Validate®

DELIVERS MORE

EASY · FAST · EFFICIENT

Linearity and Calibration Verification

PRODUCT CATALOG

Validate®

VALIDATE® PRODUCTS ARE SYNONYMOUS WITH **EFFICIENCY** AND **QUALITY**.

READY-TO-USE LINEARITY SETS:
Liquid samples require no reconstitution. Simply add product to your sample cup and run in replicates.

MULTIPLE PRODUCT CONFIGURATIONS:
LGC Maine Standards specifically formulates its VALIDATE® product line into specialized configurations with different analyte concentrations that challenge your analyzers' full reportable range.

EASY-TO-USE FOR RETESTING OR TROUBLESHOOTING:
With long open-vial stability, you'll have adequate product for repeats or troubleshooting. These are unique samples to have available for troubleshooting, since VALIDATE® products challenge your full reportable range.

EQUAL-SPACED LEVELS:
Levels 1 through 5 are prepared to create “equal deltas” as recommended by the CLSI EP06-A guideline for linearity and calibration verification.

TWO TESTING CYCLES FOR ONE INSTRUMENT:
We will provide adequate product volume to complete two linearity and calibration verification cycles.

PRECISION COMES STANDARD.

Every VALIDATE® linearity and calibration verification product is developed and produced with our unwavering commitment to precision and accuracy. Our facility's Quality Management System is certified to ISO 13485:2016 by DEKRA Certification B.V.

ISO CERTIFIED: Our facility's Quality Management System is certified to ISO 13485:2016 by DEKRA Certification B.V.

U.S. FDA REGISTERED FACILITY: Our facility is registered with the U.S. FDA and complies with the U.S. FDA Quality System Regulation (QSR).

DEA REGISTERED FACILITY: Our facility is registered by the U.S. Drug Enforcement Administration for the manufacture and analytical laboratory testing of Schedule 1 - 5 controlled substances.

VALIDATE® PRODUCTS ARE CE MARKED:
Check with international distributors for specific product availability.

ACCREDITATION REQUIREMENTS: Use of VALIDATE® products, while augmenting daily QC, assists with fulfilling various quality control requirements - such as Analytical Measurement Range (AMR) and Clinically Reportable Range (CRR) - for linearity and calibration verification under CLIA '88, CAP, COLA, JCAHO, JCI and ISO 15189.

YOU HAVE OUR GUARANTEE.

You can depend on LGC Maine Standards to make your job easier. With medical technologists on staff, we understand the demands of clinical laboratories. We are committed to constant product innovation and strive to deliver outstanding technical and customer support. That's why we can stand behind our products and service with a promise of **100%** customer satisfaction.

SERVICE FEATURES AND BENEFITS

You can always depend on LGC Maine Standards to make your job easier. We understand the demands of clinical laboratories, and we are committed to providing you with outstanding customer service.

Working with us is always a guarantee of responsive service. Too often customer service and support means listening to a recorded message or waiting for answers that never come. When you call LGC Maine Standards, you reach a knowledgeable, friendly person ready to help you.

LGC Maine Standards' experts are qualified laboratory professionals with clinical laboratory experience. Our unparalleled technical support staff is familiar with all VALIDATE® products, data reduction reports, and a wide range of analyzers, as well as linearity and calibration verification requirements and regulations of inspection agencies.

SETTING THE STANDARD FOR CUSTOMER SERVICE

When you call LGC Maine Standards, you reach a knowledgeable, friendly person ready to help.

- Shipping on your schedule.
- Data reduction services are included at no charge with every purchase.
- We will return your data reduction reports within five business days.
- Guaranteed, live, same-day Technical Support during LGC Maine Standards' hours of operation.

98%

QUALITY SATISFACTION RATING

of customers surveyed in an anonymous Net Promoter Score survey say they would recommend LGC Maine Standards to a colleague.

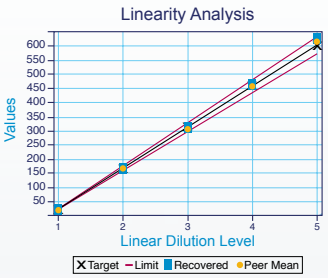
MSDRx®

DATA REDUCTION SOFTWARE:

MSDRx®, LGC Maine Standards' free, do-it-yourself software, delivers real-time analysis of your linearity and calibration verification results. Using the same algorithm as our in-house data Reduction Service, MSDRx® puts the power of analysis at your fingertips. As a user-friendly program, MSDRx® does not require an internet connection to analyze linearity results. Peer group analysis is available by sending LGC Maine Standards your data via email right from the program.

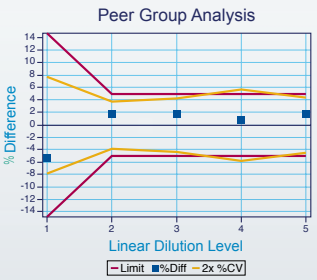
LINEARITY ANALYSIS FEATURES

- Target values calculated based on your results.
- Evaluation versus industry-accepted limits by level.
- Results are graphed for easy visual evaluation.
- If you participate in peer group analysis, peer means by level are also plotted on the same graph.



PEER GROUP ANALYSIS FEATURES

- Peer based on instrument system and method type.
- Evaluation versus industry-accepted limits by level.
- A percent difference plot is provided for easy visual evaluation of results.
- The plot displays lines representing two times the coefficient of variations (%CV) for the peer group.



Break free from LN Surveys. **Discover YES.**

Break free from LN Surveys. **Discover YES.** LGC Maine Standards' Yearly Evaluation Subscription (YES) program is the best way to validate AMR requirements.

YES Yearly Evaluation Subscription

With LGC Maine Standards' Yearly Evaluation Subscription (YES) program, you'll never worry again about remembering to order and test for linearity and calibration verification. You can leave it to us to automatically schedule and ship products.

ADVANTAGES OF THE YES PROGRAM:

- **Optimized to challenge the limits of your analyzers' full reportable range.** LGC Maine Standards specifically formulates its VALIDATE® product line into specialized configurations with different analyte concentrations that challenge your analyzers' full reportable range.
- **Hassle-free scheduling.** YES features testing schedules that align with the College of American Pathologists' LN Surveys. No gaps. No worries.
- **Regulatory compliance.** VALIDATE® products satisfy requirements for all accrediting agencies, including Analytical Measurement Range (AMR) requirements.
- **Outstanding service.** Our rapid turnaround of data reduction means you'll be able to quickly identify any possible testing issues — eliminating weeks of potentially inaccurate patient results.
- **Guaranteed, live, same-day Technical Support** during LGC Maine Standards' hours of operation.
- **Two testing cycles for one instrument.** We will provide enough product volume to complete two linearity and calibration verification cycles.
- **100% satisfaction guaranteed.**

VALIDATE® linearity and calibration verification kits are intended for ***in vitro*** diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range.

myCalVer®

YOUR ONLINE RESOURCE FOR LINEARITY AND CALIBRATION VERIFICATION

Everything you need to know about linearity and calibration verification, all at your fingertips. Access your linearity data and peer group statistics, connect with the latest industry news and regulations, or participate in our P.A.C.E® approved myCalVer® training program.

myCalVer.com is a website offering:

- P.A.C.E.® approved educational webinar to keep your training current and on your schedule.
- Access to Peer Group Statistics, anytime.
- Centralized organization of your current and past VALIDATE® testing results.
- Most relevant listing of the linearity and calibration verification industry's top news and regulatory developments.

EDUCATION PAGE

As part of LGC Maine Standards commitment to making linearity and calibration verification as easy as possible, we offer a convenient, web-based Professional Acknowledgment for Continuing Education (P.A.C.E.®) approved educational training. Created specifically for busy laboratory professionals, this free, 1.5 credit online course includes examples from current laboratory best practices and offers real-world, tangible knowledge that can be immediately applied in your laboratory.

P.A.C.E.®

PEER GROUP STATISTICS

This value-added feature allows you to access and evaluate VALIDATE® linearity and calibration verification Peer Group Statistics directly from your myCalVer® account.

DATA SERVICES PAGE

Evaluate and access your VALIDATE® linearity and calibration verification in one convenient place with myCalVer®. Our data reduction service is free of charge with the purchase of any VALIDATE® test kit.

Note: Maine Standards Company is approved as a national provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E.® Program. Since this program is ASCLS P.A.C.E.® approved on the national level versus the state level, Florida licensees cannot earn credits for completing this course. P.A.C.E.® is a registered trademark for Professional Acknowledgment for Continuing Education used here by permission.

You can also email your reports directly to us for peer group analysis and future online access. If you would like to submit your VALIDATE® linearity test results to LGC Maine Standards for complimentary data processing, simply fill out a data submission form and send it to us. Data can be sent to LGC Maine Standards as often as you need. Once you send us your VALIDATE® linearity data, your linearity reports and peer group analysis will be available to view in only five business days.

Finding your data and archived reports has never been faster or easier. myCalVer® securely stores all of your data reports on a rolling four-year basis, saving you time and resources.

INDUSTRY NEWS, REGULATIONS, AND NATIONAL ASSOCIATIONS PAGE

Staying on top of the latest clinical diagnostic industry news, regulations, and national associations is easier with myCalVer®. Using only the most relevant and reliable sources, myCalVer® saves you time and reduces the hassle of having to search the internet for specific information important to the linearity and calibration verification industry.

Registering with www.myCalVer.com is free and easy.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

GENERAL CHEMISTRY CE

GC1
ALB (Albumin)
BUN (Blood Urea Nitrogen)
CA (Calcium)
CL (Chloride)
CHOL (Cholesterol)
CREA (Creatinine)
GLU (Glucose)
LAC (Lactate)
LI (Lithium)
MG (Magnesium)
PHOS (Phosphorus)
K (Potassium)
NA (Sodium)
TP (Total Protein)
TRIG (Triglycerides)
UA (Uric Acid)

GC2
NH3 (Ammonia)
CO2 (Carbon Dioxide)
ETOH (Ethyl Alcohol)
FE (Total Iron)
UA (Uric Acid)

GC3
ALT (Alanine Aminotransferase)
ALP (Alkaline Phosphatase)
AMY (Amylase)
AST (Aspartate Aminotransferase)
CK (Creatine Kinase)
GGT (Gamma-Glutamyltransferase)
LD (Lactate Dehydrogenase)
LIP (Lipase)

GC4
BC (Conjugated Bilirubin)
DBIL (Direct Bilirubin)
TBIL (Total Bilirubin)

IRON BINDING CAPACITY CE

IBC
TIBC (Total Iron Binding Capacity)
UIBC (Unsaturated Iron Binding Capacity)

GLYCOHEMOGLOBIN CE

HbA1c
% Glycohemoglobin A1c (HbA1c)

LIPOPROTEINS CE

LP
Apo-A1 (Apolipoprotein A)
Apo-B (Apolipoprotein B)
HDL (High Density Lipoprotein)
LDL (Low Density Lipoprotein)

WHOLE BLOOD GLUCOSE CE

GLU (Glucose)

THERAPEUTIC DRUGS CE

TDM1
ACTM (Acetaminophen)
AMIK (Amikacin)
CARB (Carbamazepine)
DIGN (Digoxin)
GENT (Gentamicin)
LIDO (Lidocaine)
NAPA (N-Acetylprocainamide)
PHNO (Phenobarbital)
PHYT (Phenytoin)
PRIM (Primidone)
PROC (Procainamide)
QUIN (Quinidine)
SALY (Salicylate)
THEO (Theophylline)
TOB (Tobramycin)
VALP (Valproic Acid)
VANC (Vancomycin)

URINE CHEMISTRY CE

UC1
CL (Chloride)
Ethyl Alcohol (ETOH)
GLU (Glucose)
K (Potassium)
NA (Sodium)
UTP (Total Protein)
UUN (Urea Nitrogen)
UA (Uric Acid)

UC4
CA (Calcium)
CREA (Creatinine)
MG (Magnesium)
PHOS (Phosphorus)

UC5
AMY (Amylase)
µALB (Micro-Albumin)
PAMY (Pancreatic Amylase)

UC6
ALB (Albumin)
CREA (Creatinine)

OSMOLALITY CE

OSMO
SOSMO (Serum Osmolality)
UOSMO (Urine Osmolality)

CARDIAC MARKERS CE

CM1
CK-MB (Creatine Kinase-MB)
MYO (Myoglobin)

CM2
BNP (Brain Natriuretic Peptide)
hs-CRP (High Sensitivity C-Reactive Protein)
NT-proBNP (N-terminal Prohormone of Brain Natriuretic Peptide)
TnI (Troponin I)
TnT (Troponin T)

HIGH SENSITIVE TROPONIN
hsTnI (High Sensitivity Troponin I)
hsTnT (High Sensitivity Troponin T)

THYROID CE

THY
CORT (Cortisol)
FT4 (Free Thyroxine)
FT3 (Free Triiodothyronine)
TSH (Thyroid Stimulating Hormone)
TT4 (Total Thyroxine)
TT3 (Total Triiodothyronine)

VITAMIN D CE

VIT D
VIT D (Vitamin D)

SERUM PROTEINS CE

SP1
AAT (α1-Antitrypsin)
C3 (Complement C3)
C4 (Complement C4)
IGA (Immunoglobulin A)
IGG (Immunoglobulin G)
IGM (Immunoglobulin M)
TRFN (Transferrin)

SP2
ALB (Albumin)
CRP (C-Reactive Protein)
CER (Ceruloplasmin)
HPT (Haptoglobin)
PAB (Prealbumin)
RF (Rheumatoid Factor)

SP3
AAG (α1-Acid Glycoprotein)
ASO (Antistreptolysin O)
B2M (B2-Microglobulin)
IgE (Immunoglobulin E)

TUMOR MARKERS CE

PSA*
fPSA (free Prostate-Specific Antigen)
tPSA (total Prostate-Specific Antigen)
* Not CE approved.

TUMOR MARKERS
CA 15-3 (Cancer Antigen 15-3)
CA 19-9 (Cancer Antigen 19-9)
CA 125 (Cancer Antigen 125)
CEA (Carcinoembryonic Antigen)

ANEMIA CE

ANEMIA
FERR (Ferritin)
FOL (Folate)
Vit B12 (Vitamin B12)

FERRITIN
FERR (Ferritin)

FERTILITY CE

FERTILITY 1
FSH (Follicle-Stimulating Hormone)
hCG (Human Chorionic Gonadotropin)
LH (Luteinizing Hormone)
PRL (Prolactin)
TSTO (Testosterone)

FERTILITY 2
AFP (α1-fetoprotein)
DHEA-S (Dehydroepiandrosterone Sulfate)
E2 (Estradiol)
PRGE (Progesterone)

HEMOSTASIS CE

D-DIMER
D-Dim (D-Dimer)

HEPARIN
HP (Heparin Anti-Xa)

FIBRINOGEN
FIBR (Fibrinogen)

PROCALCITONIN CE

PCT (Procalcitonin)

BODY FLUIDS CE

ALB (Albumin)
AMY (Amylase)
CA 19-9 (Cancer Antigen 19-9)
CEA (Carcinoembryonic Antigen)
CHOL (Cholesterol)
CREA (Creatinine)
CSF-TP (Cerebrospinal Fluid Total Protein)
GLU (Glucose)
LAC (Lactate)
LD (Lactate Dehydrogenase)
TP (Total Protein)
TRIG (Triglycerides)
UN (Urea Nitrogen)

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® GC

- 30 ANALYTES AVAILABLE
- GENERAL CHEMISTRIES, ENZYMES & SELECT LIPIDS
- LIQUID, READY-TO-USE
- FIVE LEVELS

GENERAL CHEMISTRY

GC1

CE

PRODUCT NAME: GC1
STORAGE: -10 TO -25°C

Product Configuration: Five Levels
1100ab is Six Levels
1100bc, 1100ro are Two Sets of Five Levels

		Abbott ARCHITECT ORDER NO. 1100ab	Beckman Coulter AU ORDER NO. 1100au	Beckman Coulter DxC ORDER NO. 1100bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
SET 1				
ALB (Albumin)	g/dL	0.4 - 10.5	1.5 - 6.0	1.0 - 7.0
BUN (Blood Urea Nitrogen)	mg/dL	2 - 125	2 - 130	5 - 100
CA (Calcium)	mg/dL	2.0 - 24.0	4.0 - 18.0	2.0 - 20.0
CL (Chloride)	mmol/L	50 - 150	50 - 200	50 - 200
CHOL (Cholesterol)	mg/dL	7 - 705	25 - 700	5 - 750
CREA (Creatinine)	mg/dL	0.2 - 37.0	0.2 - 25.0	0.3 - 25.0
GLU (Glucose)	mg/dL	5 - 800	10 - 800	5 - 700
LAC (Lactate)	mg/dL	1.5 - 120	2.0 - 90	2.7 - 99
LI (Lithium)	mmol/L	0.1 - 3.5	0.1 - 5.0	0.0 - 3.0
MG (Magnesium)	mg/dL	0.7 - 9.5	0.5 - 8.0	0.1 - 7.0
PHOS (Phosphorus)	mg/dL	0.7 - 25.3	1.0 - 20.0	1.0 - 12.0
K (Potassium)	mmol/L	1.0 - 10.0	1.0 - 10.0	1.0 - 15.0
NA (Sodium)	mmol/L	100 - 200	50 - 200	100 - 200
TP (Total Protein)	g/dL	0.8 - 18.4	3.0 - 12.0	3.0 - 12.0
TRIG (Triglycerides)	mg/dL	7 - 1,420	10 - 1,000	10 - 1,000
SET 2 (MODULAR)				
BUNm† (Blood Urea Nitrogen)	mg/dL	—	—	1 - 150
GLUm† (Glucose)	mg/dL	—	—	10 - 600
PHOSm† (Phosphorus)	mg/dL	—	—	1.0 - 12.0

†For Beckman Modular Assays

		Roche COBAS INTEGRA® ORDER NO. 1100ri	Roche cobas® ORDER NO. 1100ro	Siemens ADVIA® ORDER NO. 1100sa
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
SET 1				
ALB (Albumin)	g/dL	0.2 - 6.0	0.2 - 6.0	1.0 - 6.0
BUN (Blood Urea Nitrogen)	mg/dL	1.4 - 112	1.4 - 112	5 - 150
CA (Calcium)	mg/dL	0.4 - 20	0.8 - 20.1	1.0 - 15.0
CL (Chloride)	mmol/L	20 - 250	60 - 140	50 - 200
CHOL (Cholesterol)	mg/dL	3.87 - 800	3.86 - 800	25 - 618
CREA (Creatinine)	mg/dL	0.12 - 30.0	—	0.15 - 30.0
CREA (Creatinine Plus)	mg/dL	—	0.1 - 30.5	—
GLU (Glucose)	mg/dL	4.32 - 720	2 - 750	4.0 - 700
LAC (Lactate)	mg/dL	1.8 - 140	1.8 - 140	0.6 - 110
LI (Lithium)	mmol/L	0.1 - 4.0	0.05 - 3	0.1 - 3.0
MG (Magnesium)	mg/dL	0.4 - 6.1	0.2 - 4.9	0.5 - 5.0
PHOS (Phosphorus)	mg/dL	0.31 - 20.0	0.31 - 20.0	0.3 - 20.0
K (Potassium)	mmol/L	0.2 - 30.0	1.5 - 10	1.0 - 10.0
NA (Sodium)	mmol/L	20 - 250	80 - 180	50 - 200
TP (Total Protein)	g/dL	0.2 - 12.0	0.2 - 12	2 - 12.0
TRIG (Triglycerides)	mg/dL	8.85 - 885	9 - 885	10 - 550
SET 2 (CREAT JAFFE SET)				
CREA (Creatinine Jaffe)	mg/dL	—	0.2 - 24.9	—

GC1 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

GC1

CE

PRODUCT NAME: GC1
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Siemens Dimension® ORDER NO. 1100sd	Siemens Dimension Vista® ORDER NO. 1100sv
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
GC1 Set			
ALB (Albumin)	g/dL	0.6 - 8	0.6 - 8
BUN (Blood Urea Nitrogen)	mg/dL	0 - 150	0 - 150
CA (Calcium)	mg/dL	5 - 15	5 - 15
CL (Chloride)	mmol/L	50 - 200	—
CHOL (Cholesterol)	mg/dL	50 - 600	50 - 600
CREA (Creatinine)	mg/dL	0.15 - 20	0.15 - 20
GLU (Glucose)	mg/dL	0 - 500	0 - 500
LAC (Lactate)	mg/dL	2.7 - 135.1	2.7 - 135.1
LI (Lithium)	mmol/L	0.2 - 5	0.2 - 5
MG (Magnesium)	mg/dL	0 - 20	0 - 20
PHOS (Phosphorus)	mg/dL	0.5 - 9	0.5 - 9
K (Potassium)	mmol/L	1.0 - 10.0	—
NA (Sodium)	mmol/L	50 - 200	—
TP (Total Protein)	g/dL	2 - 12	2 - 12
TRIG (Triglycerides)	mg/dL	15 - 1,000	15 - 1,000
Chem 17 Set			
CL (Chloride)	mmol/L	—	50 - 200
K (Potassium)	mmol/L	—	1.0 - 10.0
NA (Sodium)	mmol/L	—	50 - 200

PRODUCT NAME: GC1
STORAGE: -10 TO -25°C

Product Configuration: 1100vt is Two Sets of Five Levels

		Ortho VITROS® ORDER NO. 1100vt
ANALYTE	UNITS	Typical Ranges:
SET 1		
CA (Calcium)	mg/dL	1.0 - 14.0
CHOL (Cholesterol)	mg/dL	50 - 325
CREA (Creatinine)	mg/dL	0.05 - 14
GLU (Glucose)	mg/dL	20 - 625
LAC (Lactate)	mmol/L	0.5 - 12
LI (Lithium)	mmol/L	0.2 - 4
PHOS (Phosphorus)	mg/dL	0.5 - 13
TRIG (Triglycerides)	mg/dL	10 - 525
UA (Uric Acid)	mg/dL	0.5 - 17
SET 2		
ALB (Albumin)	g/dL	1.0 - 6.0
BUN (Blood Urea Nitrogen)	mg/dL	2 - 120
CL (Chloride)	mmol/L	50 - 175
MG (Magnesium)	mg/dL	0.2 - 10.0
K (Potassium)	mmol/L	1.0 - 14.0
NA (Sodium)	mmol/L	75 - 250
TP (Total Protein)	g/dL	2.0 - 11.0

GENERAL CHEMISTRY

GC2

CE

PRODUCT NAME: GC2
STORAGE: 2 TO 8°C

Product Configuration: Two Sets of Five Levels
1200vt is Five Levels

		Abbott ARCHITECT ORDER NO. 1200ab	Beckman Coulter AU ORDER NO. 1200au	Beckman Coulter DxC ORDER NO. 1200bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
SET 1				
NH3 (Ammonia)	µmol/L	5 - 998	10 - 600	9 - 1,000
CO2 (Carbon Dioxide)	mmol/L	5 - 50	2 - 45	5 - 50
ETOH (Ethyl Alcohol)	mg/dL	10 - 600	10 - 600	5 - 600
FE (Total Iron)	µg/dL	5 - 1,000	10 - 1,000	5 - 500
SET 2				
UA (Uric Acid)	mg/dL	1.00 - 33.1	1.5 - 30.0	0.5 - 12

		Roche cobas® ORDER NO. 1200re	Siemens ADVIA® ORDER NO. 1200sa
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
NH3 (Ammonia)	µmol/L	10 - 700	10 - 750
CO2 (Carbon Dioxide)	mmol/L	1.5 - 50	10 - 40
ETOH (Ethyl Alcohol)	mg/dL	10 - 500	10 - 600
FE (Total Iron)	µg/dL	5 - 1,000	2 - 1,000
SET 2			
UA (Uric Acid)	mg/dL	0.2 - 25	0.5 - 20

		Siemens Dimension® ORDER NO. 1200sd*	Ortho VITROS® ORDER NO. 1200vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
NH3 (Ammonia)	µmol/L	10 - 750	8.7 - 500
CO2 (Carbon Dioxide)	mmol/L	5 - 45	5 - 40
ETOH (Ethyl Alcohol)	mg/dL	3 - 300	10 - 300
FE (Total Iron)	µg/dL	5 - 1,000	10.1 - 600
SET 2			
UA (Uric Acid)	mg/dL	0 - 20	—

GC2 NOTES:
* 1200sd: CO2 not compatible with Siemens Dimension QuikLYTE® TCO2 method.
Typical ranges or recommended Level usage for products are intended as a guide only.

GC3

CE

PRODUCT NAME: GC3
STORAGE: -10 TO -25°C

Product Configuration: Five Levels
1300ab is Six Levels

		Abbott ARCHITECT ORDER NO. 1300ab	Beckman Coulter AU ORDER NO. 1300au	Beckman Coulter DxI ORDER NO. 1300bcc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
ALT (Alanine Aminotransferase)	U/L	6 - 4,113	3 - 500	5 - 400
ALP (Alkaline Phosphatase)	U/L	5 - 4,555	5 - 1,500	5 - 1,000
AMY (Amylase)	U/L	3 - 6,554	10 - 2,000	5 - 1,200
AST (Aspartate Aminotransferase)	U/L	3 - 4,202	3 - 1,000	5 - 400
CK (Creatine Kinase)	U/L	7 - 4,267	10 - 2,000	5 - 1,200
GGT (Gamma-Glutamyltransferase)	U/L	4 - 9,256	3 - 1,200	5 - 750
LD (Lactate Dehydrogenase)	U/L	10 - 4,500	25 - 1,200	5 - 750
LIP (Lipase)	U/L	4 - 1,200	3 - 600	10 - 200

		Roche cobas® ORDER NO. 1300re	Siemens ADVIA® ORDER NO. 1300sa	Siemens Dimension® ORDER NO. 1300sd
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
ALT (Alanine Aminotransferase)	U/L	4 - 700	7 - 1,100	6 - 1,000
ALP (Alkaline Phosphatase)	U/L	5 - 1,200	10 - 1,000	11 - 1,000
AMY (Amylase)	U/L	3 - 2,000	5 - 1,500	0 - 650
AST (Aspartate Aminotransferase)	U/L	5 - 800	8 - 1,000	0 - 1,000
CK (Creatine Kinase)	U/L	7 - 2,000	5 - 1,300	7 - 1,000
GGT (Gamma-Glutamyltransferase)	U/L	3 - 1,200	7 - 1,200	0 - 800
LD (Lactate Dehydrogenase)	U/L	10 - 1,000	20 - 700	6 - 1,000
LIP (Lipase)	U/L	3 - 300	9 - 700	10 - 1,500

		Ortho VITROS® ORDER NO. 1300vt
ANALYTE	UNITS	Typical Ranges:
ALT (Alanine Aminotransferase)	U/L	6 - 1,000
ALP (Alkaline Phosphatase)	U/L	20 - 1,500
AMY (Amylase)	U/L	30 - 1,200
AST (Aspartate Aminotransferase)	U/L	3 - 750
CK (Creatine Kinase)	U/L	20 - 1,600
GGT (Gamma-Glutamyltransferase)	U/L	10 - 1,400
LD (Lactate Dehydrogenase)	U/L	100 - 2,150
LIP (Lipase)	U/L	10 - 2,000

GC3 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

GENERAL CHEMISTRY

GC4

CE

PRODUCT NAME: GC4
STORAGE: -10 TO -25°C

Product Configuration: Five Levels
1400au, 1400ri, 1400vt are Two Sets of Five Levels

		Abbott ARCHITECT ORDER NO. 1400ab	Beckman Coulter DxC ORDER NO. 1400bc	Roche cobas® ORDER NO. 1400re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
DBIL (Direct Bilirubin)	mg/dL	0.1 - 15.0	0.1 - 10	0.2 - 10.0
TBIL (Total Bilirubin)	mg/dL	0.1 - 25.0	0.1 - 30	0.15 - 35.1

		Siemens ADVIA® ORDER NO. 1400sa	Siemens Dimension® ORDER NO. 1400sd
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
DBIL (Direct Bilirubin)	mg/dL	0.1 - 15	0.05 - 16
TBIL (Total Bilirubin)	mg/dL	0.1 - 35	0.1 - 25

		Beckman Coulter AU ORDER NO. 1400au	Roche COBAS INTEGRA® ORDER NO. 1400ri
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
DBIL Set			
DBIL (Direct Bilirubin)	mg/dL	0.0 - 10	0.10 - 25.0
TBIL Set			
TBIL (Total Bilirubin)	mg/dL	0.0 - 30	0.15 - 35.1

		Ortho VITROS® ORDER NO. 1400vt
ANALYTE	UNITS	Typical Ranges:
SET 1		
TBIL (Total Bilirubin)	mg/dL	0.1 - 27
SET 2		
Bc (Conjugated Bilirubin)	mg/dL	0.0 - 27

GC4 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

IRON BINDING CAPACITY

VALIDATE® IBC

- TWO ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

IBC

CE

PRODUCT NAME: IBC
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Roche cobas® ORDER NO. 203ro	Siemens Dimension® ORDER NO. 203sd	Ortho VITROS® ORDER NO. 203vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
TIBC (Total Iron Binding Capacity)	µg/dL	—	51 - 1,002	61 - 641
UIBC (Unsaturated Iron Binding Capacity)	µg/dL	42 - 712	—	—

IBC NOTES:
* Analyzers testing TIBC or UIBC and not listed should run Levels 1 through 5.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® HbA1c

- % GLYCOHEMOGLOBIN A1c
- HUMAN WHOLE BLOOD
- LIQUID, READY-TO-USE
- FIVE LEVELS

GLYCOHEMOGLOBIN

HbA1c

CE

PRODUCT NAME: HbA1c
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

ANALYTE	**ORDER NO. 605** Typical Level Usage*	**ORDER NO. 605to** Typical Ranges:
HbA1c (% Glycohemoglobin A1c)		
Abbott ARCHITECT (*i*)	Levels 1 - 4	—
Beckman Coulter AU	Levels 1 - 5	—
Beckman Coulter Unicel® DxC / Synchron®	Levels 1 - 5	—
Bio-Rad VARIANT™	—	Levels 1 - 5
Ortho VITROS®	Levels 1 - 3	—
Roche cobas®	Levels 1 - 5	—
Roche COBAS INTEGRA®	Levels 1 - 5	—
Siemens ADVIA®	Levels 1 - 4	—
Siemens Dimension®	Levels 1 - 4	—
Siemens Dimension Vista®	Levels 1 - 4	—
Tosoh HLC-728 G8	—	3.7 - 17.4%

HbA1c NOTES:
*Typical ranges or recommended Level usage for products are intended as a guide only. Analyzers not listed should run Levels 1 through 5.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® LP

- TWO ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

LIPOPROTEINS

LP

CE

PRODUCT NAME: LP
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Abbott ARCHITECT ORDER NO. 501ab*	Beckman Coulter AU ORDER NO. 501au*
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	5 - 180	2.5 - 200
LDL (Low Density Lipoprotein)	mg/dL	1 - 800	7 - 400

		Beckman Coulter DxC ORDER NO. 501bc*	Siemens Dimension ORDER NO. 501db*
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	5 - 135	3 - 150
LDL (Low Density Lipoprotein)	mg/dL	10 - 550	5 - 300

		Roche COBAS INTEGRA® ORDER NO. 501ro*	Siemens ADVIA® ORDER NO. 501sa*
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	3.1 - 150	34 - 122
LDL (Low Density Lipoprotein)	mg/dL	3 - 550	12 - 922

		Siemens ATELLICA® ORDER NO. 501sa*	Ortho VITROS® ORDER NO. 501vt*
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	34 - 122	5 - 110
LDL (Low Density Lipoprotein)	mg/dL	12 - 922	30 - 350

LP NOTES:
* 501ab, 501au, 501bc, 501db, 501ro, 501sa, 501vt: Test kits also contain Apo-A1 and Apo-B as part of the HDL and LDL components. U.S. Patent # 7,244,618.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® WHOLE BLOOD GLUCOSE

- FIVE LEVELS
- HUMAN WHOLE BLOOD
- LIQUID, READY-TO-USE

WHOLE BLOOD GLUCOSE CE

PRODUCT NAME: WHOLE BLOOD GLUCOSE
STORAGE: 2 TO 8°C

Product Configuration: Five Levels

		Roche ACCU-CHECK® Inform II ORDER NO. 607ro
ANALYTE	UNITS	Typical Ranges:
GLU (Glucose)	mg / dL	20 - 600

WHOLE BLOOD GLUCOSE NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® TDM1

- 17 ANALYTES AVAILABLE
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

THERAPEUTIC DRUGS

TDM1

CE

PRODUCT NAME: TMD1
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Abbott ARCHITECT ORDER NO. 301ab	Beckman Coulter AU ORDER NO. 301au
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
ACTM (Acetaminophen)	µg/mL	3 - 377	10 - 200
AMIK (Amikacin)	µg/mL	—	2.5 - 50
CARB (Carbamazepine)	µg/mL	1.9 - 20	2.0 - 20
DIGN (Digoxin)	ng/mL	0.15 - 5	0.2 - 5.0
GENT (Gentamicin)	µg/mL	0.5 - 10	0.25 - 10
LIDO (Lidocaine)	µg/mL	—	1 - 12
NAPA (N-Acetylprocainamide)	µg/mL	0 - 30	1 - 16
PHNO (Phenobarbital)	µg/mL	0.5 - 80	5.0 - 80
PHYT (Phenytoin)	µg/mL	0.5 - 40	2.5 - 40
PRIM (Primidone)	µg/mL	—	2.5 - 20
PROC (Procainamide)	µg/mL	0 - 20	1 - 12
QUIN (Quinidine)	µg/mL	0.2 - 8	0.5 - 8.0
SALY (Salicylate)	mg/dL	5 - 100	2.5 - 80
THEO (Theophylline)	µg/mL	0.5 - 40	2.5 - 40
TOB (Tobramycin)	µg/mL	0.2 - 10	0.6 - 10
VALP (Valproic Acid)	µg/mL	12.5 - 150	10.0 - 150
VANC (Vancomycin)	µg/mL	3.0 - 100	2.0 - 50

		Beckman Coulter DxC ORDER NO. 301bc	Siemens Dimension® ORDER NO. 301db
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
ACTM (Acetaminophen)	µg/mL	10 - 300	2 - 300
AMIK (Amikacin)	µg/mL	1.5 - 50	—
CARB (Carbamazepine)	µg/mL	2 - 20	0.5 - 20
DIGN (Digoxin)	ng/mL	0.2 - 4.5	0.06 - 5
GENT (Gentamicin)	µg/mL	0.5 - 12	0.2 - 12
LIDO (Lidocaine)	µg/mL	1 - 10	—
NAPA (N-Acetylprocainamide)	µg/mL	1 - 16	—
PHNO (Phenobarbital)	µg/mL	5 - 80	2.1 - 80
PHYT (Phenytoin)	µg/mL	2.5 - 40	0.5 - 40
PRIM (Primidone)	µg/mL	2.5 - 20	—
PROC (Procainamide)	µg/mL	1 - 12	—
QUIN (Quinidine)	µg/mL	0.5 - 8	—
SALY (Salicylate)	mg/dL	4 - 100	1.7 - 100
THEO (Theophylline)	µg/mL	2 - 40	2 - 40
TOB (Tobramycin)	µg/mL	0.5 - 12	0.3 - 12
VALP (Valproic Acid)	µg/mL	10 - 150	3 - 150
VANC (Vancomycin)	µg/mL	3.5 - 40	0.8 - 50

TDM1

CE

PRODUCT NAME: TMD1
STORAGE: -10 TO -25°C

Product Configuration: 301ri is Five Levels plus High ACTM
301vt is Two Sets of Five Levels

		Roche COBAS INTEGRA® ORDER NO. 301ri
ANALYTE	UNITS	Typical Ranges:
ACTM (Acetaminophen)	µg/mL	5.0 - 200
AMIK (Amikacin)	µg/mL	0.3 - 40
CARB (Carbamazepine)	µg/mL	0.11 - 20
DIGN (Digoxin)	ng/mL	0.3 - 5
GENT (Gentamicin)	µg/mL	0.04 - 10
LIDO (Lidocaine)	µg/mL	0.11 - 10
NAPA (N-Acetylprocainamide)	µg/mL	0.3 - 30
PHNO (Phenobarbital)	µg/mL	1.0 - 60
PHYT (Phenytoin)	µg/mL	0.42 - 40
PRIM (Primidone)	µg/mL	0.03 - 24
PROC (Procainamide)	µg/mL	0.13 - 16
QUIN (Quinidine)	µg/mL	0.09 - 8
SALY (Salicylate)	µg/mL	1.35 - 700
THEO (Theophylline)	µg/mL	0.16 - 40
TOB (Tobramycin)	µg/mL	0.04 - 10
VALP (Valproic Acid)	µg/mL	2.4 - 150
VANC (Vancomycin)	µg/mL	0.74 - 80

		Ortho VITROS® ORDER NO. 301vt
ANALYTE	UNITS	Typical Ranges:
SET 1		
ACTM (Acetaminophen)	µg/mL	10 - 200
CARB (Carbamazepine)	µg/mL	3 - 20
DIGN (Digoxin)	ng/mL	0.4 - 4
GENT (Gentamicin)	µg/mL	0.6 - 10
PHNO (Phenobarbital)	µg/mL	3 - 80
PHYT (Phenytoin)	µg/mL	3 - 40
THEO (Theophylline)	µg/mL	1 - 40
TOB (Tobramycin)	µg/mL	0.6 - 10
VALP (Valproic Acid)	µg/mL	10 - 150
VANC (Vancomycin)	µg/mL	5 - 50
SET 2		
SALY (Salicylate)	mg/dL	1 - 40

TDM1 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® UC

- 15 ANALYTES
- HUMAN URINE MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

URINE CHEMISTRY

UC1

CE

PRODUCT NAME: UC1 **Product Configuration: Two sets of Five Levels**
STORAGE: 2 TO 8°C

		Beckman Coulter AU ORDER NO. 701au	Beckman Coulter DxC ORDER NO. 701bc	Siemens Dimension® ORDER NO. 701db
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
SET 1				
UA (Uric Acid)	mg/dL	1.0 - 100	5 - 100	0 - 100
SET 2				
CL (Chloride)	mmol/L	15 - 400	15 - 300	10 - 375
ETOH (Ethyl Alcohol)	mg/dL	10 - 600	5 - 600	3 - 300
GLU (Glucose)	mg/dL	10 - 700	5 - 700	0 - 500
K (Potassium)	mmol/L	2 - 200	2 - 300	1 - 300
NA (Sodium)	mmol/L	10 - 400	10 - 300	5 - 300
UTP (Total Protein)	mg/dL	4 - 200	6 - 150	6 - 250
UUN (Urea Nitrogen)	mg/dL	20 - 1,300	50 - 1,000	0 - 1,500

		Roche COBAS INTEGRA® ORDER NO. 701ri	Roche cobas® ORDER NO. 701ro	Ortho VITROS® ORDER NO. 701vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
SET 1				
UA (Uric Acid)	mg/dL	0.2 - 100	2.2 - 100	5.5 - 100
SET 2				
CL (Chloride)	mmol/L	20 - 350	20 - 250	15 - 300
ETOH (Ethyl Alcohol)	mg/dL	10 - 498	10 - 500	—
GLU (Glucose)	mg/dL	4.32 - 720	2 - 750	20 - 650
K (Potassium)	mmol/L	1 - 150	3 - 100	2.5 - 175
NA (Sodium)	mmol/L	20 - 350	20 - 250	5 - 250
UTP (Total Protein)	mg/dL	4 - 200	4 - 200	5 - 200
UUN (Urea Nitrogen)	mg/dL	2.8 - 5,600	2.9 - 5,600	67 - 2,520

UC4

CE

PRODUCT NAME: UC4 **Product Configuration: Five Levels**
STORAGE: 2 TO 8°C

		Beckman Coulter AU ORDER NO. 704au	Beckman Coulter DxC ORDER NO. 704bc	Siemens Dimension® ORDER NO. 704db
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
CA (Calcium)	mg/dL	0 - 40	2 - 30	5 - 15
CREA (Creatinine)	mg/dL	1 - 300	10 - 400	5 - 400
MG (Magnesium)	mg/dL	0.5 - 10	1 - 70	0 - 20
PHOS (Phosphorus)	mg/dL	10 - 200	10 - 120	0 - 90

		Roche COBAS INTEGRA® ORDER NO. 704ri	Roche cobas® ORDER NO. 704ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
CA (Calcium)	mg/dL	0.8 - 30.1	0.8 - 30.1
CREA (Creatinine)	mg/dL	0.3 - 452	1.1 - 610
MG (Magnesium)	mg/dL	1.8 - 30.4	1.4 - 26.7
PHOS (Phosphorus)	mg/dL	3.41 - 285	3.4 - 285

UC5

CE

PRODUCT NAME: UC5
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Beckman Coulter AU ORDER NO. 705au*	Beckman Coulter DxC ORDER NO. 705bcc**	Siemens Dimension® ORDER NO. 705db
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
AMY (Amylase)	U/L	10 - 1,500	5 - 1,200	0 - 650
µALB (Micro-Albumin)	mg/L	7 - 450	2 - 300	1.3 - 100
PAMY (Pancreatic Amylase)	U/L	—	—	0 - 650

		Roche COBAS INTEGRA® ORDER NO. 705ri***	Roche cobas® ORDER NO. 705ro	Ortho VITROS® ORDER NO. 705vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
AMY (Amylase)	U/L	3 - 2,000	3 - 1,500	30 - 1,200
µALB (Micro-Albumin)	mg/L	12 - 200	12 - 400	5 - 200
PAMY (Pancreatic Amylase)	U/L	3 - 1,500	3 - 1,500	—

UC6

CE

PRODUCT NAME: UC6
STORAGE: 2 TO 8°C

Product Configuration: Two sets of Five Levels

		Alere Afinion™ ORDER NO. 706af
ANALYTE	UNITS	Typical Ranges:
ALB SET		
ALB (Albumin)	mg/L	5.0 - 200.0
CREAT SET		
CREA (Creatinine)	mg/dL	16.4 - 339.9

UC1 and UC4 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

UC5 NOTES:
* 705au: Test kit also contain PAMY as part of the AMY component.
** 705bcc: Test kits also contain PAMY as part of the AMY component.
*** 705ri: Assay Levels 1 through 4 only for PAMY. Level 5 will typically recover above the reportable range.
Typical ranges or recommended Level usage for products are intended as a guide only.

UC6 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® OSMO

- TWO SETS — SERUM & URINE
- HUMAN-BASED MATRICES
- LIQUID, READY-TO-USE
- FIVE LEVELS

OSMO

CE

PRODUCT NAME: OSMO
STORAGE: 2 TO 8°C

Product Configuration: Two Sets of Five Levels

		Fiske 2400 ORDER NO. 703
ANALYTE	UNITS	Typical Ranges:
SET 1		
UOSMO (Urine Osmolality)	mOsm/kg H_2O	0 - 2,000
SET 2		
SOSMO (Serum Osmolality)	mOsm/kg H_2O	0 - 2,000

OSMO NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® CM

- NINE ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

CARDIAC MARKER PRODUCTS

CM1

CE

PRODUCT NAME: CM1 **Product Configuration: Five Levels**
STORAGE: -10 TO -25°C

		Abbott ARCHITECT ORDER NO. 401ab	Beckman Coulter DxC ORDER NO. 401bc	Siemens Dimension® ORDER NO. 401db
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
CK-MB (Creatine Kinase-MB)*	ng/mL	0 - 300	0 - 300	0.5 - 300
MYO (Myoglobin)	ng/mL	0 - 1,200	0 - 4,000	1 - 1,000

CM2

CE

PRODUCT NAME: CM2 **Product Configuration: Five Levels**
STORAGE: -10 TO -25°C **402ab is Five Levels plus a High TnI**

		Abbott ARCHITECT ORDER NO. 402ab	Beckman Coulter DxC ORDER NO. 402bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
BNP (Brain Natriuretic Peptide)	pg/mL	10 - 5,000	1 - 5,000
hs-CRP (High Sensitivity C-Reactive Protein)	mg/dL	0.01 - 16.0	0.02 - 8
TnI (Troponin I)	ng/mL	0.02 - 50	0.03 - 80

		Ortho VITROS® ORDER NO. 402vt	Roche cobas® ORDER NO. 402re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
hs-CRP (High Sensitivity C-Reactive Protein)	mg/L	0.29 - 12.5	0.2 - 20
NT-proBNP (Brain Natriuretic Peptide)	pg/mL	40 - 34,757	5 - 35,000
TnI (Troponin I)	ng/mL	0.02 - 77.3	—
TnT (Troponin T)	ng/mL	—	0.01 - 25

HIGH SENSITIVE TROPONIN

CE

PRODUCT NAME: High Sensitive Troponin **Product Configuration: Five Levels**
STORAGE: -10 TO -25°C

		Roche cobas® ORDER NO. 405ro	Beckman Coulter DxI ORDER NO. 405ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
hsTnI (High Sensitivity TnI)	ng/L	—	5.3 - 24,696
hsTnT (High Sensitivity TnT)	ng/L	12 - 9,360	—

CM1 NOTES:
* Intended for use with mass CK-MB methods. Not compatible with CK-MB immunoinhibition methods measured in activity (U/L).
Typical ranges or recommended Level usage for products are intended as a guide only.

CM2 NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

HIGH SENSITIVE TROPONIN NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® THY

- SIX ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

THY

CE

PRODUCT NAME: THY
STORAGE: -10 TO -25°C

Product Configuration: THY Set is Five Levels
FT4 Set is Five Levels

		Beckman Coulter DxI ORDER NO. 901bc	Roche cobas® ORDER NO. 901re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
FT4 SET			
FT4 (Free Thyroxine)	ng/dL	0.28 - 4.78	0.1 - 7.77
THY SET			
CORT (Cortisol)	µg/dL	0.4 - 52.3	0.036 - 63.4
Free T3 (Free Triiodothyronine)	ng/mL	2.7 - 26.9	*
TSH (Thyroid Stimulating Hormone)	µIU/mL	0.07 - 43	0.005 - 100
TT4 (Total Thyroxine)	µg/dL	0.2 - 26.2	0.420 - 24.9
TT3 (Total Triiodothyronine)	ng/mL	0.6 - 7.3	0.195 - 6.51

THY NOTES:
* FT3 is a component of TT3. Results may vary.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VITAMIN D

VALIDATE® VIT D

- TOTAL 25 (OH) VITAMIN D
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

VIT D

CE

PRODUCT NAME: VIT D
STORAGE: -10 TO -25°C

Product Configuration: Five Levels
506ab is Six Levels

		Abbott ARCHITECT ORDER NO. 506ab	Siemens ADVIA Centaur® ORDER NO. 506	Ortho VITROS® ORDER NO. 506vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
VIT D (Vitamin D)	ng/mL	7 - 132	4.0 - 150	20 - 120

VIT D NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® SP

- 17 ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

SERUM PROTEIN PRODUCTS

SP1

CE

PRODUCT NAME: SP1
STORAGE: -10 TO -25°C

Product Configuration: 601bc is Five Levels
601bcs is Five Levels plus a High IgM

		Beckman Coulter DxC ORDER NO. 601bc	Beckman Coulter DxC ORDER NO. 601bcs
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
AAT (α1-Antitrypsin)	mg/dL	20 - 600	—
C3 (Complement C3)	mg/dL	10 - 350	10 - 350
C4 (Complement C4)	mg/dL	5 - 120	5 - 120
IGA (Immunoglobulin A)	mg/dL	40 - 700	40 - 700
IGG (Immunoglobulin G)	mg/dL	200 - 3,200	200 - 3,200
IGM (Immunoglobulin M)	mg/dL	25 - 400	25 - 2,400
TRFN (Transferrin)	mg/dL	70 - 850	70 - 850

SP2

CE

PRODUCT NAME: SP2
STORAGE: 2 TO 8°C

Product Configuration: Five Levels

	Beckman Coulter DxC ORDER NO. 602bc
ANALYTE	Typical Level Usage*
ALB (Albumin)	Levels 1 - 5
CRP (C-Reactive Protein)	Levels 1 - 5
HPT (Haptoglobin)	Levels 1 - 5
PAB (Prealbumin)	Levels 1 - 5
RF (Rheumatoid Factor)	Levels 1 - 5

		Roche cobas® ORDER NO. 602re
ANALYTE	UNITS	Typical Ranges:
ALB (Albumin)	g/dL	1.1 - 5.8
CER (Ceruloplasmin)	mg/dL	7 - 140
CRP (C-Reactive Protein)	mg/L	0.7 - 364
HPT (Haptoglobin)	mg/dL	14 - 550
PAB (Prealbumin)	mg/dL	6 - 77
RF (Rheumatoid Factor)	IU/dL	18 - 135

SP3

PRODUCT NAME: SP3
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Roche cobas® ORDER NO. 603ro
ANALYTE	UNITS	Typical Ranges:
AAG (α1-Acid Glycoprotein)	mg/dL	14 - 370
ASO (Antistreptolysin O)	IU/mL	27 - 534
B2M (B2-Microglobulin)	mg/L	0.2 - 7.4
IGE (Immunoglobulin E)	IU/mL	5 - 2176

SP1 NOTES: Typical ranges or recommended Level usage for products are intended as a guide only.
SP2 NOTES: *Analyzers not listed should run Levels 1 through 5. Typical ranges or recommended Level usage for products are intended as a guide only.
SP3 NOTES: Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® TUMOR MARKERS

- FOUR ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

TUMOR MARKERS

CE

PRODUCT NAME: TUMOR MARKERS
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

	Roche cobas® ORDER NO. 407re	Siemens ADVIA Centaur® ORDER NO. 407sa
ANALYTE	Typical Level Usage*	Typical Level Usage*
CA 15-3 (Cancer Antigen 15-3)	Levels 1 - 5	Levels 1 - 5
CA 19-9 (Cancer Antigen 19-9)	Levels 1 - 5	Levels 1 - 5
CA 125 (Cancer Antigen 125)	Levels 1 - 5	Levels 1 - 5
CEA (Carcinoembryonic Antigen)	Levels 1 - 5	Levels 1 - 5

TUMOR MARKER NOTES:
* Analyzers not listed should run Levels 1 through 5.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

PROSTATE SPECIFIC ANTIGEN

VALIDATE® PSA

- TWO ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

PSA

PRODUCT NAME: PSA
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Beckman Coulter DxC ORDER NO. 406bc	Roche cobas® ORDER NO. 406re*
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
fPSA (Free PSA)	ng/mL	0.005 - 20	0.018 - 50
tPSA (Total PSA)	ng/mL	0.008 - 150	0.014 - 100

PSA NOTES:
* 406re: Not intended for use with complex PSA methods.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® ANEMIA

- THREE ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

ANEMIA

CE

PRODUCT NAME: ANEMIA
STORAGE: -10 TO -25°C

Product Configuration: FERR set is Five Levels
308bc FOL / B12 Set is Six Levels
308re FOL / B12 Set is Five Levels

ANALYTE	ORDER NO. 308bc** Typical Level Usage*
FERR Set	
FERR (Ferritin)	
Beckman Coulter Unicel® DxI / Access®	Levels 1 - 5
Ortho VITROS®	Levels 1 - 4
FOL / B12 Set	
FOL (Folate)	
Beckman Coulter Unicel® DxI / Access®	Levels 1 - 6
Ortho VITROS®	Levels 1 - 6
B12 (Vitamin B12)	
Beckman Coulter Unicel® DxI / Access®	Levels 1 - 4
Ortho VITROS®	see notes

ANALYTE	ORDER NO. 308re Typical Level Usage*
FERR Set	
FERR (Ferritin)	
Abbott Architect (*i*)	Levels 1 - 4
Roche cobas® / Elecsys	Levels 1 - 5
FOL / B12 Set	
FOL (Folate)	
Abbott Architect (*i*)	Levels 1 - 5
Roche cobas® / Elecsys	Levels 1 - 5
B12 (Vitamin B12)	
Abbott Architect (*i*)	Levels 1 - 5
Roche cobas® / Elecsys	Levels 1 - 5

ANEMIA NOTES:
***** This product is not intended for use on the Siemens Advia Centaur. Analyzers not listed should run Levels 1 through 5.
****** 308bc: Less than three Vitamin B12 levels may be within the Ortho Vitros instrument's measuring range.
Typical ranges or recommended Level usage for products are intended as a guide only.

VALIDATE® FERRITIN

- ONE ANALYTE
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

FERRITIN

CE

PRODUCT NAME: FERRITIN
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

ANALYTE	ORDER NO. 307 Typical Level Usage*
FERR (Ferritin)	
Abbott Architect (*i*)	Levels 1 - 4
Beckman Coulter Unicel® DxI / Access®	Levels 1 - 5
Ortho VITROS®	Levels 1 - 4
Roche cobas® / Elecsys	Levels 1 - 5
Siemens ADVIA Centaur®	Levels 1 - 5
Siemens Dimension®	Levels 1 - 3
Siemens Dimension Vista®	Levels 1 - 5

FERRITIN NOTES:
* Analyzers not listed should run Levels 1 through 5.
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® FERTILITY

- NINE ANALYTES
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

FERTILITY

FERTILITY 1

CE

PRODUCT NAME: FERTILITY 1
STORAGE: -10 TO -25°C

Product Configuration: Two Sets of Five Levels

	Roche cobas® / Elecsys ORDER NO. 502re
ANALYTE	Typical Level Usage*
FERT 1 Set	
FSH (Follicle-stimulating Hormone)	Levels 1 - 5
hCG (Human Chorionic Gonadotropin)	Levels 1 - 5
LH (Luteinizing Hormone)	Levels 1 - 5
PRL (Prolactin)	Levels 1 - 5
TSTO Set	
TSTO (Testosterone)	Levels 1 - 5

FERTILITY 2

CE

PRODUCT NAME: FERTILITY 2
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

	Roche cobas® / Elecsys ORDER NO. 504re
ANALYTE	Typical Level Usage*
AFP (α1-fetoprotein)	Levels 1 - 5
DHEA-S (Dehydroepiandrosterone Sulfate)	Levels 1 - 5
E2 (Estradiol)	Levels 1 - 5
PRGE (Progesterone)	Levels 1 - 5

FERTILITY NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

VALIDATE® HEMOSTASIS

- THREE ANALYTES
- HUMAN PLASMA MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

D-DIMER

CE

PRODUCT NAME: D-DIMER
STORAGE: -10 TO -25°C
Product Configuration: Five Levels

	Instrumentation Laboratory ACL TOP® ORDER NO. 902il	Siemens Sysmex CS ORDER NO. 902se	Stago STA® ORDER NO. 902st
ANALYTE	Typical Ranges:	Typical Ranges:	Typical Ranges:
D-Dim (D-Dimer)	191 - 3,290 ng/mL DDU	0.30 - 3.86 mg/L FEU	0.32 - 3.23 µg/mL FEU

HEPARIN

CE

PRODUCT NAME: HEPARIN
STORAGE: -10 TO -25°C
Product Configuration: Five Levels

	Instrumentation Laboratory ACL TOP® ORDER NO. 903il	Siemens Sysmex CS ORDER NO. 903se	Stago STA® ORDER NO. 903st
ANALYTE	Typical Ranges:	Typical Ranges:	Typical Ranges:
HP (Heparin Anti-Xa)	0.11 - 1.77 IU/mL	0.13 - 1.29 IU/mL	0.19 - 1.79 IU/mL

FIBRINOGEN

CE

PRODUCT NAME: FIBRINOGEN
STORAGE: -10 TO -25°C
Product Configuration: Five Levels

	Instrumentation Laboratory ACL TOP® ORDER NO. 904il	Siemens Sysmex CS ORDER NO. 904se	Stago STA® ORDER NO. 904st
ANALYTE	Typical Ranges:	Typical Ranges:	Typical Ranges:
FIBR (Fibrinogen)	55 - 794 mg/dL	94 - 432 mg/dL	207 - 762 mg/dL

HEMOSTASIS NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

PROCALCITONIN

VALIDATE® PROCALCITONIN

- FIVE LEVELS
- HUMAN SERUM MATRIX
- LIQUID, READY-TO-USE

PROCALCITONIN

CE

PRODUCT NAME: PROCALCITONIN
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Roche cobas® ORDER NO. 403ro	Abbott ARCHITECT ORDER NO. 403ab
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
PCT (Procalcitonin)	ng/mL	0.08 - 91.7	0.03 - 92.5

PROCALCITONIN NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

VALIDATE® BODY FLUIDS

- 13 ANALYTES AVAILABLE
- SIMULATED BODY FLUID MATRIX
- LIQUID, READY-TO-USE
- FIVE LEVELS

This product contains purified albumin, amylase, cerebrospinal fluid total protein, cholesterol, creatinine, glucose, lactate, lactate dehydrogenase, total protein, triglycerides and urea nitrogen in a synthetic matrix designed to simulate cerebrospinal, peritoneal ascites, pleural and pericardial fluids.

BODY FLUIDS

CE

PRODUCT NAME: BODY FLUIDS
STORAGE: -10 TO -25°C

Product Configuration: 2 Sets of Five Levels

		Roche cobas® ORDER NO. 205bf	Roche cobas® ORDER NO. 205ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
ALB (Albumin)	g/dL	0.3 - 5.5	0.3 - 5.5
AMY (Amylase)	U/L	8 - 1,137	8 - 1,137
CA 19-9 (Cancer Antigen 19-9)	U/mL	—	2.4 - 871
CEA (Carcinoembryonic Antigen)	ng/mL	—	3.6 - 949
CHOL (Cholesterol)	mg/dL	6 - 756	6 - 756
CREA (Creatinine)	mg/dL	0.3 - 22.5	0.3 - 22.5
GLU (Glucose)	mg/dL	5 - 697	5 - 697
LAC (Lactate)	mg/dL	3 - 132	3 - 132
LD (Lactate Dehydrogenase)	U/L	9 - 907	9 - 907
TP (Total Protein)	g/dL	0.5 - 9.2	0.5 - 9.2
TRIG (Triglycerides)	mg/dL	9 - 863	9 - 863
UUN (Urea Nitrogen)	mg/dL	3.0 - 113	3.0 - 113
SET 2			
CSF-TP (Cerebrospinal Fluid Total Protein)	mg/dL	5 - 188	5 - 188

BODY FLUIDS NOTES:
Typical ranges or recommended Level usage for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

LGC maine standards | *Providing* ***More***

SCIENCE FOR A SAFER WORLD

Our employees set us apart from the competition. Their in-depth knowledge and expertise across a breadth of scientific areas enable our business to provide high-caliber solutions to our customers. We encourage our employees to set the bar high and challenge them continuously to look for ways to exceed our customers' expectations. It is through their infectious energy to do their best every day that we constantly challenge today's science to create tomorrow's innovations.

We work closely with our customers, to ensure we deliver quality products and services, supporting them in their measurement and testing challenges. Many of our innovations are born from cooperating with customers and understanding their issues.

Our operating model fosters an agile and responsive organization, with clear communication and lean and effective processes. Our science and innovation team works across all our divisions, with experts in key scientific domains to share knowledge and foster innovation.


Validate


myCalVer


MSDRx

Maine Standards Company, LLC
221 US Route 1
Cumberland Foreside, ME 04110
1.800.377.9684 or 1.207.892.1300
www.mainestandards.com

Maine Standards Company, LLC
221 US Route 1
Cumberland Foreside, ME 04110
1.800.377.9684 or 1.207.892.1300
www.mainestandards.com

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