



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:

UGC 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 EP6-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 DENKA 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.

30-00000-01

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:

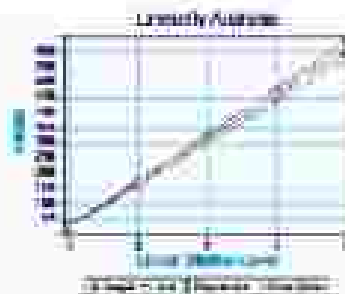
MSDRx®, LGC Maine Standards' free, do-it-yourself software, delivers real-time analysis of your linearity and calibration verification results.

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.

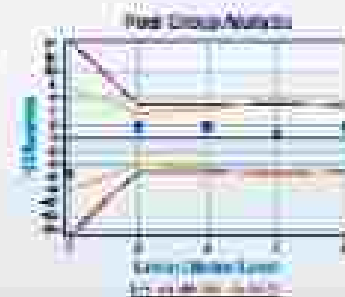
LINEARITY ANALYSIS FEATURES

- 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 variation (%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 surpluses.
- **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.**

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 like-minded industry peers 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, MyData.
- 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 Labs' steadfast 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.



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 the convenient place with myCalVer[®]. Our data reduction service is free of charge with the purchase of any VALIDATE[®] test kit.

LGC Labs' Peerless Compliance is proud to be a myCalVer[®] continuing education program in the online laboratory compliance by ANAB (ANAB.org) and CMAA (CMAA.org) approved P.A.C.E.[®] approved on-line training and award the same credit hours as the same on-line training. For more information, visit www.P.A.C.E.org or call 1-800-828-2222. For more information, visit www.CMAA.org or call 1-800-828-2222. For more information, visit www.ANAB.org or call 1-800-828-2222.

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 email 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.





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TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9534 OR 1.307.392.1100

 **validate**

VALIDATE® GC

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



GENERAL CHEMISTRY

GC1

Product Name: GC1
STORAGE: -10 to +35°C

Product Configuration: Five Levels
 11000 is Top Level
 11000a is Top Level and Five Levels
 11000a Set 1 is Top Level, Set 2 is Five Levels

ANALYTE	UNIT	Abbott ARCHITECT ORDER NO. 11000ab	Bechman Coulter AU ORDER NO. 11000a	Bechman Coulter DxG ORDER NO. 11000c
ANALYTE	UNIT	Typical Range	Typical Range	Typical Range
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 - 16.0	2.0 - 20.0
CL (Chloride)	mmol/L	50 - 150	80 - 200	50 - 200
CHOL (Cholesterol)	mg/dL	7 - 705	25 - 750	5 - 750
CREA (Creatinine)	mg/dL	0.2 - 37.0	0.2 - 25.0	0.2 - 25.0
GLU (Glucose)	mg/dL	5 - 500	10 - 500	5 - 700
LAC (Lactate)	mg/dL	1.5 - 100	2.0 - 90	2.7 - 80
LI (Lithium)	mmol/L	0.1 - 3.5	0.1 - 5.0	0.0 - 3.0
MG (Magnesium)	mg/dL	0.7 - 9.6	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 - 230	100 - 250
TP (Total Protein)	g/dL	0.8 - 16.4	3.0 - 12.0	3.0 - 12.0
TRIG (Triglycerides)	mg/dL	7 - 1,400	10 - 1,000	10 - 1,000
SET 2 (Creatinine)				
BUNmf (Blood Urea Nitrogen)	mg/dL	—	—	1 - 150
GLUmf (Glucose)	mg/dL	—	—	10 - 500
PHOSmf (Phosphorus)	mg/dL	—	—	1.0 - 12.0

†U: Beckman Medical Aways

ANALYTE	UNIT	Roche COBAS INTEGRA® ORDER NO. 11000i	Roche cobas® ORDER NO. 11000ii	Siemens ADVIA® ORDER NO. 11000ia
ANALYTE	UNIT	Typical Range	Typical Range	Typical Range
SET 1				
ALB (Albumin)	g/dL	0.2 - 6.0	0.2 - 7.0	1.0 - 6.0
BUN (Blood Urea Nitrogen)	mg/dL	1.4 - 112	1.4 - 185	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	60 - 200
CHOL (Cholesterol)	mg/dL	3.87 - 500	3.85 - 500	25 - 518
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 - 700	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 - 6.0
PHOS (Phosphorus)	mg/dL	0.31 - 20.0	0.01 - 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	50 - 160	60 - 250
TP (Total Protein)	g/dL	0.2 - 12.0	0.2 - 12	2 - 12.0
TRIG (Triglycerides)	mg/dL	8.85 - 668	8.85 - 1,000	10 - 550
SET 2 (Creatinine Jaffe)				
CREA (Creatinine Jaffe)	mg/dL	—	0.2 - 24.9	—

GC1 NOTES:

* (HWH) - HWH uses not Level 4 for ALB, BUN, and TRIG

† Typical ranges or recommendations for use (usage for product are provided as a guide only)

GC1

CE

PRODUCT NAME: GC1
STORAGE: -18 to -25°C

Product Configuration: Five Panels

Analyte	Units	Standard Dimensional [®]	Standard Dimensional [®]
		ORDER NO. 11004	ORDER NO. 11004
		3000 (µg/mL)	1000 (µg/mL)
GC1 Set			
ALB (Albumin)	g/dL	0.6 - 6	0.6 - 6
BUN (Blood Urea Nitrogen)	mg/dL	0 - 100	0 - 100
CA (Calcium)	mg/dL	5 - 15	5 - 15
CL (Chloride)	mmol/L	60 - 200	—
CHOL (Cholesterol)	mg/dL	50 - 600	50 - 600
CREA (Creatinine)	mg/dL	0.10 - 3	0.15 - 3
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	60 - 200	—
TP (Total Protein)	g/dL	2 - 12	2 - 12
TRIG (Triglycerides)	mg/dL	10 - 1000	15 - 1000
Chem 17 Set			
CL (Chloride)	mmol/L	—	60 - 200
K (Potassium)	mmol/L	—	1.0 - 10.0
NA (Sodium)	mmol/L	—	50 - 200

PRODUCT NAME: OCT
STORAGE: -18 to -25°C

Product Configuration: THREE 3-Test Sets of Two Panels

Analyte	Units	Ortho VANCE [®]	
		ORDER NO. 11004	ORDER NO. 11004
		3000 (µg/mL)	1000 (µg/mL)
SET 1			
CA (Calcium)	mg/dL	1.0 - 14.0	—
CHOL (Cholesterol)	mg/dL	50 - 320	—
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

PRODUCT NAME: GC2
STORAGE: 2-8°C

Product Configuration: Two Sets of Two Channels
12004 & 12005 Units

ANALYTE	Units	Abbott ARCHITECT [®]	Beckman Coulter AU	Beckman Coulter DxC
		ORDER NO. 020405	ORDER NO. 100404	ORDER NO. 100405
Total Range				
SET 1				
NH ₃ (Ammonia)	µmol/L	5 - 368	10 - 600	5 - 1,000
CO ₂ (Carbon Dioxide)	mmol/L	5 - 80	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

ANALYTE	Units	Roché cobas [®]	Siemens AD/AL [®]
		ORDER NO. 120404	ORDER NO. 120405
Total Range			
SET 1			
NH ₃ (Ammonia)	µmol/L	10 - 700	10 - 700
CO ₂ (Carbon Dioxide)	mmol/L	1.5 - 50	10 - 40
ETOH (Ethyl Alcohol)	mg/dL	10 - 600	3 - 300
FE (Total Iron)	µg/dL	5 - 1,000	2 - 1,000
SET 2			
UA (Uric Acid)	mg/dL	0.2 - 35	0.5 - 25

ANALYTE	Units	Siemens Dimension [®]	Critch VITROS [®]
		ORDER NO. 120404 [*]	ORDER NO. 120405
Total Range			
SET 1			
NH ₃ (Ammonia)	µmol/L	10 - 750	8.7 - 500
CO ₂ (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 PARTS:

* (2016) GC2 not compatible with Siemens Dimension DxC (ITE) CO₂ reagent

(Typical ranges or recommended level usage for products not intended as a guide only)

GC3**PRODUCT NAME: GC3**
STORAGE: -18 to -22°C**Product Configuration: Five Levels**
12000 x 300 Levels

ANALYTE	UNIT	Product Configuration: Five Levels		
		Abbot ARCHITECT ORDER NO. 15054	Beckman Coulter AU ORDER NO. 15054	Beckman Coulter DU ORDER NO. 15054
ALT (Alanine Aminotransferase)	U/L	6 - 4,113	3 - 900	5 - 400
ALP (Alkaline Phosphatase)	U/L	5 - 4,553	5 - 1,500	5 - 1,000
AMY (Amylase)	U/L	3 - 6,654	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 - 5,255	3 - 1,200	5 - 750
LD (Lactate Dehydrogenase)	U/L	10 - 4,603	25 - 1,200	5 - 750
LIP (Lipase)	U/L	4 - 1,200	3 - 600	10 - 200

ANALYTE	UNIT	Product Configuration: Five Levels		
		Beckman AU480 ORDER NO. 13054	Siemens ADVIA ORDER NO. 13054	Siemens Dimension ORDER NO. 13054
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 - 600	6 - 1,000	0 - 1,000
CK (Creatine Kinase)	U/L	7 - 2,000	5 - 1,000	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	5 - 700	0 - 1,600

ANALYTE	UNIT	Product Configuration: Five Levels
		Orna VITROS ORDER NO. 13054
ALT (Alanine Aminotransferase)	U/L	5 - 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 - 1,500
GGT (Gamma-Glutamyltransferase)	U/L	10 - 1,400
LD (Lactate Dehydrogenase)	U/L	100 - 2,150
LIP (Lipase)	U/L	10 - 2,000

GC3 10775

Typical ranges of recommended panel usage by product are provided as a guideline.

GENERAL CHEMISTRY

GC4

CE

PRODUCT NAME: GC4		Product Calibration: Five Levels		
STORAGE: 10 to 20°C		Address: 11000, 11001 are Two-Level and Five Levels		
ANALYTE	UNIT	Abbott ARCHITECT [®] ORDER NO. 19000	Beckman Coulter DxC ORDER NO. 14000	Roche cobas [®] ORDER NO. 14000
		Total Range	Total Range	Total Range
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 - 30.1

		Siemens ADVIA [®] ORDER NO. 14000	Siemens Dimension [®] ORDER NO. 14000
ANALYTE	UNIT	Total Range	Total Range
DBIL (Direct Bilirubin)	mg/dL	0.1 - 15	0.25 - 15
TBIL (Total Bilirubin)	mg/dL	0.1 - 30	0.1 - 25

		Beckman Coulter AU ORDER NO. 14000	Roche COBAS BIFERON [®] ORDER NO. 14000	
ANALYTE	UNIT	Total Range	Total Range	
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	

		Orion VEROSEP [®] ORDER NO. 14000
ANALYTE	UNIT	Total Range
SET 1		
TBIL (Total Bilirubin)	mg/dL	0.1 - 27
SET 2		
Sc (Conjugated Bilirubin)	mg/dL	0.0 - 27

GC4 NOTE:

Total ranges of recommended total ranges for products are provided as a guide only.

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IRON BINDING CAPACITY



IBC

VALIDATE® IBC

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



IBC

PRODUCT NAME: IBC
STORAGE: -10 to -20°C

Product Configuration: Five Levels

CE

ANALYZER	IRON (µg/dL) Total Iron Range*	UNSATURATED IRON (µg/dL) Total Iron Range**	IRON (µg/dL) Total Range
TIBC (Total Iron Binding Capacity)			
Orion VITROS®	—	—	50 - 600 µg/dL
Siemens Dimension®	—	Levels 1-5	—
Siemens Dimension VIM®	—	Levels 1-5	—
UIBC (Unsaturation Iron Binding Capacity)			
Abbott ARCHITECT	Levels 1-4	—	—
Beckman Coulter AU	Levels 1-4	—	—
Roche cobas®	Levels 1-5	—	—

IBC Formula:

* Analyzers testing UIBC and total iron should run Levels 1 through 5

** Analyzers testing TIBC should run Levels 1 through 5

Typical ranges are recommended, but usage for detection is intended as a guideline.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.292.1300

GLYCOHEMOGLOBIN

validate

VALIDATE[®] HbA1c

HbA1c

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



GLYCOHEMOGLOBIN

HbA1c

PRODUCT NAME: HbA1c
STORAGE: -10 to 30°C

Product Configuration: Five Levels

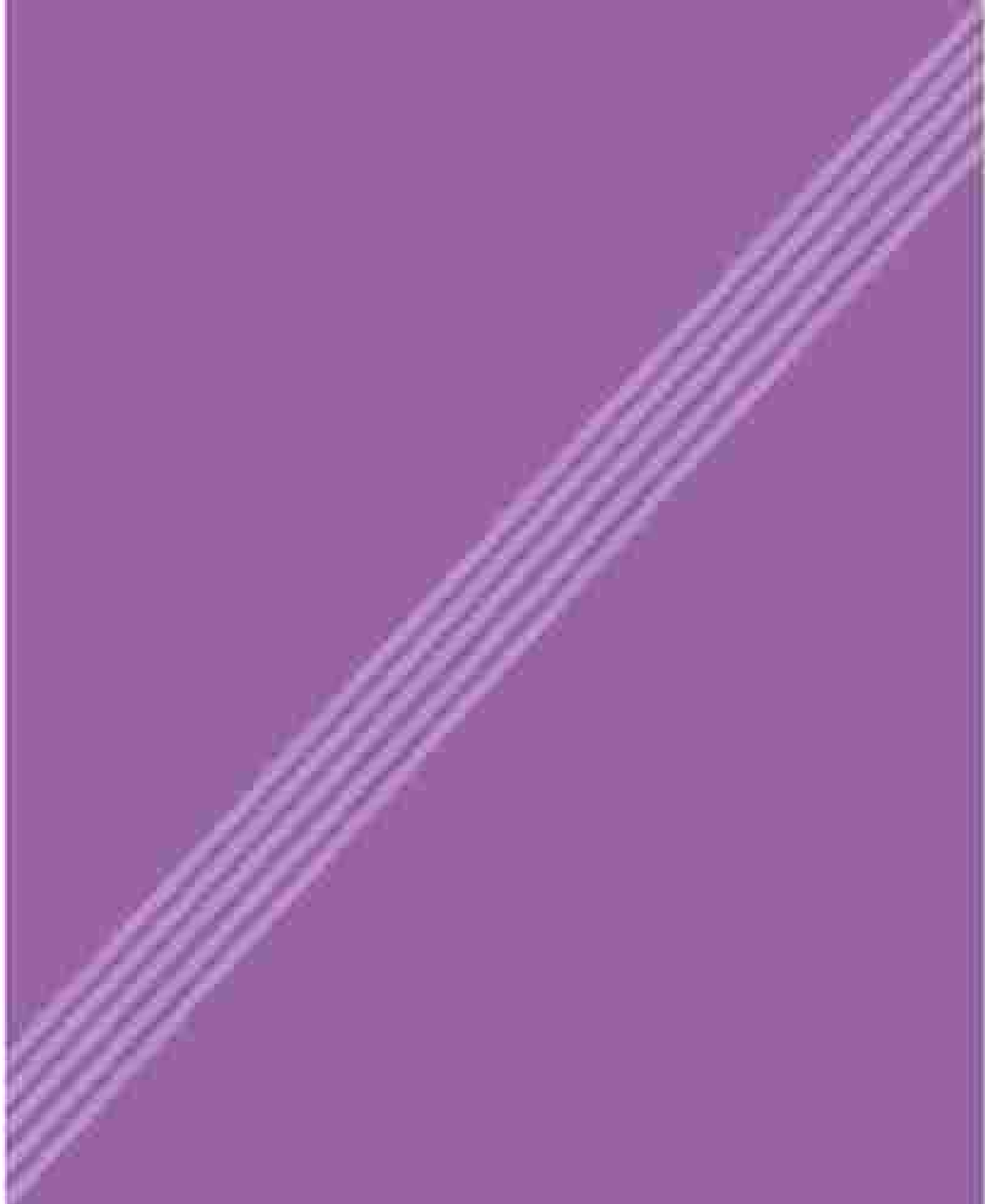
CE

ANALYTE	CHECK KIT USE *Using Level 1 only*	CHECK KIT USE *Using Levels 2-5*
HbA1c (% Glycohemoglobin A1c)		
Ablin ARCHITECT (g)	Levels 1-5	—
Beckman Coulter AU	Levels 1-5	—
Beckman Coulter Unic® DxC / Synchro®	Levels 2-5	—
Bio-Rad VARIANT™	—	Levels 1-5
Orion INTROS®	Levels 1-5	—
Roche cobas®	Levels 1-5	—
Roche Cobas INTEGRAL®	Levels 2-5	—
Siemens ADVIA®	Levels 1-4	—
Siemens Dimension®	Levels 1-4	—
Siemens Dimension Vista®	Levels 1-4	—
Tosoh HCD-728 GII	—	1.7-17.4%

HbA1c NOTES:

*Typical ranges or recommended panel usage for products are provided as a guide only. Analyzers not listed check for Levels 2 through 5.





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TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.5654 OR 1.307.392.1100

Validate

VALIDATE® LP

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



LIPOPROTEINS

LP

CE

PRODUCT MODEL LP
STORAGE: -15 to 30°C

Product Configuration: Two Levels

		Abbott ARCHIMED [®] ORDER NO. 50167 [*]	Beckman Coulter AU ORDER NO. 50167 [*]
Warm	Units	Units Range	Units Range
HDL (High Density Lipoprotein)	mg/dL	5 - 160	2.5 - 200
LDL (Low Density Lipoprotein)	mg/dL	1 - 300	1 - 400

		Beckman Coulter DuC ORDER NO. 50167 [*]	Siemens Dimension ORDER NO. 50167 [*]
Warm	Units	Units Range	Units Range
HDL (High Density Lipoprotein)	mg/dL	5 - 125	3 - 150
LDL (Low Density Lipoprotein)	mg/dL	10 - 500	5 - 300

		Roche COBAS INTENSIF ORDER NO. 50167 [*]	Orion VITROS [®] ORDER NO. 50167 [*]
Warm	Units	Units Range	Units Range
HDL (High Density Lipoprotein)	mg/dL	3.1 - 150	5 - 110
LDL (Low Density Lipoprotein)	mg/dL	3 - 350	10 - 250

LP NOTES:

* Model 50167, 50168, 50169, 50170, 50171. Test kit includes certain Accessories and Accessories as part of the HDL.

Level LDL components: U.S. Patent 7,744,618

Types, ranges and intervals are for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.0484 OR 1.287.392.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.3664 OR 1.267.292.1300

WHOLE BLOOD GLUCOSE

Validate

VALIDATE[®] WHOLE BLOOD GLUCOSE

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



WHOLE BLOOD GLUCOSE CE

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

Product Configuration: Five Levels

Roche ACCU-CHEK[®] Inform II
STRIP (NO. 5011)

ANALYTE
GLU (Glucose)

Typical Clinical Usage¹
Levels 3-5

WHOLE BLOOD GLUCOSE NOTES:





¹ Analyzers not listed operate in Levels 1 through 5.

² Typical ranges of measurement level ranges for products are intended as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9664 OR 1.207.892.1300

validate

VALIDATE[®] TDM1

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

TDM1



THERAPEUTIC DRUGS

TDM1

PACKAGE NAME: TDM1
STORAGE: -10 to 30°C

Product Configuration: Five Levels

CE

ANALYTE	UNIT	Abbott ARCHITECT	Beckman Coulter AU
		CHECK NO. 3114	CHECK NO. 3114a
		Total Range	Total Range
ACTM (Acetaminophen)	µg/mL	3 - 377	0.6 - 377
AMIK (Amikacin)	µg/mL	—	2.5 - 50
CARB (Carbamazepine)	µg/mL	1.0 - 20	2.0 - 20
DIGM (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

ANALYTE	UNIT	Beckman Coulter DxC	Beckman Dimensional
		CHECK NO. 3310	CHECK NO. 3010a
		Total Range	Total Range
ACTM (Acetaminophen)	µg/mL	10 - 300	2 - 300
AMIK (Amikacin)	µg/mL	1.5 - 50	—
CARB (Carbamazepine)	µg/mL	2 - 20	0.5 - 20
DIGM (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 - 6	—
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



PRODUCT NAME: TDM1
STORAGE: 18°C - 25°C

Reagent Configuration: 200µL Pink Levels plus HIGH WATER
100µL in Two Sets of Pink Levels

Reagent: COBAS INTEGRA® ORDER NO. 4111		
ANALYTE	UNIT	Typical Range
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-Acetylmethamphetamine)	µg/mL	0.5 - 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 - 6
SALY (Salicylate)	µg/mL	1.35 - 710
THEO (Theophylline)	µg/mL	0.38 - 40
TGB (Tobramycin)	µg/mL	0.04 - 10
VALP (Valproic Acid)	µg/mL	2.4 - 150
VANC (Vancomycin)	µg/mL	0.74 - 30

Reagent: VITROS® ORDER NO. 1011		
ANALYTE	UNIT	Typical Range
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 - 60
PHYT (Phenytoin)	µg/mL	3 - 40
THEO (Theophylline)	µg/mL	1 - 40
TGB (Tobramycin)	µg/mL	0.8 - 10
VALP (Valproic Acid)	µg/mL	10 - 150
VANC (Vancomycin)	µg/mL	5 - 60
SET 2		
SALY (Salicylate)	mg/dL	1 - 40

NOTE:

Typical ranges of concentrations listed above for products are provided as a guide only.



TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.852.1300

validate

VALIDATE[®] UC

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

UC



URINE CHEMISTRY

UC1

CE

PRODUCT NAME: UC1		Product Configuration: Two Tests at Five Levels		
STORAGE: 2-8°C		BioMérieux Coulter AU ORDER NO. 701au	BioMérieux Coulter DC ORDER NO. 701dc	Siemens Dimension® ORDER NO. 701ub
ANALYTE	Units	Typical Range	Typical Range	Typical Range
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	4 - 150	4 - 250
UAH (Urea Nitrogen)	mg/dL	20 - 1,300	50 - 1,000	0 - 1,500

		Roche Cobas INTEGRAL ORDER NO. 701i	Roche cobas® ORDER NO. 701s	Orbis VITROS® ORDER NO. 701v
ANALYTE	Units	Typical Range	Typical Range	Typical Range
SET 1				
UA (Uric Acid)	mg/dL	0.2 - 100	2.2 - 100	5.5 - 100
SET 2				
Cl ⁻ (Chloride)	mmol/L	20 - 300	20 - 250	15 - 310
EtOH (Ethyl Alcohol)	mg/dL	10 - 400	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
UAH (urea Nitrogen)	mg/dL	2.8 - 5,600	2.8 - 5,600	67 - 2,520

UC4

CE

PRODUCT NAME: UC4		Product Configuration: Five Levels		
STORAGE: 2-8°C		BioMérieux Coulter AU ORDER NO. 704au	BioMérieux Coulter DC ORDER NO. 704dc	Siemens Dimension® ORDER NO. 704ub
ANALYTE	Units	Typical Range	Typical Range	Typical Range
CA (Calcium)	mg/dL	0 - 40	2 - 30	5 - 15
CREA (Creatinine)	mg/dL	0 - 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 INTEGRAL ORDER NO. 704i	Roche cobas® ORDER NO. 704s
ANALYTE	Units	Typical Range	Typical Range
CA (Calcium)	mg/dL	0.8 - 30.1	0.8 - 30.1
CREA (Creatinine)	mg/dL	0.3 - 450	0.1 - 610
MG (Magnesium)	mg/dL	1.8 - 30.4	1.4 - 26.7
PHOS (Phosphorus)	mg/dL	3.41 - 285	3.4 - 265

UC5



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

Product Configuration: Five Levels

ANALYTE	UNITS	Roche Cobas Integra®		
		Reclina® Counter RD ORDER NO. 70501*	Reclina® Counter DxC ORDER NO. 70502**	Summa Dimension® ORDER NO. 71001
AMY (Amylase)	U/L	10 - 1,800	5 - 1,200	0 - 650
µALB (Micro-Albumin)	mg/L	2 - 400	2 - 300	1.3 - 100
PANFY (Pancreatic Amylase)	U/L	—	—	0 - 650

ANALYTE	UNITS	Roche COBAS INTEGRA®		
		Reclina® Counter RD ORDER NO. 70501**	Reclina® Counter DxC ORDER NO. 70502	Orta VITROS® ORDER NO. 70501
AMY (Amylase)	U/L	3 - 2,000	3 - 1,500	30 - 1,200
µALB (Micro-Albumin)	mg/L	1.2 - 200	1.2 - 400	5 - 200
PANFY (Pancreatic Amylase)	U/L	3 - 1,800	3 - 1,500	—

UC6



PRODUCT NAME: UC6
STORAGE: 2 to 8°C

Product Configuration: Two sets of Five Levels

ANALYTE	UNITS	Item Within®	
		ORDER NO. 70501	ORDER NO. 70502
ALB SET			
ALB (Albumin)	mg/L	5.0 - 300.0	
CREAT SET			
CREA (Creatinine)	mg/dL	0.4 - 3.0	

UC5 and UC6 NOTES:

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

UC5 NOTES:

* 70501: Test kit also contains PANFY as part of the AMY component.

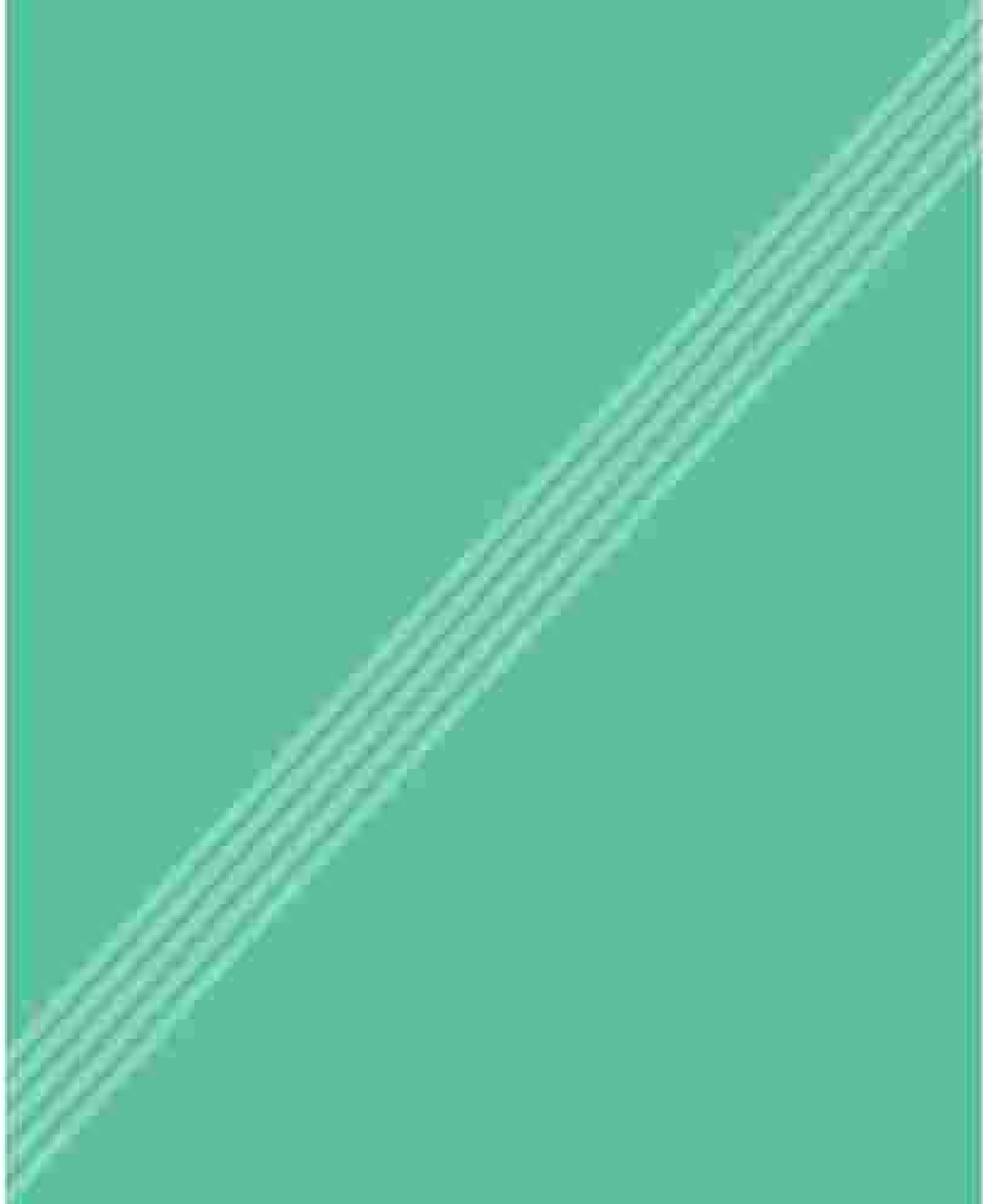
** 70502: Test kit also contains PANFY as part of the AMY component.

*** 70501: Assay Levels 1 through 4 only for PANFY. Level 5 will typically require above the specified 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 1.800.577.5664 OR 1.202.492.1500

OSMOLALITY

Validate

VALIDATE[®] OSMO

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



OSMO

CE

PRODUCT NAME: OSMO
STORAGE: 2-8°C

Product Configuration: Two Sets of Five Levels

Part #100
Order No. 700

NOTE	UNIT	Total Range
SET 1		
UOSMO (Urine Osmolality)	mOsm/kg H ₂ O	0 – 2,000
SET 2		
SOSMO (Serum Osmolality)	mOsm/kg H ₂ O	0 – 2,000





CLINICAL NOTES:

Typical ranges or recommended level ranges for products are provided as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.3684 OR 1.307.893.1506



VALIDATE[®] CM

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



GARDIAC MARKER PRODUCTS

CM1

CE

PRODUCT NAME: CM1
STORAGE: -10 to -20°C

Product Configuration: Five Levels

ANALYTE	UNITS	Product Configuration: Five Levels		
		Abbott ARCHITECT ORDER NO. 411a0	Beckman Coulter DxC ORDER NO. 491a	Siemens Dimension® ORDER NO. 401a
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
STORAGE: -10 to -20°C

Product Configuration: Five Levels
4020 is Five Levels plus a High Td

ANALYTE	UNITS	Product Configuration: Five Levels	
		Abbott ARCHITECT ORDER NO. 401a	Beckman Coulter DxC ORDER NO. 401a
BNP (Brain Natriuretic Peptide)	pg/mL	10 - 5,000	1 - 5,000
hs-CRP (High Sensitivity C-Reactive Protein)	mg/dL	0.01 - 15.0	0.02 - 8
TnI (Troponin I)	ng/mL	0.02 - 50	0.03 - 100

ANALYTE	UNITS	Product Configuration: Five Levels
		Siemens Dimension® ORDER NO. 401a
hs-CRP (High Sensitivity C-Reactive Protein)	mg/L	0.2 - 20
NT-proBNP (Brain Natriuretic Peptide)	pg/mL	5 - 35,000
TnT (Troponin T)	ng/mL	0.01 - 35

CM1 NOTES

* Intended for use as a 90-minute CK-MB method. Not compatible with CK-MB immunoassay methods intended for use by IVD. Typical ranges or measurement level usage for products are provided as a guide only.

CM2 NOTES

Typical ranges or measurement level usage for products are provided as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9654 OR 1.202.392.1300

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.4184 OR 1.207.292.1300

THYROID

Validate

VALIDATE® THY

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



THY

THY



PRODUCT NAME: THY
STORAGE: -10 to +35°C

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

		Beckman Coulter Del ORDER NO. 9910c	Roche cobas® ORDER NO. 9910c
SKU/III	Units	Typical Range	Typical Range
FT4 SET			
FT4 (Free Thyroxine)	ng/dL	0.25 - 6.0	0.1 - 7.77
THY SET			
CORT (Cortisol)	µg/dL	0.4 - 6.0	0.036 - 63.4
Free T3 (Free Triiodothyronine)	ng/mL	*	*
TSH (Thyroid Stimulating Hormone)	µIU/mL	0.01 - 50	0.005 - 100
TT4 (Total Thyroxine)	µg/dL	0.5 - 30	0.430 - 34.9
TT3 (Total Triiodothyronine)	ng/mL	0.1 - 6.0	0.195 - 6.51

THY NOTES:

FT3 is a component of TT3. Results may vary.

*Typical ranges or recommended) Limit usage for production intended as a 3000 unit.



TO ORDER OR FOR MORE INFORMATION, CALL 1.866.377.3634 OR 1.877.892.1288

VITAMIN D



VALIDATE® VIT D

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



VIT D

VIT D

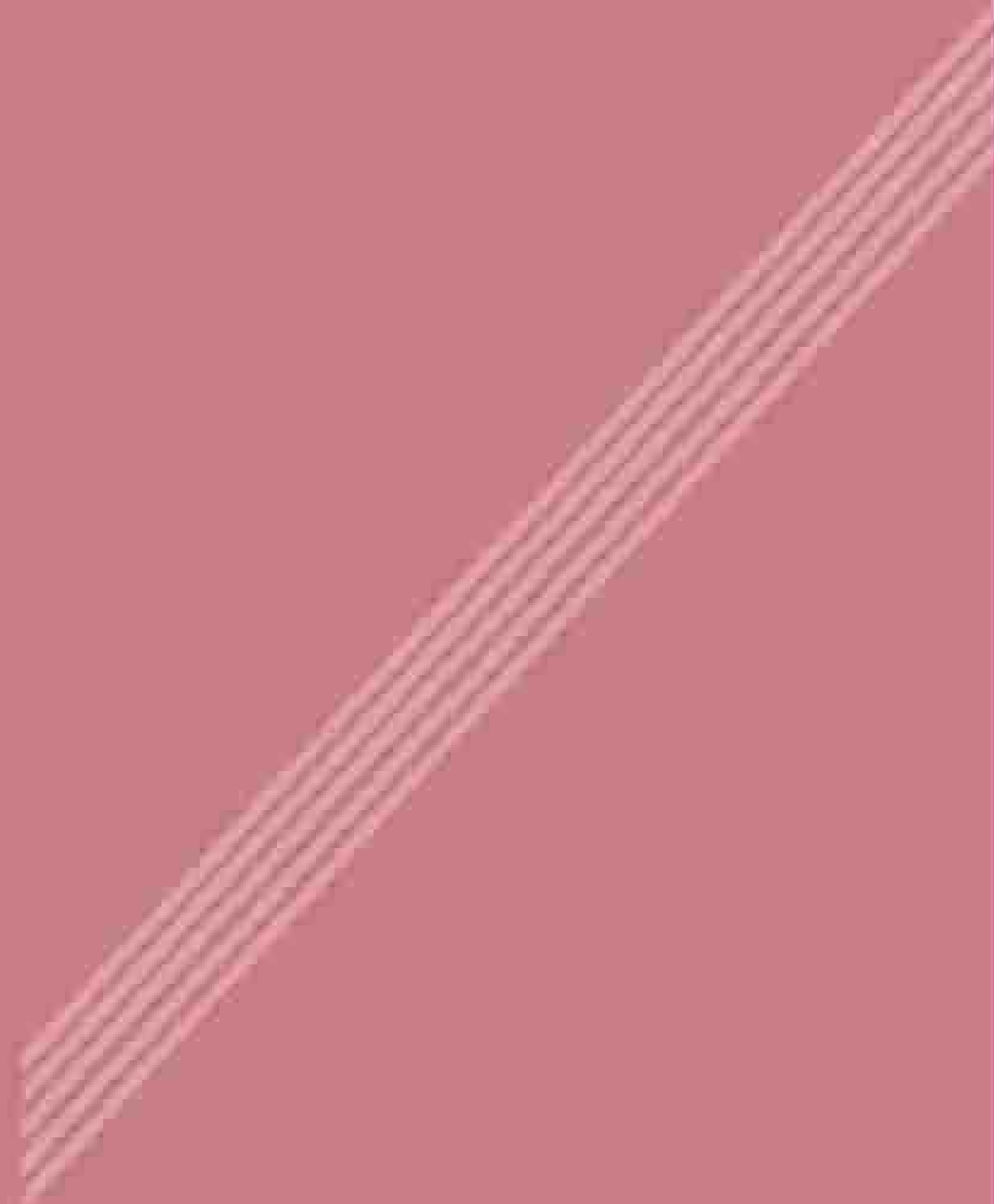
CE

PRODUCT NAME: VIT D
STORAGE: -10 to +20°C

Product Configuration: Five Levels
30000 IU Six Levels

ANALYTE	UNITS	Abbott ARCHITECT	Siemens ADVIA Centaur®	Orion VITROS®
		ORDER NO. 8046	ORDER NO. 104	ORDER NO. 4914
		Typical Range	Typical Range	Typical Range
VIT D (Vitamin D)	ng/mL	7 - 132	4.0 - 150	20 - 120

VIT D NOTES:
Typical ranges or recommendations used for products are intended as a guide only.



TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.833.1336

SERUM PROTEIN PRODUCTS

Validate

VALIDATE[®] SP

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



SP1

CE

PRODUCT NAME: SP1
STORAGE: -10 to -20°C

Available Configuration: 50 Levels and 5 Levels
Shipping: 100 Levels and 5 Levels

Analyte	Units	Serum Control DcC	
		Order No. 8910c	Order No. 8910c
		Total Range	Type Range
AAT (α1-Antitrypsin)	mg/dL	20 - 600	—
C3 (Complement C3)	mg/dL	10 - 360	10 - 360
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
IGH (Immunoglobulin M)	mg/dL	25 - 400	25 - 3,400
TRFN (Transferrin)	mg/dL	70 - 850	70 - 850

SP1 NOTES:

Type ranges are recommended. Use range for products are intended as a guideline.

SP

SERUM PROTEIN PRODUCTS

SP2

CE

Intended Use: SP2 Product Configuration: Full Lines
 STORAGE: 2-8°C

	BeAman Sartin DAC Order No. 11201
Component	Order Line Range*
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

	Units	Order Range*
Component	Units	Order Range
ALB (Albumin)	g/dL	1.1 - 5.8
CEP (Ceruloplasmin)	mg/dL	7 - 140
CRP (C-Reactive Protein)	mg/L	0.7 - 364
HPT (Haptoglobin)	mg/dL	14 - 500
PAB (Prealbumin)	mg/dL	8 - 77
RF (Rheumatoid Factor)	IU/dL	18 - 135

SP2 NOTES:

* Analytical test lines should run Levels 1 through 5.

† Typical ranges are maximums only. Usage for products are limited to a (µ)50 only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.558.377.2664 OR 1.207.852.1200



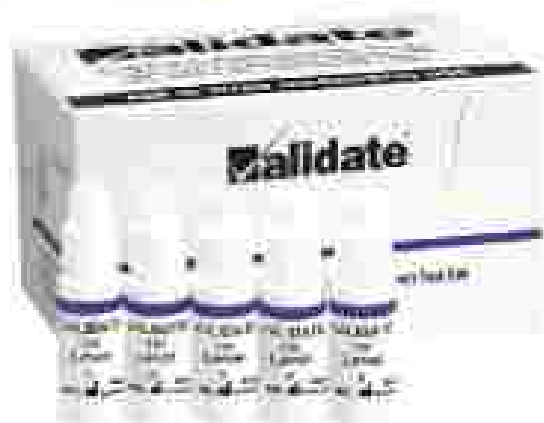
TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9684 OR 1.207.892.1300

TUMOR MARKERS



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

Analyte	Roché assay [®] cobas [®] c04574	Siemens ADMA Cobas [®] cobas [®] c04574
	Typical Use Usage	Typical Use Usage
CA 15-3 (Cancer Antigen 15-3)	Levels 1 - 5	Levels 1 - 5
CA 18-8 (Cancer Antigen 18-8)	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:

- * Analyte not listed should be Levels 1 through 5.
- † Use of range is recommended for usage for products intended as a guide only.

TUMOR MARKERS

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.4654 OR 1.507.893.1300

PROSTATE SPECIFIC ANTIGEN

Validate[®]

VALIDATE[®] PSA

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



PSA

PRODUCT NAME: PSA
STORAGE: 18°C - 25°C

Format Configuration: Five Levels

		Roche cobas [®] Counter DxC ORDER NO. 4049	Roche cobas [®] ORDER NO. 4051*
(WAS 13)	MUS	Topic: 100011	Topic: 100011
IPSA (Free PSA)	ng/mL	0.005 - 20	0.015 - 50
IPSA (Total PSA)	ng/mL	0.005 - 100	0.015 - 100

PSA NOTES:

*4051: Not intended for use with coagula PSA reagents.

*Typical (approximate) recommended level usage for products are intended as a guideline.



TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9644 OR 1.307.292.1300

ANEMIA

Validate[®]

VALIDATE[®] ANEMIA

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



validate

ANEMIA

ANEMIA



PRODUCT NAME: ANEMIA
STORAGE: -10 to +35°C

Product Configuration: FERR set is FOL Level
With FOL, B12 set is FOL Level
With FOL, B12 set is FOL Level

ANALYTE	CLINICAL USE: Indication	Typical Range*
FERR Set		
FERR (Ferritin)		
Beckman Coulter Unicel® DxJ / Access®	Levels 1 - 5	
Orion VITROS®	Levels 1 - 4	
FOL / B12 Set		
FOL (Folate)		
Beckman Coulter Unicel® DxJ / Access®	Levels 1 - 5	
Orion VITROS®	Levels 1 - 5	
B12 (Vitamin B12)		
Beckman Coulter Unicel® DxJ / Access®	Levels 1 - 4	
Orion VITROS®	see notes	
ANALYTE	CLINICAL USE: Indication	Typical Range*
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 licensed for use on the Siemens Advia Centaur. Analyzers not listed should run Levels 1 through 5.

** See the Top 3000 for more Vitamin B12 levels available with the Orion VITROS instrument's measuring range.

* Typical ranges/level ranges/level usage for products are marked as (i) (j) (k) (l) (m).

ANEMIA



Validate

VALIDATE[®] FERRITIN

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



ANEMIA

FERRITIN

CE

PRODUCT NAME: FERRITIN
STORAGE: -10 to +35°C

Product Certification: For Levels

ANALYTE:

CHEMICAL: IRON
Tested Level Range*

FERR (Fer 2n)

Abbott Architect (i)	Levels 1 - 4
Beckman Coulter Unic® DxI / Access®	Levels 1 - 5
Ohta VITROS®	Levels 1 - 4
Roché 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 will still run Levels 1 through 5.

† Type(s) in grey or recommended Level(s) in grey for products are provided as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.9555 OR 1.207.892.1300



TO ORDER OR FOR MORE INFORMATION, CALL 1.800.277.9894 OR 1.202.892.1300

Validate[®]

VALIDATE[®] FERTILITY

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



FERTILITY

FERTILITY 1

CE

PRODUCT NAME: FERTILITY 1
STORAGE: -10 to -30°C

Physical Configuration: Two Sets of Five Levels

NAME	Radioactivity/Element ORIGIN NO. ISOTOPE
UNITS	1 (Scale in U/L)
FERT 1 Set	
FSH (Follicle-stimulating Hormone)	Levels 1 - 5
HCG (Human Chorionic Gonadotroph)	Levels 1 - 5
LH (Luteinizing Hormone)	Levels 1 - 5
PRL (Prolactin)	Levels 1 - 5
TSTD Set	
TSTD (Testosterone)	Levels 1 - 5

FERTILITY 2

CE

PRODUCT NAME: FERTILITY 2
STORAGE: -10 to -30°C

Physical Configuration: Two Sets of Five Levels

NAME	Radioactivity/Element ORIGIN NO. ISOTOPE
UNITS	1 (Scale in U/L)
AFF (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 listed on a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.577.8654 OR 1.207.892.1300





TO ORDER OR FOR MORE INFORMATION, CALL 1.800.777.9894 OR 1.207.892.1300

HEMOSTASIS



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VALIDATE[®] HEMOSTASIS

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



Validate

HEMOSTASIS

D-DIMER

CE

PRODUCT NAME: D-DIMER
STORAGE: -15 to 37°C

Product Configuration: Flat Level

	Instrumentation Laboratory ACL TOP® ORDER NO. 9039	Siemens Systems CS ORDER NO. 9039e	Siigo STP® ORDER NO. 9039t
ANALYTE	Type: Range	Type: Range	Type: Range
D-Dim (D-Dimer)	151 - 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: -15 to 37°C

Product Configuration: Flat Level

	Instrumentation Laboratory ACL TOP® ORDER NO. 9039	Siemens Systems CS ORDER NO. 9039e	Siigo STP® ORDER NO. 9039t
ANALYTE	Type: Range	Type: Range	Type: Range
HP (Heparin Anti-Xa)	0.11 - 1.77 U/mL	0.13 - 1.29 U/mL	0.19 - 1.70 U/mL

FIBRINOGEN

CE

PRODUCT NAME: FIBRINOGEN
STORAGE: -15 to 37°C

Product Configuration: Flat Level

	Instrumentation Laboratory ACL TOP® ORDER NO. 9041	Siemens Systems CS ORDER NO. 9041e	Siigo STP® ORDER NO. 9041t
ANALYTE	Type: Range	Type: Range	Type: Range
FBR (Fibrinogen)	55 - 714 mg/dL	94 - 432 mg/dL	207 - 762 mg/dL

TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.5634 OR 1.307.392.1300



TO ORDER OR FOR MORE INFORMATION, CALL 1.800.377.6634 OR 1.307.322.1100

PROCALCITONIN

Validate

VALIDATE[®] PROCALCITONIN

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



PROCALCITONIN

CE

PRODUCT NAME: Procalcitonin
STORAGE: 18 to 25°C

Product Configuration: Five Levels

ANALYTE	UNIT	Roche cobas [®] ORDER NO. 45316	Abbott ARCHITECT [®] ORDER NO. 40346
PCT (Procalcitonin)	ng/mL	0.05 - 51.7	0.03 - 52.5

PROCALCITONIN NOTES:

Typical ranges of measurement and usage for products are provided as a guide only.

TO ORDER OR FOR MORE INFORMATION, CALL 1-800-272-9444 OR 1-202-393-1152



VALIDATE[®] BODY FLUIDS

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



BODY FLUIDS

BODY FLUIDS

HighCen™ 500FAS105
 10000001000000

HighCen™ 500FAS105

CE

Analyte	Units	Roche status*
		Order ID: 3000
ALB (Albumin)	g/dL	0.3 - 5.5
AMY (Amylase)	U/L	8 - 1,137
CA 19-9 (Cancer Antigen 19-9)	U/ml	2.4 - 871
CEA (Carcinoembryonic Antigen)	ng/mL	3.8 - 949
CHOL (Cholesterol)	mg/dL	4 - 768
CREA (Creatinine)	mg/dL	0.3 - 22.5
GLU (Glucose)	mg/dL	5 - 697
LAC (Lactate)	mg/dL	3 - 132
LD (Lactate Dehydrogenase)	U/L	9 - 907
TP (Total Protein)	g/dL	0.5 - 9.2
TRIG (Triglycerides)	mg/dL	8 - 863
UUN (Urea Nitrogen)	mg/dL	3.0 - 113

*Body Fluids Acute

Tyical ranges or recommended levels usage in products are intended as a guide only

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