QUALITY CONTROLS
FOR OPTIMAL PATIENT CARE
Dear Reader

For ease of navigation, internal links are included in this document:

• Items in the list of Contents are linked to their corresponding pages
• Click on any page number to return to the Contents page
• URLs in the document are linked to their websites (internet access required)
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Introduction

Technopath Clinical Diagnostics is an Irish company driven by innovation with a mission to become the global leader in test-consolidated third party quality control materials and real time peer review and QC data management software solutions. We aim to support clinical laboratories to operate more efficiently while improving the quality of patient test results.

We operate in the high growth in vitro diagnostics (IVD) sector. Our business is focused on four core elements:

- Human based quality control material for clinical laboratories - Multichem™
- Quality control software and data management solutions - IAMQC®
- Proficiency testing software and sera - Proficiency testing solutions
- High quality IVD raw materials - IVD Raw Materials

Company Timeline

Founded in 2004 - Technopath Clinical Diagnostics has a track record of achievement driven by our customer focus. We constantly challenge ourselves through our products to improve the efficiency, compliance and cost effectiveness of clinical laboratories while improving the accuracy and quality of patient test results.
Technopath Clinical Diagnostics QC Solutions

Multichem™

Technopath Clinical Diagnostics is one of the largest manufacturers of quality control materials in the world. With an extensive list of analytes included in our Multichem™ product range, choice and flexibility are guaranteed for all customers. Our liquid stable control products include General Clinical Chemistry, Immunoproteins, Immunoassay, Diabetes and Esoteric controls.

An extensive range of kit formats are currently available, providing greater customer flexibility and choice. As part of a commitment to customer demand to provide an increasing test menu, Technopath Clinical Diagnostics is committed to expanding its range of quality controls with new products currently being added to the product offering available to end-users.

Our Multichem™ product range includes liquid-only unassayed and assayed products based on human formulations. Technopath Clinical Diagnostics human based control matrix offers unrivalled test consolidation through 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.
Quality Control Software

Designed to complement and support Technopath Clinical Diagnostics’ Multichem™ Quality Control (QC) product range, IAMQC™ Software provides laboratory managers and technologists with a range of QC software tools to analyse their QC results in real-time.

IAMQC™ Software products allow users to automate, centralise, standardise and improve QC processes in a laboratory setting. Our combination of modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

Technopath Clinical Diagnostics’ full suite of software products provide clinical laboratories significant cost and time savings, whilst delivering higher confidence in analytical testing methods. Choose from Intranet and/or Internet based statistical quality control and quality assurance software products. IAMQC™ software products are practical, graphical, user-definable and easy to use.
Quality Control Material

The requirement for an internal QC program is stated as an integral part of compliance with International accreditation standards. This is simply stated but involves considerable thought and planning on the part of a laboratory. QC strategy begins with a definition of the character of QC material to be employed and the decision making process in a laboratory. This includes

- Selecting the types of QC materials to be used: liquid vs lyophilised, kit vs third party.
- Selecting the characteristics of QC materials based on needs: commutability and matrix effects, target values and traceability.
- Frequency of testing control materials, implementation of appropriate statistical process control rules such as Westgard rules, and evaluation of QC results constitute the core of the internal QC program.
- The final piece of a QC program is vigilance-based, and entails regular review of the effectiveness and relevance of the program. It is important for the internal QC program to identify medically important error and when such error occurs, with a minimum of false alarms. Each of these items is complex and decisions pertaining to them can have a significant impact to the overall quality of examination procedures and patient outcomes.
Liquid controls offer convenience of use and improved vial to vial variability, which will lead to better precision because reconstitution is unnecessary. In order to verify the quality of patient results, control materials should mimic a human sample as closely as possible. Matrix interferences should be minimal and the control material should interact with the test system in a manner similar to the patient sample. The potential for matrix interferences can be minimized in part by using a control material that is made from human plasma, serum or urine. Technopath Clinical Diagnostics has developed propriety processing techniques which make all Multichem™ control materials less dependent on preservatives and stabilizers, thus offering unrivalled product performance.

Features to consider when choosing independent third party QC

Test Consolidation
Third Party QC
Shelf Life / Stability
Value Assignment
Interlaboratory Program
Storage Requirements
Handling
Waste
Test Consolidation

Technopath Clinical Diagnostics is the leading provider globally of multi-analyte, third party controls designed to help streamline QC in all laboratories irrespective of test menu or throughput. Our unique proprietary processing techniques allow incorporation of greater combinations of analytes, which enables extensive test menu consolidation. As a result, our solution offers increased efficiencies with a reduction in inventory management and cost savings, without compromising quality or performance. The use of fewer control vials will, in effect, simplify QC procedures in any laboratory. The inclusion of analytes at clinically relevant concentrations in all Technopath Clinical Diagnostics’ Multichem™ Controls will eliminate the need to purchase additional low or high level controls at extra cost to the customer. The laboratory should evaluate the medical usefulness of the control material in terms of target values. Concentrations of analytes in Technopath Clinical Diagnostics’ Multichem™ Control products are routinely manufactured at levels of medical interest.

Third Party Controls

Control material may be provided by the instrument manufacturer or by an independent control manufacturer. The control materials provided by the manufacturer of the instrument or reagents are often referred to as “in kit” controls. The control materials provided by an independent manufacturer are often referred to as “third party” controls.

The term “third party” is used to describe a quality control product that helps provide an independent assessment of a diagnostic device or method, and is not optimized for any specific instrument or reagent system. Third party controls are manufactured independently of the test system calibrators and reagents. Such controls generally begin with a human base matrix that helps provide a product analogous to a patient sample. Third party controls with a longer shelf life allow use of the same control lot over multiple changes in reagents and calibrators, giving the laboratory the ability to detect shifts that may occur with new reagents or calibrators.

Multichem™ Third Party Controls have distinct advantages over control materials that are linked into reagent/calibrator/analyser systems in that these ‘system’ controls are designed for use only on their own test systems. More importantly, system controls are often manufactured from the same materials as the calibrators. Consequently, the control may mimic the calibrator, making it less sensitive to changes in device performance. This can lead to acceptance of patient test results with analytical
error that could be medically important. Often times a laboratory using an instrument manufacturer or in-kit control may receive a different control lot with each new reagent lot. This does not provide the laboratory with the benefits of long-term QC monitoring.

Regulatory Requirements Emphasize the Need for Using Third Party Quality Controls:

The following are examples of international regulatory standards and guidelines:

“...quality control materials should be different from the calibrator materials to ensure that the QC procedure provides an independent assessment of the measurement procedure’s performance in its entirety, including the procedure for calibration of the measurement.” ¹

“For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytical process.” ²

“Controls independent of those produced by the manufacturer of the test or analyzer should be used.”

“The laboratory must have a system of long-term monitoring of internal quality control results to assess method performance.” ³

“Medical laboratories shall perform internal quality control. Use of third party human matrix quality control is recommended for all analytes.” ⁴

2. 42 CFR Part 493.1256 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Final Rule.
3. NATA (National Association of Testing Authorities)AS 4633 (ISO 15189), Australia, 5.6.1 Internal Quality Control
4. Essential Standards for Registration of Medical Testing Laboratories in India, Quality Council of India, 3.5.2 Quality Assurance
Stability / Shelf Life

Product shelf-life and working stability are important considerations when choosing quality control material. Technopath Clinical Diagnostics’ Multichem™ Control products generally have a shelf life of up to 36 months from the date of manufacture ensuring continuity of lot supply. Each individual control will have its own open vial stability claims and some parameters will have limitations which are noted in the product IFU. The extended open vial stability of many Technopath Clinical Diagnostics’ Multichem™ controls will help laboratories to eliminate waste and ultimately reduce costs through increased efficiencies.

Value Assignment

With continuous innovation in diagnostic instrumentation and techniques, it is more important than ever to have effective, efficient quality control to monitor laboratory assay precision. Our internal value assignment process employs proven value assignment protocols based on specific analyte performance based evidence, ensuring the availability of data for a wide range of instruments and methods.

This protocol is further supplemented with participation of International Reference Laboratories, permitting Technopath Clinical Diagnostics to provide a Multichem™ Control range of unsurpassed reliability.

Technopath Clinical Diagnostics’ Multichem™ Controls utilise a human based serum matrix and are intended for use in monitoring specific analytes on automated analyser platforms. As the Multichem™ Control manufacturing process includes analyte level assessment to a manufacturing specification as part of the production process, Technopath Clinical Diagnostics documents these guideline targets on the IFU, including the instrument on which the results were generated. The end user assigns expected results to unassayed QC material, Technopath Clinical Diagnostics having indicated whether the specific analyte is present or absent.

An assayed control will have analyte values specified in the labelling by Technopath Clinical Diagnostics. These analyte values and associated ranges are only provided as guidelines to the end user. The clinical laboratory establishes its own ranges based on its own test system and criteria.
Storage Requirements

With the volume of testing ever-increasing in the modern laboratory, freezer space is at a premium. Technopath Clinical Diagnostics has focussed on creating a lean kit design that ensures end-users minimise their carbon footprint, whilst reclaiming storage space in their freezer. Consolidating multiple analytes in to fewer products allows Technopath Clinical Diagnostics to minimise the number of products to be purchased to cover your QC strategy. Switching to a consolidated solution frees up space in the freezer which can ultimately be used for alternative purposes or to hold stock of QC that will cover a much longer time period.
Handling

Reducing the number of vials handled in each QC run through consolidation shortens the overall turn-around-time for testing QC in a laboratory setting. Independent studies* have shown that switching to a consolidated QC solution not only reduces the overall time for handling/preparing QC by up to 75%, but also reduces the testing time on the instrument by up to 20% as the platform has less samples to process. Simplifying the handling process with fewer vials also reduces the likelihood of mixing up QC levels/products. Lean IQC procedures facilitates more time for patient testing and frees up staff time for other activities. Technopath Clinical Diagnostics' lean QC solutions facilitate the global trend of streamlining the modern laboratory.

*Efficiency Performance Metrics: Independent comparison of Technopath Clinical Diagnostics and Bio-Rad Third Party Quality Control Materials
Waste

Smaller, more compact kits means less waste going in to the recycling bins and fewer vials to cover your QC strategy means less biohazardous waste. Technopath Clinical Diagnostics is focused on delivering ‘green’ environmentally friendly solutions. In addition, reducing the number of separate products required to cover your QC strategy also facilitates an overall reduction in dead volume QC waste. Each time a QC sample is dispensed in to a sample cup, there is a specific volume of sample at the bottom of the cup that will not be aspirated by the testing platform. This is known as the ‘dead’ volume. There is a cost associated with this waste that can be reduced by minimising the number of separate vials in each QC run through consolidation. Reducing your dead volume waste facilitates a reduction in the overall volume of QC material required to be purchased.

### Technopath Multichem IA Plus

<table>
<thead>
<tr>
<th>Analytes</th>
<th>Test Volume</th>
<th>Dead Volume Waste</th>
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</thead>
<tbody>
<tr>
<td>62</td>
<td>2790ul</td>
<td>6.69%</td>
</tr>
</tbody>
</table>

### Competitor IA Plus

- Cardiac: 2115ul, 200ul, 8.64%
- Tumor Marker: 315ul, 200ul, 38.8%
- Speciality: 450ul, 200ul, 30.8%
- 4 Analytes = 180ul, 200ul, 52.6%

### Dead Volume Waste = 800ul
Interlaboratory Program

IAMQC™ Peer is an innovative, real-time, Peer Comparison Software. This web based system facilitates laboratories testing the same lot number of control material to access valuable information from their colleagues through peer comparison. The reports that are generated in IAMQC™ Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can be extremely valuable, indicating the user’s performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.

To participate in IAMQC™ Peer, each individual laboratory submits their individual results or summary statistics (mean, standard deviation, and number of data points) to the central database maintained by Technopath. Laboratories data may be submitted manually on-line or, alternatively, captured by one of our many live interfacing options. The information provided by IAMQC™ Peer can be used on a monthly basis to evaluate how well lab's methods are operating relative to the overall peer group. Users can also look at this peer data in real-time interactive tables online, when they are investigating a potential problem with accuracy or precision in an individual method.
Quality Policy

Every day we are committed to delivering high quality, safe and effective clinical diagnostic products to achieve maximum customer satisfaction; by complying with the appropriate regulatory requirements supported by our Quality Management System.

Technopath Clinical Diagnostics commitment to quality is achieved by accreditation to internationally recognized standards

CERTIFIED BY:

LICENCED BY:
Multichem™ Chemistry Quality Controls

Clinical Chemistry Quality Controls

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<tr>
<td>Multichem CSF</td>
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Multichem™ S Plus

Providing Third-Party Test Consolidation for Serum Chemistry and Immunology QC in a Liquid Stable Format

Features
- Human based proprietary formulation.
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use.

Specifications
- 36 month closed vial stability at -20°C to -80°C.
- 10 day open vial stability at 2°C to 8°C.

Chemistry
- Albumin
- Bilirubin, Direct
- Bilirubin, Total
- Calcium
- Carbon Dioxide (Bicarbonate)
- Chloride
- Creatinine
- Glucose
- Iron
- Lactate (Lactic acid)
- Magnesium
- Phosphorous
- Potassium
- Protein, Total
- Sodium
- Total Iron Binding Capacity (TIBC)
- Unsaturated Iron Binding Capacity (UIBC)
- Urea
- Uric Acid

Immunoproteins
- Alpha-1 Acidglycoprotein
- Alpha-1 Antitrypsin
- Alpha-2-Macroglobulin*
- Antistreptolysin O (ASO)*
- ADNase B (Anti-Streptococcal DNase B)*
- Antithrombin III*
- Apolipoprotein A1 (Apo A1)
- Apolipoprotein B (Apo B)
- Beta -2 Microglobulin
- C1 inhibitor*
- CH50 (Total hemolytic Complement)*
- Cystatin C*
- Complement C3
- Complement C4
- Ceruloplasmin
- C-Reactive Protein
- Ferritin*
- Haptoglobin
- Hemopexin*
- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- IgE*
- IgG1, Subclass*
- IgG2, Subclass*
- IgG3, Subclass*
- IgG4, Subclass*
- Kappa Light Chain*
- Lambda Light Chain*
- Lipoprotein (a)*
- Prealbumin
- Properdin Factor B*
- Retinol Binding Protein*
- Rheumatoid Factor
- Transferrin
- sTfR (Soluble Transferrin Receptor)*

Enzymes
- Acid Phosphatase
- Alanine Aminotransferase (ALT)
- Alkaline Phosphatase (ALP)
- Amylase (Pancreatic)
- Amylase (Total)
- Aspartate Aminotransferase (AST)
- Alpha Hydroxybutyrate Dehydrogenase*
- Beta Hydroxybutyrate Dehydrogenase*
- Cholinesterase
- Creatine Kinase (CK)
- CKMB*
- Gamma Glutamyltransferase
- Lactate Dehydrogenase (LDH)
- Lipase
- Prostatic Acid Phosphatase*

Lipids
- Cholesterol, HDL
- Cholesterol, LDL
- Cholesterol, Total
- Phospholipids*
- Triglycerides

Therapeutic Drugs
- Acetaminophen
- Amikacin
- Carbamazepine
- Digoxin
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Salicylate
- Theophylline
- Tobramycin
- Valproic Acid
- Vancomycin

*: Please refer to lot specific package inserts for stability and performance claims.
# Multichem™ S

Providing Third-Party Test Consolidation for Serum Chemistry and Immunology QC in a Liquid Stable Format

## Features
- Human based proprietary formulation.
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use.

## Specifications
- 36 month closed vial stability at -20°C to -80°C.
- 10 day open vial stability at 2°C to 8°C.

## Product Description

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
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<td>15 x 10ml</td>
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<td>Multichem S L2</td>
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<td>CH102X</td>
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<td></td>
<td>Multichem S L3</td>
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<td>CH103X</td>
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</table>

### Chemistry
- Albumin
- Bilirubin, Direct
- Bilirubin, Total
- Calcium
- Carbon Dioxide (Bicarbonate)
- Chloride
- Creatinine
- Glucose
- Iron
- Lactate (Lactic acid)
- Magnesium
- Phosphorous
- Potassium
- Protein, Total
- Sodium
- Total Iron Binding Capacity (TIBC)
- Unsaturated Iron Binding Capacity (UIBC)
- Urea
- Uric Acid

### Immunoproteins
- Alpha-1-Acidglycoprotein
- Alpha-1-Antitrypsin
- Alpha-2-Macroglobulin
- Antithrombin III
- Apolipoprotein A1 (APO A1)
- Apolipoprotein B (APO B)
- Anti-1.2 Microglobulin
- CH50 (Total hemolytic Complement)
- C3 Complement
- C4 Complement
- Ceruloplasmin
- Ferritin
- Haptoglobin
- Hemopexin
- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- IgE
- IgG1, Subclass
- IgG2, Subclass
- IgG3, Subclass
- IgG4, Subclass
- Kappa Light Chain
- Lambda Light Chain
- Lipoprotein (a)
- Prealbumin
- Properdin Factor B
- Retinol Binding Protein
- Transferrin
- sTfR (Soluble Transferrin Receptor)

### Enzymes
- Acid Phosphatase
- Alanine Aminotransferase (ALT)
- Alkaline Phosphatase (ALP)
- Amylase (Pancreatic)
- Amylase (Total)
- Aspartate Aminotransferase (AST)
- Alpha Hydroxybutyrate Dehydrogenase
- Beta Hydroxybutyrate Dehydrogenase
- Cholinesterase
- Creatine Kinase (CK)
- CRP
- Gamma Glutamyltransferase
- Lactate Dehydrogenase (LDH)
- Lipase
- Prostatic Acid Phosphatase

### Lipids
- Cholesterol, HDL
- Cholesterol, LDL
- Cholesterol, Total
- Phospholipids
- Triglycerides

### Therapeutic Drugs
- Acetaminophen
- Amikacin
- Carbamazepine
- Digoxin
- Gentamicin
- Lithium
- Phenobarbital
- Phenytoin
- Salicylate
- Theophylline
- Tobramycin
- Valproic Acid
- Vancomycin

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ P
Supplementary Immunoprotein QC in a Liquid Stable Format

Features
- Human based proprietary formulation.
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use.

Specifications
- 36 month closed vial stability at -20°C to -80°C.
- 14 day open vial stability at 2°C to 8°C.

Specifications
- Designated to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

IAMQC Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time. IAMQC Software products allow users to automate, centralise and standardise QC processes in a laboratory setting. Our combination of software modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

For more information, visit www.technopathcd.com

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Immunoproteins
- Alpha-1 Acidglycoprotein
- Alpha-1 Antitrypsin
- Alpha-2-Macroglobulin*
- Antstreptolysin O (ASO)*
- ADNase B (Anti-Streptococcal DNase B)*
- Antithrombin III*
- Apolipoprotein A1 (APO A1)
- Apolipoprotein B (APO B)
- Beta-2 Microglobulin
- C1 Inhibitor*
- CH50 (Total hemolytic Complement)*
- Cystatin C*

Chemistry Analytes
- Albumin*
- Angiotensin Converting Enzyme*
- Total Protein*
- Complement C3
- Complement C4
- Ceruloplasmin
- C-Reactive Protein
- Ferritin*
- Haptoglobin
- Hemopexin*
- Immunoglobulin A
- Immunoglobulin G
- Immunoglobulin M
- IgE*
- IgG1, Subclass*
- IgG2, Subclass*
- IgG3, Subclass*
- IgG4, Subclass*
- Kappa Light Chain*
- Lambda Light Chain*
- Lipoprotein (a)*
- Prealbumin
- Properdin Factor B*
- Retinol Binding Protein*
- Rheumatoid Factor
- Transferrin
- sTIR (Soluble Transferrin Receptor)*

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ U
Providing Third-Party Test Consolidation for Urinary Chemistry QC in a Liquid Stable Format

Features
- Human based proprietary formulation.
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use

Specifications
- 24 Month closed vial stability at 2°C to 8°C.
- 30 Day open vial stability at 2°C to 8°C.

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<td>UC202X</td>
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Multichem™ U
Urine Chemistry Analyte List

General Chemistry
- Amylase
- Calcium
- Chloride
- Creatinine
- Glucose
- Osmolality*
- Phosphorus
- Potassium
- Sodium
- Specific Gravity*
- Urea Nitrogen
- Uric Acid
- Urinary Protein

Pituitary/Adrenal
- Cortisol*

Reproductive/Fertility
- hCG*

*Please refer to lot specific package inserts for stability and performance claims.

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

IAMQC Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time. IAMQC Software products allow users to automate, centralise and standardise QC processes in a laboratory setting. Our combination of software modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

For more information, visit www.technopathcd.com
Multichem™ NB
Providing Third-Party Test Consolidation for Neonatal Bilirubin QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation.
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 14 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
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<td>Multichem NB</td>
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Multichem™ NB
Neonatal Bilirubin
Analyte List

Chemistry
- Bilirubin, Direct
- Bilirubin, Total

Therapeutic Drugs
- Caffeine*
- Theophylline

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

IAMQC Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time. IAMQC Software products allow users to automate, centralise and standardise QC processes in a laboratory setting. Our combination of software modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

For more information, visit www.technopathcd.com

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ AE
Providing Third-Party Test Consolidation for Ammonia and Ethanol QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation.
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 14 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem AE</td>
<td>Multichem AE L1</td>
<td>12 x 2ml</td>
<td>AE611X</td>
</tr>
<tr>
<td></td>
<td>Multichem AE L2</td>
<td>12 x 2ml</td>
<td>AE612X</td>
</tr>
<tr>
<td></td>
<td>Multichem AE L3</td>
<td>12 x 2ml</td>
<td>AE613X</td>
</tr>
<tr>
<td></td>
<td>Multichem AE (Bi-Level)</td>
<td>2 x 6 x 2ml</td>
<td>AE600X</td>
</tr>
<tr>
<td></td>
<td>Multichem AE (Tri-level)</td>
<td>3 x 4 x 2ml</td>
<td>AE610X</td>
</tr>
</tbody>
</table>

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

IAMQC Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time. IAMQC Software products allow users to automate, centralise and standardise QC processes in a laboratory setting. Our combination of software modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

For more information, visit www.technopathcd.com
Multichem™ CSF
Providing Third-Party Cerebral Spinal Fluid QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 30 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem CSF</td>
<td>Multichem CSF (Bi-Level)</td>
<td>2 x 6 x 2ml</td>
<td>CF100X</td>
</tr>
</tbody>
</table>

Multichem™ CSF Analyte List

Analytes
- Glucose
- Lactate
- IgG
- Protein

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

IAMQC Software provides Laboratory Managers and Technologists with a range of QC software tools to analyse their QC results in real-time. IAMQC Software products allow users to automate, centralise and standardise QC processes in a laboratory setting. Our combination of software modules satisfy the varying levels of QC requirements in individual laboratories and are easily tailored to meet different QC management expectations.

For more information, visit www.technopathcd.com
Multichem™ Immunoassay Quality Controls

Immunoassay Quality Controls

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>KIT CONFIGURATION</th>
<th>PRODUCT PART NO</th>
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</thead>
<tbody>
<tr>
<td>Multichem IA+</td>
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<td>IA310X</td>
</tr>
<tr>
<td>Multichem IA</td>
<td>3 x 4 x 5mL</td>
<td>IA300X</td>
</tr>
<tr>
<td>Multichem Speciality IA</td>
<td>3 x 4 x 2mL</td>
<td>BP300X</td>
</tr>
<tr>
<td>Multichem hsTn</td>
<td>12 x 3mL</td>
<td>HS301X</td>
</tr>
<tr>
<td>Multichem WBT</td>
<td>3 x 4 x 2mL</td>
<td>WB000X</td>
</tr>
<tr>
<td>Multichem WBT Assayed</td>
<td>3 x 4 x 2mL</td>
<td>WB000A</td>
</tr>
</tbody>
</table>
MULTICHEM™ IMMUNOASSAY QUALITY CONTROLS

**Multichem™ IA Plus**

Providing Third-Party Test Consolidation for Immunoassay QC in a Liquid Stable Format

### Features
- Human based proprietary formulation
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use.

### Specifications
- 36 month closed vial stability at -20°C to -80°C.
- 10 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem IA Plus (Tri-Level)</td>
<td>3 x 4 x 5ml</td>
<td>IA310X</td>
</tr>
</tbody>
</table>

**Multichem™ IA Plus - Immunoassay Analyte List**

- **Cancer Markers**
  - Alpha Fetoprotein
  - CA 125
  - CA 15-3
  - CA 19-9
  - Carcinoembryonic Antigen
  - Prostate Specific Antigen, Free
  - Prostate Specific Antigen, Total

- **Cardiac**
  - BNP
  - CK-MB
  - Myoglobin
  - NT-pro BNP
  - Troponin I
  - Troponin T
  - Ultrasensitive CRP*

- **Allergy**
  - IgE

- **Thyroid**
  - Anti-Thyroperoxidase
  - Anti-Thyroglobulin
  - Calcitonin
  - Thyroglobulin
  - Thyroid Stimulating Hormone
  - Thyroxine Binding Globulin*
  - Thyroxine, Free (FT4)
  - Thyroxine, Total (TT4)
  - Triiodothyronine, Free (FT3)
  - Triiodothyronine, Total (TT3)
  - T Uptake

- **Anaemia**
  - Erythropoietin (EPO)
  - Ferritin

- **Folate**
  - Vitamin B12

- **Pituitary/Adrenal**
  - Adrenocorticotropic hormone (ACTH)
  - Aldosterone*
  - Androstenedione*
  - Cortisol
  - Human Growth Hormone

- **Drugs**
  - Acetaminophen
  - Amikacin
  - Caffeine*
  - Carbamazepine
  - Carbamazepine, Free*
  - Chloramphenicol*
  - Cyclosporine*
  - Digoxin
  - Disopyramide*
  - Ethosuximide*
  - Gentamicin
  - Ibuprofen*
  - Lidocaine*
  - Lithium
  - N-Acetyl procainamide*
  - Phenobarbital
  - Phenytoin
  - Phenytoin, Free*
  - Primidone*
  - Procainamide*
  - Quinidine*
  - Salicylate
  - Theophylline
  - Tobramycin
  - Valproic Acid
  - Valproic Acid, Free*
  - Vancomycin

- **Renal**
  - Angiotensin*
  - Renin*

- **Bone Metabolism**
  - Ostase*
  - Parathyroid hormone (PTH)
  - Procollagen NP Type I*

- **Reproductive/Fertility**
  - DHEA Sulfate
  - Estriol, Free
  - Estriol, Total*
  - Estrogen, Total*
  - Estradiol
  - Follicle Stimulating Hormone
  - Human Chorionic Gonadotropin
  - 17-Hydroxyprogesterone*
  - Leutinizing Hormone
  - Progesterone
  - Prolactin
  - Sex Hormone Binding Globulin (SHBG)
  - Testosterone
  - Testosterone, Free*

- **Diabetes**
  - C-Peptide
  - Insulin
  - Insulin-like Growth Factor (IGF-1)*

- **Esoterics**
  - 25 (OH) Vitamin D
  - Homocysteine

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ IA
Providing Third-Party Test Consolidation for Immunoassay QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation.
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use.

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 10 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem IA</td>
<td>Multichem IA (Tri-Level)</td>
<td>3 x 4 x 5ml</td>
<td>IA300X</td>
</tr>
</tbody>
</table>

Cancer Markers
Alpha Fetoprotein
Carcinogenic Embryonic Antigen
Prostate Specific Antigen, Free
Prostate Specific Antigen, Total

Cardiac
BNP
CK-MB
Myoglobin
NT-pro BNP
Troponin I
Troponin T
Ultrasensitive CRP*

Allergy
IgE

Thyroid
Anti-Thyroperoxidase
Anti-Thyroglobulin
Calcitonin
Thyroglobulin
Thyroid Stimulating Hormone
Thyroxine Binding Globulin*
Thyroxine, Free (Free T4)
Thyroxine, (Total T4)
Triiodothyronine, Free (Free T3)
Triiodothyronine, (Total T3)
T Uptake

Anaemia
Erythropoietin (EPO)
Ferritin
Folate
Vitamin B12

Pituitary/Adrenal
Adrenocorticotropic hormone (ACTH)
Aldosterone*
Androstenedione*
Cortisol
Human Growth Hormone

Drugs
Acetaminophen
Amikacin
Caffeine*
Carbamazepine
Carbamazepine, Free*
Chloramphenicol*
Cyclosporine*
Digoxin
Disopyramide*
Ethosuximide*
Gentamicin
Ibuprofen*
Lidocaine*
Lithium
N-Acetyl procainamide*
Phenobarbital
Phenytoin
Phenytoin, Free*
Primidone*
Procaainamide*
Quinidine*
Salicylate
Theophylline
Tobramycin
Valproic Acid
Valproic Acid, Free*
Vancomycin

Renal
Angiotensin*
Renin*

Bone Metabolism
Ostase*
Parathyroid hormone (PTH)
Procollagen NP Type I*

Reproductive/Fertility
DHEA Sulfate
Estriol, Free
Estriol, Total*
Estrogen, Total*
Estradiol
Follicle Stimulating Hormone
Human Chorionic Gonadotropin
17-Hydroxyprogesterone*
Leutinizing Hormone
Progesterone
Prolactin
Sex Hormone Binding Globulin (SHBG)
Testosterone
Testosterone, Free*

Diabetes
C-Peptide
Insulin
Insulin-like Growth Factor (IGF-1)*

Esoterics
25 (OH) Vitamin D
Homocysteine

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ IA Speciality

Providing Third-Party Speciality Peptide Hormone QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use.

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 14 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem IA Speciality</td>
<td>IA Speciality (Tri-Level)</td>
<td>3 x 4 x 2ml</td>
<td>BP300X</td>
</tr>
</tbody>
</table>

Multichem™ IA Speciality Analyte List

<table>
<thead>
<tr>
<th>Analytes</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>BNP</td>
<td></td>
</tr>
<tr>
<td>PTH Intact</td>
<td></td>
</tr>
<tr>
<td>ACTH*</td>
<td></td>
</tr>
<tr>
<td>Calcitonin*</td>
<td></td>
</tr>
<tr>
<td>Procalcitonin*</td>
<td></td>
</tr>
</tbody>
</table>

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

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For more information, visit www.technopathcd.com

*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ hsTn
Providing Third-Party High Sensitive Troponin QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use.

Specifications
◆ 36 month closed vial stability at -20°C to -80°C.
◆ 10 day open vial stability at 2°C to 8°C.

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Configuration</th>
<th>Part Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem hsTn</td>
<td>Multichem hsTn</td>
<td>12 x 3ml</td>
<td>HS301X</td>
</tr>
</tbody>
</table>

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For more information, visit www.technopathcd.com

Multichem™ hsTn
Analyte List

Analytes
hs TnI
hs TnT
Multichem™ WBT
Providing Third-Party Test Consolidation for Immunosuppressant QC in a Liquid Stable Format

Features
◆ Human based proprietary formulation.
◆ Mimics performance of patient samples.
◆ Targeted at key clinical decision points.
◆ Liquid for ease of use

Specifications
◆ 30 month closed vial stability at -20°C to -80°C.
◆ 10 day open vial stability at 2°C to 8°C.

Multichem™ WBT
Immunosuppressant Analyte List

Chemistry
Folate*
Glucose*

Immunosuppressant
Cyclosporine
Sirolimus
Tacrolimus

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*Please refer to lot specific package inserts for stability and performance claims.
Multichem™ Diabetes Quality Controls

Diabetes Quality Controls

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>KIT CONFIGURATION</th>
<th>PRODUCT PART NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multichem HbA1c</td>
<td>2 x 6 x 1mL</td>
<td>HB000A</td>
</tr>
<tr>
<td>Multichem HbA1c Level 1</td>
<td>12 x 1mL</td>
<td>HB001A</td>
</tr>
<tr>
<td>Multichem HbA1c Level 2</td>
<td>12 x 1mL</td>
<td>HB002A</td>
</tr>
</tbody>
</table>

Multichem™ A1c
Providing Third-Party Diabetes Haemoglobin A1c QC in a Liquid Stable Format

Features
- Human based proprietary formulation.
- Mimics performance of patient samples.
- Targeted at key clinical decision points.
- Liquid for ease of use.

Specifications
- 12 month closed vial stability at -20°C to -80°C.
- 30 day open vial stability at 2°C to 8°C.

Multichem™ A1c Analyte List

<table>
<thead>
<tr>
<th>Analytes</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1c</td>
</tr>
<tr>
<td>% HbA1c</td>
</tr>
</tbody>
</table>

Designed to complement and support TECHNOPATH’s Multichem Quality Control (QC) product range.

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External Quality Assessment and Proficiency Testing Solutions

Participating in External Quality Assurance (EQA) or Proficiency Testing (PT) Schemes has become essential for all accredited clinical laboratories as part of their overall quality control process. EQA measures a laboratory’s accuracy using standardised samples that are analysed on the participating laboratories’ instruments as if they were patient samples. This verification testing is performed on a scheduled, blinded basis. Participating laboratories then return their test results to the scheme organiser for compilation and statistical analysis purposes. Laboratories then receive comprehensive statistical reports comparing their individual performance relative to other participants in the programme.

Technopath Clinical Diagnostics provides scheme organisers with all of their requirements for both EQA specimens and the software solutions necessary to manage their schemes in an efficient and cost effective way.

Technopath Clinical Diagnostics is the world’s leading provider of Proficiency Testing software, known as IAMQC™ PT. Our PT module is currently used by over 10,000 laboratories worldwide across a number of international schemes.

IAMQC™ PT is an integral component in PT schemes around the world, providing users with an electronic portal to submit results and thereby eliminating the requirement for paper-based submissions. The system also has the ability to interpret paper forms, scanning and digitalising the information submitted by participants. IAMQC™ PT can provide significant efficiencies (up to 75% time saved in analysing data submissions) to PT scheme providers without electronic means to gather results from their participants. It also provides the added benefit of reducing the turn-around time between test result submission and report generation.

Technopath Clinical Diagnostics maintains a particular expertise in human-based custom formulations, test consolidation and analyte stabilisation. This expertise ensures that not only can we facilitate QC material requirements, but also enables us to provide high quality EQA and proficiency testing samples to a global customer base. We use fresh frozen plasma, from healthy donors, as the base material for our plasma and serum proficiency testing specimens. We also extract lipoprotein complexes in-house from the same human serum using proprietary techniques developed by Technopath Clinical Diagnostics. Our focus on high quality, human-based raw materials produces an end-product that closely mimics the performance of patient samples.
and provides a solution that is commutable across multiple platforms. We also offer fully customisable materials for your EQA requirements ensuring that your desired parameters are targeted at the required concentrations.

We offer an extensive range of EQA specimens covering the following areas of interest for scheme providers:

- General chemistry
- Urine chemistry
- Lipids (human sourced)
- Enzymes
- Specific proteins
- Hormone
- Cardiac
- Therapeutic drugs
- Diabetes
- Metabolism
- Immunoassay
- Fertility panels

### Features and Benefits

- Custom manufacture of test samples to your exact requirements under a recognised quality system
- A wide range of analytes available and all specimens are manufactured in our ISO:13485 accredited and FDA registered facility
- Human-based matrices closely reflecting performance of patient samples
- Sample volumes between 0.5mL and 10mL depending on customer requirements
- Analytes concentrations can be targeted at medical interest points
- Complete software solution to collect, analyse and compare results
  - Cloud based real time analysis of all results and 24/7 access to reports
  - Powerful reporting options and custom reports available
  - Automate your internal scheme processes to improve efficiency, saving time and minimising cost
  - Eliminate paper forms and reduce lead time for report generation

For more information, please visit our website or contact us at the email address below:

http://www.technopathclinicaldiagnostics.com/products/proficiency-sera
PSSupport@TechnopathCD.com
IVD Raw Material

Technopath Clinical Diagnostics manufacture and supply high quality IVD materials to a wide-ranging customer base. We have developed our own proprietary processing techniques to satisfy the raw material requirements of the IVD industry. We provide a range of IVD raw materials made to our own “off-the-shelf” specification, however here at Technopath Clinical Diagnostics we also offer the added-value of developing and manufacturing raw materials that are fully customised to ensure we provide our customers with the best solution possible.

All of our IVD raw materials are manufactured by our experienced team at our FDA registered facility under an established quality system. We hold an ISO: 13485 accreditation and our customers can be confident in the quality of our products.

Our primary objective is to provide our customers with IVD raw materials of the highest quality, tailored to their requirements, when they need them, delivered anywhere in the world. We are also interested in establishing long-lasting partnerships with our customers and continuing to develop those relationships over the long term.

Our IVD raw material products are used in the following areas:

- Research and Development
- Manufacture of IVD reagents, calibrators and controls
- Manufacture of proficiency testing samples and EQA specimens

Features and Benefits:

- Save valuable time and resources in your manufacturing facility. As Technopath Clinical Diagnostics manufacture the material to customer specific requirements, reduced levels of processing are required in your facility.

- Reduce your lead-time. Technopath has the ability to perform a significant portion of upstream processing ensuring that our customers can focus on the core value-added elements of their manufacturing process.
• Proven track record for delivering on time to a global customer base. For over 10 years, Technopath Clinical Diagnostics has supplied our IVD Raw material products to customers in Europe, North and South America and Asia. We can also provide our customers with a call-off schedule to facilitate level-loading of their production orders and time deliveries to support just-in-time manufacturing practices.

• Proprietary processing techniques developed by our team to overcome the challenges of manufacturing human based IVD products. Technopath Clinical Diagnostics serum products do not contain bovine thrombin resulting in lower levels of protease activity in our serum pools. Analytes that are affected by increased levels of protease activity are not compromised in the finished product.

• Reduced variation together with small to large-scale manufacturing capability. Technopath Clinical Diagnostics have the capacity to manufacture material from small scale to large scale, with volumes ranging from 50mL for research purposes up to 1000s of litres for large-scale production requirements. We can also reserve product for our customers so that they can use the same lot number of IVD raw material for multiple batches of product.

Product examples:

• Fresh frozen human plasma. Available as individual units or pooled.
• Normal human serum
• Delipated human serum (low cholesterol human serum)
• Off-clot human serum
• Human Low density lipoprotein extract (LDL)
• Human High density lipoprotein extract (HDL)
• Human lipoprotein extract (HLPX- combination of LDL and HDL in physiological ratios)
• Normal human urine (stabilised uric acid and creatinine)
• Lysed red blood cells
• Triglyceride concentrate (avian source)
• Depleted sera (Low TSH, low Vitamin D, etc.)
IVD Raw Material customisation workflow

- All of our IVD raw material products can be customised to align with specific customer requirements.
- By working with our customers, our team of experts can tailor each of our products to your desired preferences. To provide some examples, our customisation process ranges from matrix selection, preservative cocktail, analyte selection and targeting as well as aliquot size.
- We follow the below workflow to ensure that we satisfy each of our customers’ needs:

  - Discuss specific requirements with customer
  - Technopath draft specifications based on customer input
  - Customer review and approval
  - Technopath manufacture product to customer specification
  - QC testing and QA approval and product release
  - Shipment to customer facility

For more information on any of our IVD raw materials please visit www.technopathclinicaldiagnostics.com/products/ivd-raw-materials or email your enquiry to IVDSupport@TechnopathCD.com.
Quality Control Software

IAMQC™ QUALITY CONTROL SOFTWARE

QUALITY CONTROLS FOR OPTIMAL PATIENT CARE

IVD RAW MATERIAL

Quality Control Software

Recommended QC Rules

QC Data for PEER

INTRANET DATABASE

INTERNET DATABASE

INTRANET DATABASE

INTRANET DATABASE

INTERNET DATABASE

Summary QC Data

Recommended Parameters for IAMQC™ EXPERT

Manual Entry

Bi-Directional Middleware

Uni-Directional Communicator

LIS
Technopath’s Software Products Help:

Bench Technologists:
- Spend less time on false positive QC flags
- Concentrate on tests, which require their attention
- Spend less time trouble-shooting
- Know how to react when the mean shifts
- Assess the acceptability of new reagent lots and calibrations
- Solve QC problems
- Gain understanding and confidence in the QC process

Lab Managers:
- Choose QC rules to maximise true rejects and minimise false rejects
- Quickly see the tests that require their attention
- Skim graphics to quickly review current or historical data by lab, department, instrument or test
- Monitor performance in groups of laboratories
- Review problem tests and QA activities in local and remote labs

Lab or Hospital Administrators:
- Save money
- Improve quality
- Improve service
- Review Administrative Summary Reports to ensure quality performance
IAMQC™ Peer is an innovative, real-time, Peer Comparison Software. This web based system facilitates laboratories testing the same lot number of control material to access valuable information from their colleagues through peer comparison.

The reports that are generated in IAMQC™ Peer compare the accuracy and precision of analytical processes between laboratories and peer groups. This information can be extremely valuable, indicating the user’s performance relative to their peer group and also providing powerful troubleshooting tools when attempting to resolve potential problems.

To participate in IAMQC™ Peer, each individual laboratory submits their individual results or summary statistics (mean, standard deviation, and number of data points) to the central database maintained by Technopath. Laboratories data may be submitted manually on-line or, alternatively, captured by one of our many live interfacing options. The information provided by IAMQC™ Peer can be used on a monthly basis to evaluate how well lab’s methods are operating relative to the overall peer group. Users can also look at this peer data in real-time interactive tables online, when they are investigating a potential problem with accuracy or precision in an individual method.
Each one of the IAMQC™ Peer comparison reports are generated in PDF format and are available on the web. These reports can be generated by the user or automatically on a user defined schedule. The generated reports can be emailed automatically as well as printed. At any time, the reports are available online and can be downloaded by users using their login name and password.

**Group Coordinator Report**

This report provides a test by test listing of statistics for the lab and its peer groups for up to 3 levels of control material. A peer group is a group of labs using the same control material and the same analytical method. The Group Coordinator Report documents all of the relevant data points submitted to IAMQC™ and automatically provides a statistical analysis in table format. This report provides a centralised review of all instruments from the moment the customer begins to report data and thus facilitates users meeting accreditation requirements, with respect to the storage, retrieval and statistical analysis of quality control data.

**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.

This report also provides a super-imposed version of all QC levels at the bottom of each sheet, highlighting any level specific bias. The top of the graph displays a summary of both monthly and cumulative data, including all of the relevant statistics for the laboratory.
Monthly Summary Report

For each test, and control level, this report displays summary statistics for the last twelve individual months and Lot-to-Date period for the laboratory and its peer groups. This data is useful for long-term intra-laboratory and inter-laboratory comparisons.

This report provides the customer with an indication of the ‘usual’ method accuracy and precision, allowing them to view any unexpected trending or increases in imprecision. The report also displays the customer’s monthly SDI and CVI, indicating any shifts from the peer group. The ‘monthly summary’ report facilitates the user investigating changes in performance over time.

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. If a specific assay does not meet specific performance criteria the information is highlighted to the user as an exception.
The Exception Notes Report indicates the following flags:

**Flag L** - This value did not pass the Laboratory Outlier check, which highlights values more than +/- 3 standard deviations from the lab’s mean for the month. This value was included in the calculation of the lab’s mean and SD for this month.

**Flag P** - This value did not pass the Peer Outlier Check, which highlights values more than +/- 3 standard deviations from the peer’s mean for the month. This value was included in the calculation of the peer’s mean and SD for this month.

**Flag G** - This value did not pass the Gross Outlier Check, which excludes extremely discrepant data that falls outside of present limits for each test. This data was not processed and is not included in IAMQC™ Reports and was excluded from the calculation of the peer stats.

**Youden Plot Report**

The Youden Report describes internal laboratory performance against the test system peer and method principle peer using the Youden Plot design. Laboratory data is tabularised at the top of the page by individual analyte. The lower half of the page provides a laboratory vs. peer comparison in the form of a Youden plot. The centre of each Youden plot represents the mean of the associated peer group.

It is appropriate to assume that each laboratory has its own systematic error. A user that has good precision could unknowingly have an error within their laboratory that is operating to displace their results from the values achieved by the rest of the peer group. The Youden plot visualizes both bias and imprecision and can be used to evaluate systematic and / or random error.
IAMQC™ Daily is a comprehensive Internal Quality Control software that applies Westgard and/or any user-defined QC rules to individual QC results. The software automatically builds interactive Levey-Jennings charts and tables and provides summary and detailed customised reports to the end user. IAMQC™ Daily integrates with Microsoft Excel to produce customised electronic reports. The system also allows the import of pre-defined templates, resulting in instant system setups. Users can create audit trails, action logs and summary reports at the click of a button.

IAMQC™ Daily comprises a centralised program that facilitates the analysis of multiple QC materials, across numerous departments in a laboratory setting. The system can be configured to submit approved results automatically to IAMQC™ Peer via our proprietary driver solutions. This will help to satisfy both Internal and External QC requirements.

**KEY FEATURES**

- Works with multiple Sites, Departments, Instruments, Tests and Levels.
- Applies Westgard and/or any user-defined QC rules.
- Works with both quantitative and qualitative results.
- Focused troubleshooting for failed QC results via the system Action Log.
- Technologist and Supervisor Reviews and sign-off capabilities.
- Automatic Reverse Levels function.
- QC management at different administrative levels.
- Works on a single PC, LAN, WAN, and/or over the Internet.
- Runs on a powerful Database Management System to support large volumes of data in real time.
- Advanced functions for fast and easy setup.
- Multiple ways to enter data manually.
- Powerful reporting and charting capabilities.
IAMQC™ Daily offers a centralised review of all QC data from all laboratories/instruments. Central administrator access facilitates managers to review QC performance at multiple facilities – no need to visit each laboratory site. Closer monitoring of QC from remote locations without additional costs provides a flexible option for managing the inter and intra-lab performance. The software works on an ‘open’ platform that allows the end user to add all types of control material from a range of laboratories. Both IAMQC™ Daily and Expert can run using an internet OR intranet connection. Each PC license allows the user to manage an unlimited number of departments, control materials (not limited to

Interactive Data Review Screen

Super Impose Instruments
Technopath materials) and instruments. An unlimited number of user logins can be added to the system at any stage. An administrator module can also manage user logins, customising the functionality that is available to each user. All data can also be filtered using the same logic to apply a user-friendly atmosphere and save time scrolling through data.
IAMQC™ Expert is an interactive system that helps front-line laboratory staff select QC rules, reduce unnecessary repeats and make meaningful QC decisions. IAMQC™ Expert creates graphical color-coded representations of accuracy and precision, illustrating performance relative to target values and error limits. Interactive modules such as ‘Reagent Verification’, ‘Calibration Check’ and ‘Mean Shift Analysis’ assist with problem solving and decision-making.

IAMQC™ Expert allows the end-user to monitor method performance relative to clinical requirements and focus on the tests that require their attention. The system can also be integrated with IAMQC™ Daily to automatically capture summary data for analysis. Upon entering the IAMQC™ Expert database, the software automatically analyses the data and suggests QC rules to maximise true rejects and minimise false rejects.

KEY FEATURES

- Works with multiple Sites, Departments, Instruments, Tests and Levels.
- Recommends QC rules for IAMQC™ Daily software.
- Powerful QC troubleshooting tools.
- Integrates with various Laboratory Information Systems and/or instruments.
- Works on a single PC, LAN, WAN, and over the Internet.
- Runs on a powerful Database Management System.
- Powerful reporting and charting capabilities.
Times and technologies are changing rapidly. Instruments and methodologies are more accurate, precise and stable than they were a decade ago. Most laboratories have adopted these new technical advances, but few have modified their QC processes to match. Many laboratories are still using a 1-2s rule as recommended by Levey and Jennings in 1951.

In 1981 Westgard recommended using a multi-rule algorithm to avoid the false positive flags inherent in using only a 1-2s rule. Technology has come a long way since 1981, and for the past ten years industry leaders such as James Westgard, Per Hyltoft Petersen and Callum Fraser have advised the use of a variety of QC rules to match the analytical capability and stability of each test. With the dramatically improved precision of today’s methods, we now see shifts of several SD for the same control on the same test from time to time within a single laboratory. We have designed a QC system that will alert users to significant changes and not generate QC flags when the system is operating safely within acceptable limits.

The system compares method performance to defined quality requirements (rather than to last month’s data) and recommends QC strategies that will warn users when QC data points exceed acceptable performance - with a minimal number of false flags. In the design of our QC system we “balance” the quality control system to meet the changing performance and stability of the analytical system.
Our analytical processes also vary in their susceptibility to the occurrence of significant errors. Error rates vary from low to moderate to high, depending on the frequency of significant errors that occur in a specific test system. Some methods seldom encounter significant problems. Others are susceptible to relatively frequent sources of significant error. Methods with high error rates frequently see significant shifts in the mean or have ongoing precision problems; these methods may also be susceptible to frequent instrument breakdowns or problems.

We monitor method performance (accuracy and precision) relative to a quality requirement by calculating critical systematic error (^SEc). Critical systematic error is an extremely powerful and useful statistic. ^SEc indicates in one number how method accuracy and precision compare to the target and TEa limit set for each control. ^SEc indicates the number of standard deviations the mean can shift before the results will exceed error limits. Therefore changes in either the mean or SD will be reflected in a change in critical systematic error.

Our QC system has an improved error detection process when methods are close to the error limit (have a low "^SEc) or when methods have poor stability and are prone to errors. In this case we will select a higher number of controls or run our existing controls more frequently and we will select QC rules that are more powerful when assessing small changes in method performance. When the "^SEc is
high (method performance is well within quality requirements) and the analytical system is stable, we will run fewer controls or run controls less frequently and we will select QC rules to minimise false QC flags.

Critical systematic error is a valuable indicator of the size of the shift in the mean that we must detect. We can easily visualize how it would be appropriate to use “tighter” QC rules when the method is closer to the error limit and to use “looser” QC rules when a method can shift many standard deviations before exceeding the quality requirement. When we run more levels of controls or run the same controls more frequently, we increase our probability of detecting errors. Unfortunately, we also increase the probability of false rejection. Remember, if we are using a 1-2S rule, we will see 5% of our “good” data falling between 2 and 3 SD. Therefore, the more controls we run, the higher the probability in any given run that one of them will fall outside two standard deviations. When it is necessary to design a QC process to detect a very small change in the analytical system, one of the strategies we can use is to increase the number and frequency of the controls.

IAMQC™ Expert is a user-friendly interactive expert system that helps front-line laboratory staff select QC rules, reduce unnecessary repeats and make meaningful QC decisions. The software creates graphical colour-coded representations of accuracy and precision illustrating performance relative to target values and error limits for several departments or groups of affiliated laboratories. Interactive modules assist with problem solving and decision-making.

IAMQC™ Expert Helps Bench Technologists:
- Spend less time on false positive QC flags
- Concentrate on tests which require their attention
- Spend less time trouble-shooting
- Know how to react when the mean shifts
- Assess the acceptability of new reagent lots and calibrations
- Solve QC problems
- Gain understanding & confidence in the QC process

IAMQC™ Expert Helps Lab Managers:
- Monitor method performance relative to CLIA or clinical requirements
- Choose QC rules to maximise true rejects and minimise false rejects
- Quickly see the tests that require their attention
- Skim graphics to quickly review current or historical data by lab, department, instrument or test
- Monitor performance in groups of laboratories
- Review problem tests and QA activities in local and remote labs

IAMQC™ Expert Helps Lab Or Hospital Administrators:
- Save money
- Improve quality
- Improve service
- Review Administrative Summary Reports to ensure quality performance

Expert Reports in Microsoft Excel
IAMQC Transfer

The most advanced connectivity solution available for laboratory instrumentation.

IAMQC Transfer is a connectivity device that can communicate with Laboratory Information Systems (LIS), Middleware, automated instrumentation and Point Of Care platforms. Through the use of our proprietary drivers and a single board computer device, IAMQC Transfer processes and communicates data from your system to any one of our powerful IAMQC software packages; IAMQC Peer, IAMQC Daily, IAMQC Expert or IAMQC Proficiency Testing module. By combining software and hardware elements, we can eliminate the requirement for additional PCs or servers. A plug-and-play set up, combined with over 200 available connectivity options ensure an un-matched level of flexibility - all within an incredibly small, seamless enclosure.

Automated data collection. Easy to Implement. Introducing IAMQC Transfer into your laboratory will drive efficiency through automation, whilst increasing quality by transitioning away from manual entry programs. IAMQC Transfer can function as a uni-directional interface to process QC files and data streams of all formats. However, in addition to receiving the results, IAMQC Transfer can also work as a bi-directional interface, where it will communicate back to the instrument, LIS or middleware. To satisfy the requirements of laboratories of all sizes and configurations, Technopath Clinical Diagnostics introduces IAMQC Transfer, a next-generation informatic solution.

More than just an interface to IAMQC Software, IAMQC Transfer is available to purchase as a stand-alone connectivity device for your software program. By providing a comprehensive solution that can work with multiple information systems, Technopath Clinical Diagnostics’ IAMQC Transfer can automate your data collection process. Contact us at qcssoftware@technopathcd.com for more information.
## Connectivity

Providing the flexibility for an internet or intranet connection facilitates the customer in choosing their preference with regards to connectivity. The system can run locally behind a firewall, or alternatively, over the web should access be required outside of the local network.

Built-in real-time and semi-real time interface solutions are available to capture data from all types of instruments, middleware systems, and LIS across all departments. To date, we have developed over 200 types of drivers for data capturing purposes. IAMQC™ Daily can also capture QC results from diagnostic instruments that are not interfaced to the DMS and from manual result entry programs on a daily basis. IAMQC™ Drivers include, but are not limited to, the following list:

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<tr>
<th>Abbott Architect</th>
<th>Dawning UC</th>
<th>RCM Beziers</th>
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<td>Abbott AXSYM</td>
<td>EPIC LIS SDF 1.0</td>
<td>Roche COBAS</td>
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<td>ERMA</td>
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<td>Roche HITACHI 747</td>
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<td>HMS LIS</td>
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**Technopath Clinical Laboratories**

**IAMQC™ QUALITY CONTROL SOFTWARE**
IAMQC™ QUALITY CONTROL SOFTWARE

Benefits

1. **Centralised review** of all QC data from all laboratories/instruments. Central administrator access to review QC performance at multiple facilities - no need to visit each laboratory site

2. **Closer monitoring** of QC from remote locations without additional costs

3. **Built-in real-time and semi-real time interface solutions.** Integrate with various Laboratory Information Systems and/or instruments

4. **Capture QC results** from diagnostic instruments and manual result entry programs on a daily basis

5. **Compare each result to Assigned Mean & SD**

6. **Assess QC results** against a set mean and standard deviation using QC rules (Westgard and/or User-defined): single or multiple QC rules

7. **Auto-approval protocol**

8. **Troubleshoot problematic daily QC**

9. **Manage multiple Sites, Departments, Instruments, Tests and QC Levels on one central database**

10. **Manage both quantitative and qualitative results**

11. **Manage different departments** (Chemistry, Haematology, Microbiology, etc.) on one software system

12. **Focused troubleshooting** for failed QC results

13. **Technologist and Supervisor Reviews/Sign-off**

14. **“Reverse Levels”** automatic function

15. **QC management at different levels:** administrative and bench technologists

16. **Document all activities** regarding daily QC

17. **Tracking of proficiency testing performance and problem resolution**

18. **Documentation of new reagent/calibrator/QC lot numbers and studies**

19. **Monthly reporting on-line** for management

20. **Document activities and administrative comments** for summarized QC data

21. **Transfer detail and summary data** between a Laboratory and a single QC database in real time over the Internet

22. **Internal/External peer QC review capability.** Collect, analyse and compare individual laboratory data immediately with a worldwide peer group at the touch of a button over the Internet

23. **Works on a single PC, LAN, WAN, and over the Internet**

24. **Runs on a powerful Database Management System** to support large volumes of data in real time

25. **Multiple Assign and Advanced Setup/Copy functions** for fast and easy setup and ongoing maintenance

26. **Multiple ways to enter data manually** (by Level, Test or Instrument; one at a time or many at a time)

27. **Monthly Supervisor Review**

28. **Powerful reporting and charting capabilities.** Includes User-definable reports

29. **Multi-user environment**

30. **Audit trail/Admin module** for setting up users with different security profiles