

Independent Quality Controls and Informatic Software Solutions for Roche **cobas**® Systems







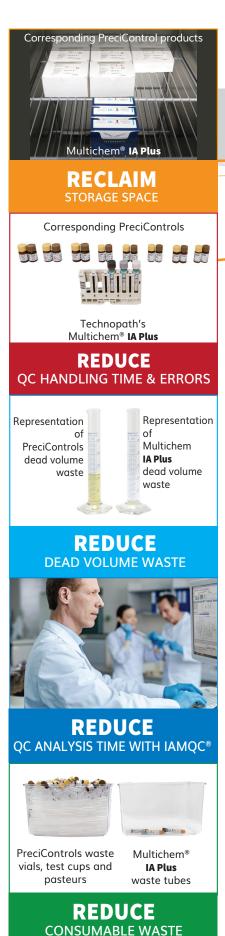
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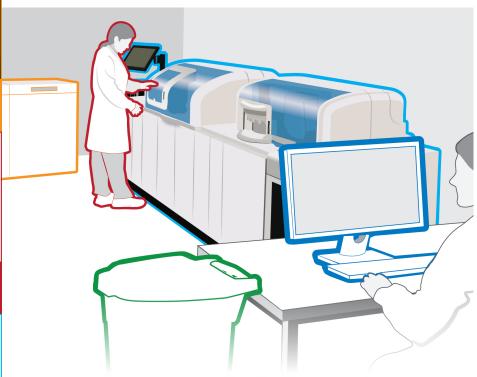
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Enhance laboratory efficiencies with Technopath Clinical Diagnostics QC solutions



Reclaim storage space

Switching to a consolidated solution frees up space in the laboratory freezer which can ultimately be used for alternative purposes or to hold stock of QC that will cover a much longer time period.

Reduce QC handling time and errors

Consolidating QC materials results in significant labour savings by reducing the handling requirements involved in running a QC process. Independent studies have also shown that a reduction in the physical numbers of internal quality control vials can lead to a reduction in transposition errors made by laboratory staff.

Reduce dead volume waste

Consolidating a number of products in to one leads to a reduction in dead volume waste, which in turn means a reduction in the overall volume of QC material required to be purchased.

Reduce QC analysis time

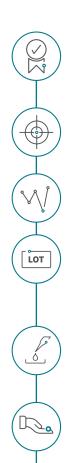
Automated connectivity solutions with IAMQC® interlaboratory peer program, streamlines data collection thus reducing QC analysis time.

Reduce weight of consumable waste

Fewer vials and less packaging means a laboratory will produce less waste, significantly reducing it's carbon footprint.



Technopath and Roche help your laboratory achieve greater efficiencies in QC processes through reduced handling time, reduced costs and barcoded vials.



Accreditation/regulatory compliance

Independent QC material facilitates meeting accreditation and regulatory guidelines, such as CLIA, CLSI, CAP, ISO and RiliBÄK.

Targeted at clinical decision points

Controls material targeted at clinical decision points helps improve clinicians' confidence in the validity of test results.

Value assigned

Value assignment saves technologist time when setting up initial reference intervals.

Automated configuration of new QC lots

Faster turn around time for quality control set up. Use the automated QC configuration process to upload the QC targets and ranges directly on to your Roche system, reducing errors and increasing productivity.

Human-based matrices

Human-based matrices provide patient-like performance to increase confidence in QC material results.

Reduction in handling errors

All Technopath Multichem controls are liquid, meaning no reconstitution of lyophilised controls.

Streamlined supply chain

Reduction in the number of part numbers to be purchased streamlines the supply chain. Fewer part numbers equates to a lower number of lots to manage.



Results upload to IAMQC Peer with Roche cobas® mobile solutions connector Automatic upload of QC results to IAMQC Peer. [1]

Inter-Lab QC Comparison Reports

Technopath IAMQC® Peer software offers Six-Sigma, Levey-Jennings, Youden, Bias, Group Coordinator, Measurement of Uncertainty, Monthly Summary, and Exceptions reports to give your laboratory the information it requires to monitor QC. Multiple languages are supported. [2] [3]

^{1.} Contact your Roche representative for more information on the cobas Mobile Solutions Connector.

^{2. &}quot;The laboratory shall participate in inter-laboratory comparisons" ISO15189:2022.

^{3. &}quot;[A] laboratory should actively participate in inter-laboratory QC programs when such programs are available." CLSI C-24 4th edition.



A Guide on How to Access and Review **Multichem Instructions for Use (IFU)**

Multichem independent third party quality control (QC) materials are classed as in-vitro diagnostic medical devices. Therefore, it is important that the Instructions For Use (IFU) for each lot is read and adhered to.

The IFU contains important information in relation to:

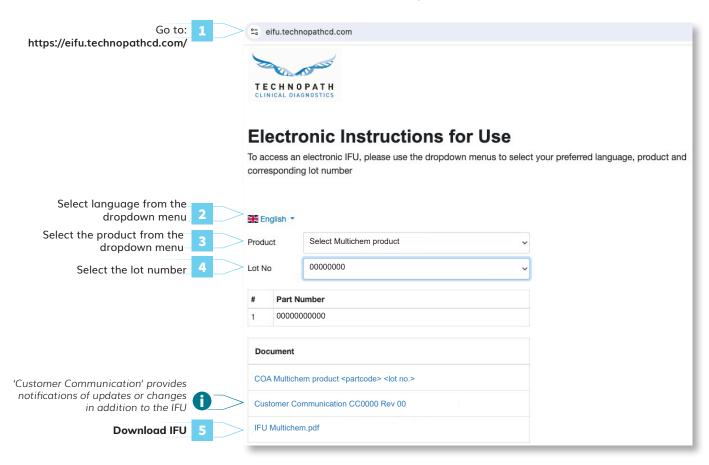
- Precautions that users should take while handling the product
- Procedure for use
- Storage, stability and exceptions where applicable
- Limitations of the product
- Representative values, specific to each lot of product



Accessing Multichem IFUs

https://eifu.technopathcd.com/

Multichem IFUs for Roche cobas® are available from the Technopath eIFU website.





Important information contained in the Multichem IFU

All details contained with the IFU are important. For daily running of QC, particular attention should be given to the sections below.

Precautions

PRECAUTIONS

Warning: Biological source material. Treat as potentially infectious.

For In Vitro Diagnostic Use.

All users should make themselves familiar with the precautions set out in the IFU. This information will help the user to take the necessary steps for the safe handling of materials.

Procedure for Use

PROCEDURE FOR USE

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent

Procedure for use varies between different Multichem controls. Laboratory personnel should review product specific handling information.

Storage

STORAGE

This product will be stable until the expiration date when stored unopened

Multichem control storage requirements vary between products. Multichem quality controls are stable until the expiration date when stored correctly.

Product Stability & Exceptions



Review each lot number for product specific stability claims and exceptions

Limitations

LIMITATIONS

- Do not use the product past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the tube.

Refer to the material limitations, ensuring correct use of the product.

Representative Values



Analyte target values and ranges are provided in the IFU. Values are derived from multiple replicates and are specific for each lot.

Target values and ranges can be downloaded onto compatible **cobas**® instruments via Cobas Link.





Multichem® IA Plus

Test consolidation for immunoassay quality control in a liquid stable format



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Test consolidated immunoassay control includes general IA, cardiac markers and tumor markers
- Assayed and value assigned for Roche cobas® systems
- Tri-level utility

Specifications

- 36 month closed vial stability at -20°C to -80°C
- 10 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem IA Plus	Assayed Level 1	12 x 4mL (48mL)	09339825190
	Assayed Level 2	12 x 4mL (48mL)	09339841190
	Assayed Level 3	12 x 4mL (48mL)	09339850190

Analytes with performance and stability claims*:

Adrenocorticotropic hormone (ACTH)	Ferritin	Prolactin
Alpha-Fetoprotein (AFP)	Folate	Prostate Specific Antigen, Free
Androstenedione	Folicle Stimulating Hormone (FSH)	Prostate Specific Antigen, Total
Anti-Thyroglobulin (Anti-Tg)	Human Chorionic Gonadotropin +ß	Sex Hormone Binding Globulin (SHBG)
Anti-Thyroperoxidase (Anti-TPO)	(hCG+ß) STAT	T Uptake
CA 125	Human Chorionic Gonadotropin +B	Testosterone
CA 15-3	(hCG+ß)	Thyroglobulin (Tg)
CA 19-9	Human Growth Hormone (hGH)	Thyroid Stimulating Hormone (TSH)
Calcitonin	IGF-1	Thyroxine, Free (FT4)
Carcinogenic Embryonic Antigen (CEA)	Immunoglobulin E (IgE)	Total T3
CK-MB	Insulin	Total T4
Cortisol	Leutinizing Hormone (LH)	Triiodothyronine, Free (FT3)
C-Peptide	Myoglobin	Troponin I
DHEA-S	Parathyroid Hormone (PTH)	Troponin T
Digoxin	Parathyroid Hormone 1 - 84 (PTH)	Vitamin B12
Estradiol	NT-pro BNP	Vitamin D, Total
	Progesterone	

Analytes below may be present in the product. No claims are made regarding performance and stability.

17-OH Progesterone	Estriol, Free	Primidone
Acetaminophen	Estriol, Total	Procainamide
Aldosterone	Estrogen, Total	Procollagen NP Type 1
Amikacin	Ethosuximide	Quinidine
Angiotensin	Gentamicin	Renin
Anti-CCP	Homocysteine	Salicylate
BNP	Ibuprofen	Testosterone, Free
Caffeine	Lidocaine	Theophylline
Carbamazepine	Lithium	Thyroxine Binding Globulin
Carbamazepine, Free	N-Acetyl procainamide	Tobramycin
Chloramphenicol	Ostase	Ultra-sensitive CRP
Cyclosporine	Phenobarbital	Valproic Acid
Disopyramide	Phenytoin	Valproic Acid, Free
EPO	Phenytoin, Free	Vancomycin

^{*}Refer to lot specific IFU for analyte performance and stability claims.



Multichem® S Plus

Test consolidation for serum chemistry and immunology quality control in a liquid stable format



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed and value assigned for Roche cobas® systems
- Tri-level utility for cholesterol HDL & LDL, Apo A1, Apo B and immunoproteins including sTfR

Specifications

- 36 month closed vial stability at -20°C to -80°C
- 10 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem S Plus	Assayed Level 1	12 x 4mL (48mL)	09339795190
	Assayed Level 2	12 x 4mL (48mL)	09339809190
	Assayed Level 3	12 x 4mL (48mL)	09339817190

Analytes with performance and stability claims*:

Acetaminophen Acid Phosphatase (Total)

Alanine Aminotransferase (ALT)

Albumin

Alkaline Phosphatase (ALkP) Alpha-1 Acid Glycoprotein Alpha-1 Antitrypsin

Alpha-Hydroxybutyrate dehydrogenase

Amikacin

Amylase, Pancreatic Amylase, Total Anti-streptolysin O (ASO) Apolipoprotein A1 (APO A1) Apolipoprotein B (APO B)

Aspartate Aminotransferase (AST)

Beta-2 Microglobulin Bicarbonate (CO2) Bilirubin Direct Bilirubin Total Calcium Carbamazepine Ceruloplasmin Chloride

Cholesterol, HDL

Cholesterol, LDL Cholesterol, Total Cholinesterase Complement C3 Complement C4 C-Reactive Protein (CRP)

Creatine Kinase (CK) Creatinine Diaoxin Ethanol Ferritin

Fructosamine Gamma Glutamyltransferase (GGT)

Gentamicin Glucose Haptoglobin Homocysteine Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM)

Kappa Light Chain

Lactate

Lactate Dehydrogenase (LDH) Lambda Light Chain

Lipase

Lipoprotein (a) Lithium Magnesium Phenobarbital Phenytoin **Phosphate** Potassium Prealbumin

Rheumatoid Factors (RF)

Salicylate Sodium

Soluble Transferrin Receptor (sTfR)

Theophylline **Tobramycin Total Protein** Transferrin **Triglycerides** Ultra sensitive CRP

Unsaturated Iron-Binding Capacity (UIBC)

Urea Uric Acid Valproic acid Vancomycin

Analytes below may be present in the product. No claims are made regarding performance and stability.

Acid Phosphatase (Non Prostatic) ADNase B (Anti-Streptococcal DNase B) Alpha 2 Macroglobulin Anti-thrombin III Beta Hydroxybutyrate Dehydrogenase

Bile acids Bilirubin Indirect C1 Inhibitor Caffeine

Calcium Ionized

CH50 (Total hemolytic Complement)

CKMB Copper Cortisol Cystatin C Hemopexin IgG1, Subclass IgG2, Subclass

IgG3, Subclass

IgG4, Subclass Osmolality Phospholipids Properdin Factor B Protein Electrophoresis Retinol Binding Protein **Total Iron Binding Capacity** Thyroxine (T4)

Triiodothyronine Zinc

^{*}Refer to lot specific IFU for analyte performance and stability claims.



Multichem® P

Test consolidation for serum elevated immunoprotein quality control in a liquid stable format



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed and value assigned for Roche **cobas**® systems
- Supplementary single-level immunoprotein control to complement Multichem S Plus
- Provides tri-level utility for RF when used in conjunction with Multichem S Plus

Specifications

- 36 month closed vial stability at -20°C to -80°C
- 14 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem P	Level P	12 x 4mL (48mL)	09339884190

Analytes with performance and stability claims*:

Abumin Alpha-1 Acid Glycoprotein Alpha-1 Antitrypsin Apolipoprotein A-1 (APO A1) Apolipoprotein B (APO B) Beta-2 Microglobulin Ceruloplasmin

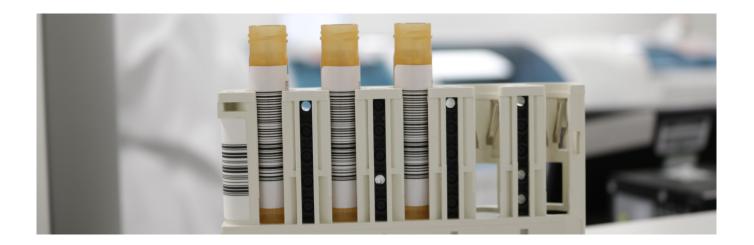
Complement C3 Complement C4 C-Reactive Protein (CRP) Haptoglobin Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM)

Prealbumin Rheumatoid Factors (RF) Soluble Transferrin Receptor (sTfR) **Total Protein** Transferrin

Analytes below may be present in the product. No claims are made regarding performance and stability.

ADNase B (Anti-Streptococcal DNase B) Cystatin C Alpha-2 Macroglobulin Ferritin Angiotensin Converting Enzyme Hemopexin Antistreptolysin O (ASO) laE Antithrombin III lgG1, Subclass C1 Inhibitor IgG2, Subclass CH50 (Total hemolytic Complement) IgG3, Subclass IgG4, Subclass Kappa Light Chain Lambda Light Chain Lipoprotein (a) Properdin Factor B **Retinol Binding Protein**

^{*}Refer to lot specific IFU for analyte performance and stability claims.





Multichem® U

Test consolidation for urinary chemistry quality control in a liquid stable format



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- · Bi-level utility
- Greater stability and performance for creatinine
- Assayed and value assigned for Roche **cobas**® systems
- Addition of human-based microalbumin provides greater accuracy and performance

Specifications

- 24 month closed vial stability at 2°C to 8°C
- 30 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem U	Assayed Level 1	12 x 3mL (36mL)	09339868190
	Assayed Level 2	12 x 3mL (36mL)	09339876190

Analytes with performance and stability claims*:

Amylase Magnesium **Total Protein Urine** Calcium Microalbumin Urea Chloride Phosphate Uric acid Creatinine Potassium Glucose Sodium

Analytes below may be present in the product. No claims are made regarding performance and stability.

Cortisol Osmolality hCG Specific Gravity

^{*}Refer to lot specific IFU for analyte performance and stability claims.





Multichem® ID-G

Multi-analyte infectious disease quality control



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Qualitative quality control optimized for Roche cobas® systems and reagents.
- Suitable for HIV Duo assay with negative claim for HIV 1 p24 antigen

Specifications

- 24 month closed vial stability at 2°C to 8°C
- 30 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem ID-G	Single Level	4 x 4mL (16mL)	09339892190
Positive For:			
Anti-HBc IgG		Anti-HTLV I IgG ¹	
Anti-HCV IgG		Anti-Treponema palli	dum IgG
Anti-HIV 1 lgG		HBsAg	

Multichem® ID-HIV p24

Infectious disease quality control



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Qualitative quality control optimized for Roche cobas® systems and reagents.
- Suitable for HIV Duo assay with negative claim for Anti-HIV 1 IgG

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- 24 month closed vial stability at 2°C to 8°C
- 30 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem ID-HIV p24	Single Level	4 x 4mL (16mL)	09915494190
Positive For:			

HIV 1 p24 Antigen

Multichem® ID-GNeg

Multi-analyte infectious disease quality control



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Qualitative quality control optimized for Roche cobas® systems and reagents.

Specifications

- 36 month closed vial stability at 2°C to 8°C
- 30 day open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem ID-GNeg	Single Level	4 x 4mL (16mL)	09339906190

Negative For: Anti-HBc IgG Anti-Treponema pallidum IgG Anti-HCV IgG HBsAg Anti-HIV 1 lgG HIV 1 p24 Antigen Anti-HTLV I IgG1



IAMOC® Interlaboratory peer program

The easiest way to automate QC data from Technopath's Multichem® independent quality controls.



Technopath's IAMQC interlaboratory peer program enables a laboratory to choose **real-time peer comparison** from laboratories within group or across the globe for all QC test data. This allows the laboratory to easily monitor its own reliability and precision.



https://register.iamqc.com/



Full automation options available



Daily comparison of internal lab system or global comparisons



Powerful automated inter-laboratory QC comparison reports



Track shifts and trends over time and across reagent lots



Meet accreditation requirements for peer comparison



Setting up Roche cobas® Instruments with IAMQC® Interlaboratory Peer Program

It's as simple as step 1, 2 and 3.











REGISTER

Fill laboratory details in to the online Activation Form here: https://register.iamqc.com/

ACTIVATE

Account is activated by Technopath after verification

LOGON

Once the account is activated, the laboratory will receive login details and a user guide



Quality controls for Roche cobas® systems

Order information:

Order through your local Roche affiliate

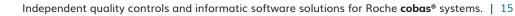
Product	Features	Specifications	Part Code	Kit Config
Multichem IA Plus	Assayed Immunoassay QC Tri-level utility Direct load, liquid for ease of use Human-based proprietary formulation	 36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C 	Level 1: 09339825190 Level 2: 09339841190 Level 3: 09339850190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem S Plus	 Assayed Chemistry QC Tri-level utility Direct load, liquid for ease of use Human-based proprietary formulation 	 36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C 	Level 1: 09339795190 Level 2: 09339809190 Level 3: 09339817190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem P	Assayed immunoprotein QC Direct load, liquid for ease of use Human-based proprietary formulation	 36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C 	Level P: 09339884190	12 x 4mL (48mL)
Multichem U	 Assayed urine chemistry QC Bi-level utility Direct load, liquid for ease of use Mimics performance of patient samples 	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	Level 1: 09339868190 Level 2: 09339876190	12 x 3mL (36mL) 12 x 3mL (36mL)
Multichem ID-G	Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09339892190	4 x 4mL (16mL)
Multichem ID-HIV p24	 Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	 24 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09915494190	4 x 4mL (16mL)
Multichem ID-GNeg	 Qualitative quality control optimized for Roche cobas® systems and reagents. Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	 36 month closed vial stability at 2°C to 8°C 30 day open vial stability at 2°C to 8°C 	09339906190	4 x 4mL (16mL)



Additional complementary independent quality controls from **Technopath Clinical Diagnostics**

PRODUCT NAME	TECHNOPATH LIST NO.	KIT CONFIG.	ANALYTES	FEATURE SET
Multichem A1c Single level (level 1) assayed Single level (level 2) assayed Bi-level assayed	HB001A HB002A HB000A	12 x 1mL 12 x 1mL 2 x 6 x 1mL	• HbA1c	 24 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
bi-level ussayeu		ZXOXIIIL		
Multichem AE Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) assayed	AE611A AE612A AE613A	12 x 2mL 12 x 2mL 12 x 2mL	• Ammonia • Ethanol	 36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C
Bi-level assayed Tri-level assayed	AE600A AE610A	2 x 6 x 2mL 3 x 4 x 2mL		
Multichem AMH Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) Assayed Tri-level assayed	AM501A AM502A AM503A AM500A	12 x 2mL 12 x 2mL 12 x 2mL 3 x 4 x 2mL	• Anti-Müllerian Hormone	 36 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Multichem CSF Single level (Level 1) assayed Single level (Level 2) assayed Bi-level assayed	CF101A CF102A CF100A	12 x 2mL 12 x 2mL 2 x 6 x 2mL	• Glucose • Lactate • IgG • Protein	 36 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Bi-level assayed	CF100A	2 x 6 x 2mL		
Multichem D-Dimer Single level (level 1) assayed Single level (level 2) assayed Bi-level assayed	DM901A DM902A DM900A	12 x 1mL 12 x 1mL 2 x 6 x 1mL	• D-Dimer	 36 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
Multichem hsTn Single level (assayed)	HS301A	12 x 3mL	Troponin I Troponin T	36 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C
Multichem IA Speciality Single level (level 1) assayed Single level (level 2) assayed Single level (level 3) assayed Tri-level assayed	BP301A BP302A BP303A BP300A	12 x 2mL 12 x 2mL 12 x 2mL 3 x 4 x 2mL	ACTH BNP Calcitonin Procalcitonin PTH Intact	 36 month closed vial stability at -20°C to -80°C 7 day open vial stability at 2°C to 8°C
Multichem NB Single level (assayed)	NB800A	12 x 2mL	Direct Bilirubin Total Bilirubin Caffeine* Theophylline	36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C
Multichem WBT Tri-level assayed	WB000A	3 x 4 x 2mL	Cyclosporine Red Blood Cell Folate* Glucose* Sirolimus Tacrolimus	 30 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C

 $^{{}^{\}star}\mathsf{Refer}$ to lot specific IFU for analyte performance and stability claims.







Notes





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IN PARTNERSHIP WITH

