



TECHNOPATH
CLINICAL DIAGNOSTICS



Third Party Quality Controls for **Abbott Alinity ci Systems**

THE QUALITY CONTROL COMPANY

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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

Enhanced Laboratory Efficiencies with Technopath QC Solutions 3

Alinity ci-Series Quality Controls 4

Greater Operational Efficiencies in QC Processes 5

Quality Control Materials

Multichem IA Plus 6

Multichem S Plus 7

Multichem P 8

Multichem A1c 8

Multichem U 9

Multichem WBT 9

Quality Control Software

Peer Software 10

Ordering Information

Technopath Ordering Information for Alinity Systems 11

Technopath Ordering Information for Architect Systems 12

Enhanced laboratory efficiencies with Technopath Clinical Diagnostics QC solutions

Customers who use Technopath's Multichem QC increase the efficiency of their laboratory, improve the quality of their patient care and reduce the cost of their quality control program.

"The main driver for change was a mandate to consolidate and improve workflow efficiencies. Reduced physical cost, coupled with a reduction in staff time, proved significant."

- Eoin O'Rourke,
Head of Pathology, Blackrock Clinic Ltd., Blackrock, County Dublin, Ireland

Technopath was the first company in the world to develop truly consolidated third party quality controls for hospital laboratories. The proprietary manufacturing processes allow incorporation of greater numbers of analytes in to a single matrix, which enables extensive test menu consolidation. Technopath's two flagship products, Multichem® IA Plus and Multichem® S Plus, contain more than 190 tests combined. These two products can replace up to 8 competitor products, driving significant efficiencies for laboratories.

The raw materials used to create the matrix for Technopath's range of QC material are all sourced directly from national blood banks. Having direct access to high quality fresh frozen plasma ensures Technopath's Multichem QC products mimic the performance of patient samples. Technopath are experts in the stabilisation of labile analytes (i.e. Troponin, Bilirubin, etc.) and they use human based lipid additions to ensure commutability across testing systems. The combination of these high quality raw materials and a proprietary process gives Technopath a significant competitive advantage over key global competitors.

REDUCE QC HANDLING REQUIREMENTS

BY UP TO
80%

Save up to 7 days of technologist time per year.¹

Competitor Product



Multichem® QC

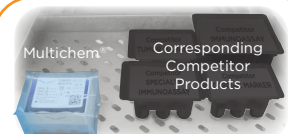
REDUCE DEAD SPACE QC MATERIAL¹

BY UP TO **75%**



REDUCE INSTRUMENT TESTING TIME¹

BY UP TO **17%**



REDUCE STORAGE REQUIREMENTS¹

BY UP TO **80%**

REDUCE CARBON FOOTPRINT

Consolidated controls use fewer vials and less packaging than corresponding competitor controls, reducing a laboratory's carbon footprint.¹



REDUCE THE NUMBER OF NEW QC LOT EVALUATIONS¹

BY UP TO **87%**

1. Microcoat Study, 2016. External study commissioned by Technopath Clinical Diagnostics. Data on file.

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



Bar coded quality controls make loading faster, easier and less prone to errors.¹ No pipetting or manual order entry is necessary for manufacturer barcoded vials.²

Up to six quality controls can be loaded on a single rack and up to four racks can be loaded on the instrument.



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

Technopath and Abbott help your lab achieve greater operational efficiencies in QC processes.



Accreditation/Regulatory Compliance

Third-party QC material facilitates meeting accreditation and regulatory guidelines, such as CLIA, CLSI, CAP and ISO.



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.



XML File

XML File available to facilitate automatic upload of ranges for Alinity and Architect systems, reducing errors and increasing productivity.



Human-Based Matrices

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



Lot Confirmation

Lot confirmation testing of top 20 assays helps speed up QC material troubleshooting*.



Large Lot Sizes

Large lot sizes and fewer lot changes, on average two per year.



Automatic Results Upload To IAMQC® Peer with No Hardware Installation Required

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

Peer Group Size

Peer data from over 1,500 Abbott systems.

Inter-Lab QC Comparison Reports

Technopath IAMQC® software offers Six-Sigma, Levey-Jennings, Youden, Bias, Group Coordinator, Monthly Summary, and Exceptions reports to give your laboratory the information it requires to monitor QC.

*Currently available for Architect systems only.

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

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

Multichem® IA Plus

Onboard and Offboard
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
- 86 Analytes (35 assayed)
- Test consolidated immunoassay control includes general IA, cardiac markers and tumor markers
- Tri-level utility for binding proteins including SHBG, Anti TG, and Anti TPO

- Assayed and optimized for Alinity and aimed at the clinical decision points:
With particular benefits for Free T4 and Free T3

Specifications

- 28 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

Analyte List: Value Assigned for Alinity

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

Analyte List: No Value Claimed

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

Multichem® S Plus

Onboard and Offboard
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
- 104 Analytes (56 assayed)
- Tri-level utility for immunoproteins
- Addition of human lipid extracts
- Facilitates tri-level utility for Cholesterol HDL & LDL, Apo A1, and Apo B

- Full range of TDMs including Lithium, Amikacin and Vancomycin

Specifications

- 28 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
	Unassayed Single level (Level 1)	12 x 5mL (60mL)	08P87-10
	Unassayed Single level (Level 2)	12 x 5mL (60mL)	08P87-11
	Unassayed Single level (Level 3)	12 x 5mL (60mL)	08P87-12

Analyte List: Value Assigned for Alinity

Alpha-1 Acidglycoprotein	Beta -2 Microglobulin*	Creatinine Picrate	Magnesium
Alpha-1 Antitrypsin	Bile Acids	C-Reactive Protein	Phenobarbital
Activated Alanine	Bilirubin, Direct	Digoxin	Phenytoin
Aminotransferase (AALT)	Bilirubin, Total	Ethanol	Phosphorous
Activated Aspartate	Calcium	Gamma Glutamyltransferase	Potassium
Aminotransferase (AAST)	Carbamazepine	Gentamicin	Prealbumin
Albumin BCG	Carbon Dioxide	Glucose	Protein, Total
Albumin BCP	(Bicarbonate)	Haptoglobin	Rheumatoid Factor
Alkaline Phosphatase	Ceruloplasmin	Immunoglobulin A	Salicylate
(ALKP)	Chloride	Immunoglobulin G	Sodium
Alanine Aminotransferase	Cholesterol HDL	Immunoglobulin M	Theophylline
(ALT)	Cholesterol LDL	Iron	Tobramycin
Amikacin	Cholesterol Total	Unsaturated Iron Binding	Transferrin
Amylase	Cholinesterase	Capacity	Triglycerides
Amylase Pancreatic	Creatine Kinase (CK)	Lactate	Urea Nitrogen
Apolipoprotein A1	Complement C3	Lactate Dehydrogenase	Uric Acid
Apolipoprotein B	Complement C4	(LDH)	Valproic Acid
Aspartate Aminotransferase	Creatinine Enzymatic	Lithium	Vancomycin
(AST)			

Analyte List: No Value Claimed

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

* Coming Soon

Multichem® P

Onboard and Offboard Test Consolidation for Serum Immunoprotein QC in a Liquid Stable Format



Features

- Human based proprietary formulation
- Mimics performance of patient samples
- Liquid for ease of use.
- 39 Analytes (16 assayed)
- Supplementary single-level immunoprotein control to complement Multichem S Plus
- Provides truly elevated values of specific proteins to control the analytical range

- Provides tri-level utility for RF when used in conjunction with Multichem S Plus

Specifications

- 28 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	O8P90-10

Analyte List: Value Assigned for Alinity

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

Analyte List: No Value Claimed

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

Multichem® A1c

Offboard Only Diabetes Haemoglobin A1c QC in a Liquid Stable Format



Features

- Optimized and value-assigned for Abbott ARCHITECT and Alinity systems
- Liquid-frozen and ready for use
- Target values across bi-level material to monitor clinical and analytical range at key clinical decision points
- Mimics performance of patient sample

- Analytes: A1c, %HbA1

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	O4VO6-10

Analyte List: Value Assigned for Alinity

% HbA1c

Multichem® U

Onboard and Offboard

Test Consolidation for Urinary Chemistry QC in a Liquid Stable Format



Features

- Liquid stable, human-based bi-level control
- Mimics performance of patient samples.
- 18 Analytes (14 assayed)
- Greater stability and performance for creatinine
- Assayed and optimized for Alinity family of analyzers

- Addition of human based microalbumin provides greater accuracy and performance

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

Analyte List: Value Assigned for Alinity

Amylase
Calcium
Chloride
Creatinine Enzymatic
Creatinine Picrate

Glucose
Magnesium
Microalbumin
Phosphorous
Potassium

Sodium
Urea Nitrogen
Uric Acid
Urinary Protein

Analyte List: No Value Claimed

Cortisol
Osmolality

Human Chorionic Gonadotropin
Specific Gravity

Multichem® WBT

Offboard Only

Immunosuppressant QC in a Liquid Stable Format



Features

- Liquid stable, human-based Tri-Level Control
- Human-based matrix optimizes performance and recovery of immunosuppressants
- 5 Analytes (3 assayed)
- Assayed and optimized for Abbott 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

Analyte List: Value Assigned for Alinity

Cyclosporine
Sirolimus
Tacrolimus

Analyte List: No Value Claimed

RBC Folate
Glucose



Enhance laboratory operations with the only Peer comparison software supported by Abbottlink



IAMQC® Peer facilitates laboratories testing the same lot number of control material to access valuable information from fellow instrument users through peer comparison. Reports from IAMQC Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can help labs to determine if their systems are in control by reviewing their instrument results and quickly ascertaining the performance relative to the peer group.

Sigma Metrics Report

Offers end-users the opportunity to automatically calculate and review their sigma metric performance.

Bias Report

The bias report gives a detailed comparison between laboratory, affiliation, and peer group analytics. This report outputs to Microsoft Excel format.

Group Coordinator Report

Provides a test by test listing of statistics for the lab and its peer groups. The Group Coordinator Report documents all relevant data submitted to IAMQC and automatically provides a statistical analysis.

Levey Jennings Report

The Levey Jennings Report displays individual daily QC means for the selected month for a specific analyte. The report can be generated for two or three levels of QC material.

Monthly Summary Report

For each test and control level, this report summarizes statistics for the last twelve months and Lot-to-Date period for the laboratory and its peer groups for long-term intra-laboratory and inter-laboratory comparisons.

Exception Notes Report

This report summarizes the laboratory's tests and analytical methods which differ in performance from its peer group using SDI, CVI and Total Error performance criteria.

Youden Plot Report

The Youden Report describes internal laboratory performance against the test system peer and method principle peer using the Youden Plot design.

Quality Controls for Alinity Systems

Order through your
Local Abbott Affiliate

PRODUCT NAME	ABBOTT LIST NO.	KIT CONFIG.	FEATURE SET
Multichem IA Plus	08P86-10	3 x 4 x 5mL	<ul style="list-style-type: none"> • Tri-level • Immunoassay QC • Serum base • 86 analytes (35 assayed)
Multichem S Plus Assayed	Level 1: 08P88-10 Level 2: 08P88-11 Level 3: 08P88-12	12 x 5mL 12 x 5mL 12 x 5mL	<ul style="list-style-type: none"> • Single Level • Serum Chemistry and Immunology QC • Serum Base • 104 analytes (56 assayed)
Multichem S Plus Unassayed	Level 1: 08P87-10 Level 2: 08P87-11 Level 3: 08P87-12	12 x 5mL 12 x 5mL 12 x 5mL	<ul style="list-style-type: none"> • Single Level • Serum Chemistry and Immunology QC • Serum Base • 104 analytes
Multichem hsTn	04W26-10	12 x 3 mL	<ul style="list-style-type: none"> • Single Level • Serum base • Assayed
Multichem P	08P90-10	12 x 3mL	<ul style="list-style-type: none"> • Single Level • Serum Immunoprotein QC • Serum base • 39 analytes (16 assayed)
Multichem A1c	04VO6-10	2 x 6 x 1mL	<ul style="list-style-type: none"> • Bi-level • HbA1c QC • Whole blood base • 1 analyte, assayed
Multichem U	08P89-10	2 x 6 x 5mL	<ul style="list-style-type: none"> • Bi-level • Urine Chemistry QC • Urine base • 18 analytes (14 assayed)
Multichem WBT	04S16-10	3 x 4 x 2mL	<ul style="list-style-type: none"> • Tri-level • Whole Blood Transplant QC • Whole blood base • 5 analytes (3 assayed)

Quality Controls for ARCHITECT Systems

Order through your
Local Abbott Affiliate

PRODUCT NAME	ABBOTT LIST NO.	KIT CONFIG.	FEATURE SET
Multichem IA Plus	05P76-10	3 x 12 x 5mL	<ul style="list-style-type: none"> • Tri-level • Immunoassay QC • Serum base • 86 analytes (35 assayed)
Multichem S Plus - Assayed	Level 1: 05P78-10 Level 2: 05P78-11 Level 3: 05P78-12	12 x 5mL	<ul style="list-style-type: none"> • Single Level • Serum Chemistry and Immunology QC • Serum Base • 104 analytes (56 assayed)
Multichem S Plus - Unassayed	Level 1: 05P79-10 Level 2: 05P79-11 Level 3: 05P79-12	12 x 5mL	<ul style="list-style-type: none"> • Single Level • Serum Chemistry and Immunology QC • Serum Base • 104 analytes
Multichem hsTn	04W26-10	12 x 3 mL	<ul style="list-style-type: none"> • Single Level • Serum base • Assayed
Multichem P	05P81-10	12 x 3mL	<ul style="list-style-type: none"> • Single Level • Serum Immunoprotein QC • Serum base • 39 analytes (16 assayed)
Multichem U	05P80-10	2 x 12 x 5mL	<ul style="list-style-type: none"> • Bi-level • Urine Chemistry QC • Urine base • 18 analytes (14 assayed)
Multichem A1c	04VO6-10	2 x 6 x 1mL	<ul style="list-style-type: none"> • Bi-level • HbA1c QC • Whole blood base • 1 analyte, assayed
Multichem WBT	05P77-10	3 x 12 x 5mL	<ul style="list-style-type: none"> • Tri-level • Whole Blood Transplant QC • Whole blood base • 5 analytes (3 assayed)
Dropper Tips	06P18-01	100 per bag	



TECHNOPATH
CLINICAL DIAGNOSTICS

THE QUALITY CONTROL COMPANY

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