TECHNOPATH
CLINICAL DIAGNOSTICS

THE QUALITY CONTROL COMPANY

Our mission is to improve the quality, efficiency and cost effectiveness of clinical laboratories quality control activities to benefit patients. We achieve this by providing clinical laboratories with best in class QC material and software solutions.

Welcome

In 2008, Technopath Clinical Diagnostics (Technopath) launched the IVD industry's first truly consolidated Immunochemistry Quality Control (QC) materials. The proprietary manufacturing processes we have developed positions Technopath as the global technology leader in matrix stability and consolidation matrices for clinical diagnostics Quality Control products.

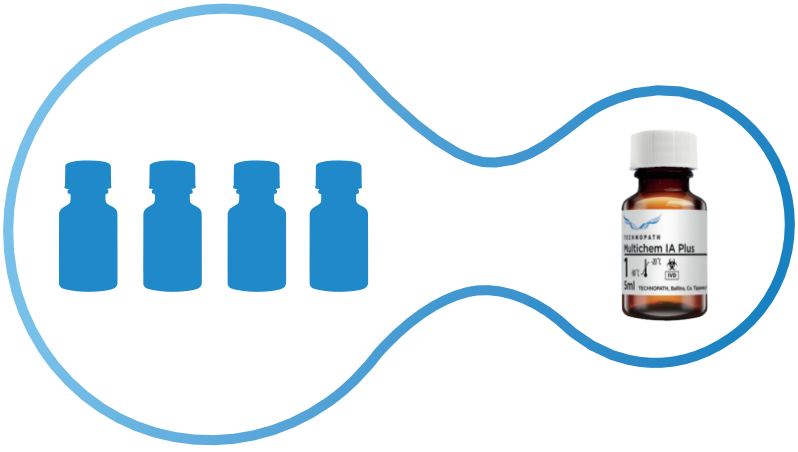
Historically, the wide range of blood tests used in hospitals were performed in a number of different specialised laboratories within the hospital, with each group of blood tests requiring their own specific quality control materials. Over the past twenty years, most hospital laboratories have evolved radically in order to lower costs, satisfy increasing demand and utilise new efficient technologies. These changes resulted in equipment manufacturers developing consolidated IVD platforms which helped to replace multiple specialised laboratories. However, amidst this transformation, the quality control solutions that were used to monitor patient testing were completely overlooked. Quality control materials remained fragmented and separated in to different panels of tests, reflecting the historic lab setup.

Technopath's break through was to remove the need for multiple test materials through consolidation of a large number of analytes in to a single product. Consolidation enables clinical laboratories to significantly reduce handling requirements, reclaim storage space and minimise waste, leading to a more efficient quality control process.

Technopath is now a high growth company based upon the success we have enjoyed in our home markets and the recent closure of significant product development and supply agreements on a global basis. Technopath has been ISO 13485 accredited since 2009 and has successfully achieved US FDA 510K and China FDA approvals for all of its Multichem® QC products.

We aim to become the global leader in third party quality control solutions and I am confident that the benefits and quality of our products coupled with the expertise and innovation of our team will deliver on our ambition.

Malcolm Bell
Founder and CEO



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Enhanced Laboratory Efficiencies with Technopath Clinical Diagnostics QC solutions

Laboratory Quality Control (QC) is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results, in order to improve the quality of the results reported by the laboratory. Laboratory QC material is usually run at the beginning of each shift, after an instrument is serviced, when test kits are changed, after calibration, and whenever patient results seem inappropriate.

Our customers increase the efficiency of their laboratory, improve the quality of their patient care and reduce the cost of their quality control program.

REDUCE
QC ANALYSIS TIME
SIGNIFICANTLY

REDUCE
CARBON FOOTPRINT

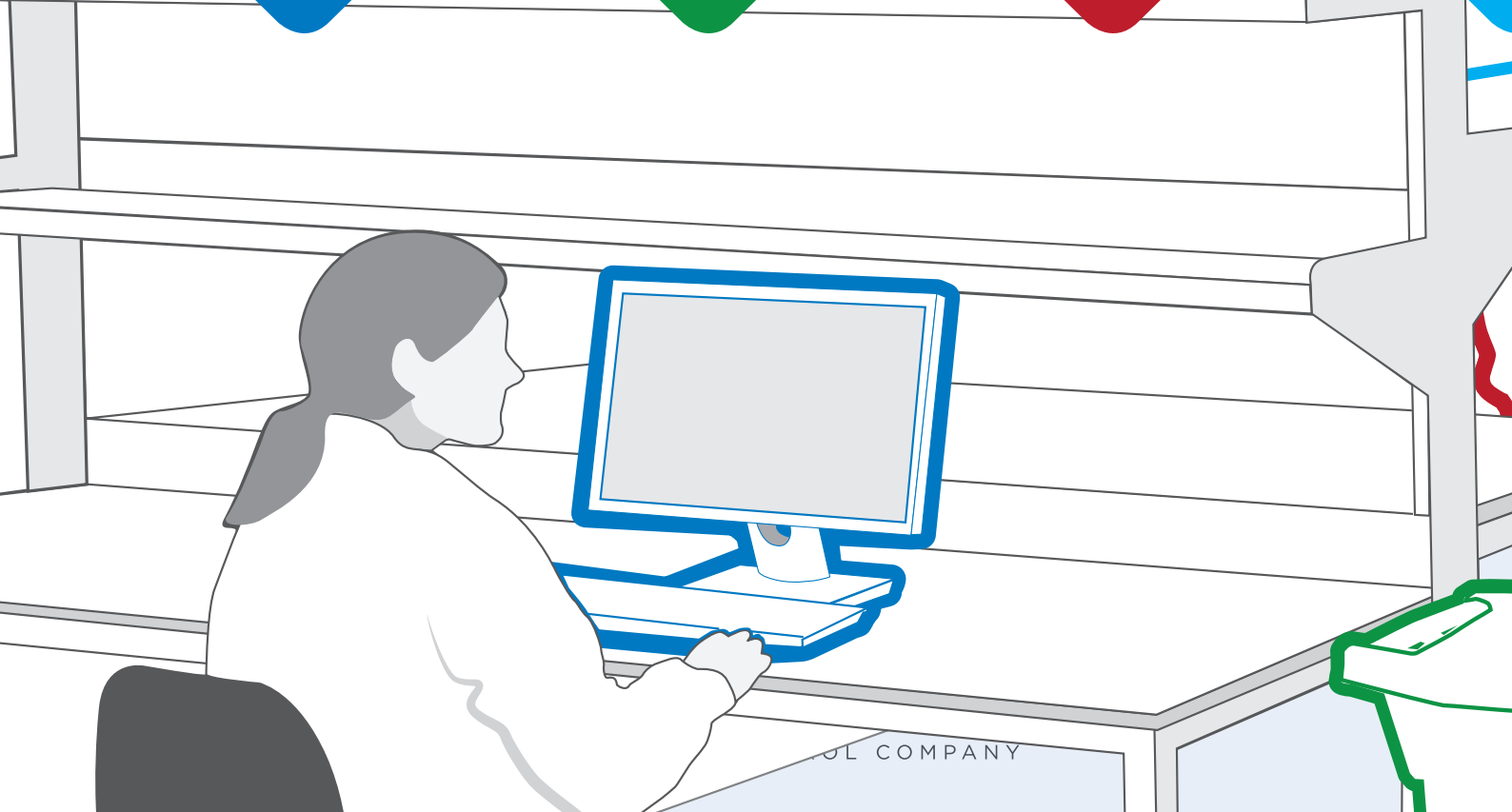
Competitor waste vials (left) versus Multichem waste vials (right)

REDUCE
QC HANDLING TIME
BY UP TO

80%

REDUCE AN
ON QC BY
DEAD V
BY U

7



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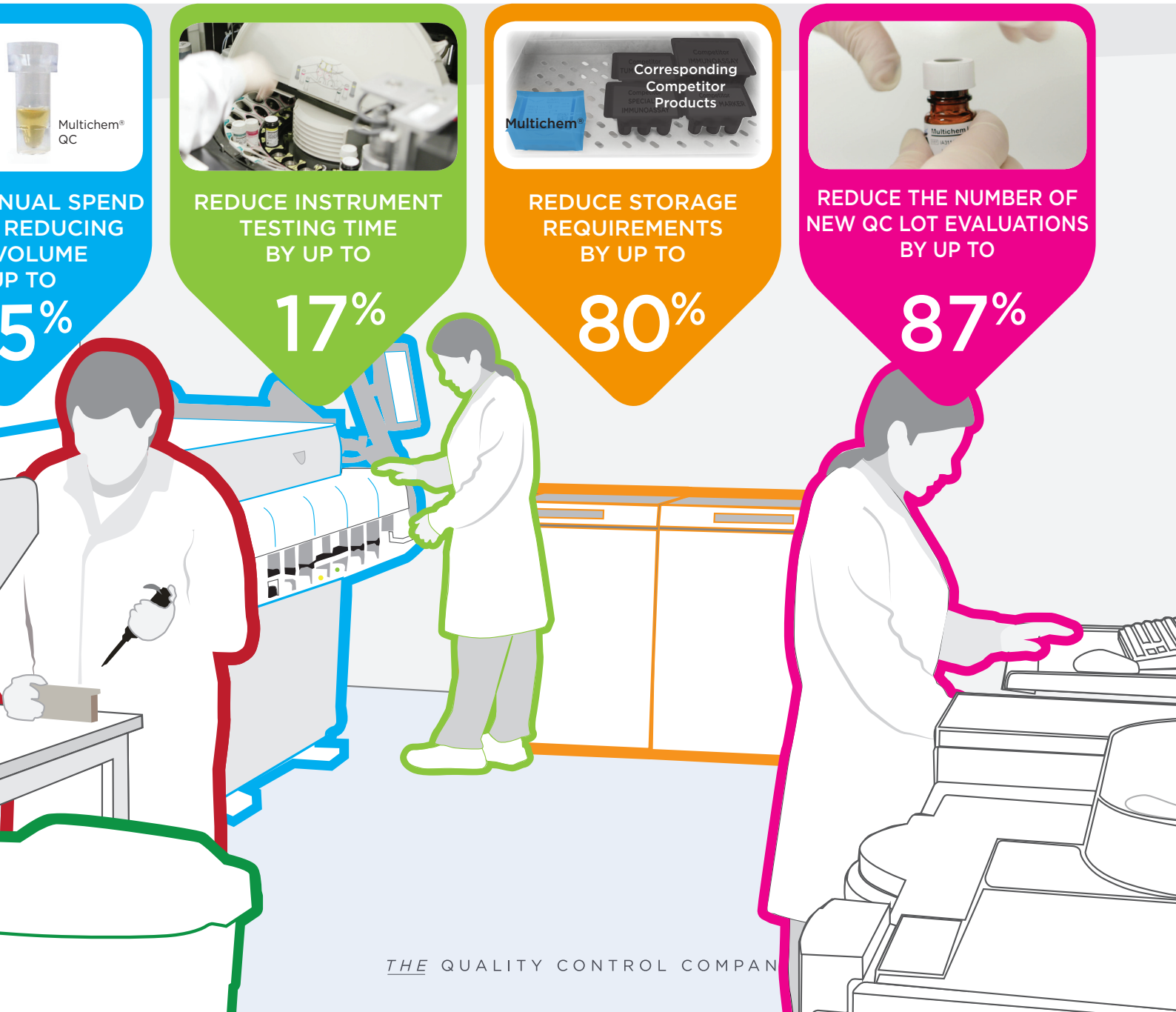
Technopath was the first company in the world to develop truly consolidated third party quality controls for hospital laboratories.

Our proprietary manufacturing processes allow incorporation of greater numbers of analytes in to a single matrix, which enables extensive test menu consolidation. Our 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 that our products mimic the performance of patient samples. We maintain particular expertise in the stabilisation of labile analytes (i.e Troponin, Bilirubin, etc.) and we also use human based lipid additions to ensure commutability across testing systems. The combination of these high quality raw materials and our proprietary process gives Technopath a significant competitive advantage over key global competitors.



Multiple independent studies have documented the enhanced performance of Technopath QC solutions compared to other leading suppliers:

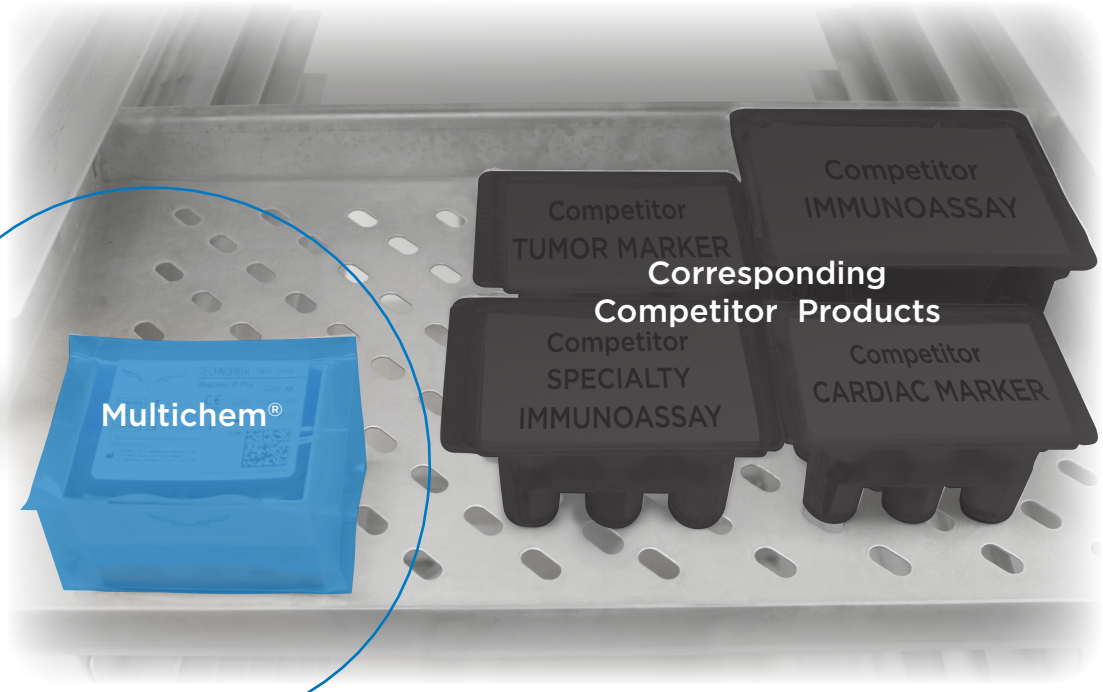
"World Class Six Sigma performance is seen with both Technopath and competitor controls on the majority of the Sigma-metric data. Contrary to conventional expectations, the data demonstrated that the controls had comparable performance."[1]

Consolidating QC materials results in significant labour savings by reducing the handling requirements involved in running a QC process. Independent studies[2] have also shown that a reduction in the physical numbers of internal quality control vials can lead to a reduction in transposition errors made by laboratory staff. Using fewer vials for QC leads to a reduction in QC turn-around-times in the laboratory. This facilitates an increase in patient testing volumes as the instrument will be available for testing much sooner than under existing practises.

Technopath has focussed on creating a lean product design that ensures end-users minimise their carbon footprint.

Switching to a consolidated solution frees up space in the laboratory freezer which can ultimately be used for alternative purposes or to hold stock of QC that will cover a much longer time period. In addition, consolidating a number of products in to one leads to a reduction in dead volume waste, which in turn means a reduction in the overall volume of QC material required to be purchased.

Reclaim laboratory storage space with Multichem® consolidated third party quality controls



Compared with competitor products, Multichem® offers fewer vials, creating savings across laboratory processes and in turn, increasing efficiencies.

1: Westgard S., MS, Westgard QC, Shih J. PhD, FACB, Abbott Laboratories. "Benchmarking Analytical Performance: Comparison of Third Party Quality Controls".
2: Dedman T., Clinical Biochemistry, Homerton University Hospital, London. "Implementing a New QC Program in the UK: Drivers For Change".

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Technopath Clinical Diagnostics - A Global Leader in Third Party Quality Controls

Technopath Clinical Diagnostics is a global leader in the development, manufacturing and distribution of:

- Independent Quality Control materials
- Comprehensive Quality Control software tools
- Speciality calibrators
- Proficiency sera
- IVD raw materials (blood components, plasma, serum, lipoproteins and immunoproteins)

More than 3,000 laboratories in over 120 countries worldwide have improved efficiencies by introducing Multichem® Third Party QC and IAMQC® Software

2018

Signe
agree
major

2018

TECHNOPATH CLINICAL DIAGNOSTICS | Northwell Health

2016Q4

i-plaq™ Test for Lp-PLA2

Launch of i-plaq™ Test for Lp-PLA$_2$

2016Q3

Trinity Biotech

Sign LOI with Trinity Biotech

2015

2015Q3

2015Q2

LAQC

Acquired Technology IP underlyi IAMQC® from LAQC Systems

2012

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d **Global**
ment with
IVD company

Joint Venture with
Northwell Health
established

2016Q2

New Version
of **IAMQC®**
Released

2016Q1

Sign **Global**
Contract
with
Radiometer

5Q4

Re-brand &
Launch of
New Website

2015Q1

Launch of
Multichem®
NB, AE & A1c

2015

Chinese
CFDA
Approval

Commenced
Facility
Expansion

2014

Global
Launch of
Multichem®

y &
ng

2013

FDA 510k
Approval

510(k)

2008

Technopath
Launches the
World's First
Consolidated
Immunochemistry
QC

2004

Technopath
Clinical
Diagnostics
Founded as
R&D Company

Abbott

Sign **Global**
Contract
with Abbott

1997

Technopath
Distribution
Founded

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Multichem®

QUALITY CONTROLS

Multichem **A1c**
Diabetes QC

Multichem **AE**
Ammonia &
Ethanol QC

Multichem **AMH**
Anti-Müllerian
Hormone QC

Multichem **CSF**
Cerebral Spinal
Fluid QC

Multichem
D-Dimer

Multichem **hsTn**
High Sensitive
Troponin QC

Multichem **IA**
Test Consolidation
for Immunoassay QC

Multichem **IA Plus**
Test Consolidation for
Immunoassay QC

Multichem
IA Speciality
Speciality Peptide
Hormone QC

Multichem **NB**
Neonatal
Bilirubin QC

Multichem **P**
Supplementary
Immunoprotein QC

Multichem **S**
Test Consolidation
for Serum Chemistry
& Immunology QC

Multichem **S Plus**
Test Consolidation
for Serum Chemistry
& Immunology QC

Multichem **U**
Urinary
Chemistry QC

Multichem **WBT**
Test Consolidation for
Immunosuppressant QC

Our class leading third party QC product range

With an extensive list of analytes included in our Multichem® product range - quality, choice and flexibility is guaranteed for all customers. The Multichem® product range includes General Clinical Chemistry, Immunoassay, Immunology, Immunoproteins, Esoteric, Diabetes, Urine Chemistry and Immunosupressant Controls.

An extensive range of kit formats are currently available, providing greater customer flexibility and choice. As part of our commitment to meet customer requirements as testing menu's increase, Technopath is committed to expanding its range of quality controls with new products regularly 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. Our human based control matrix offers unrivalled test consolidation through increased control stability and diminished matrix effects. Together, this aspect of control characteristics offer greater control efficiencies without compromising compliance or confidence in patient results.

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OUR FLAGSHIP IMMUNOASSAY AND CHEMISTRY QC PRODUCTS:

Multichem IA Plus and Multichem S Plus

FEATURES

- Human based proprietary preparation
- Mimics performance of patient samples
- Targeted key clinical decision points
- Tri-level
- Liquid stable frozen product

SPECIFICATIONS

- 36 month closed vial stability at -20ºC to -80ºC
- 10 day open vial stability at 2ºC to 8`ºC

Description	Configuration	Part Code
Multichem IA Plus Tri-level	3 x 4 x 5mL	IA310X
Multichem S Plus Level 1	15 x 10mL	CH101CRP
Multichem S Plus Level 2	15 x 10mL	CH102CRP
Multichem S Plus Level 3	15 x 10mL	CH103CRP

Multichem® Immunoassay QC

Multichem IA Plus

Multichem IA Plus (Immunoassay QC) is intended for use as third party quality control to monitor the precision of laboratory testing procedures for Immunoassay Assays. Multichem IA Plus contains 86 analytes including fertility and thyroid hormones, steroid hormones, tumour markers, cardiac markers, anaemia markers, therapeutic drugs, adrenal and bone metabolism markers.

Multichem Chemistry QC

Multichem S Plus

Multichem S Plus (Chemistry QC) contains 103 analytes including General Chemistry, Immunoproteins, Enzymes, Lipid Markers, Therapeutic Drugs and Esoterics. Multichem S Plus is also designed as a tri-level, liquid stable frozen product.

For more information on Multichem third-party quality controls, please visit: **www.technopathcd.com/products/quality-control-material**

IAMQC®

YOUR 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 tools 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's full suite of software products provide clinical laboratories with significant cost and time savings, whilst delivering higher confidence in analytical testing methods. IAMQC software products are practical, graphical, user-definable and easy to use.

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IAMQC® SOFTWARE PRODUCTS HELPS:

BENCH TECHNOLOGISTS:

- Spend less time on false positive QC flags
- Concentrate on tests that require their attention
- Spend less time trouble-shooting QC
- Know how to react when the mean shifts
- Assess the acceptability of new reagent lots and calibration events
- Solve QC problems

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

LABORATORY OR HOSPITAL ADMINISTRATORS:

- Save money
- Improve quality
- Improve service
- Review administrative summary reports to ensure quality performance

For more information on IAMQC informatic software solutions please visit:
www.technopathcd.com/products/quality-control-software

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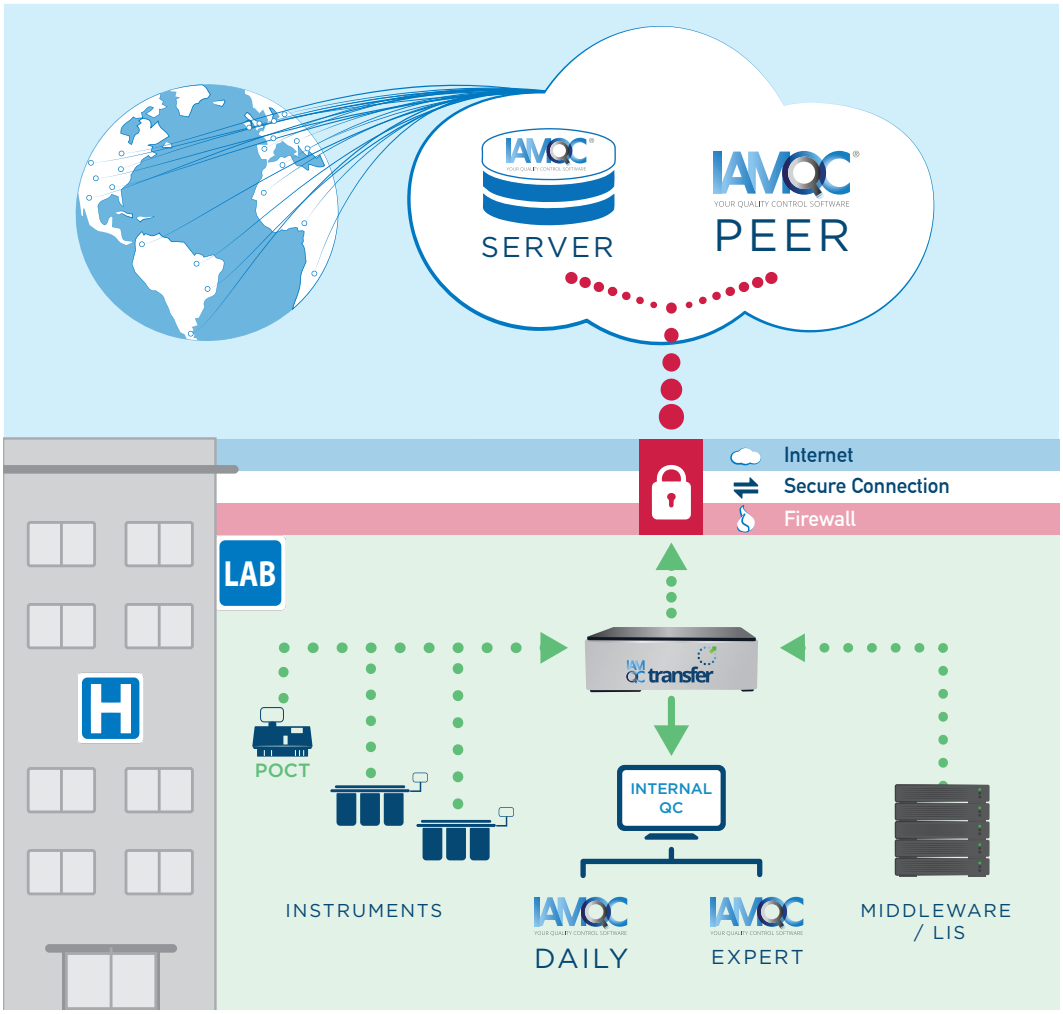

IAMQC® Connectivity

The most advanced connectivity solution available for laboratory instrumentation.

In 2016, Technopath introduced IAMQC® Transfer, a next-generation connectivity device that can communicate with Laboratory Information Systems (LIS), Middleware, automated instrumentation and Point Of Care platforms. Through the use of proprietary drivers and a single board computer device, IAMQC Transfer processes and communicates data from a laboratory system to any one of the powerful IAMQC software packages; IAMQC Peer, IAMQC Daily, IAMQC Expert or IAMQC Proficiency Testing module. By combining software and hardware elements, IAMQC Transfer can eliminate the requirement for additional PCs or servers for connectivity. 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.

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Company Developments

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 QC software solutions. 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.

Research and Development

We invest significantly in research and development focused on our core base matrix technology and developing new products to meet our customers needs – whether for the automated analyser platform or focused point of care (POC) testing equipment. Our unique technology platform has facilitated our class leading test-consolidated Multichem® product range which is unmatched in our industry. Our experienced R&D team comprises highly qualified scientists with a constant focus on delivering industry leading solutions.

Quality and Manufacturing

As a quality driven globalisation certified to ISO 9001:2008/13485 we develop and manufacture all of our products in our dedicated state of the art modern facilities at Technopath Life Sciences Park, Fort Henry, Ballina, Co. Tipperary, Ireland. Our products are sold in over 120 countries globally and approved by regulatory agencies including US FDA and Chinese FDA.

Technopath Clinical Diagnostics commitment to quality is recognised by accreditation to internationally recognised standards.

CERTIFIED BY:

TÜV SÜD

CE

LICENSED BY:

FDA

CFDA

ANVISA

Health Canada Santé Canada

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.

Future Developments

We recently completed a major expansion of our capabilities including a capital investment program which has greatly increased our manufacturing capacity to meet growing demand for our products and significant investments in new product development to meet customer demands.

Keep up to date on our progress by visiting **www.technopathcd.com**

or follow us on LinkedIn.

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Emerging Areas

IVD Raw Materials

Technopath Clinical Diagnostics manufacture and supply high quality IVD materials to a wide-ranging customer base. The company's proprietary processing techniques satisfies the raw material requirements of the IVD industry and provides IVD raw materials made to their own "off-the-shelf" specification. In addition, Technopath offer the added-value of developing and manufacturing raw materials that are fully customised to ensure customers receive the best solution possible for their specific applications and needs.

www.**technopathcd**.com/products/ivd-raw-materials

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i-plaq™ Test for Lp-PLA$_2$

The i-plaq™ Test for Lp-PLA$_2$ is Technopath Clinical Diagnostics first Diagnostic Reagent product. The test enables clinicians to quickly detect Lp-PLA$_2$, a vascular-specific inflammatory marker critical in the formation of rupture-prone plaque from a standard blood test. Higher levels of Lp-PLA$_2$ may indicate that the atherosclerotic plaque is more likely to rupture, leading to a dangerous blood clot that could result in cardiovascular disease (CVD) events. Technopath expects that i-plaq's superior test performance and ease of use will significantly improve the CVD risk assessment for patients.

The i-plaq Test for Lp-PLA$_2$ is CE Marked and available for use on multiple analysers.

www.**iplaqtest**.com

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