



CLINICAL
DIAGNOSTICS

Independent Quality Controls for
Roche **cobas**® Mass Spectrometry Solution



Independent Third Party Mass Spectrometry
Quality Controls for Roche **cobas**® i 601 analytical unit



TECHNOPATH
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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

Quality controls targeted at clinical decision points, giving 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 with commutability in test measurement to increase confidence in QC 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. "The laboratory shall participate in inter-laboratory comparisons" ISO15189:2022.
 3. "[A] laboratory should actively participate in inter-laboratory QC programs when such programs are available." CLSI C-24 4th edition.

Enhance Laboratory Efficiencies with Multichem® Independent Quality Controls and IAMQC® QC data management software.



CONSOLIDATION

Fewer products required to meet your core laboratory control needs, leading to increased operational efficiencies and reduced waste.



AUTOMATION

Load and go barcoded controls with target values and ranges pre-loaded on the cobas enterprise system. reducing handling and setup time.



QUALITY

Independent, 3rd party, human-matrix based controls with analytes targeted at clinical decision points supporting clinician quality goals.

Internal Laboratory Quality Control (IQC) is important in ensuring confidence in patient test results and in meeting accreditation requirements including CLIA, CLSI, CAP, RiliBÄK and ISO.

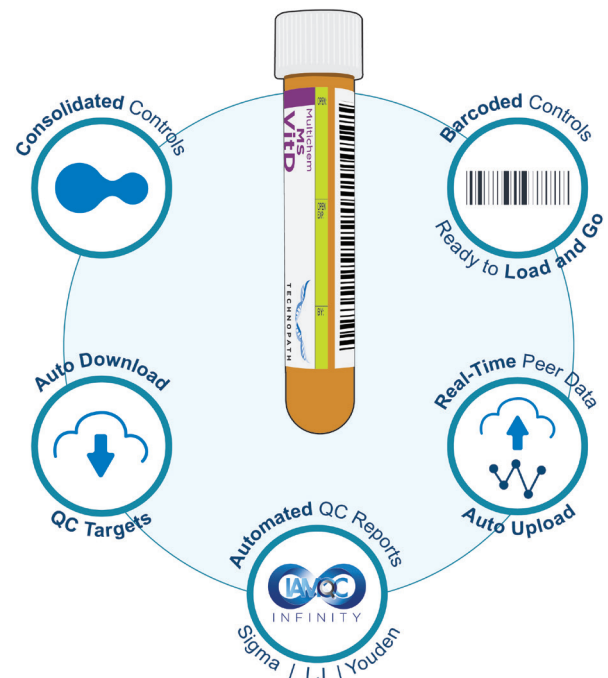
Increasingly Laboratories seek objective assessment and comparison of analytical methods and instrumentation performance, to meet their quality goals.

Technopath's Independent quality control solution, Multichem QC and IAMQC software, provides clinical laboratories with significant cost, handling and time savings, whilst delivering higher confidence in analytical testing methods.

Advancing Quality Control in the Clinical Laboratory

By utilising Multichem barcoded QC materials, laboratories can optimise their QC workflow and minimise handling errors. It is supported and complemented with IAMQC® data management system.

Learn more here:
<https://www.technopathclinicaldiagnostics.com/knowledge-centre-roche-customer/>

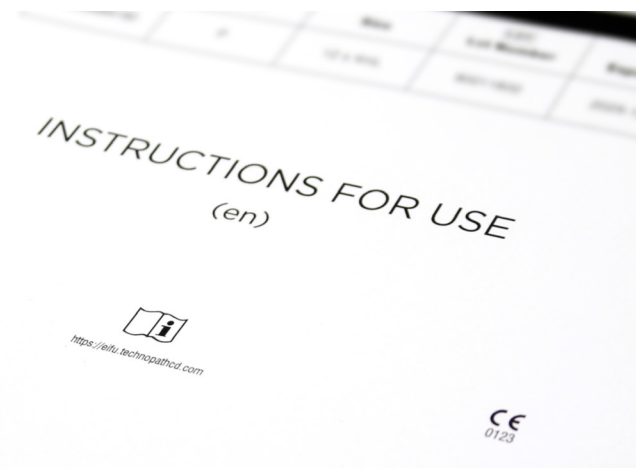


A Guide on How to Access and Review Multichem Instructions for Use (IFU)

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.

Go to: <https://eifu.technopathcd.com/> **1**

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Electronic Instructions for Use

To access an electronic IFU, please use the dropdown menus to select your preferred language, product and corresponding lot number

Select language from the dropdown menu **2** → English

Select the product from the dropdown menu **3** → Product: Select Multichem product

Select the lot number **4** → Lot No: 00000000

#	Part Number
1	00000000000

Document

- COA Multichem product <partcode> <lot no.>
- Customer Communication CC0000 Rev 00
- IFU Multichem.pdf

'Customer Communication' provides notifications of updates or changes in addition to the IFU **i**

Download IFU **5**

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

STABILITY	
Analyte stability located here.	
EXCEPTIONS	
Analyte	Duration
-	-

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

Roche Systems			Applications included in the automated data transfer		UNITS		LEVEL LOT NO				
ANALYTES	Short Name	ACN	Mean	Min	Max	Std Dev					

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.

Never Miss an IFU Update!

Sign up for notifications of updates to Multichem IFUs

SIGN UP HERE

or visit

www.technopathclinicaldiagnostics.com/landing-pages/sign-up-for-notification-of-changes-to-ifus/

Multichem[®] MS TDMs

QC to monitor accuracy and precision of laboratory testing procedures for therapeutic drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**[®] i 601 analytical unit
- Bi-level utility

Specifications

- 24 months* closed vial stability at -20°C to -80°C
- 5 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS TDMs	Assayed Level 1	12 x 4.5mL (54mL)	09922571190
	Assayed Level 2	12 x 4.5mL (54mL)	09922580190

Analytes with performance and stability claims*:

Amikacin	Methotrexate	Topiramate
Carbamazepine	Mycophenolic Acid (MPA)	Valproic Acid
Carbamazepine-10,11-epoxide	Mycophenolic Acid Glucuronide	Vancomycin
Gabapentin	Phenobarbital	Voriconazole
Gentamicin	Phenytoin	Zonisamide
Lamotrigine	Primidone	
Linezolid	Tobramycin	

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

Acetaminophen	Piperacillin
Digoxin	Salicylate
Levetiracetam	Theophylline
Meropenem	



*Refer to IFU for analyte performance and stability claims.

Multichem® MS Free TDMs

QC to monitor accuracy and precision of laboratory testing procedures for therapeutic drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**® i 601 analytical unit
- Bi-level utility

Specifications

- 24 months* closed vial stability at -20°C to -80°C
- 10 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS Free TDMs Assayed Level 1	Assayed Level 1	12 x 4.5mL (54mL)	10162066190
Multichem MS Free TDMs Assayed Level 2	Assayed Level 2	12 x 4.5mL (54mL)	10162074190

Analytes with performance and stability claims*:

Phenytoin, free
Valproic Acid, free

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

Phenytoin
Valproic Acid



*Refer to IFU for analyte performance and stability claims.

Multichem[®] MS VitD

QC to monitor accuracy and precision of laboratory testing procedures for vitamin D



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**[®] i 601 analytical unit
- Bi-level utility

Specifications

- 12 months* closed vial stability at -20°C to -80°C
- 10 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS VitD	Assayed Level 1	12 x 4.5mL (54mL)	09922555190
	Assayed Level 2	12 x 4.5mL (54mL)	09922563190

Analytes with performance and stability claims*:

- | | |
|---------------------------------|----------------------------|
| 24,25-Dihydroxy Vitamin D2 | 25-Hydroxy Vitamin D2 |
| 24,25-Dihydroxy Vitamin D3 | 25-Hydroxy Vitamin D3 |
| 24,25-Dihydroxy Vitamin D total | 25-Hydroxy Vitamin D total |

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

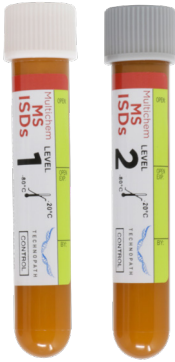
- 1,25-Dihydroxy Vitamin D2
- 1,25-Dihydroxy Vitamin D3



*Refer to FU for analyte performance and stability claims.

Multichem[®] MS ISDs

QC to monitor accuracy and precision of laboratory testing procedures for immunosuppressant drugs



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**[®] i 601 analytical unit
- Bi-level utility

Specifications

- 24 months* closed vial stability at -20°C to -80°C
- 10 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS ISDs	Assayed Level 1	12 x 4.5mL (54mL)	09922598190
	Assayed Level 2	12 x 4.5mL (54mL)	09922601190

Analytes with performance and stability claims*:

Cyclosporine
Everolimus

Sirolimus
Tacrolimus



*Refer to IFU for analyte performance and stability claims.

Multichem[®] MS Steroids

QC to monitor accuracy and precision of laboratory testing procedures for steroids



Features

- Human-based proprietary formulation
- Mimics performance of patient samples
- Direct load, liquid, for ease of use
- Assayed quality control
- Test consolidated
- Barcoded vials for ease of use
- Assayed and value assigned for Roche **cobas**[®] i 601 analytical unit
- Bi-level utility

Specifications

- 24 months* closed vial stability at -20°C to -80°C
- 5 days* open vial stability at 2°C to 8°C

Product	Description	Configuration	PART NO
Multichem MS Steroids	Assayed Level 1	12 x 4.5mL (54mL)	09922512190
	Assayed Level 2	12 x 4.5mL (54mL)	09922547190

Analytes with performance and stability claims*:

Aldosterone
Androstenedione

Estradiol
Testosterone

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

17-Hydroxyprogesterone
Cortisol
Cortisone

DHEA
DHEA-S
Dihydrotestosterone

Progesterone



*Refer to IFU for analyte performance and stability claims.

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.

**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® interlaboratory peer program






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



Mass spectrometry quality controls for Roche cobas® i 601 analytical unit

Order information:

Order through your local Roche affiliate

Product	Features	Specifications	Part Code	Kit Config
Multichem MS TDMs 	<ul style="list-style-type: none"> Assayed QC Bi-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 24 months closed vial stability at -20°C to -80°C 5 days open vial stability at 2°C to 8°C 	Level 1: 09922571190 Level 2: 09922580190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS Free TDMs 	<ul style="list-style-type: none"> Assayed QC Bi-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 24 months closed vial stability at -20°C to -80°C 10 days open vial stability at 2°C to 8°C 	Level 1: 10162066190 Level 2: 10162074190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS VitD 	<ul style="list-style-type: none"> Assayed QC Bi-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 12 months closed vial stability at -20°C to -80°C 10 days open vial stability at 2°C to 8°C 	Level 1: 09922555190 Level 2: 09922563190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS ISDs 	<ul style="list-style-type: none"> Assayed QC Bi-level utility Liquid, for ease of use Mimics performance of patient samples 	<ul style="list-style-type: none"> 24 months closed vial stability at -20°C to -80°C 10 days open vial stability at 2°C to 8°C 	Level 1: 09922598190 Level 2: 09922601190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)
Multichem MS Steroids 	<ul style="list-style-type: none"> Assayed QC Bi-level utility Direct load, liquid, for ease of use Mimics performance of patient samples 	<ul style="list-style-type: none"> 24 months closed vial stability at -20°C to -80°C 5 days open vial stability at 2°C to 8°C 	Level 1: 09922512190 Level 2: 09922547190	12 x 4.5mL (54mL) 12 x 4.5mL (54mL)

Other Multichem quality controls for compatible Roche **cobas**[®] systems

Order information:

Order through your local Roche affiliate

Product	Features	Specifications	Part Code	Kit Config
Multichem IA Plus 	<ul style="list-style-type: none"> Assayed immunoassay QC Tri-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Assayed chemistry QC Tri-level utility Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Assayed immunoprotein QC Direct load, liquid, for ease of use Human-based proprietary formulation 	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Assayed urine chemistry QC Bi-level utility Direct load, liquid, for ease of use Mimics performance of patient samples 	<ul style="list-style-type: none"> 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)
- Coming Soon - Multichem ID-G 	<ul style="list-style-type: none"> Assayed for Roche cobas[®] systems Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	<ul style="list-style-type: none"> 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)
- Coming Soon - Multichem ID-HIV p24 	<ul style="list-style-type: none"> Assayed for Roche cobas[®] systems Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	<ul style="list-style-type: none"> 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)
- Coming Soon - Multichem ID-GNeg 	<ul style="list-style-type: none"> Assayed for Roche cobas[®] systems Direct load, liquid for ease of use Human-based proprietary formulation Mimics performance of patient samples 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> HbA1c 	<ul style="list-style-type: none"> 24 month closed vial stability at -20°C to -80°C 30 day open vial stability at 2°C to 8°C
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	<ul style="list-style-type: none"> Ammonia Ethanol 	<ul style="list-style-type: none"> 36 month closed vial stability at -20°C to -80°C 14 day open vial stability at 2°C to 8°C
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	<ul style="list-style-type: none"> Anti-Müllerian Hormone 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Glucose Lactate IgG Protein 	<ul style="list-style-type: none"> 36 month closed vial stability at -20°C to -80°C 30day open vial stability at 2°C to 8°C
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	<ul style="list-style-type: none"> D-Dimer 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Troponin I Troponin T 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> ACTH BNP Calcitonin Procalcitonin PTH Intact 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Direct Bilirubin Total Bilirubin Caffeine* Theophylline 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Cyclosporine Red Blood Cell Folate* Glucose* Sirolimus Tacrolimus 	<ul style="list-style-type: none"> 30 month closed vial stability at -20°C to -80°C 10 day open vial stability at 2°C to 8°C

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



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