



**CLINICAL  
DIAGNOSTICS**

**Independent Quality Controls  
for Abbott ci Systems**



**Abbott ci Systems**



**TECHNOPATH  
CLINICAL DIAGNOSTICS**

## Dear Reader,

This document is intended for use with Abbott ci Systems.  
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## The Alinity ci-series quality control automation can help increase the operational productivity of your laboratory

Laboratory Quality Control (QC) processes are vitally important in ensuring accurate patient test results, but are often time consuming for laboratory staff. As a result, laboratories are looking for ways to optimize their processes, without compromising the accuracy and timeliness of the results they deliver to physicians and their patients. Now, with the Alinity ci-series, you can leverage quality control system capabilities to help optimize your overall lab performance.



## Quality control management helps you automate and improve QC management processes



Barcoded quality controls make loading faster, easier and less prone to errors.<sup>1</sup>  
No pipetting or manual order entry is necessary for manufacturer barcoded vials.<sup>2</sup>



Up to six quality controls vials can be loaded on a single rack and up to four racks can be loaded on the instrument.  
Potentially QC up to 190 assays from a single rack for all three levels.



Continuous Loading - Quality controls can be loaded anytime, without interruption to your sample processing.



Quality controls can be stored onboard the system, in a temperature controlled reagent carousel, and automatically run at user-defined intervals.

1. Technopath provides five multi-constituent controls across clinical chemistry and immunoassay, four of which can be stored onboard the system.  
2. For selected assays.

## Enhanced Laboratory Efficiencies with Technopath QC Solutions

Today's healthcare systems are often asked to produce higher patient quality with fewer resources. In response, many labs are looking into all areas of their operations for efficiencies, including their QC processes, and are adopting better means of utilizing existing resources to impact the bottom line.

Technopath's total 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.

With an extensive list of analytes included in the Multichem range of quality control products, choice and flexibility are guaranteed for all customers. The Independent quality control products include General Clinical Chemistry, Immunoproteins, Immunoassay, Cardiac, Urine Chemistry, Infectious Disease, Diabetes and other Esoteric controls. The controls are assayed for ARCHITECT and Alinity i and c systems, please see each product specification listed in the product pages.

Technopath Clinical Diagnostics human based control matrix offers unrivalled test consolidation with increased control stability and diminished matrix effects. Together, these aspects of control manufacture offer greater control efficiencies without compromising compliance or confidence in patient results.



1. Based on minimum dead volume waste as indicated in Alinity i Operation Manual.
2. Available on Alinity ci-series only.
3. Technopath study on file.

### Enhance Laboratory Efficiencies

Corresponding Competitor Product

Technopath's Multichem® IA Plus

**REDUCE**  
HANDLING REQUIREMENTS

BY UP TO **98%**

Competitor Off Board Dead Volume Waste

Multichem IA Plus On Board Dead Volume Waste

**REDUCE**  
DEAD VOLUME WASTE<sup>1</sup>

BY UP TO **98%**

Competitor Waste Vials, Test Cups and Pipettes

Multichem® IA Plus Waste Vials

**REDUCE**  
WEIGHT OF CONSUMABLES

BY UP TO **99%**

Competitor TUMOR MARKER, Competitor IMMUNOASSAY, Competitor SPECIALTY IMMUNOASSAY, Competitor CARDIAC MARKER

Corresponding Competitor Products

Multichem® On Board QC

**REDUCE**  
STORAGE REQUIREMENTS

BY UP TO **77%**

**REDUCE**  
QC ANALYSIS TIME<sup>2</sup>

**100%**  
AUTOMATED

Based on an internal Technopath study<sup>3</sup> running 4 competitor QC products (Tumor Marker, Cardiac Marker, Immunoassay and Specialty Immunoassay), each level three times daily for 5 days off-board on Alinity i versus Technopath's Multichem IA Plus 5 days onboard Alinity i, the above efficiencies were observed.



# Technopath and Abbott help Clinical Diagnostic Laboratories Achieve Their Quality Goals



## 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 Abbott 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.



## 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. <sup>[1]</sup> <sup>[2]</sup>

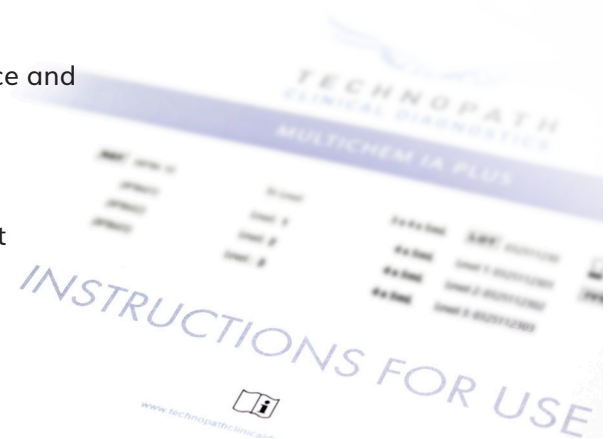
1. "The laboratory shall participate in inter-laboratory comparisons ...." ISO15189:2022.

2. "[A] laboratory should actively participate in inter-laboratory QC programs when such programs are available." CLSI C-24 4<sup>th</sup> edition.

# A Guide on How to Access and Review Multichem IFUs

Supporting the laboratory's confidence in patient test results, the Multichem IFU provides helpful information to ensure best practice and use of lot-specific QC material.

- The IFU contains helpful 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 - Current lot number required

<https://connect.technopathcd.com/Home/TLLogin>

Multichem IFUs for Abbott Alinity and Architect quality controls are available from the Technopath Technical Library.

Log into the Technopath Technical Library

1

Open EDocuments folder

2

Select the product from the dropdown menu

3

Download IFU

4

connect.technopathcd.com/Home/TechLibrary

TECHNOPATH CLINICAL DIAGNOSTICS

HOME EDOCUMENTS REAGENT INFO MSDS FILES HELP LOGOUT

Home

EDocuments Instructions for use, data sheets & XML files

Reagent info Access Reagent verification data

MSDS Files View / Save MSDS File

Access Material Safety Data Sheets (MSDS)

Step 1: Select Product

Multichem IA Plus (08P86-10) (Alinity)

Edit

Search for Multichem product by entering lot number: Lot number Find

| # | Part Number |
|---|-------------|
| 1 | 08P86-10    |

Search by lot number to filter the list view in 'Step 2'

Step 2: Select Lot Number

| Lots      |                                        |                 |                                                                                                                 |                    |
|-----------|----------------------------------------|-----------------|-----------------------------------------------------------------------------------------------------------------|--------------------|
| Lot No    | Product Name                           | Expiration Date | IFU (Lot) Documentation                                                                                         |                    |
| 032807240 | Multichem IA Plus (08P86-10) (Alinity) | 2026-11-30      | <a href="#">English Monolingual Lot 0328 Rev 01</a>                                                             | View Download Info |
| 032511230 | Multichem IA Plus (08P86-10) (Alinity) | 2026-03-31      | <a href="#">Customer Communication CC0197 Rev 01 - Update on NT-pro BNP English Monolingual Lot 0325 Rev 01</a> | View Download Info |
| 032411230 | Multichem IA Plus (08P86-10) (Alinity) | 2026-03-31      | <a href="#">Customer Communication CC0197 Rev 01 - Update on NT-pro BNP English Monolingual Lot 0324 Rev 01</a> | View Download Info |

View, download or get help with XML files

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

# 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. Example IFU: IA Plus for Alinity systems.

## Precautions

### PRECAUTIONS

**Warning: Biological source material. Treat as potentially infectious.**

- For In Vitro Diagnostic Use.
- Each donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and nonreactive for HBsAg. Because no test method can offer complete assurance that HIV, hepatitis B virus and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of

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

Multichem IA Plus Control should be treated the same as patient specimens. It can be used in one of two ways with the Alinity analyser and the Alinity reagents:

- On board storage:** Multichem IA Plus is stored on board the Alinity analyser for the duration of the predetermined on board stability.
  - Allow the control vial to stand at room temperature (18 to 25 °C) for 30 minutes or until completely thawed. The control must be completely solubilized before continuing to the next step.
  - Place the thawed control vial on a suitable mixing device, e.g. roller mixer for 15 minutes, to achieve a homogeneous solution.

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

## Storage

### STORAGE

For optimum performance, avoid storage in a frost-free freezer or in a freezer which is opened regularly for other applications such as storage of clinical samples. Store vials away from the light. Bilirubin values may decrease during the product shelf life. The Control material can only be used in the On board storage or the Off board storage application. Not a combination of both.

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

## Product Stability & Exceptions

### STABILITY

The control material is stable at -20 to -80 °C until its expiry date.

| Storage Condition                                                                                   | Temperature                  | Maximum storage time    | Exceptions             |                    |
|-----------------------------------------------------------------------------------------------------|------------------------------|-------------------------|------------------------|--------------------|
|                                                                                                     |                              |                         | Analyte                | Duration           |
| Off Board Storage (Manual Sampling)                                                                 | 2 to 8 °C (Off the analyser) | xx days (after opening) | Analyte 1<br>Analyte 2 | xx days<br>xx days |
| Off Board Storage (Direct Sampling)                                                                 | 2 to 8 °C (Off the analyser) | xx days (after opening) | Analyte 1<br>Analyte 2 | xx days<br>xx days |
| Analytes not suitable for Off Board Storage (Direct Sampling): Analyte 1, Analyte 2                 |                              |                         |                        |                    |
| On Board Storage                                                                                    | Alinity System Temperature   | xx days                 | Analyte 1<br>Analyte 2 | xx days<br>xx days |
| Analytes not suitable for storage on board the analyzer: Analyte 1, Analyte 2, Analyte 3, Analyte 4 |                              |                         |                        |                    |

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 vial.
- This product is not intended for use as a standard or calibrator.

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

## Assignment of Values

| ALINITY/ARCHITECT Chemistry Systems |      |         | LEVEL 1  |       | LEVEL 2 |       | LEVEL 3 |       |
|-------------------------------------|------|---------|----------|-------|---------|-------|---------|-------|
| ANALYTES                            | ARCH | Alinity | Mean     | Range | Mean    | Range | Mean    | Range |
|                                     |      |         | SI UNITS |       |         |       |         |       |

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

- i** Lot-specific target values and ranges can be downloaded in xml file format from the Technical Library (for Alinity systems only).

# 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/](http://www.technopathclinicaldiagnostics.com/landing-pages/sign-up-for-notification-of-changes-to-ifus/)



# Immunoassay Quality Controls

## Multichem® IA Plus

Test Consolidation for  
Immunoassay QC in a Liquid  
Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Onboard Storage (Alinity)
- Test consolidated immunoassay control includes general IA, cardiac markers and tumor markers
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 5 day onboard vial stability
- 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 Tri-level | 3 x 4 x 5mL (60mL) | 08P86-10 |

## Analytes with performance and stability claims:

|                         |                              |                            |                               |
|-------------------------|------------------------------|----------------------------|-------------------------------|
| 25-OH Vitamin D         | C-Peptide                    | Insulin                    | Sex Hormone Binding           |
| Alpha Fetoprotein (AFP) | DHEA-Sulfate                 | Luteinizing Hormone        | Globulin                      |
| Anti-thyroglobulin      | Estradiol                    | Myoglobin                  | Testosterone                  |
| Anti-thyroperoxidase    | Ferritin                     | NT Pro-BNP                 | Thyroglobulin                 |
| BNP (1-32)              | Folate                       | Parathyroid Hormone (PTH)  | Thyroid Stimulating           |
| CA 125                  | Follicle Stimulating Hormone | (1-84)                     | Hormone (TSH)                 |
| CA 15-3                 | (FSH)                        | Progesterone               | Thyroxine, Free (FT4)         |
| CA 19-9                 | High Sensitive Troponin I    | Prolactin                  | Thyroxine, Total (TT4)        |
| Carcinogenic Embryonic  | Homocysteine                 | Prostate Specific Antigen, | Triiodothyronine, Free (FT3)  |
| Antigen (CEA)           | Human Chorionic              | Free                       | Triiodothyronine, Total (TT3) |
| CK-MB                   | Gonadotropin (BhCG)          | Prostate Specific Antigen, | T-Uptake                      |
| Cortisol                | Immunoglobulin E (IgE)       | Total                      | Vitamin B12                   |

## Analytes below may be present in the product.

### No claims are made regarding performance and stability.

|                        |                      |                            |                            |
|------------------------|----------------------|----------------------------|----------------------------|
| 17-Hydroxyprogesterone | Chloramphenicol      | Insulin Like Growth Factor | Quinidine                  |
| Acetaminophen          | Cyclosporine         | (IgF-1)                    | Renin                      |
| Adrenocorticotrophic   | Digoxin              | Lidocaine                  | Salicylate                 |
| Hormone (ACTH)         | Disopyramide         | Lithium                    | Testosterone, Free         |
| Aldosterone            | EPO                  | N-Acetyl procainamide      | Theophylline               |
| Amikacin               | Estriol, Free        | Ostase                     | Thyroxine Binding Globulin |
| Androstenedione        | Estriol, Total       | Phenobarbital              | Tobramycin                 |
| Angiotensin            | Estrogen, Total      | Phenytoin                  | Troponin T                 |
| Caffeine               | Ethosuximide         | Phenytoin, Free            | Ultra Sensitive CRP        |
| Calcitonin             | Gentamicin           | Primidone                  | Valproic Acid              |
| Carbamazepine          | Human Growth Hormone | Procainamide               | Valproic Acid, Free        |
| Carbamazepine, Free    | Ibuprofen            | Procollagen NP Type 1      | Vancomycin                 |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

## Multichem® hsTn

Independent QC assayed for High Sensitivity Troponin I assays



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- High Sensitivity control targeting IFCC recommendations
- Assayed and value assigned for ARCHITECT and Alinity systems

### 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 hsTn | Assayed Single Level | 12 x 3mL (36mL) | 04W26-10 |

## Analytes with performance and stability claims:

Troponin I

## Multichem® IA Speciality

Peptide Hormone QC in a Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 7 day open vial stability at 2°C to 8°C
- Lot specific exceptions noted in IFU

| Product                 | Description                    | Configuration   | PART NO  |
|-------------------------|--------------------------------|-----------------|----------|
| Multichem IA Speciality | Assayed Single level (Level 1) | 12 x 2mL (24mL) | 06S78-31 |
|                         | Assayed Single level (Level 2) | 12 x 2mL (24mL) | 06S78-32 |
|                         | Assayed Single level (Level 3) | 12 x 2mL (24mL) | 06S78-33 |

## Analytes with performance and stability claims:

BNP  
Parathyroid Hormone  
Procalcitonin

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

ACTH  
Calcitonin

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

## Multichem® WBT

Immunosuppressant QC in a  
Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Tri-Level utility
- Human-based matrix optimizes performance and recovery of immunosuppressants
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 30 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 WBT | Assayed Tri-level | 3 x 4 x 2mL (24mL) | 04S16-10 |

### Analytes with performance and stability claims:

Cyclosporine  
Sirolimus  
Tacrolimus

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

Folate  
Glucose



NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.



# Clinical Chemistry Quality Controls

## 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 for ease of use
- Onboard Storage (Alinity)
- Tri-level utility for immunoproteins
- Addition of human lipid extracts
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 5 day onboard vial stability
- 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 Single level (Level 1) | 12 x 5mL (60mL) | 08P88-10 |
|                  | Assayed Single level (Level 2) | 12 x 5mL (60mL) | 08P88-11 |
|                  | Assayed Single level (Level 3) | 12 x 5mL (60mL) | 08P88-12 |

### Analytes with performance and stability claims:

|                                     |                              |                             |                                          |
|-------------------------------------|------------------------------|-----------------------------|------------------------------------------|
| Acetaminophen                       | Beta Hydroxybutyrate Bile    | Ethanol                     | Phenytoin                                |
| Acid Phosphatase                    | Acids                        | Fructosamine                | Phosphorous                              |
| Alanine Aminotransferase (ALT)      | Bilirubin, Direct            | Gamma Glutamyltransferase   | Potassium                                |
| Albumin BCG                         | Bilirubin, Total             | Gentamicin                  | Prealbumin                               |
| Alkaline Phosphatase (ALP)          | Calcium                      | Glucose                     | Protein, Total                           |
| Alpha Hydroxybutyrate Dehydrogenase | Carbamazepine                | Haptoglobin                 | Rheumatoid Factor                        |
| Alpha-1 Acidglycoprotein            | Carbon Dioxide (Bicarbonate) | Immunoglobulin A            | Salicylate                               |
| Alpha-1 Antitrypsin                 | Ceruloplasmin                | Immunoglobulin G            | Sodium                                   |
| Amikacin                            | Chloride                     | Immunoglobulin M            | Theophylline                             |
| Amylase                             | Cholesterol HDL              | Iron                        | Tobramycin                               |
| Amylase Pancreatic                  | Cholesterol LDL              | Kappa Light Chain           | Transferrin                              |
| Anti-streptolysin O (ASO)           | Cholesterol Total            | Lactate                     | Triglycerides                            |
| Apolipoprotein A1                   | Cholinesterase               | Lactate Dehydrogenase (LDH) | Unsaturated Iron Binding Capacity (UIBC) |
| Apolipoprotein B                    | Complement C3                | Lambda Light Chain          | Urea Nitrogen                            |
| Aspartate Aminotransferase (AST)    | Complement C4                | Lipase <sup>1</sup>         | Uric Acid                                |
| Beta -2 Microglobulin               | C-Reactive Protein           | Lipoprotein (a)             | Valproic Acid                            |
|                                     | Creatine Kinase (CK)         | Lithium                     | Vancomycin                               |
|                                     | Creatinine Enzymatic         | Magnesium                   |                                          |
|                                     | Digoxin                      | Phenobarbital               |                                          |

### Analytes below may be present in the product.

### No claims are made regarding performance and stability.

|                                       |                                   |                            |                                     |
|---------------------------------------|-----------------------------------|----------------------------|-------------------------------------|
| Alpha-2-Macroglobulin                 | C1 Inhibitor                      | Hemopexin                  | Protein Electrophoresis             |
| ADNase B (Anti-Streptococcal DNase B) | Caffeine                          | IgE                        | Retinol Binding Protein             |
| Angiotensin Converting Enzyme         | Calcium Ionized                   | IgG1, Subclass             | sTfR (Soluble Transferrin Receptor) |
| Antithrombin III                      | CH50 (Total hemolytic Complement) | IgG2, Subclass             | Thyroxine, Total (TT4)              |
| Beta Hydroxybutyrate Dehydrogenase    | Copper                            | IgG3, Subclass             | Total Iron Binding Capacity         |
| Bilirubin Indirect                    | Cortisol                          | IgG4, Subclass             | Triiodothyronine, Total (TT3)       |
|                                       | Cystatin C                        | Osmolality                 | Zinc                                |
|                                       | Ferritin                          | Properdin Factor B         |                                     |
|                                       |                                   | Prostatic Acid Phosphatase |                                     |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

1: Multichem LPS also available

## Multichem® LPS

Lipase QC in a Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Tri-level utility
- Human based Lipase provides greater accuracy and performance
- Assayed and value assigned for ARCHITECT and Alinity systems

### 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
- Value Assignment
- Abbott Lipase 2 (Lip2) assay 4U00 (Alinity)
- Abbott Lipase 2 (Lip2) assay 4T04 (ARCHITECT)
- Target values available for ARCHITECT Lipase assay 7D80

| Product       | Description       | Configuration | PART NO  |
|---------------|-------------------|---------------|----------|
| Multichem LPS | Assayed Tri-level | 3 x 4 x 3mL   | 06V83-10 |

## Analytes with performance and stability claims:

Lipase

## Multichem® P

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



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use.
- Onboard Storage (Alinity)
- Provides truly elevated values of specific proteins to control the analytical range
- Supplementary single-level immunoprotein control to complement Multichem S Plus
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 7 day onboard vial stability
- 14 day open vial stability at 2°C to 8°C
- Lot specific exceptions noted in IFU

| Product     | Description          | Configuration | PART NO  |
|-------------|----------------------|---------------|----------|
| Multichem P | Assayed Single Level | 12 x 3mL      | 08P90-10 |

## Analytes with performance and stability claims:

|                            |                       |                    |                   |
|----------------------------|-----------------------|--------------------|-------------------|
| Alpha-1 Antitrypsin        | Beta -2 Microglobulin | C-Reactive Protein | Immunoglobulin M  |
| Alpha-1-acid glycoprotein  | Ceruloplasmin         | Haptoglobin        | Prealbumin        |
| Apolipoprotein A1 (APO A1) | Complement C3         | Immunoglobulin A   | Rheumatoid Factor |
| Apolipoprotein B (APO B)   | Complement C4         | Immunoglobulin G   | Transferrin       |

## Analytes below may be present in the product.

### No claims are made regarding performance and stability.

|                                     |                                   |                    |                                     |
|-------------------------------------|-----------------------------------|--------------------|-------------------------------------|
| ADNase B (Anti-Streptococcal DNase) | Antithrombin III                  | IgE                | Lipoprotein (a)                     |
| Albumin                             | C1 Inhibitor                      | IgG1, Subclass     | Properdin Factor B                  |
| Alpha 2-macroglobulin               | CH50 (Total hemolytic Complement) | IgG2, Subclass     | Retinol Binding Protein             |
| Angiotensin Converting Enzyme       | Cystatin C                        | IgG3, Subclass     | sTfR (Soluble Transferrin Receptor) |
| Antistreptolysin O (ASO)            | Ferritin                          | IgG4, Subclass     | Total Protein                       |
|                                     | Hemopexin                         | Kappa Light Chain  |                                     |
|                                     |                                   | Lambda Light Chain |                                     |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance 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 for ease of use
- Onboard Storage (Alinity)
- Greater stability and performance for creatinine
- Addition of human based microalbumin provides greater accuracy and performance
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 24 month closed vial stability at 2°C to 8°C
- 7 day onboard stability
- 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 Bi-level | 2 x 6 x 5mL (60mL) | 08P89-10 |

### Analytes with performance and stability claims:

Amylase  
Calcium  
Chloride  
Cortisol  
Creatinine

Glucose  
Magnesium  
Microalbumin  
Phosphorous  
Potassium

Sodium  
Urea Nitrogen  
Uric Acid  
Urinary Protein

### Analytes below may be present in the product.

**No claims are made regarding performance and stability.**

Human Chorionic Gonadotropin  
Osmolality  
Specific Gravity

## Multichem® A1c

Diabetes Haemoglobin  
A1c QC in a Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Target values across bi-level material to monitor clinical and analytical range at key clinical decision points
- Mimics performance of patient sample
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 24 month closed vial stability at -20°C to -80°C
- 30 day open vial stability at 2°C to 8°C
- Lot specific exceptions noted in IFU

| Product       | Description      | Configuration | PART NO  |
|---------------|------------------|---------------|----------|
| Multichem A1c | Assayed Bi-level | 2 x 6 x 1mL   | 04V06-10 |

### Analytes with performance and stability claims:

HbA1c

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

## Multichem® CSF

Cerebral Spinal Fluid QC in a  
Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 30 day open vial stability at 2°C to 8°C
- Lot specific exceptions noted in IFU

| Product       | Description                    | Configuration   | PART NO  |
|---------------|--------------------------------|-----------------|----------|
| Multichem CSF | Assayed Single level (Level 1) | 12 x 2mL (24mL) | 06S78-01 |
|               | Assayed Single level (Level 2) | 12 x 2mL (24mL) | 06S78-02 |

### Analytes with performance and stability claims:

Glucose  
Urinary Protein

Lactate<sup>1</sup>  
Immunoglobulin G (IgG)<sup>2</sup>



NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

1. Analytes have been tested with assays intended for matrices other than spinal fluid. Please refer to information provided by the assay manufacturer.
2. Analytes tested on chemistry systems other than Abbott ci systems.



## Multichem® NB

Elevated Neonatal Bilirubin QC in  
a Liquid Stable Format



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed and value assigned for ARCHITECT and Alinity systems

### 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 NB | Assayed Single level (Level B) | 12 x 2mL (12mL) | 06S78-80 |

### Analytes with performance and stability claims:

Bilirubin, Direct  
Bilirubin, Total  
Theophylline

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

Caffeine

## Multichem® D-Dimer

Independent QC to monitor the  
precision of laboratory testing  
procedures for D-Dimer



### Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use
- Assayed and value assigned for ARCHITECT and Alinity systems

### Specifications

- 36 month closed vial stability at -20°C to -80°C
- 30 day open vial stability at 2°C to 8°C
- Lot specific exceptions noted in IFU

| Product           | Description                    | Configuration   | PART NO  |
|-------------------|--------------------------------|-----------------|----------|
| Multichem D-Dimer | Assayed Single level (Level 1) | 12 x 1mL (12mL) | 06S78-91 |
|                   | Assayed Single level (Level 2) | 12 x 1mL (12mL) | 06S78-92 |

### Analytes with performance and stability claims:

D-Dimer

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

## IAMQC® Interlaboratory Peer Program

The easiest way to automate Technopath's Multichem® QC data.

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



- 100% automated with AbbottLINK®
- Track shifts and trends over time and across reagent lots on Levey Jennings
- 100% automated with Sigma calculations and reagent lot change tracking
- Peer data automatically uploads every 24 hours
- Daily comparison of internal lab system and global comparisons
- Group Coordinator, Levey Jennings and Exception reports automatically emailed to the laboratory on a monthly basis.

**100%**  
AUTOMATED  
PEER COMPARISON  
SOFTWARE

### Setting up Abbott Instruments with IAMQC Inter-laboratory Peer Program

It's as simple as step 1, 2 and 3.  
The Technopath service team will get your laboratory  
set up and ready to go.

**1**

#### REGISTER

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

**2**

#### ACTIVATE

Account is activated  
after verification

**3**

#### LOGON

Once the account is activated,  
the Technopath service team  
will send the laboratory login  
details and a user guide.

## Order Information:

Abbott list numbers are ordered through the standard Abbott order process.

| Multichem® QC for Abbott ci Systems |                                                             |                                  |                                  |                                                                                                                                                                                                                                       |
|-------------------------------------|-------------------------------------------------------------|----------------------------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunoassay QC                      |                                                             |                                  |                                  |                                                                                                                                                                                                                                       |
| PRODUCT NAME                        | ABBOTT LIST NO.                                             | VIAL CODE                        | KIT CONFIG.                      | FEATURES                                                                                                                                                                                                                              |
| Multichem IA Plus                   | 08P86-10                                                    | 8P8601<br>8P8602<br>8P8603       | Tri-level<br>3 x 4 x 5mL         | <ul style="list-style-type: none"> <li>Barcoded Vial</li> <li>Direct Sampling</li> <li>Onboard Storage</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Immunoassay Menu</li> <li>Human-based Matrix</li> </ul>              |
| Multichem hsTn                      | 04W26-10                                                    | HS301A                           | 12 x 3mL                         | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Cardiac QC: Troponin I</li> <li>Human-based Matrix</li> </ul>                                                                                              |
| Multichem IA Speciality             | Level 1: 06S78-31<br>Level 2: 06S78-32<br>Level 3: 06S78-33 | BP301A<br>BP302A<br>BP303A       | 12 x 2mL<br>12 x 2mL<br>12 x 2mL | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Peptide Hormone QC: ACTH, BNP, Calcitonin, Parathyroid Hormone, Procalcitonin</li> <li>Human-based Matrix</li> </ul>                                       |
| Multichem WBT                       | 04S16-10                                                    | 04S16101<br>04S16102<br>04S16103 | Tri-level<br>3 x 4 x 2mL         | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Immunosuppressant QC: Cyclosporine, Folate, Glucose, Sirolimus, Tacrolimus</li> <li>Whole Blood Base</li> </ul>                                            |
| Clinical Chemistry QC               |                                                             |                                  |                                  |                                                                                                                                                                                                                                       |
| PRODUCT NAME                        | ABBOTT LIST NO.                                             | VIAL CODE                        | KIT CONFIG.                      | FEATURES                                                                                                                                                                                                                              |
| Multichem S Plus                    | Level 1: 08P88-10<br>Level 2: 08P88-11<br>Level 3: 08P88-12 | 8P8801<br>8P8802<br>8P8803       | 12 x 5mL<br>12 x 5mL<br>12 x 5mL | <ul style="list-style-type: none"> <li>Barcoded Vial</li> <li>Direct Sampling</li> <li>Onboard Storage</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Chemistry and Immunology Menu</li> <li>Human-based Matrix</li> </ul> |
| Multichem LPS                       | 06V83-10                                                    | 06V8301<br>06V8302<br>06V8303    | Tri-level<br>3 x 4 x 3mL         | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Lipase QC: Lipase</li> <li>Human-based Matrix</li> </ul>                                                                                                   |
| Multichem P                         | 08P90-10                                                    | 8P90PA                           | 12 x 3mL                         | <ul style="list-style-type: none"> <li>Barcoded Vial</li> <li>Direct Sampling</li> <li>Onboard Storage</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Immunoprotein Menu</li> <li>Human-based Matrix</li> </ul>            |
| Multichem U                         | 08P89-10                                                    | 8P8901<br>8P8902                 | Bi-level<br>2 x 6 x 5mL          | <ul style="list-style-type: none"> <li>Barcoded Vial</li> <li>Direct Sampling</li> <li>Onboard Storage</li> <li>Bi-level</li> <li>Consolidated Urine Chemistry Menu</li> <li>Human Urine-based Matrix</li> </ul>                      |
| Multichem A1c                       | 04V06-10                                                    | HB001X<br>HB002X                 | Bi-level<br>2 x 6 x 1mL          | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Diabetes QC: HbA1c</li> <li>Whole Blood Base</li> </ul>                                                                                                    |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

## Multichem® QC for Abbott ci Systems

| PRODUCT NAME      | ABBOTT LIST NO.                        | VIAL CODE        | KIT CONFIG.          | FEATURES                                                                                                                                                                                             |
|-------------------|----------------------------------------|------------------|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multichem CSF     | Level 1: 06S78-01<br>Level 2: 06S78-02 | CF101A<br>CF102A | 12 x 2mL<br>12 x 2mL | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Cerebral Spinal Fluid QC: Glucose, Lactate, Urinary Protein</li> <li>Human-based Matrix</li> </ul>                        |
| Multichem NB      | 06S78-80                               | NB800A           | 12 x 2mL             | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Neonatal Bilirubin QC: Bilirubin, Direct, Bilirubin, Total, Caffeine, Theophylline</li> <li>Human-based Matrix</li> </ul> |
| Multichem D-Dimer | Level 1: 06S78-91<br>Level 2: 06S78-92 | DM901A<br>DM902A | 12 x 1mL<br>12 x 1mL | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Coagulation QC: D-Dimer</li> <li>Human-based Matrix</li> </ul>                                                            |

## Additional Multichem® QC for Abbott ci Systems

### Immunoassay QC

| PRODUCT NAME      | ABBOTT LIST NO. | VIAL CODE                  | KIT CONFIG.              | FEATURES                                                                                                                                                                                   |
|-------------------|-----------------|----------------------------|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multichem IA Plus | 05P76-10        | IA311A<br>IA312A<br>IA313A | Tri-level<br>3 x 4 x 5mL | <ul style="list-style-type: none"> <li>Standard Vial</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Immunoassay Menu</li> <li>Human-based Matrix</li> </ul>                     |
| Multichem WBT     | 05P77-10        | WB001A<br>WB002A<br>WB003A | Tri-level<br>3 x 4 x 2mL | <ul style="list-style-type: none"> <li>Liquid Frozen Ready to Use</li> <li>Immunosuppressant QC: Cyclosporine, Folate, Glucose, Sirolimus, Tacrolimus</li> <li>Whole Blood Base</li> </ul> |

### Clinical Chemistry QC

| PRODUCT NAME     | ABBOTT LIST NO.                                             | VIAL CODE                                 | KIT CONFIG.                      | FEATURES                                                                                                                                                                            |
|------------------|-------------------------------------------------------------|-------------------------------------------|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multichem S Plus | Level 1: 05P78-10<br>Level 2: 05P78-11<br>Level 3: 05P78-12 | CH101PLA.05<br>CH102PLA.05<br>CH103PLA.05 | 12 x 5mL<br>12 x 5mL<br>12 x 5mL | <ul style="list-style-type: none"> <li>Standard Vial</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Chemistry and Immunology Menu</li> <li>Human-based Matrix</li> </ul> |
| Multichem P      | 05P81-10                                                    | SP40PA                                    | 12 x 3mL                         | <ul style="list-style-type: none"> <li>Standard Vial</li> <li>Liquid Frozen Ready to Use</li> <li>Consolidated Immunoprotein Menu</li> <li>Human-based Matrix</li> </ul>            |
| Multichem U      | 05P80-10                                                    | UC201A<br>UC202A                          | Bi-level<br>2 x 6 x 5mL          | <ul style="list-style-type: none"> <li>Standard Vial</li> <li>Consolidated Urine Chemistry Menu</li> <li>Human Urine-based Matrix</li> </ul>                                        |

### Dropper Tips

| PRODUCT NAME | ABBOTT LIST NO. | VIAL CODE | KIT CONFIG. | FEATURES |
|--------------|-----------------|-----------|-------------|----------|
| Dropper Tips | 06P18-01        | -         | -           | -        |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.



## Order Information:

Contact your local sales representative.

### Complementary Quality Controls from Technopath Clinical Diagnostics

#### Immunoassay QC

| PRODUCT NAME  | TECHNOPATH PART CODE | KIT CONFIG.              | ANALYTES                       | FEATURES                                                               |
|---------------|----------------------|--------------------------|--------------------------------|------------------------------------------------------------------------|
| Multichem AMH | AM500A               | Tri-level<br>3 x 4 x 2mL | • Anti-Müllerian Hormone (AMH) | • Liquid Frozen Ready to Use<br>• Fertility QC<br>• Human-based Matrix |

#### Clinical Chemistry QC

| PRODUCT NAME | TECHNOPATH PART CODE                                  | KIT CONFIG.                      | ANALYTES               | FEATURES                                              |
|--------------|-------------------------------------------------------|----------------------------------|------------------------|-------------------------------------------------------|
| Multichem AE | Level 1: AE611A<br>Level 2: AE612A<br>Level 3: AE613A | 12 x 2mL<br>12 x 2mL<br>12 x 2mL | • Ammonia<br>• Ethanol | • Liquid Frozen Ready to Use<br>• Ammonia, Ethanol QC |

#### Infectious Disease Serology QC

| PRODUCT NAME                        | TECHNOPATH PART CODE | KIT CONFIG. | ANALYTES                                                                                                                                         | FEATURES                                                                                                                                                                                                                   |
|-------------------------------------|----------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multichem ID-B <sup>1,2</sup>       | SR101B               | 4 x 5mL     | • Anti-HIV-1 IgG<br>• Anti-HCV IgG<br>• Anti-HBc IgG<br>• HBsAg<br>• Anti-HTLV-1 IgG<br>• Anti-Treponema Pallidum IgG                            | • Barcoded Tube<br>• Direct Sampling<br>• Qualitative Quality Control<br>• Liquid for Ease of Use<br>• Consolidated Serology QC<br>• Human-based Proprietary Formulation<br>• Mimics Performance of Patient Samples        |
| Multichem ID-HEP <sup>1,2</sup>     | 2000-0106            | 4 x 4mL     | • HBeAg<br>• Anti-HAV IgM<br>• Anti-HBc IgM                                                                                                      | • Barcoded Tube<br>• Direct Sampling<br>• Qualitative Quality Control<br>• Liquid Frozen for Ease of Use<br>• Consolidated Serology QC<br>• Human-based Proprietary Formulation<br>• Mimics Performance of Patient Samples |
| Multichem ID-HEP <sup>2,1,2</sup>   | 2000-0107            | 4 x 4mL     | • Anti-HAV IgG<br>• Anti-HBs<br>• Anti-HBe                                                                                                       | • Barcoded Tube<br>• Direct Sampling<br>• Qualitative Quality Control<br>• Liquid for Ease of Use<br>• Consolidated Serology QC<br>• Human-based Proprietary Formulation<br>• Mimics Performance of Patient Samples        |
| Multichem ID-MMNeg <sup>1,2</sup>   | 2010-0026            | 4 x 4mL     | • Anti-HAV IgG<br>• Anti-HAV IgM<br>• Anti-HBc<br>• Anti-HBc IgM<br>• Anti-HBe<br>• Anti-HBs<br>• Anti-HCV<br>• Anti-HIV 1/2<br>• Anti-HTLV I/II | • CMV IgG<br>• CMV IgM<br>• HBeAg<br>• HBsAg<br>• HCV Ag<br>• Lyme IgG<br>• Lyme IgM<br>• Syphilis TP                                                                                                                      |
| Multichem ID-SeroNeg <sup>1,2</sup> | SR100N               | 4 x 5mL     | • Anti-HIV-1 IgG<br>• Anti-HCV IgG<br>• Anti-HBc IgG<br>• HBsAg<br>• Anti-HTLV-1 IgG<br>• Anti-Treponema Pallidum IgG                            | • Barcoded Tube<br>• Direct Sampling<br>• Qualitative Quality Control<br>• Liquid for Ease of Use<br>• Consolidated Serology QC<br>• Human-based Proprietary Formulation<br>• Mimics Performance of Patient Samples        |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

1. This is an unassayed product, with no platform claims in the USA

2. This product is not intended for use in donor screening testing

Products sold by LGC Technopath and information here is noted for awareness only.

## Complementary Quality Controls from Technopath Clinical Diagnostics

### Infectious Disease Serology QC

| PRODUCT NAME                            | TECHNOPATH<br>PART CODE | KIT<br>CONFIG. | ANALYTES                                                           | FEATURES                                                                                                                                                                                                          |
|-----------------------------------------|-------------------------|----------------|--------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Multichem<br>ID-COVID19 G <sup>1</sup>  | CVG200P                 | 4 x 4mL        | Positive for<br>Immunoglobulin G (IgG) antibodies<br>to SARS-CoV-2 | <ul style="list-style-type: none"> <li>• Qualitative Quality Control</li> <li>• Liquid for Ease of Use</li> <li>• Human-based Proprietary Formulation</li> <li>• Mimics Performance of Patient Samples</li> </ul> |
| Multichem<br>ID-COVID19Neg <sup>1</sup> | CVN200N                 | 4 x 4mL        | Negative for<br>Immunoglobulin G (IgG) antibodies<br>to SARS-CoV-2 | <ul style="list-style-type: none"> <li>• Qualitative Quality Control</li> <li>• Liquid for Ease of Use</li> <li>• Human-based Proprietary Formulation</li> <li>• Mimics Performance of Patient Samples</li> </ul> |

NOTE: For all products, please refer to lot specific IFU and Data Sheet for stability and performance claims.

1. This is an unassayed product, with no platform claims in the USA

Products sold by LGC Technopath and information here is noted for awareness only.



**TECHNOPATH**  
CLINICAL DIAGNOSTICS

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[technopathcd.com](http://technopathcd.com)

Technopath Life Sciences Park  
Fort Henry, Ballina,  
Co. Tipperary V94FF1P, Ireland.

Tel: +353 61 525700

Distributed by:



corelaboratory.abbott  
100 Abbott Park Road,  
Abbott Park, IL 60054-6083

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