



Independent Quality Controls and Informatic software solutions for Roche **cobas**® systems.



THE QUALITY CONTROL COMPANY







Dear Reader,

This is a digital document. Please click on an item in the contents to go directly to that page. Click on the page number to return to the table of contents.

Contents

Introduction

Enhanced Laboratory Efficiencies with Technopath QC Solutions
Greater Efficiencies in QC Processes
Independent Quality Control Materials for Roche Systems
Multichem IA Plus
Multichem S Plus
Multichem P
Multichem U
Multichem ID-G
Multichem ID-GNeg9
Quality Control Software
IAMQC Interlaboratory Peer Program
Ordering Information
Ordering Information for Independent QC for Roche systems
Additional Complementary Controls from Technopath Clinical Diagnostics





Corresponding PreciControl Products Multichem® IA Plus

RECLAIM STORAGE SPACE

Corresponding PreciControls



Technopath's Multichem® **IA Plus**

REDUCE QC HANDLING TIME & ERRORS



Representation of Multichem IA Plus Dead Volume Waste

REDUCE DEAD VOLUME WASTE



REDUCE QC ANALYSIS TIME WITH IAMQC®



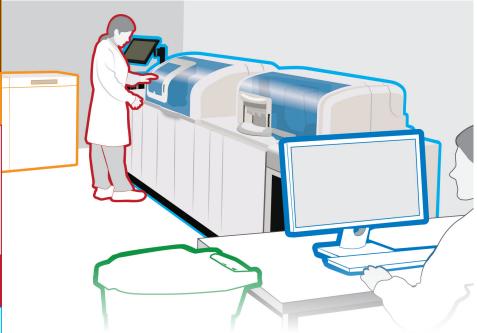
PreciControls Waste Vials, Test Cups and Pasteurs Multichem®

IA Plus

Waste Tubes

REDUCE
WEIGHT OF 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 [1] 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 $^{\circ}$ 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 No Hardware Installation Required

Automatic upload of QC results to IAMQC Peer, with no additional hardware or software required to fulfill accreditation requirements.^{1,2}

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.

^{1. &}quot;The laboratory shall participate in interlaboratory comparisons"ISO 15189: 2003(E), Subclause 5.6.4.

^{2. &}quot;[A] laboratory should actively participate in interlaboratory QC programs when such programs are available." CLSI, C24-A3, Vol. 26, No. 25.





Multichem® 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
- 73 Analytes
- 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 IFII

Product	Description	Configuration	PART NO
Multichem IA Plus	Assayed Level 1		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)
Anti-Thyroglobulin (Anti-Tg)
Anti-Thyroperoxidase (Anti-TPO)
CA 125
CA 15-3
CA 19-9
Calcitonin
Carcinogenic Embryonic Antigen
(CEA)
CK-MB

CK-MB
Cortisol
C-Peptide
DHEA-S
Digoxin

Estradiol Ferritin Folate

Folicle Stimulating Hormone (FSH) Human Chorionic Gonadotropin +ß

(HcG+ß)

Human Growth Hormone (hGH)

Immunoglobulin E (IgE)

Insulin

Leutinizing Hormone (LH)

Myoglobin

Parathyroid Hormone (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 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 Androstenedione Anti-CCP BNP Carbamazepine

Carbamazepine, Free Cyclosporine Estriol, Free Gentamicin HcG STAT Homocysteine

IGF-1 Lidocaine Lithium

N-Acetyl procainamide

Phenobarbital
Phenytoin
Phenytoin, Free
Procainamide

Procollagen NP Type 1

Quinidine Salicylate

Testosterone, Free

Theophylline Tobramycin

Ultra-sensitive CRP Valproic Acid Valproic Acid, Free Vancomycin

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





Multichem® S Plus

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



Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid frozen for ease of use
- Assayed Chemistry QC
- 82 Analytes
- 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

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

Creatinine Digoxin

Ethanol Fructosamine

Gamma Glutamyltransferase (GGT)

Gentamicin Glucose Haptoglobin 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 Theophylline Tobramycin **Total Protein** Transferrin **Triglycerides**

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*.

Alpha 2 Macroglobulin Anti-thrombin III Bilirubin Indirect Calcium Ionized

Cystatin C Ferritin IgG1, Subclass IgG2, Subclass IgG3, Subclass IgG4, Subclass

Soluble Transferrin Receptor (sTfR)

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







TECHNOPATH

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
- 31 Analytes
- Assaved 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
- · 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)

Total Protein

Transferrin

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

Alpha-2 Macroglobulin Antistreptolysin O (ASO)

Antithrombin III Cystatin C

Ferritin

IgG1, Subclass IgG2, Subclass

IgG3, Subclass

IgG4, Subclass

Kappa Light Chain

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









Multichem® **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
- 13 Analytes
- 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 HK Magnesium Microalbumin Phosphate Potassium Sodium

Total Protein Urine Urea Uric acid

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







Multichem® ID-G

Positive multi-analyte infectious disease QC



Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- 6 Analytes
- 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

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

Positive For:

Anti-HBc IgG Anti-HCV IgG Anti-HIV 1 lgG Anti-HTLV I lgG Anti-Treponema pallidum IgG HBsAg

Multichem® ID-GNeg

Negative multi-analyte infectious disease QC



Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- 6 Analytes
- 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 lgG Anti-HTLV I lgG Anti-Treponema pallidum IgG HBsAg





IAMQC® 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.



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 73 Analytes* Liquid frozen for ease of use Human Based Proprietary Formulation	36 month closed tube stability at -20°C to -80°C 10 day open tube 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 82 Analytes* Liquid frozen for Ease of Use Human Based Proprietary Formulation 	36 month closed tube stability at -20°C to -80°C 10 day open tube 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 31 Analytes* Liquid Frozen for Ease of Use Human Based Proprietary Formulation	36 month closed tube stability at -20°C to -80°C 14 day open tube stability at 2°C to 8°C	Level P: 09339884190	12 x 4mL (48mL)
Multichem U	Assayed Urine Chemistry QC Bi-level Utility 13 Analytes* Liquid Stable Mimics Performance of Patient Samples	 24 month closed tube stability at 2°C to 8°C 30 day open tube stability at 2°C to 8°C 	Level 1: 09339868190 Level 2: 09339876190	12 x 3mL (36mL) 12 x 3mL (36mL)
- Coming Soon - Multichem ID-G	Ready to Use Liquid Stable QC Analytes* Technical and Scientific Support	 24 month closed tube stability at 2°C to 8°C 90 day open tube stability at 2°C to 8°C 	Positive: 09339892190	4 x 4mL (16mL)
- Coming Soon - Multichem ID-GNeg	Ready to Use Liquid Stable QC Analytes* Technical and Scientific Support	 36 month closed tube stability at 2°C to 8°C 90 day open tube stability at 2°C to 8°C 	Negative: 09339906190	4 x 4mL (16mL)

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





Additional Complementary

Independent quality controls from Technopath Clinical Diagnostics

Contact your local Technopath Representative for more information on these products.

PRODUCT NAME	TECHNOPATH LIST NO.	KIT CONFIG.	ANALYTES	FEATURE SET
Multichem A1c Single Level (Level 1) Assayed Single Level (Level 2) Assayed	HB001A HB002A	12 x 1mL 12 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-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	AE611A AE612A AE612A AE600A	12 x 2mL 12 x 2mL 12 x 2mL 2 x 6 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
Multichem AMH Tri-level Assayed	AM500A	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
Multichem D-Dimer Single Level (Level 1) Assayed Single Level (Level 2) Assayed	DM901A DM902A	12 x 1mL 12 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
Bi-Level Assayed	DM900A	2 x 6 x 1mL		
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 ID-COVID19 G** Unassayed Positive QC for Antibodies to SARS-CoV-2 (including IgG)	CVG300P	4 x 4mL	 Positive for Antibodies to SARS-CoV-2 (including IgG) 	 21 Month Closed Vial Stability at 2°C to 8°C 21 Day Open Vial Stability at 2°C to 8°C
Multichem ID-COVID19Neg** Unassayed Negative QC for Antibodies to SARS-CoV-2 (including IgG)	CVN200N	4 x 4mL	Negative for Antibodies to SARS-CoV-2 (including IgG)	 36 Month Closed Vial Stability at 2°C to 8°C 30 Day Open Vial Stability at 2°C to 8°C
Multichem NB Single Level (Assayed)	NB800A	12 x 2mL	Direct BilirubinTotal BilirubinCaffeine*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 Folate* Glucose* Sirolimus Tacrolimus 	 36 Month Closed Vial Stability at -20°C to -80°C 30 Day Open Vial Stability at 2°C to 8°C

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

** Refer to lot specific IFU for more information.



IN PARTNERSHIP WITH

