



**DELIVERS MORE**



**EASY · FAST · EFFICIENT**

*Linearity and Calibration Verification*



**PRODUCT CATALOG**



## 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

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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.

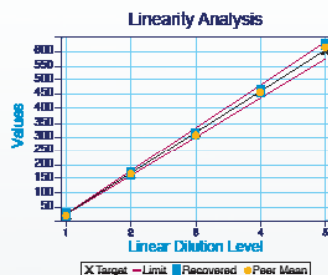


## DATA REDUCTION SOFTWARE:

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.

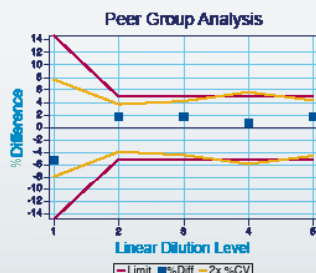
## LINEARITY ANALYSIS FEATURES

- 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.

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.**





## 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.<sup>®</sup> approved myCalVer<sup>®</sup> training program.

### myCalVer.com is a website offering:

- P.A.C.E.<sup>®</sup> 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<sup>®</sup> 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.<sup>®</sup>) 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.



### PEER GROUP STATISTICS

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

### DATA SERVICES PAGE

Evaluate and access your VALIDATE<sup>®</sup> linearity and calibration verification in one convenient place with myCalVer<sup>®</sup>. Our data reduction service is free of charge with the purchase of any VALIDATE<sup>®</sup> 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.<sup>®</sup> Program. Since this program is ASCLS P.A.C.E.<sup>®</sup> approved on the national level versus the state level, Florida licensees cannot earn credits for completing this course. P.A.C.E.<sup>®</sup> is a registered trademark for Professional Acknowledgment for Continuing Education used here by permission. All rights reserved.



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](http://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)

## LIPOPROTEINS

CE

### LP

HDL (High Density Lipoprotein)  
LDL (Low Density Lipoprotein)

### LP2

APO A1 (Apolipoprotein A1)  
APO B (Apolipoprotein B)

## ACTH

CE

### ACTH

Adrenocorticotrophic Hormone

## ANEMIA

CE

### ANEMIA

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

### FERRITIN

FERR (Ferritin)

## BODY FLUIDS

CE

### BF

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)

### BF2

Alkaline Phosphatase  
Calcium  
Chloride  
Potassium  
Sodium  
Total Bilirubin  
Uric Acid

## BONE

CE

### PTH\*

PTH (Parathyroid Hormone)  
\* Not CE approved.

### VIT D

VIT D (Vitamin D)

## CARDIAC

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)

### CM3

Homocysteine  
Lipoprotein (a)

## HIGH SENSITIVE TROPONIN

hsTnI (High Sensitivity Troponin I)  
hsTnT (High Sensitivity Troponin T)

## DIABETES

CE

### DIABETES\*

Beta-Hydroxybutyrate  
C-Peptide  
Glucose  
Insulin  
Fructosamine  
\* Not CE approved.

### HbA1c

% Glycohemoglobin A1c (HbA1c)

## 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)  
PROG (Progesterone)

## HEMOSTASIS

CE

### D-DIMER

D-Dim (D-Dimer)

### FIBRINOGEN

FIBR (Fibrinogen)

### HEPARIN

HP (Heparin Anti-Xa)

## OSMOLALITY

CE

### OSMO

SOSMO (Serum Osmolality)  
UOSMO (Urine Osmolality)

## POC

CE

### WBG

GLU (Glucose)

## SEPSIS

CE

### IL-6\*

IL-6 (Interleukin-6)  
\* Not CE approved.

### PCT

PCT (Procalcitonin)

## 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)

## 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)

## THYROID ANALYTES

CE

### THY

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

## 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)

## 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)





# validate®

## VALIDATE® GC

- ✓ 40 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 / ALINITY ORDER NO. 1100ab	Beckman Coulter AU ORDER NO. 1100au	Beckman Coulter DxC ORDER NO. 1100bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
<b>SET 1</b>				
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
<b>SET 2 (MODULAR)</b>				
BUNm <sup>†</sup> (Blood Urea Nitrogen)	mg/dL	—	—	1 - 150
GLUm <sup>†</sup> (Glucose)	mg/dL	—	—	10 - 600
PHOSm <sup>†</sup> (Phosphorus)	mg/dL	—	—	1.0 - 12.0

<sup>†</sup>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:
<b>SET 1</b>				
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
<b>SET 2 (CREAT JAFFE SET)</b>				
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.

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:
<b>GC1 Set</b>			
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
<b>Chem 17 Set</b>			
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:
<b>SET 1</b>		
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
<b>SET 2</b>		
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 / ALINITY 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 - 300
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.

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

**Product Configuration: Five Levels**  
**1300ab is Six Levels**

		<b>Abbott ARCHITECT / ALINITY ORDER NO. 1300ab</b>	<b>Beckman Coulter AU ORDER NO. 1300au</b>	<b>Beckman Coulter Dxl ORDER NO. 1300bcc</b>
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

		<b>Roche cobas® ORDER NO. 1300re</b>	<b>Siemens ADVIA® ORDER NO. 1300sa</b>	<b>Siemens Dimension® ORDER NO. 1300sd</b>
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

		<b>Ortho VITROS® ORDER NO. 1300vt</b>
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



PRODUCT NAME: GC4 STORAGE: -10 TO -25°C	Product Configuration: Five Levels 1400au, 1400ri, 1400vt are Two Sets of Five Levels
--	--

		Abbott ARCHITECT / ALINITY 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.

# IRON BINDING CAPACITY

# IBC

CE

IBC

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

Product Configuration: Five Levels

ANALYTE	UNITS	Roche cobas® ORDER NO. 203ro	Siemens Dimension® ORDER NO. 203sd	Ortho VITROS® ORDER NO. 203vt
		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.



# LIPOPROTEINS

## LP

CE

**PRODUCT NAME:** LP  
**STORAGE:** -10 to -25°C

**Product Configuration:** Five Levels

		Abbott ARCHITECT / ALINITY ORDER NO. 501ab	Beckman Coulter AU ORDER NO. 501au	Beckman Coulter UniCel® DxC/Synchron® ORDER NO. 501bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	5 - 180	2.5 - 200	5 - 135
LDL (Low Density Lipoprotein)	mg/dL	1 - 800	7 - 400	10 - 550

		Siemens Dimension® ORDER NO. 501db	Roche cobas® ORDER NO. 501ro	Siemens Atellica® ORDER NO. 501sa
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	3 - 150	3.1 - 150	34 - 122
LDL (Low Density Lipoprotein)	mg/dL	5 - 300	3 - 550	12 - 922

		Ortho VITROS® ORDER NO. 501vt
ANALYTE	UNITS	Typical Ranges:
HDL (High Density Lipoprotein)	mg/dL	5 - 110
LDL (Low Density Lipoprotein)	mg/dL	30 - 350

## LP2

CE

**PRODUCT NAME:** LP2  
**STORAGE:** -10 to -25°C

**Product Configuration:** Five Levels

		Roche cobas® ORDER NO. 507ro
ANALYTE	UNITS	Typical Ranges:
APO A1 (Apolipoprotein A1)	mg/dL	21 - 357
APO B (Apolipoprotein B)	mg/dL	26 - 351

### LP NOTES:

\*Test kits also contain APO-A 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



# ACTH



## VALIDATE® ACTH

ACTH

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



## ACTH



PRODUCT NAME: ACTH  
STORAGE: -10 to -25°C

Product Configuration: Five Levels

Roche cobas®  
ORDER NO. 302mm

ANALYTE	UNITS	Typical Ranges
ACTH (Adrenocorticotrophic Hormone)	pg/mL	3.5 - 1,833

### ACTH 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

# ANEMIA



## VALIDATE® ANEMIA

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



# ANEMIA

## 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	
		Abbot ARCHITECT / ALINITY ORDER NO. 308ab	Beckman Coulter Unicel® DxI / Access® ORDER NO. 308bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
B12 (Vitamin B12)	pg/mL	224 - 1,717	-
FERR (Ferritin)	pg/mL	4.6 - 1,133	3 - 1,375
FOL (Folate)	ng/mL	3.4 - 17.5	-
SET 2			
B12 (Vitamin B12)	pg/mL	-	13 - 1,420
FOL (Folate)	ng/mL	-	3.4 - 21.2

		Roche cobas® ORDER NO. 308re	Ortho VITROS® ORDER NO. 308vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
B12 (Vitamin B12)	pg/mL	-	172 - 925
FERR (Ferritin)	pg/mL	3 - 1,708	1.6 - 877
FOL (Folate)	ng/mL	-	0.8 - 18.8
SET 2			
B12 (Vitamin B12)	pg/mL	184 - 1,733	-
FOL (Folate)	ng/mL	3.6 - 16.1	-

## FERRITIN

CE

PRODUCT NAME: FERRITIN STORAGE: -10 TO -25°C		Product Configuration: Five Levels
		Roche cobas® ORDER NO. 307
ANALYTE	UNITS	Typical Ranges
FERR (Ferritin)	ng/mL	3 - 1,708

**ANEMIA NOTES:**  
308vt pending CE mark  
308ab pending CE mark.  
This product is not intended for use on the Siemens Advia Centaur.  
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



# BODY FLUIDS



## VALIDATE® BODY FLUIDS

- ✓ 20 ANALYTES AVAILABLE
- ✓ LIQUID, READY-TO-USE
- ✓ FIVE LEVELS

**Body Fluids** 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 2** contains alkaline phosphate, calcium, chloride, potassium, sodium, total bilirubin and uric acid in a human ascites base.





# BODY FLUIDS

## BF



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 - 190	5 - 190

## BF2



PRODUCT NAME: BODY FLUIDS 2

STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Roche cobas® ORDER NO. 206ro
ANALYTE	UNITS	Typical Ranges:
ALP (Alkaline Phosphatase)	U/L	10 - 1,063
CA (Calcium)	mg/dL	1.7 - 18.2
CL (Chloride)	mmol/L	54 - 131
K (Potassium)	mmol/L	3.1 - 9.2
NA (Sodium)	mmol/L	67 - 167
TB (Total Bilirubin)	mg/dL	0.4 - 31.6
UA (Uric Acid)	mg/dL	1 - 22

**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**

# BONE



## VALIDATE® BONE



2 ANALYTES AVAILABLE



LIQUID, READY-TO-USE

BONE

### PTH

CE

PRODUCT NAME: PTH  
STORAGE: -10 to -25°C

Product Configuration: Five Levels

Roche cobas®  
ORDER NO. 303ro

ANALYTE	UNITS	Typical Ranges:
PTH	pg/mL	5.1 - 4,578

### VIT D

CE

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

Product Configuration: Five Levels  
506ab is Six Levels

Abbott ARCHITECT /  
ALINITY  
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

PTH NOTES:  
303ro pending CE mark.

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

# CARDIAC PRODUCTS



## VALIDATE® CM

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



# CARDIAC PRODUCTS

## CM1

CE

**PRODUCT NAME:** CM1  
**STORAGE:** -10 to -25°C

Product Configuration: Five Levels

		Abbott ARCHITECT / ALINITY ORDER NO. 401ab	Beckman Coulter DxC 700 AU ORDER NO. 401bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
CK-MB (Creatine Kinase-MB)*	ng/mL	0 - 300	0 - 300
MYO (Myoglobin)	ng/mL	0 - 1,200	0 - 4,000

		Siemens Dimension® ORDER NO. 401db	Roche cobas® ORDER NO. 401ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
CK-MB (Creatine Kinase-MB)*	ng/mL	0.5 - 300	2 - 254
MYO (Myoglobin)	ng/mL	1 - 1,000	25 - 2,571

## CM2

CE

**PRODUCT NAME:** CM2  
**STORAGE:** -10 to -25°C

Product Configuration: Five Levels  
402ab is Five Levels plus a High TnI

		Abbott ARCHITECT / ALINITY ORDER NO. 401ab	Beckman Coulter DxC 700 AU ORDER NO. 402bc
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
<b>SET 1</b>			
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
hs-CRP (High Sensitivity C-Reactive Protein)	mg/L	0.29 - 12.5	0.2 - 20
NT-proBNP (Brain Natriuretic Peptide)	pg/mL	-	-
TnI (Troponin I)	ng/mL	0.02 - 50	0.03 - 80
TnT (Troponin T)	ng/mL	-	-

		Roche cobas® ORDER NO. 402re	Ortho VITROS® ORDER NO. 402vt
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
<b>SET 1</b>			
BNP (Brain Natriuretic Peptide)	pg/mL	-	-
hs-CRP (High Sensitivity C-Reactive Protein)	mg/dL	-	-
hs-CRP (High Sensitivity C-Reactive Protein)	mg/L	0.02 - 20	0.29 - 12.5
NT-proBNP (Brain Natriuretic Peptide)	pg/mL	5 - 35,000	40 - 34,757
TnI (Troponin I)	ng/mL	-	0.02 - 77.3
TnT (Troponin T)	ng/mL	0.01 - 25	-
<b>SET 2</b>			
NT-proBNP (Clinical Range)	pg/mL	50 - 5,000	

### 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.



# CM3

CE

PRODUCT NAME: CM3  
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

Roche cobas® ORDER NO. 409ro		
ANALYTE	UNITS	Typical Ranges:
HCY (Homocysteine)	μmol/L	6.02 - 48.03
LP(a) (Lipoprotein (a))	mg/dL	8.67 - 76.92

# TROPONIN

CE

PRODUCT NAME: High Sensitive Troponin  
STORAGE: -10 TO -25°C

Product Configuration: Five Levels

		Abbot ARCHITECT / ALINITY ORDER NO. 405ab	Roche cobas® ORDER NO. 405ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
hsTnI (High Sensitivity TnI)	ng/L	-	10 - 8,910
hsTnI (High Sensitivity TnI)	ng/L	7.9 - 42,313**	15 - 21,961*

### CM3 NOTES:

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

### TROPONIN NOTES:

\*Typical Ranges were obtained on the Beckman Coulter UniCel® DxI / Access®.

\*\*Only available on the Abbott ARCHITECT; 405ab pending CE mark.

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**

# DIABETES



## VALIDATE® DIABETES



6 ANALYTES AVAILABLE



LIQUID, READY-TO-USE

## DIABETES

PRODUCT NAME: DIABETES STORAGE: -10 TO -25°C		Product Configuration: Five Levels	
		Roche cobas® ORDER NO. 204ro	
ANALYTE	UNITS	Typical Ranges:	
SET 1			
BHP (Beta-Hydroxybutyrate)*	mmol/L	0.1 - 4.2	
C-PEP (C-Peptide)	ng/mL	0.10 - 32	
INS (Insulin)	pmol/L	1.81 - 5,961	
FRUC (Fructosamine)	µmol/L	25 - 912	
SET 2			
GLU (Glucose)	mg/dL	5 - 696	

## HbA1c

CE

PRODUCT NAME: HbA1c		Product Configuration: Five Levels		
STORAGE: -10 TO -25°C		Roche cobas® ORDER NO. 605	Siemens Atellica® ORDER NO. 605sa	Tosoh ORDER NO. 605to
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
HbA1c (% Glycohemoglobin A1c) %		4.3 - 17.6	4.7 - 13.3	3.7 - 17.4

**DIABETES NOTES:**  
204ro pending CE mark.  
\*Developed and manufactured using Stanbio's BHB reagent on the Roche cobas®

**HbA1c NOTES:**  
605sa pending CE mark.





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

# FERTILITY

## **validate®**

### VALIDATE® FERTILITY

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



# FERTILITY

## FERT 1



PRODUCT NAME: FERTILITY 1 STORAGE: -10 to -25°C		Product Configuration: Five Levels	
		Abbot ARCHITECT / ALINITY ORDER NO. 502ab	Roche cobas® ORDER NO. 502re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
FSH (Follicle-stimulating Hormone)	mIU/mL	0.7 - 129	0.7 - 180
hCG (Human Chorionic Gonadotropin)	mIU/mL	4.9 - 12,034	2.9 - 8,307
LH (Luteinizing Hormone)	mIU/mL	0.5 - 222	0.8 - 182
PRL (Prolactin)	ng/mL	4.57 - 161	1.7 - 402
TSTO (Testosterone)	ng/mL	0.1 - 13	0.2 - 13

## FERT 2



PRODUCT NAME: FERTILITY 1 STORAGE: -10 to -25°C		Product Configuration: Five Levels	
		Abbot ARCHITECT / ALINITY ORDER NO. 504ab	Roche cobas® ORDER NO. 504re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
AFP (α1-fetoprotein)	ng/mL	6.0 - 1,666	3.6 - 1,103
DHEA-S (Dehydroepiandrosterone Sulfate)	μg/dL	16 - 1,207	45 - 903
E2 (Estradiol)	pg/mL	61.3 - 742	20.6 - 2,659
PROG (Progesterone)	pg/mL	1.32 - 30	0.44 - 53

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**



# HEMOSTASIS



## VALIDATE® HEMOSTASIS

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



# HEMOSTASIS

## D-DIMER

CE

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

## FIBRINOGEN

CE

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

## HEPARIN

CE

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

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





# OSMOLALITY



## VALIDATE® OSMO

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



OSMO

## 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:
<b>SET 1</b>		
UOSMO (Urine Osmolality)	mOsm/kg H <sub>2</sub> O	0 - 2,000
<b>SET 2</b>		
SOSMO (Serum Osmolality)	mOsm/kg H <sub>2</sub> O	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® WHOLE BLOOD GLUCOSE



**FIVE LEVELS**



**HUMAN WHOLE BLOOD**



**LIQUID, READY-TO-USE**



POC

## WHOLE BLOOD GLUCOSE CE

PRODUCT NAME: WHOLE BLOOD GLUCOSE

Product Configuration: Five Levels

STORAGE: 2 to 8°C

Roche ACCU-CHECK®  
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.





# SEPSIS



## VALIDATE® PCT



FIVE LEVELS



HUMAN SERUM MATRIX



LIQUID, READY-TO-USE

## IL-6

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

Product Configuration: Five Levels

Roche cobas®  
ORDER NO. 509ro

ANALYTE	UNITS	Typical Ranges
IL-6 (Interleukin-6)	pg/mL	5.7 - 4,331

## PCT



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

Product Configuration: Five Levels

Abbott ARCHITECT /  
ALINITY  
ORDER NO. 403ab

Roche cobas®  
ORDER NO. 403ro

ANALYTE	UNITS	Typical Ranges	Typical Ranges
PCT (Procalcitonin)	ng/mL	0.03 - 92.5	0.08 - 91.7

### PROCALCITONIN NOTES:

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



# SERUM PROTEIN PRODUCTS



## VALIDATE® SP

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



# SERUM PROTEIN PRODUCTS

## SP1



PRODUCT NAME: SP1		Product Configuration: 601bc is Five Levels		
STORAGE: -10 TO -25°C		601bcs is Five Levels plus a High IgM		
		Beckman Coulter Unicel® DxC / Synchron® ORDER NO. 601bc	Beckman Coulter Unicel® DxC / Synchron® ORDER NO. 601bcs	Roche cobas® ORDER NO. 601ro
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
AAT (α1-Antitrypsin)	mg/dL	20 - 600	—	22 - 490
C3 (Complement C3)	mg/dL	10 - 350	10 - 350	9.8 - 474.5
C4 (Complement C4)	mg/dL	5 - 120	5 - 120	5.3 - 103.1
IGA (Immunoglobulin A)	mg/dL	40 - 700	40 - 700	54 - 772
IGG (Immunoglobulin G)	mg/dL	200 - 3,200	200 - 3,200	342 - 4,973
IGM (Immunoglobulin M)	mg/dL	25 - 400	25 - 2,400	34 - 642
TRFN (Transferrin)	mg/dL	70 - 850	70 - 850	31.9 - 526.7

## SP2



PRODUCT NAME: SP2		Product Configuration: Five Levels	
STORAGE: 2 TO 8°C			
		Beckman Coulter DxC ORDER NO. 602bc	
ANALYTE	UNITS	Typical Ranges:	
ALB (Albumin)	g/dL	1.2 - 6.9	
CRP (C-Reactive Protein)	mg/dL	0.8 - 18	
HPT (Haptoglobin)	mg/dL	23 - 254	
PAB (Prealbumin)	mg/dL	5 - 53	
RF (Rheumatoid Factor)	IU/mL	5 - 266	
		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		Product Configuration: Five Levels	
STORAGE: -10 TO -25°C			
		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 - 2,176	

**SP1 NOTES:** 601bcs contains 5x2mL plus 1x1.5mL for High IgM.  
**SP2 NOTES:** 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.



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# THERAPEUTIC DRUGS



## 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 / ALINITY 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**

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:
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
SALY (Salicylate)	mg/dL	1 - 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

#### TDM1 NOTES:

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

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# THYROID



## VALIDATE® THY

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



## THY



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

**Product Configuration:** Five Levels

		Beckman Coulter Dxl ORDER NO. 901bc	Roche cobas® ORDER NO. 901re
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:
SET 1			
FT4 (Free Thyroxine)	ng/dL	0.28 - 4.78	0.1 - 7.77
SET 2			
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:**

\*Free T3 is a component of Total T3. 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

# TUMOR MARKERS



## VALIDATE® TUMOR MARKERS



SIX ANALYTES



HUMAN SERUM MATRIX



LIQUID, READY-TO-USE



FIVE LEVELS

## PSA

PRODUCT NAME: PSA		Product Configuration: Five Levels	
STORAGE: -10 TO -25°C		Beckman Coulter DxC 700 AU 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

## TUMOR MARKERS



PRODUCT NAME: TUMOR MARKERS		Product Configuration: Five Levels		
STORAGE: -10 TO -25°C		Abbot ARCHITECT / ALINITY ORDER NO. 407ab	Roche cobas® ORDER NO. 407re	Siemens ADVIA Centaur® ORDER NO. 407sa
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
CA 125 (Cancer Antigen 125)	U/mL	3 - 869	4 - 2,560	5 - 536
CA 15-3 (Cancer Antigen 15-3)	U/mL	3 - 671	3 - 252	0 - 170
CA 19-9 (Cancer Antigen 19-9)	U/mL	4.5 - 965	2.8 - 863	4.8 - 585
CEA (Carcinoembryonic Antigen)	ng/mL	3.3 - 1,299	2.2 - 939	2.4 - 74

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

**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

# URINE CHEMISTRY



## VALIDATE® UC

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



# URINE CHEMISTRY

## UC1

CE

**PRODUCT NAME:** UC1  
**STORAGE:** 2 TO 8°C

**Product Configuration:** Two sets of Five Levels

		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:
<b>SET 1</b>				
UA (Uric Acid)	mg/dL	1.0 - 100	5 - 100	0 - 100
<b>SET 2</b>				
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:
<b>SET 1</b>				
UA (Uric Acid)	mg/dL	0.2 - 100	2.2 - 100	5.5 - 100
<b>SET 2</b>				
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

		Siemens Atellica® ORDER NO. 701sa
ANALYTE	UNITS	Typical Ranges:
<b>SET 1</b>		
UA (Uric Acid)	mg/dL	9 - 93
<b>SET 2</b>		
CL (Chloride)	mmol/L	23 - 297
ETOH (Ethyl Alcohol)	mg/dL	9 - 283
GLU (Glucose)	mg/dL	9 - 628
K (Potassium)	mmol/L	6 - 275
NA (Sodium)	mmol/L	20 - 261
UTP (Total Protein)	mg/dL	9 - 204
UUN (Urea Nitrogen)	mg/dL	44 - 892



# UC4

CE

PRODUCT NAME: UC4 STORAGE: 2 TO 8°C		Product Configuration: Five Levels		
		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	Siemens Atellica® ORDER NO. 704sa
ANALYTE	UNITS	Typical Ranges:	Typical Ranges:	Typical Ranges:
CA (Calcium)	mg/dL	0.8 - 30.1	0.8 - 30.1	1.0 - 26.3
CREA (Creatinine)	mg/dL	0.3 - 452	1.1 - 610	4.8 - 219.9
MG (Magnesium)	mg/dL	1.8 - 30.4	1.4 - 26.7	2.2 - 12.9
PHOS (Phosphorus)	mg/dL	3.41 - 285	3.4 - 285	7 - 87

# 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:	
SET 1			
ALB (Albumin)	mg/L	5.0 - 200.0	
SET 2			
CREA (Creatinine)	mg/dL	16.4 - 339.9	

## UC1, UC4 & UC6 NOTES:

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

## UC5 NOTES:

UC5au: Test kits also contain PAMY as part of the AMY component.

UC5bcc: Test kits also contain PAMY as part of the AMY component.

UC5ri: Assay Levels 1 through 4 only for PAMY. Level 5 will typically recover above the reportable range.



maine  
standards

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