

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







TECHNOPATH CLINICAL DIAGNOSTICS



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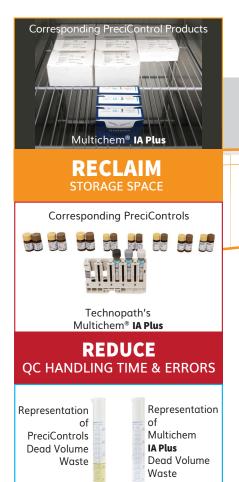
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### **Ordering Information**

Ordering Information for Independent QC for Roche systems
Additional Complementary Controls from Technopath Clinical Diagnostics



CLINICAL Diagnostics

### **REDUCE** DEAD VOLUME WASTE



### **REDUCE** QC ANALYSIS TIME WITH IAMQC®

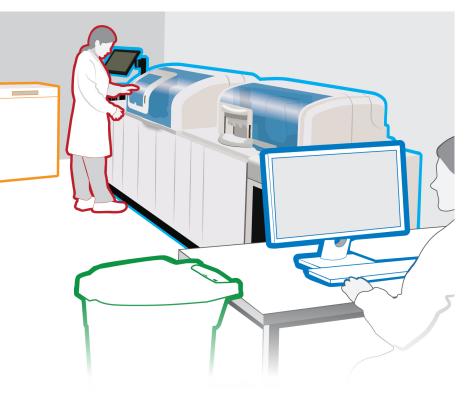


#### PreciControls Waste Vials, Test Cups and Pasteurs

**IA Plus** Waste Tubes

### **REDUCE** CONSUMABLE WASTE

# **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<sup>®</sup> 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



#### 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 (cobas Mobile

**Solutions Connector)** Automatic upload of QC results to IAMQC Peer through the Roche **cobas** Mobile Solutions Connector<sup>[1]</sup> with no additional hardware of software required to fulfil accreditation<sup>[2][3]</sup> requirements.

#### Inter-Lab QC Comparison Reports

Technopath IAMQC<sup>®</sup> 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.

1. Contact your Roche representative for more information on the **cobas** Mobile Solutions Connector.

2. "The laboratory shall participate in interlaboratory comparisons ...." ISO 15189: 2003(E), Subclause 5.6.4.

3. "[A] laboratory should actively participate in interlaboratory QC programs when such programs are available." CLSI, C24-A3, Vol. 26, No. 25.



# Multichem<sup>®</sup> IA Plus

Test Consolidation for Immunoassay QC in a Liquid Stable Format



#### **Features**

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid frozen for ease of use
- Assayed Immunoassay QC
- Test consolidated immunoassay control includes general IA, cardiac markers and tumor markers
- Assayed and value assigned for Roche cobas
- 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
- Lot specific exceptions noted in IFU

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) Alpha-Fetoprotein (AFP) Androstenedione\*\* Anti-Thyroglobulin (Anti-Tg) Anti-Thyroperoxidase (Anti-TPO) CA 125 CA 15-3 CA 19-9 Calcitonin Carcinogenic Embryonic Antigen (CEA) CK-MB Cortisol C-Peptide DHEA-S Digoxin Estradiol

Ferritin Folate Folicle Stimulating Hormone (FSH) HcG STAT\*\* Human Chorionic Gonadotropin +B (HcG+B) Human Growth Hormone (hGH) IGF-1\*\* Immunoglobulin E (IgE) Insulin Leutinizing Hormone (LH) Myoglobin Parathyroid Hormone (PTH) Parathyroid Hormone 1 - 84 (PTH)\*\* NT-pro BNP Progesterone

#### Prolactin

Prostate Specific Antigen, Free Prostate Specific Antigen, Total Sex Hormone Binding Globulin (SHBG) T Uptake Testosterone Thyroglobulin (Tg) Thyroid Stimulating Hormone (TSH) Thyroxine, Free (FT4) Total T3 Total T4 Triiodothyronine, Free (FT3) Troponin I Troponin I Troponin T Vitamin B12 Vitamin D, Total

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

17-OH Progesterone Acetaminophen Aldosterone Amikacin Angiotensin Anti-CCP BNP Caffeine Carbamazepine Carbamazepine, Free Chloramphenicol Cyclosporine Disopyramide EPO

Estriol, Free Estriol, Total Estrogen, Total Ethosuximide Gentamicin Homocysteine Ibuprofen Lidocaine Lithoum N-Acetyl procainamide Ostase Phenobarbital Phenytoin Phenytoin, Free Primidone Procainamide Procollagen NP Type 1 Quinidine Renin Salicylate Testosterone, Free Theophylline Thyroxine Binding Globulin Tobramycin Ultra-sensitive CRP Valproic Acid Valproic Acid, Free Vancomycin

\*Refer to lot specific IFU for analyte performance and stability claims.

\*\* These analytes are transitioning to claimed status, please refer to lot specific IFU.



# Multichem<sup>®</sup> S Plus

Test Consolidation for Serum Chemistry and Immunology QC in a Liquid Stable Format



#### Features

Cholesterol, LDL

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid frozen for ease of use
- Assayed Chemistry QC
- Facilitates tri-level utility for Cholesterol HDL & LDL, Apo A1, and Apo B
- Assayed and value assigned for Roche **cobas**
- Tri-level utility for 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
- Lot specific exceptions noted in IFU

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 (Non Prostatic) 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, 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) Iron 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\*.

ACE

Acid Phosphatase (Non Prostatic) ADNase B (Anti-Streptococcal DNase B) Alpha 2 Macroglobulin Anti-thrombin III Beta Hydroxybutyrate Bile acids Bilirubin Indirect C1 Inhibitor Caffeine Calcium Ionized CH50 (Total hemolytic Complement) CKMB Copper Cortisol Cystatin C Dehydrogenase Hemopexin IgE 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.

\*\* These analytes are transitioning to claimed status, please refer to lot specific IFU.



# Multichem<sup>®</sup> P

Test Consolidation for Serum elevated Immunoprotein QC in a Liquid Stable Format



#### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid frozen for ease of use
- Assayed and value assigned for Roche **cobas**
- Provides truly elevated values of specific proteins to control the analytical range
- 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
- Lot specific exceptions noted in IFU

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

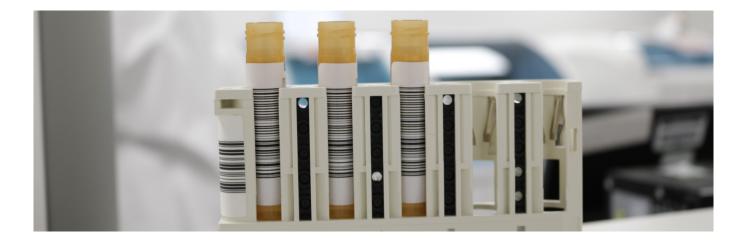
Complement C3 Complement C4 C-Reactive Protein (CRP) Haptoglobin Immunoglobulin A (IgA) Immunoglobulin G (IgG) Immunoglobulin M (IgM) Prealbumin Rheumatoid Factors (RF) Soluble Transferrin Receptor (sTfR) Total Protein Transferrin

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

\*Refer to lot specific IFU for analyte performance and stability claims.

ADNase B (Anti-Streptococcal DNase B) Alpha-2 Macroglobulin Angiotensin Converting Enzyme Antistreptolysin O (ASO) Antithrombin III C1 Inhibitor CH50 (Total hemolytic Complement) Cystatin C Ferritin Hemopexin IgE IgG1, Subclass IgG2, Subclass IgG3, Subclass

IgG4, Subclass Kappa Light Chain Lambda Light Chain Lipoprotein (a) Properdin Factor B Retinol Binding Protein





# Multichem<sup>®</sup> U

Test Consolidation for Urinary Chemistry QC in a Liquid Stable Format



#### **Features**

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid stable
- Assayed urine chemistry QC
- Bi-level utility
- Greater stability and performance for creatinine
- Assayed and value assigned for Roche **cobas**
- 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
- Lot specific exceptions noted in IFU

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

#### 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.







Positive multi-analyte infectious disease QC



#### **Features**

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Technical and Scientific Support

### **Specifications**

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

ning oon	Product	Description	Configuration	PART NO
	Multichem ID-G	Positive QC	4 x 4mL (16mL)	09339892190

#### **Positive For:**

Anti-HBc lgG Anti-HCV lgG Anti-HIV 1 IgG Anti-HTLV I IgG

Anti-Treponema pallidum IgG HBsAg

## Multichem<sup>®</sup> ID-GNeg

Negative multi-analyte infectious disease QC



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Technical and Scientific Support

#### **Specifications**

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

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

### **Negative For:**

Anti-HBc IgG Anti-HCV IgG Anti-HIV 1 IgG Anti-HIV 2 IgG Anit-HIV Group O Anti-HTLV I IgG Anti-Trypanosoma cruzi IgG (Chagas) Anti-Treponema pallidum IgG HBsAg



# IAMQC<sup>®</sup> 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.



# **REGISTER** FOR IAMQC PEER

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<sup>®</sup> 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	<ul> <li>Assayed Immunoassay QC</li> <li>Tri-level Utility</li> <li>Liquid frozen for ease of use</li> <li>Human Based Proprietary Formulation</li> </ul>	<ul> <li>36 month closed tube stability at -20°C to -80°C</li> <li>10 day open tube stability at 2°C to 8°C</li> </ul>	Level 1: 09339825190 Level 2: 09339841190 Level 3: 09339850190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem S Plus	<ul> <li>Assayed Chemistry QC</li> <li>Tri-level Utility</li> <li>Liquid frozen for Ease of Use</li> <li>Human Based Proprietary Formulation</li> </ul>	<ul> <li>36 month closed tube stability at -20°C to -80°C</li> <li>10 day open tube stability at 2°C to 8°C</li> </ul>	Level 1: 09339795190 Level 2: 09339809190 Level 3: 09339817190	12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL) 12 x 4mL (48mL)
Multichem P	<ul> <li>Assayed Immunoprotein QC</li> <li>Liquid Frozen for Ease of Use</li> <li>Human Based Proprietary Formulation</li> </ul>	<ul> <li>36 month closed tube stability at -20°C to -80°C</li> <li>14 day open tube stability at 2°C to 8°C</li> </ul>	Level P: 09339884190	12 x 4mL (48mL)
Multichem U	<ul> <li>Assayed Urine Chemistry QC</li> <li>Bi-level Utility</li> <li>Ready to Use Liquid Stable QC</li> <li>Mimics Performance of Patient Samples</li> </ul>	<ul> <li>24 month closed tube stability at 2°C to 8°C</li> <li>30 day open tube stability at 2°C to 8°C</li> </ul>	Level 1: 09339868190 Level 2: 09339876190	12 x 3mL (36mL) 12 x 3mL (36mL)
- coming Soon - Multichem ID-G	<ul> <li>Ready to Use Liquid Stable QC</li> <li>Technical and Scientific Support</li> </ul>	<ul> <li>24 month closed tube stability at 2°C to 8°C</li> <li>90 day open tube stability at 2°C to 8°C</li> </ul>	Positive: 09339892190	4 x 4mL (16mL)
- coming Soon - Multichem ID-GNeg	<ul> <li>Ready to Use Liquid Stable QC</li> <li>Technical and Scientific Support</li> </ul>	<ul> <li>36 month closed tube stability at 2°C to 8°C</li> <li>90 day open tube stability at 2°C to 8°C</li> </ul>	Negative: 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 <b>A1c</b> Single Level (Level 1) Assayed Single Level (Level 2) Assayed	HB001A HB002A	12 x 1mL 12 x 1mL	• HbA1c	<ul> <li>24 Month Closed Vial Stability at -20°C to -80°C</li> <li>30 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Bi-Assayed	HB000A	2 x 6 x 1mL		
Multichem AE Single Level (Level 1) Assayed Single Level (Level 2) Assayed Single Level (Level 3) Assayed Bi-level Assayed Tri-level Assayed	AE611A AE612A AE613A AE600A AE610A	12 x 2mL 12 x 2mL 12 x 2mL 2 x 6 x 2mL 3 x 4 x 2mL	• Ammonia • Ethanol	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>14 Day Open Vial Stability at 2°C to 8°C</li> </ul>
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	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>30 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Multichem <b>CSF</b> 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	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>30 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Multichem <b>D-Dimer</b> 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	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>30 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Multichem <b>hsTn</b> Single Level (Assayed)	HS301A	12 x 3mL	• Troponin I • Troponin T	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>10 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Multichem <b>IA Speciality</b> 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 12 x 2mL 3 x 4 x 2mL	• ACTH • BNP • Calcitonin • Procalcitonin • PTH Intact	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>7 Day Open Vial Stability at 2°C to 8°C</li> </ul>
Multichem <b>NB</b> Single Level (Assayed)	NB800A	12 x 2mL	<ul> <li>Direct Bilirubin</li> <li>Total Bilirubin</li> <li>Caffeine*</li> <li>Theophylline</li> </ul>	<ul> <li>36 Month Closed Vial Stability at -20°C to -80°C</li> <li>14 Day Open Vial Stability at 2°C to 8°C</li> </ul>
<b>Multichem WBT</b> Tri-level Assayed	WB000A	3 x 4 x 2mL	<ul> <li>Cyclosporine</li> <li>Red Blood Cell Folate*</li> <li>Glucose*</li> <li>Sirolimus</li> <li>Tacrolimus</li> </ul>	<ul> <li>30 Month Closed Vial Stability at -20°C to -80°C</li> <li>10 Days Open Vial Stability at 2°C to 8°C</li> </ul>

\*Refer to lot specific IFU for analyte performance and stability claims.



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#### IN PARTNERSHIP WITH

