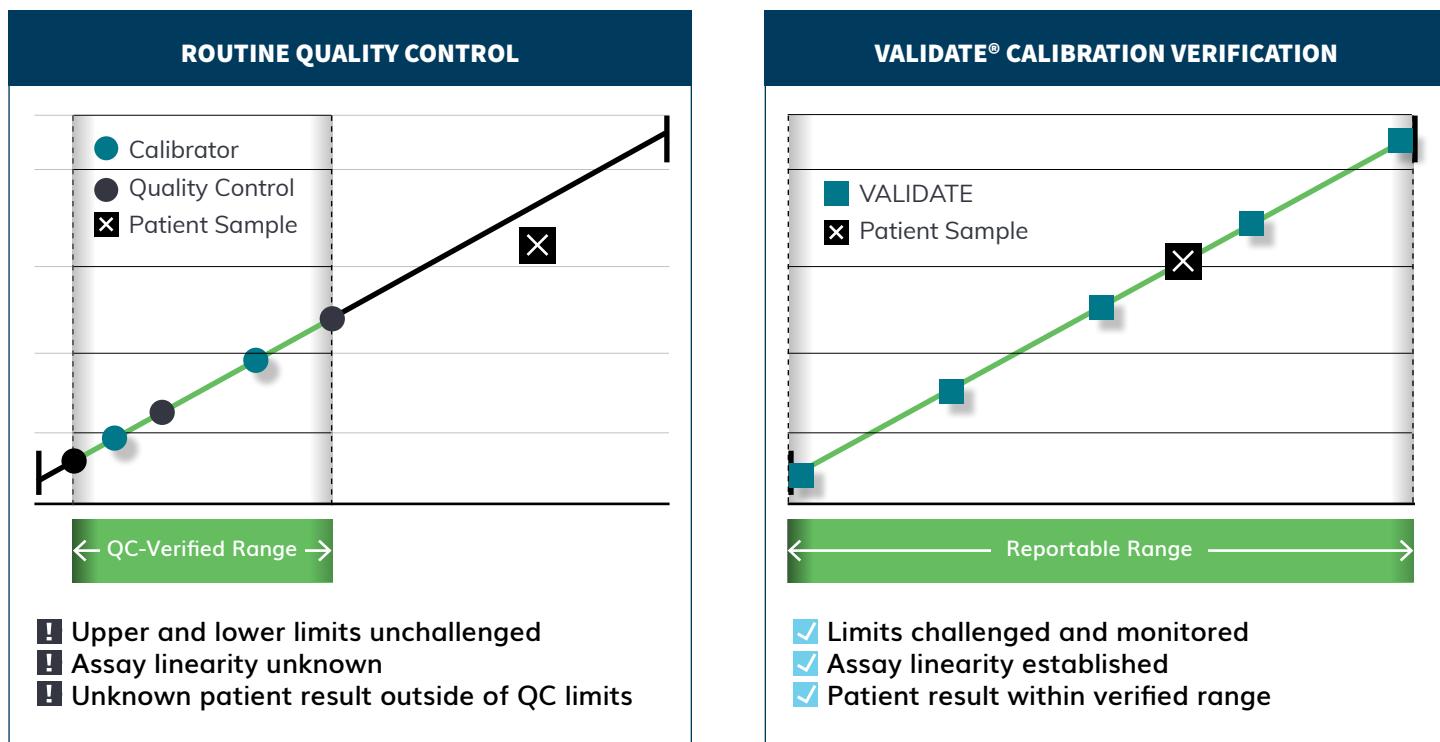


AccuTrak™	VALIDATE®
For calibration verification and reportable range verification	For linearity, calibration verification, and reportable range verification
Single analyte	Single or multi-analyte
Liquid, ready-to-use	Liquid, ready-to-use
Good for multiple uses and have extended open-vial stability	Good 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 website to see Typical Recovered Values (TRV) and lot-specific information in Product Inserts (Pls).

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	CE	FERTILITY	CE	HEMOSTASIS	CE
CM1		Fertility 1		D-DIMER	
Creatine Kinase-MB		Follicle-stimulating Hormone		D-Dimer	
Myoglobin		Human Chorionic Gonadotropin		FIBRINOGEN	
CM2*		Luteinizing Hormone		Fibrinogen	
Brain Natriuretic Peptide		Prolactin		HEPARIN	
High Sensitivity C-Reactive Protein		Testosterone		Heparin Anti-Xa	
N-Terminal Prohormone of BNP					
Troponin I					
*402pf, 402re, and 402vt are not CE-approved					
CM3		Fertility 2*		IMMUNOSUPPRESSANTS	CE
Homocysteine		Alpha-fetoprotein		ISx	
Lipoprotein (a)		Androstenedione		Cyclosporine	
HIGH SENSITIVE TROPONIN		Dehydroepiandrosterone Sulfate		Sirolimus	
High Sensitivity Troponin T		Estradiol		Tacrolimus	
High Sensitivity Troponin I		Progesterone			
		*504re not CE-approved			
DIABETES	CE	Fertility 3		OSMOLALITY	CE
Diabetes*		Anti-Müllerian Hormone		OSMO	
Cystatin C		Sex Hormone-binding Globulin		Serum Osmolality	
Beta-Hydroxybutyrate				Urine Osmolality	
C-Peptide		Fertility 4*			
Insulin		Placental Growth Factor		POC	CE
Fructosamine		*Not CE-approved		WBG	
*Not CE-approved				Glucose	
HbA1c		FERTILITY II		RHEUMATOID ARTHRITIS	
% Glycohemoglobin A1c		sFlt-1		Anti-CCP	
		Soluble fms-like Tyrosine Kinase-1		Cyclic Citrullinated Peptides IgG	
				Antibody	
		HORMONE		SARS-CoV-2 IgG	CE
		GH		SARS-CoV-2 IgG	
		Human Growth Hormone		SARS-CoV-2 IgG Antibody	
		Insulin-Like Growth Factor-1			
		GH2			
		Insulin-Like Growth Factor Binding			
		Protein-3			



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		URINE CHEMISTRY	CE
Complement C3		Procainamide		UC1*	
Complement C4		Quinidine		Chloride	
Immunoglobulin A		Salicylate		Ethyl Alcohol	
Immunoglobulin G		Theophylline		Glucose	
Immunoglobulin M		Tobramycin		Potassium	
Transferrin		Valproic Acid		Sodium	
SP2		Vancomycin		Total Protein	
Albumin		*301ab, 301au, and 301bc are not CE-approved		Urea Nitrogen	
C-Reactive Protein		THYROID	CE	Uric Acid	
Ceruloplasmin		THY*		*701re not CE-approved	
Haptoglobin		Cortisol		UC4*	
Prealbumin		Free Triiodothyronine		Calcium	
Rheumatoid Factor		Free Thyroxine		Cortisol	
SP3		Thyroid Stimulating Hormone		Creatinine	
Alpha-1-Acid Glycoprotein		Total Triiodothyronine		Magnesium	
Antistreptolysin O		Total Thyroxine		Phosphorus	
B2-Microglobulin		*901ab and 901re not CE-approved		*704ro not CE-approved	
Immunoglobulin E		THY2*		UC5	
		Thyroglobulin		Amylase	
		T-Uptake		Micro-Albumin	
		*Not CE-approved		Pancreatic Amylase	
		CT*		UC6	
		Calcitonin		Micro-Albumin	
		*Not CE-approved		Creatinine	
		THYROID II			
		aTG			
		Anti-Thyroglobulin			
		aTPO			
		Anti-Thyroid Peroxidase			



Data Submission

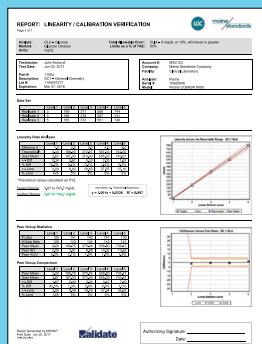
Maine Standards' Data Reduction Program puts the power of analysis at your fingertips. This free statistical software delivers real-time analysis of your calibration verification and linearity test results.

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.

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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