UK PORTFOLIO

TECHNOPATH
DISTRIBUTION

CLINICAL PATHOLOGY SOLUTIONS

SOLUTIONS FOR YOU

BROUGHT TO YOU BY: TECHNOPATH DISTRIBUTION

OUR PURPOSE

TECHNOPATH Distribution Ltd is a specialised value adding distributor, supplying essential products and services to the Healthcare, Life Sciences, Pharma and Food Sectors across Ireland and the UK.

Our headquarters is nestled in the scenic location of Ballina Co. Tipperary, from here we are able to locally support our customers all over the UK and Ireland to provide timely delivery, temperature controlled shipping and technical support in all areas of our business.

Our purpose is to deliver exceptional product and service solutions helping our customers achieve outstanding results.

OUR PEOPLE

Superior Customer Service & Support

The customer is at the forefront of everything we do and that is why we source the highest quality products, while providing technical expertise and superior support and service.
We believe that the core strength of our company lies in the level of expertise and technical knowledge evident in our workforce.

TECHNOPATH offers full technical support for each of our product lines.
Our people are all experts in their field and will be able to answer any technical questions you may have.

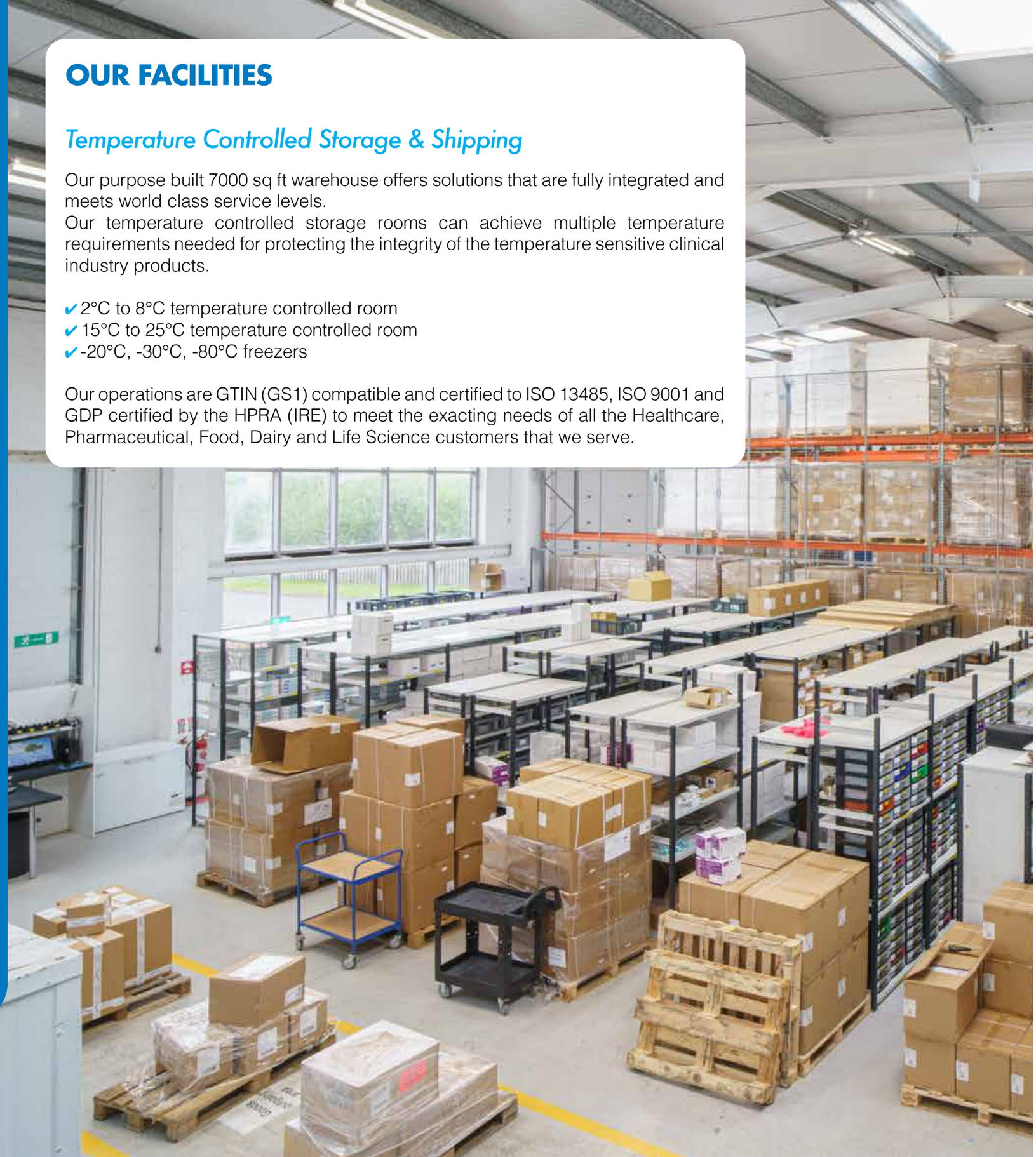
OUR FACILITIES

Temperature Controlled Storage & Shipping

Our purpose built 7000 sq ft warehouse offers solutions that are fully integrated and meets world class service levels.
Our temperature controlled storage rooms can achieve multiple temperature requirements needed for protecting the integrity of the temperature sensitive clinical industry products.

- ✔ 2°C to 8°C temperature controlled room
- ✔ 15°C to 25°C temperature controlled room
- ✔ -20°C, -30°C, -80°C freezers

Our operations are GTIN (GS1) compatible and certified to ISO 13485, ISO 9001 and GDP certified by the HPRA (IRE) to meet the exacting needs of all the Healthcare, Pharmaceutical, Food, Dairy and Life Science customers that we serve.



INTRODUCTION

Quality Controls

We partner with world leading manufacturers of clinical pathology quality control materials and diagnostic tests. Critical decisions for patient diagnoses and care are dependent on accurate and timely laboratory results. Our solutions deliver fast, reliable and informative results leading to increased efficiencies and improved patient outcomes for clinical pathology laboratories. TECHNOPATH supports these leading technologies with unrivalled levels of customer service, technical support including our **TPD LOT Management Program** and timely temperature controlled product deliveries.

TECHNOPATH CLINICAL DIAGNOSTICS

seracare™ Passion. Innovation. Precision.

maine standards COMPANY LLC

IAMQC YOUR QUALITY CONTROL SOFTWARE

Multichem® Third-Party Quality Controls

Why use Multichem® Third-Party QC?

The Multichem® range of independent quality control materials from Technopath Clinical Diagnostics, allows laboratories to simplify their inventory, reduce costs and improve efficiencies.
Multichem® QC incorporate a greater number of analytes, which enables extensive test menu consolidation.

Consolidated QC Controls for the efficiencies you need in your laboratory

- **Replace up to 4 competitor products**, wiith one Multichem® consolidated QC product
- **Reduce QC handling requirements** leading to reduced errors and improved turn around time
- **Eliminate wasted QC material** by up to 75 percent
- **Reduce QC storage** by up to 80 percent to help reclaim your inventory space
- **Reduce QC analysis time** with automation of reporting and Peer comparison data with IAMQC®

Consolidation

Our two flagship products, ***Multichem® S Plus*** *and* ***Multichem® IA Plus***, contain more than 190 tests combined. These two products can replace up to 8 competitor products, driving significant efficiencies for laboratories.

Human Based Formula

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

Lab Efficiencies

Consolidated QC product provides reduction in the number of QC lot evaluations, handling time, analysis time, dead volume waste, storage requirements and carbon footprint.

Targeted at Clinical Decision Points

Control materials targeted at clinical decision points helps improve clinicians' confidence in the validity of test results.

Meet Accreditation

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

Data Management Solutions

Automation of reporting and analysis of QC results and Peer comparison through the data management IAMQC® software solutions.

QUALITY CONTROLS

Delivering a world-class product with a world-class process

The TPD Lot Management Program

Find out more from your local representative today

WHY CHOOSE TECHNOPATH DISTRIBUTION LTD AS YOUR 3RD PARTY QC MATERIAL PROVIDER?

Introducing the TPD Lot Management Program

Multichem® Third-Party QC provides a greater number of analytes per product, which enables extensive test menu consolidation. Our Multichem® controls have a longer shelf life from date of manufacture compared to competitors which enables us to manage and lengthen laboratories time on lots, reducing the number of lot evaluations.

Ensuring high standards of product quality and delivery of this world-leading QC solution, needs a world-class process.

We achieve this through our **TPD Lot Management Program;** combining our people, facilities and systems; ensures laboratories have what they need when they need it, safe in the knowledge that product quality/stability has been maintained from the production line to your laboratory.

1. CONSULT

We actively engage with you to understand your QC Requirements.

We understand that scale, testing requirements and capacity can differ from one pathology setting to another.
We work with you and/or your chosen MSC provider to match your instrument with the most suitable QC material.

2. CUSTOMISE

We design a delivery schedule to manage your inventory

We aim to maximise your QC LOT length.
We ensure that 'lean lab' expectations are met.
We help optimise your usage for zero waste.

Consolidated QC
Liquid stable
Open and Closed Vial Stability
Long shelf life
Market leader in LOT Allocation Length

4. REVIEW

We are proactive in understanding evolving requirements

We provide regular reports on QC LOT usage and ordering patterns.
We commit to being flexible as and when required.
Advance notice with QC LOT changeovers.

3. DELIVER

We supply what laboratories want when they want it.

Fast turnaround time from PO receipt to delivery.

Stringent protocols in place for preparation and shipping, protecting product stability.


Multichem® S Plus


Multichem® IA Plus


Multichem® IA


Multichem® P


Multichem® U


Multichem® IA Speciality


Multichem® WBT


Multichem® HsTN


Multichem® AE


Multichem® A1c


Multichem® AMH


Multichem® NB


Multichem® CSF


Multichem® D-Dimer

Scheduling Production

Our Clinical Planning Team work directly with our partners ***Technopath Clinical Diagnostics*** to manufacture large LOTs of QC product.

- Providing you with the most effective QC delivery schedule in advance of shipping
- We work with you to provide samples if/when required
- We aim to maximise the time you spend on your LOT, reducing the frequency and the amount of time spent re-validating

LOT Receipt to Technopath Distribution

Our purpose built 7000sq ft temperature controlled warehousing facility can achieve multiple temperature requirements needed for the QC Material.

- 2°C to 8°C, 15°C to 25°C controlled rooms and -20°C, -30°C, and -80°C freezer
- Maintain the integrity and stability of your product as managed by Technopath.
- Regular validations are completed on site
- Back up generators are used to maintain product stability

Receiving your Order

Our teams in Order Processing, Demand Planning and Warehousing combine to provide the fastest turnaround time to prepare for shipping.

- Traffic light dispatch system to highlight priority orders
- Products are picked using barcode GTIN compatible scanners for product traceability

Preparing to Ship

Our order preparation processes ensure your product is delivered, without compromising product stability.

- We have numerous product specific packaging configurations
- We have a range of conditioning protocols for various chilled packaging components
- Product remains on dry ice throughout the order packing process
- Our facilities and processes are regularly audited by regulatory bodies.

QUALITY CONTROLS

Serum Chemistry & Immunology QC

Multichem® S Plus

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

- ✔ Frozen, Liquid stable, tri-level control
- ✔ 10 days open vial stability at 2 to 8°C
- ✔ 36 months shelf life once stored at -20 to -80°C
- ✔ 105 Analytes including C-Reactive Protein and Rheumatoid Factor
- ✔ 3 x 15 x 10mL

Replace up to 4 competitor chemistry QC products with Multichem S Plus.

ANALYTE LIST

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

Esoterics
ACE*
Bile Acids
Bilirubin, Indirect*
Caffeine*
Calcium, Ionized*
Copper*
Cortisol
Ethanol
Fructosamine*
NT-Pro BNP*
Osmolality*
Protein Electrophoresis*
Triiodothyronine, (Total T3)*
Thyroxine, (Total T4)
Troponin T*
Zinc*

Immunoproteins
Alpha-1 Acidglycoprotein
Alpha-1 Antitrypsin
Alpha-2-Macroglobulin*Antistreptolysin 0 (ASO)*
ADNase B (Anti-Streptococcal DNase B)*
Antithrombin III*
Apolipoprotein A1 (APO A1)
Apolipoprotein B (APO B)
Beta-2 Microglobulin
C1 Inhibitor*
CH5O (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*
Lamda 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
Prostactic 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® U

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

- ✔ 24 month closed vial stability at 2°C to 8°C
- ✔ 30 day open vial stability at 2°C to 8°C
- ✔ 15 x 10mL

ANALYTE LIST

Amylase	Microalbumin
Calcium	Osmolality
Chloride	Phosphorous
Cortisol	Potassium
Creatinine	Sodium
Glucose	Specific Gravity*
Human Chorionic	Urea Nitrogen
Gonadotropin	Uric Acid
Magnesium	Urinary Protein

*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

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 14 day open vial stability at 2°C to 8°C.
- ✔ Unassayed Bi-Level: 2 x 6 x 2mL
- ✔ Unassayed Tri-level: 3 x 4 x 2mL

ANALYTE LIST

Ammonia
Ethanol

Multichem® CSF

Providing Third-Party Test Consolidation for Cerebral Spinal Fluid QC in a Liquid Stable Format

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 30 day open vial stability at 2°C to 8°C.
- ✔ 2 x 6 x 2mL

ANALYTE LIST

Glucose
Lactate
IgG
Protein

QUALITY CONTROLS

Multichem® P

Supplementary Immunoprotein QC in a Liquid Stable Format

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 14 day open vial stability at 2°C to 8°C.
- ✔ 12 x 3mL

ANALYTE LIST

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*
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*
Lamda Light Chain*
Lipoprotein (a)*
Prealbumin
Properdin Factor B*
Retinol Binding Protein*
Rheumatoid Factor
Transferrin
sTIR (Soluble Transferrin Receptor)*

Chemistry Analytes
Albumin*
Angiotensin Converting Enzyme*
Total Protein*
Complement C3
Complement C4

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

Multichem® NB

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

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 14 day open vial stability at 2°C to 8°C.
- ✔ 12 x 3mL

ANALYTE LIST

Chemistry
Bilirubin, Direct
Bilirubin, Total

Therapeutic Drugs
Caffeine*
Theophylline

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

Immunoassay QC

Multichem® IA Plus

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

- ✔ Frozen, Liquid stable, tri-level control
- ✔ 10 days open vial stability at 2 to 8°C
- ✔ 36 months shelf life once stored at -20 to -80°C
- ✔ 86 Analytes including Cancer Markers
- ✔ 3 x 4 x 5mL

Replace up to 4 competitor immunoassay QC products with Multichem IA Plus.

ANALYTE LIST

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

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

Allergy
IgE

Anaemia
Erythropoietin (EPO)
Ferritin
Folate
Vitamin B12

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

Renal
Angiotensin*
Renin*

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

Bone Metabolism
Ostase*
Parathyroid hormone (PTH)
Procollagen type 1 amino-terminal propeptide (P1NP)*

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

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.

ALSO AVAILABLE

Multichem® IA

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

The main difference between **Multichem IA Plus** and **Multichem IA** product is the addition of three tumor markers to Multichem IA Plus; CA 125, CA 15-3 and CA 19-9.

QUALITY CONTROLS

Multichem® IA Speciality

Speciality Peptide Hormone QC in a Liquid Stable Format

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 14 day open vial stability at 2°C to 8°C.
- ✔ 3 x 4 x 2mL

ANALYTE LIST
BNP
PTH Intact
ACTH
Calcitonin
Procalcitonin

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

Multichem® hsTn

High Sensitive Troponin QC in a Liquid Stable Format

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 10 day open vial stability at 2°C to 8°C.
- ✔ 12 x 3mL

ANALYTE LIST
Troponin I
Troponin T

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

Speciality QC (Multichem® QC)

Multichem® A1c

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

- ✔ 24 month closed vial stability at -20°C to -80°C.
- ✔ 30 day open vial stability at 2°C to 8°C.
- ✔ 2 x 6 x 1mL

ANALYTE LIST
HbA1c

Multichem® AMH

Providing Third-Party Anti-Müllerian Hormone QC in a Liquid Stable Format

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 30 day open vial stability at 2°C to 8°C.
- ✔ 3 x 4 x 2mL

ANALYTE LIST
Anti-Müllerian Hormone

Multichem® WBT

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

- ✔ 30 month closed vial stability at -20°C to -80°C.
- ✔ 10 day open vial stability at 2°C to 8°C*.
- ✔ 3 x 4 x 2mL

ANALYTE LIST
Cyclosporine
Folate*
Glucose*
Sirolimus
Tacrolimus

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

QUALITY CONTROLS

Multichem® D-Dimer

Multichem D-Dimer Control is intended for use as a third party, bi-level, liquid stable quality control material to monitor the precision of laboratory testing procedures for D-Dimer Assays

- ✔ 36 month closed vial stability at -20°C to -80°C.
- ✔ 30 day open vial stability at 2°C to 8°C.
- ✔ 2 x 6 x 1mL

ANALYTE LIST
D-Dimer

Multichem® QC Kit Configurations

PRODUCT	DESCRIPTION	KIT CONFIGURATION	ORDER CODE
Serum Chemistry & Immunology QC			
Multichem® S Plus	Unassayed Single Level (Level 1)	15 x 10mL	CH101CRP
	Unassayed Single Level (Level 2)	15 x 10mL	CH102CRP
	Unassayed Single Level (Level 3)	15 x 10mL	CH103CRP
Multichem® U	Unassayed Single Level (Level 1)	15 x 10mL	UC201X
	Unassayed Single Level (Level 2)	15 x 10mL	UC202X
Multichem® AE	Unassayed Bi-Level	2 x 6 x 2mL	AE600X
	Unassayed Tri-Level	3 x 4 x 2mL	AE610X
Multichem® CSF	Unassayed Bi-Level	2 x 6 x 2mL	CF100X
Multichem® P	Assayed Single Level Kit	12 x 3mL	SP40PX
Multichem® NB	Unassayed Single Level Kit	12 x 2mL	NB800X
Immunoassay QC			
Multichem® IA Plus	Unassayed Tri-Level	3 x 4 x 5mL	IA310X
Multichem® IA	Unassayed Tri-Level	3 x 4 x 5mL	IA300X
Multichem® IA Speciality	Unassayed (Tri-Level)	3 x 4 x 2mL	BP300X
Multichem® hsTn	Unassayed Single Level Kit	12 x 3mL	HS301X
Speciality QC			
Multichem® A1c	Assayed Bi-Level	2 x 6 x 1mL	HB000A
Multichem® AMH	Unassayed Tri-Level	3 x 4 x 2mL	AM500X
Multichem® WBT	Unassayed Tri-Level	3 x 4 x 2mL	WB000X
Multichem® D-Dimer	Unssayed Bi-Level	2 x 6 x 1mL	DM9000X

To place an order contact our team on the below details:

orders@techno-path.com I Tel IRL: +353 (0)61 335844 I Tel UK: +44 (0)28 30833808

Serology & Molecular Infectious Disease Testing QC

Clinical laboratories require consistent, stable, and reliable sources of materials to validate and monitor their assay's performance. With increasing reliance on test results and decreasing reimbursement, "gold standard" reference materials and controls are a necessity for any lab to implement a best-in-class quality control program.

LGC SeraCare Accurun® Controls

Highest-Quality Controls and Reference Materials for Infectious Disease Testing.
The Accurun® Controls include a wide range of important viral and bacterial pathogens including HIV, HBV and HCV, C.diff, and CT/NG.

Improve the monitoring and management of your QC processes by rigorously challenging your assays and mitigating risk

ACCURUN® Serology Controls

LGC SeraCare's ACCURUN controls and reference materials are designed to be weakly reactive to help monitor your serology assays and provide additional confidence in your laboratory test results. Monitoring your assay performance can help you avoid costly repeats and, more importantly, avoid false-negative and false-positive results. With LGC SeraCare controls, you can troubleshoot your test methods and isolate system errors in your laboratory.

- Mimics a patient sample, therefore treated like a patient sample, reducing additional steps in your workflow.
- Reliable and ready-to-use, eliminates the hassle of locating external controls to meet laboratory compliance requirements.
- Single-analyte and multi-analyte formats offer you cost-effective options to conserve your laboratory's budget.

ACCURUN® Molecular Controls

Molecular controls and reference materials are whole-cell or whole-organism external controls that help you monitor all aspects of your molecular testing methods and provide additional confidence in your laboratory test results. A well-designed QC program can help you avoid costly false-negative or false-positive results. LGC SeraCare's molecular controls effectively detect low-positives closer to assay-specific cutoffs, enabling better detection of assay variability.

- Evaluates the entire testing workflow from extraction to detection.
- Weak reactivity challenges your test method more effectively to ensure confident result reporting.
- Reliable, stable, and consistent source of known-positive and negative control material saves procurement time.

REASONS TO USE ACCURUN® CONTROLS:

- ✔ **CLINICALLY RELEVANT RANGES**: Specifically designed to be weakly reactive, low-positive controls, ACCURUN truly challenges an assay's performance at critical decision points.
- ✔ **PATIENT-LIKE MATRICES**: ACCURUN controls are formulated to mimic authentic patient samples, as encountered in a daily testing environment.
- ✔ **FULL PROCESS:** Whole virus/organism controls are designed to detect failures at every stage of the testing protocol – from sample prep to detection.
- ✔ **LOT TO LOT CONSISTENCY**: SeraCare produces large lot sizes under cGMP and ISO 13485 conditions. This ensures availability of bulk quantities of a single lot for long-term QC monitoring.

QUALITY CONTROLS

IVD Assay Validation

TECHNOPATH partners with LGC SeraCare to provide their portfolio of validation and qualification panels, allowing clinicians and researchers to assess overall assay performance. Whether it's evaluating analyte specificity and sensitivity, new reagent lot qualification, method-to-method comparison, or to assess consistency in test run repeatability and reproducibility studies, our comprehensive set of panel products serve nearly all applications of IVD validation protocols to enable confidence in your test results.

LGC SeraCare Panels

For more than 30 years, **AccuSpan™ linearity panels** have been a trusted source of validation material to clinical laboratories worldwide that test for quantitative molecular analytes.

The **HIV seroconversion and performance panels** have been used for comparative studies for HIV test kit evaluations and are frequently referenced in package inserts of leading IVD infectious disease platforms.

AccuTrak™ qualification panels are utilised by clinical laboratories worldwide to help strengthen quality control protocols and procedures for infectious disease diagnostic assays including HIV, hepatitis, CMV, syphilis, HPV, and HTLV.

Validation and qualification materials to remove doubt and add confidence in your testing.

AccuSpan™ Linearity Panels

Designed to span the dynamic range of quantitative infectious disease assays and evaluate the analytical sensitivity of instrumentation. Linearity panels effectively challenge assay performance at defined intervals to ensure consistency throughout the entire reportable range. In addition to linearity studies, these panels are useful in validation procedures for new assay implementation, operator training, and troubleshooting signs of assay deterioration.

AccuVert™ Seroconversion Panels

Developed using raw, undiluted plasma collected from a single individual during the development of an infection and subsequent immunological response. Spanning an array of infectious diseases from HIV to hepatitis and syphilis, SeraCare's portfolio of seroconversion panels provides you with a diverse selection of products with high-quality datasets to help evaluate your assay. When your assay development requires natural patient specimens that represent the body's true response to an infection, you can depend on AccuVert seroconversion panels as a gold standard with which to assess your assay development milestones.

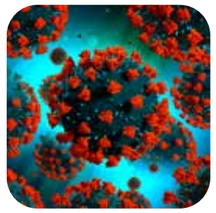
AccuTrak™ Qualification Panels

Designed as a cost-effective solution to deliver the consistent results you need to gain confidence in your assay's performance and ensure reagents are operating effectively lot-to-lot.

AccuSet™ Performance Panels

Available for use with serological and molecular assays, The panels contain highly characterised, raw, undiluted plasma specimens collected from unique individuals positive for your analytes of interest. Each panel contains a comprehensive comparative data sheet with test results from a wide variety of leading commercially available assays and platforms. The AccuSet line of performance panels can be used to evaluate assay specificity, sensitivity, repeatability, and reproducibility to assist you in validating new test methods and equipment, run head-to-head assay comparisons, demonstrate lab proficiency, and train laboratory personnel.

COVID-19 Quality Control Solutions



LGC SeraCare SARS-CoV-2 Quality Solutions

TECHNOPATH provide solutions for COVID-19 Testing from our partners LGC SeraCare in response to the COVID-19 pandemic.

MOLECULAR (PCR) SOLUTIONS

Full viral genome coverage for assay verification and ongoing performance monitoring.

AccuPlex™ SARS-CoV-2 Verification Panel is optimised for assay verification at installation by documenting test performance along the assay's range enabling laboratories to establish lower limits of detection, perform assay comparisons, and evaluate staff proficiency.

AccuPlex™ SARS-CoV-2 Reference Material is designed to measure day-to-day performance of the assay, providing both a positive and a negative reference solution.

AccuPlex™ SARS-CoV-2 in Synthetic Oral Fluid is an ideal research tool for assay developers creating novel saliva-based SARS-CoV-2 assays, as well as a complete quality solution for clinical laboratories employing such tests.

SEROLOGY SOLUTIONS

Ensure antibody testing accuracy and performance.

ACCURUN® Anti-SARS-CoV-2 Controls Kit is designed to support assay installation and monitoring of day-to-day assay performance, providing a complete quality solution for SARS-CoV-2 antibody testing.

AccuSet™ SARS-CoV-2 Performance Panel is intended to provide an out-of-the-box solution to evaluate SARS-CoV-2 antibody detection assays with highly characterised human specimens whether generating validation data for a regulatory submission or performing assay verification in a clinical laboratory setting.

AccuVert™ SARS-CoV-2 Seroconversion Panel is intended for use by diagnostic manufacturers, researchers, and clinical laboratories to develop, evaluate, or troubleshoot SARS-CoV-2 test methods.

MULTIPLEXED SOLUTIONS

AccuPlex™ offers quality solutions with targets for SARS-CoV-2, influenza A/B and respiratory syncytial virus (RSV).

AccuPlex™ Verification Panels are optimized for assay verification at installation by documenting test performance along the assay's range, enabling laboratories to establish lower limits of detection, perform assay comparisons, and evaluate staff proficiency.

AccuPlex™ Reference Material Kits are designed to measure day-to-day performance of the assay, providing both a positive and a negative reference solution.

VARIANT SOLUTIONS

Clinical Diagnostics Quality Solutions for SARS-COV-2 Variant analysis.

AccuPlex™ SARS-CoV-2 Variant Reference Materials offer complete SARS-CoV-2 genome coverage with a focus on representative S and N gene mutations in prominent variants of concern (VOC), for example Omicron B.1.1.529.

ANTIGEN SOLUTIONS

Reference materials supporting assay development and performance monitoring.

ACCURUN® SARS-CoV-2 Antigen Reference Material Kit is formulated for use with test methods that detect the nucleocapsid (NP) protein of SARS-CoV-2 virus. The kit offers both positive and negative materials for SARS-CoV-2 nucleocapsid antigen tests.

QUALITY CONTROLS

Quality Control Software

IAMQC® Peer Software provides Laboratory Managers and Technicians with a range of QC software tools to analyse their QC results in real-time - translating to improved quality management, efficiencies and cost saving.

What is IAMQC Peer?
IAMQC Peer enables real-time peer comparison between laboratories across the globe for all QC test data . This allows the laboratory to easily monitor its own reliability and precision.

- True Inter-laboratory Peer Group
- Powerful Inter-Laboratory QC Comparison Reports
- Full System Automation Supported

Reports available from IAMQC® Peer

Reagent Lot Report	The reagent lot report provides quick and easy visualisation of QC peer statistics broken out by reagent lot for each assay on the instruments in the laboratory for the chosen QC lot number.
Measurement of Uncertainty Report	There are a number of factors which must be considered when calculating uncertainty, including the chosen method, Bias, analytical errors and so on. If uncertainty is quantified it is no longer uncertainty but the confidence interval within which the results fall. Uncertainty should be assessed regularly and attempts made to improve the value.
Six Sigma Report	IAMQC® Peer offers end-users the opportunity to automatically calculate and review their sigma metric performance. The system will automatically calculate imprecision and bias and once the end-user has defined their acceptability criteria (i.e. Total Allowable Error), the software will automatically calculate a sigma score for every assay that is tested in the laboratory.
Bias Report	Test by test listing of statistics for the laboratory and its peer groups for up to 3 levels of control material. It documents each instruments performance compared to the world peer group and any selected affiliate group, in a Microsoft Excel file. It displays each instruments Mean, SD, %CV and N of tests for the selected month, along with the SDi, CVi and %Bias comparison with the world peer and affiliate groups.
Group Coordinator Report	Provides a test by test listing of statistics for the laboratory and its peer groups for up to 3 levels of control material. A centralised view of all instruments helps facilitate accreditation with respect to storage, retrieval and statistical analysis of QC data.
Levey-Jennings (LJ) Report	This report displays individual daily QC means for the selected month for a specific analyte.
Monthly Summary Report	Useful for long-term intra-laboratory and inter-laboratory comparisons. For each test and control level this report displays summary statistics for the last 12 individual months. Usual method accuracy and precision is indicated to analyse trends. Monthly SDI and CVI, indicating any shifts from the peer group is shown.
Exceptions Report	Summarises the laboratory's tests and analytical methods which differ in performance from its peer group using SDI, CVI and Total Error performance criteria. Flag L did not pass the Laboratory outlier check; Flag P did not pass the Peer outlier check; Flag G did not pass the Gross outlier check.

IAMQC® Infinity

Apply Westgard and/or any user-defined rules.

Explore consolidating all your QC requirements, for a pan-pathology solution, in one software solution.

IAMQC INFINITY
YOUR QUALITY CONTROL SOFTWARE

Incorporate the benefits of IAMQC® Peer

TECHNOPATH CLINICAL DIAGNOSTICS

maine standards COMPANY LLC

sera care™ Passion. Innovation. Precision.

IAMQC YOUR QUALITY CONTROL SOFTWARE

QUALITY CONTROL SOFTWARE

EQA Surveys

European Society for External Quality Assessment (ESfEQA) offers a wide range of External Quality Assessment Schemes. ESfEQA was founded in Heidelberg/Germany in 2013 and is accredited according to the international standard ISO 17043:2010 by the German national accreditation body DAkkS. Since its foundation, ESfEQA has expanded its program portfolio and at the same time the number of laboratories participating in ESfEQA's external quality assessment schemes.

Currently, ESfEQA offers more than 70 quantitative and qualitative EQA schemes worldwide for your medical laboratory.

Participants submit their results to the ESfEQA database via the secured TEQA web application. ESfEQA evaluates the participants' results according to ISO 13528 and provides the reports to the participants via TEQA.

ESfEQA
European Society for External Quality Assessment

ESfEQA Programs

Biochemistry	Bilirubin Neonatal, Blood Gas & Electrolytes, Cardiac Marker, **Cerebrospinal Fluid**, Clinical Chemistry, Coagulation, CO-Oximetry, Drugs of Abuse, Ethanol, Ammonia and Bicarbonate, **Fecal Occult Blood**, Glycated Hemoglobin, Prothrombin time (POCT), Qualitative Urine Analysis (Urine Stick), Therapeutic Drugs, Urine Chemistry, **Urine Sediments**
Immunology	hCG,Procalcitonin,Specific Proteins, Thyroid Antibodies, Tumour Marker & Hormones
Microbiology	**Adenovirus**, **Aspergillus Fumigatus**, Bacteriology (Pathogen Identification and Antimicrobial Susceptibility Testing,according to EUCAST and CLSI), **Borrelia, Brucella, Chagas**, Chlamydophila Pneumoniae, **Chlamydophila Trachomatis, Chikungunya Virus, Coxsackie-virus**, Dengue Virus, **ECHO Virus, Enterovirus**, Epstein-Barr Virus, Hepatitis A Virus, Hepatitis B Virus, **Hepatitis E Virus, HTLV I/II, Infectious Disease (HIV, HCV, HBV)**, Influenza A Virus, Influenza B, Virus, **Leptospira**, Malaria Microscopy (Parasite/ Stage Identification), Measles, Mosquito Transmitted Diseases (Chikungunya, West-Nile, Zika, Dengue), **Parainfluenza Virus**, Parvovirus B 19, Respiratory Syncytial Virus, SARS-CoV-2, Syphilis, ToRCH, Varicella Zoster Virus, **West-Nile-Fever Virus, Zika Virus**
Molecular Diagnostics	HBV Molecular, HCV Molecular, HIV Molecular, SARS-CoV-2 Molecular
Haematology	Blood Grouping Immunhematology, Erythrocyte Sedimentation Rate, **Erythrocyte Sedimentation Rate for Alifax and Alcor devices** Hemogram, **Hemogram including 3-part Diff**.
Educational Programs	Clinical Case Study.

How it works

1. **Registration:** Your laboratory and participants are registered on the TEQA LAB software. TEQA LAB is the ESfEQA software for external quality assessment and the user interface for submitting results and receiving performance reports.
2. **Ordering:** Choose and order the program of your choice for your medical laboratory.
3. **Shipment:** Technopath Distribution Ltd will deliver out the survey samples, under the required temperature controlled conditions, with scheduled shipments during the testing period.
4. **Analysis:** Analyse samples under laboratory routine conditions. Testing period(2-3 weeks) are indicated on the sample itself.
5. **Data Entry:** Participants submit their results to the ESfEQA database via the secured TEQA web application.
6. **Report:** Reports and certificates are provided online via the TEQA web-application. Summary indicates the lab performance: bias (%) to target value, z-score as normalised deviation.Comparison of laboratory results with "Peer-group" (same instrument, method, reagent) and general group (all participants).

Survey Reports and Statistical Evaluation

ESfEQA reports provide a comparison of laboratory results with other laboratories that use the same analytical system, in particular the same analytical device or reagent, but also provide detailed information for comparison to other analytical devices. We consider the comparison to other analytical devices, methods etc. to be very important since the medical interpretation of laboratory results is usually not associated to any particular instrument, method or reagent brand.
In addition to detailed information, ESfEQA reports contain a summary that allows participants to capture the laboratory performance at a glance.

The reports for quantitative analytes (e. g. in Clinical Chemistry, Hormones or Haematology) consist of several sections.
Participants receive the survey reports electronically as PDF-files via the TEQA web application. Reports from previous surveys are stored in the TEQA database so that participants can download them.

EXTERNAL QUALITY ASSESSMENT

VALIDATE® Linearity & Calibration Verification Test Products for Clinical Analysers

Calibration Verification, performed at regular intervals, confirms that your clinical analyser is performing to the manufacturer's claims, ensuring reliable and consistent patient test results.

Maine Standards is a market leader for linearity and calibration verification products.

VALIDATE® Products

The following VALIDATE® product groups offer in excess of 170+ analytes, formulated into standard groupings.
Visit techno-path.com website to see Typical Recovered Values and lot-specific information (PIs).

- General Chemistry
- ACTH
- Anemia
- Body Fluids
- Bone
- Cardiac
- Diabetes
- Fertility
- Hemostasis
- Immunosuppressants
- Osmolality
- Point of Care
- SARS-CoV-2
- Sepsis
- Serum Proteins
- Therapeutic Drug Monitoring
- Thyroid
- Tumor Markers
- Urine Chemistry

maine standards COMPANY LLC®

Easy

VALIDATE® test kits use human-sourced raw materials, where available, and require no reconstitution.

Liquid, ready-to-use solutions are supplied in multi-use dropper bottles for easy dispensing.

Order once per year with extended open-vial stability and additional material for troubleshooting.

Fast

VALIDATE® test kits increase productivity, reducing the need for sample preparation and manual dilutions.

Levels 1 - 5 are prepared according to CLSI's EP06-A guideline.

Fulfill CLIA '88, CAP, ISO 15189, COLA, JCAHO, JCI and other accreditation and regulatory requirements.

Efficient

Together with the MSDRx® software, VALIDATE® provides a comprehensive calibration verification assessment.

Instrument-specific configurations maximize range coverage and minimize dilutions.

Use for installation, preventative maintenance and troubleshooting of reagents, QC and calibrations.

Installation

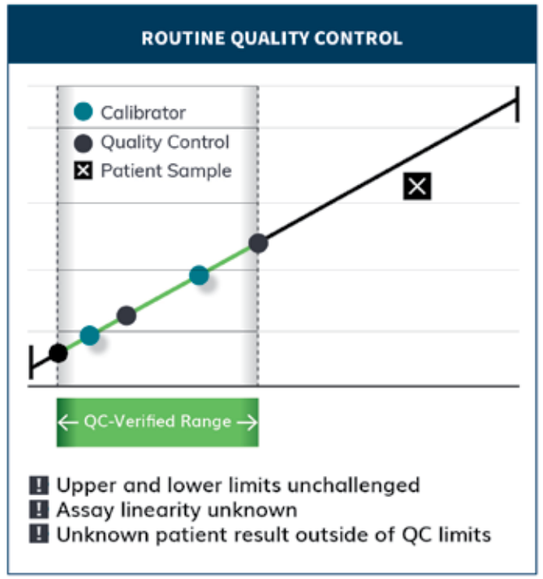
VALIDATE® products are used by major IVD manufacturers to perform verification of new instruments and assays. These instrument-specific kits are used by clinical laboratories to ensure instrument and assay specifications are being met, maintaining reliable and consistent patient results.

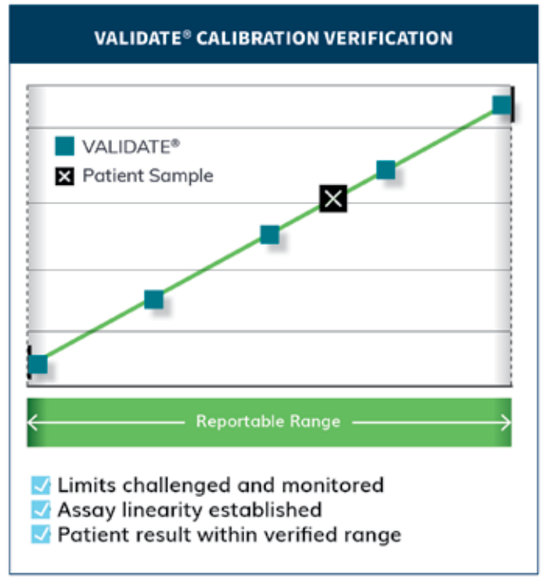
Maintenance & Troubleshooting

VALIDATE® products are multi-use with extended open-vial stability. Having the same solutions available over several months and multiple uses affords the laboratory an invaluable tool when verifying and monitoring a method's performance.

Comparison of Recovered Value vs. Concentration

Assaying materials in the same manner as patient samples, using VALIDATE®, confirms that an instrument, kit or test system has remained stable throughout the reportable range. Therefore, laboratories can expand beyond the routine quality control range with confidence.





The laboratory cannot ensure that the response curve is linear beyond the limits of the calibrator and controls. When a patient sample result falls outside this range, there is reduced confidence that the result is valid. VALIDATE® challenges the extremes of the reportable range. Assaying five levels, using the equal-delta protocol prescribed by CLSI EP06-A, verifies a linear response. Patient samples are reported with increased confidence.

Configurations Tailor-Made to Analytical Instrument Platforms

CLINICAL CHEMISTRY & IMMUNOASSAY ANALYSERS

- Abbott Laboratories
- Alfa Wassermann
- Beckman Coulter
- Ortho Clinical Diagnostics
- Roche Diagnostics
- Siemens Healthineers
- Tosoh Bioscience

HEMOSTASIS ANALYSERS

- Diagnostica Stago
- Instrumentation Laboratory
- Siemens Healthineers

LINEARITY & CALIBRATION VERIFICATION

NEWBORN SCREENING

Early disease detection through newborn screening

Technopath Distribution are proud to partner with Baebies® to support their newborn screening technology that enables early disease detection for newborns. Early detection through newborn screening – along with an associated therapy – can significantly improve a baby's health, often saving their life.

Baebies® develops newborn screening solutions like the SEEKER®, an FDA-authorised and CE-marked high throughput newborn screening platform.

Digital Microfluidic Technology from Baebies®

SEEKER Newborn Screening Platform

Powered by digital microfluidics

SEEKER® is a newborn screening laboratory solution that performs multiple assays at the same time using just one punch from a newborn dried blood spot specimen. SEEKER® is used to test thousands of babies each day around the world.

SEEKER®

Features
- ✔ Flexible
- ✔ Cost-effective
- ✔ Fast results
- ✔ Simple operation

Everything your lab needs for screening in one small workstation.

Lysosomal Storage Disorders

SEEKER® is the first FDA-authorised and CE-marked newborn screening platform for lysosomal storage disorders. SEEKER® quantitatively measures the activity of lysosomal enzymes from newborn dried blood spot specimens.
Reduced activity of these enzymes may be indicative of:

MPS I • Pompe • Gaucher • Fabry

Powered by digital microfluidics technology, Baebies SEEKER® provides newborn screening results in under 3 hours for multiple LSDs from a single DBS punch.

SEEKER's first tier enzymatic assay results can be paired with second tier genetic sequencing to reduce false positives, preventing unnecessary family anxiety.

ARTEL
BY ADVANCED INSTRUMENTS

QC Instruments for Liquid Handling

TECHNOPATH partner with ARTEL for calibration and volume verification systems for hand-held pipettes and automated liquid handlers.

Portable, efficient, and traceable to NIST standards, Artel's PCS® and MVS® instruments are an easy way to ensure data integrity for full confidence in your results.

Meeting regulatory requirements and maintaining quality doesn't have to take up a lot of valuable time. With the PCS®, MVS®, and Artel's Services, clinical labs can streamline regulatory compliance, maximising productivity.

Artel PCS® Pipette Calibration System

The Artel PCS® provides confidence in data integrity with scheduled pipette calibrations, interim performance verifications, complete documentation and pipette inventory management, even for pipettes calibrated outside of PCS® Software — and it's an ideal tool for standardising pipetting technique and assessing operator competency.

Artel MVS® Multi-channel Verification System

Understand and manage the performance of your automated liquid handlers, multichannel pipettes, labware, operators, and more. Compatible with virtually all automated liquid handling systems and multichannel hand-held pipettes, the Mobile workstation for portable rapid calibration, verifications and optimisation of dispensed volumes with high precision and accuracy.


Artel Pipette Calibration Report

Pipette LC21413

Result PASSED

Volume	Mean	Std Dev	Uncertainty	Inaccuracy	Tolerance	Imprecision	Tolerance	Result
20.00 µL	19.645 µL	0.168 µL	0.337 µL	-1.78 %	5.00 %	0.86 %	5.00 %	PASSED
50.00 µL	49.881 µL	0.425 µL	0.546 µL	-0.24 %	2.50 %	0.85 %	2.50 %	PASSED
100.00 µL	99.083 µL	0.944 µL	1.190 µL	-0.52 %	2.50 %	0.95 %	2.50 %	PASSED

Clinical departments where Artel can help:

- ✔ Calibration and volume verification
  - ✔ Single-channel hand-held pipettes
  - ✔ Automated liquid handlers
- ✔ Pipette operator proficiency assessment and training
  - ✔ Between hand-held pipettes and automated liquid handlers
  - ✔ From lab-to-lab and site-to-site across a global organisation
- ✔ Reduce variability by standardising volume transfers
- ✔ Control for lot-to-lot variability from disposable tips
- ✔ Optimise liquid class on automated liquid handlers
- ✔ Optimise processes on automated liquid handlers

Patient outcomes depend on accurate results, which depend on liquid delivery volume.

New ISO 15189 Standard Answers Need for Data Integrity in the Clinical Lab

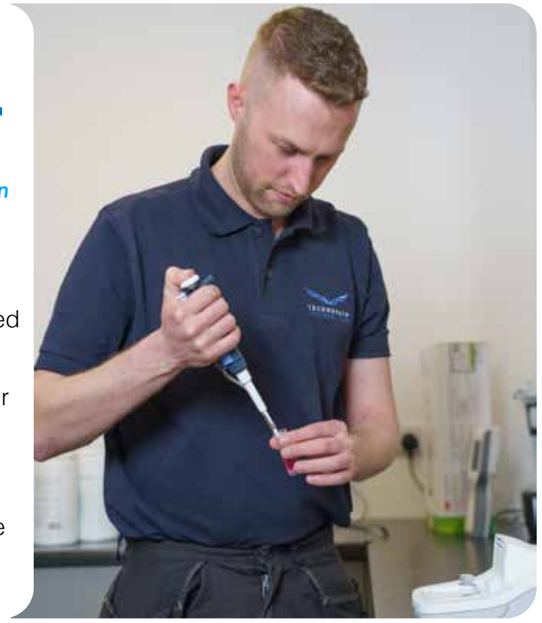
The International Organization for Standardisation (ISO) addresses this with the approval and publication of a new standard, ISO 8655-7, formally making photometric reference measurement methods this advanced and convenient methodology an internationally accepted, standard method.

Through ISO 15189 and ISO 17025, this new standard is applied to clinical laboratories.

QUALITY CONTROL INSTRUMENTATION

Instruments Servicing & Support

Certified installation and after sales service provision for all instrumentation

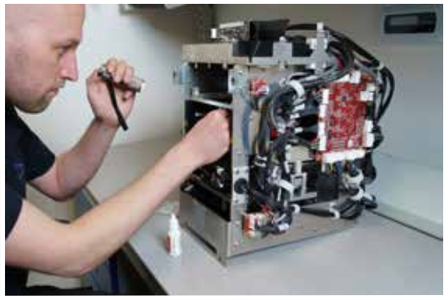


Effective installation and efficient after sales technical support of instrumentation is a key element of TECHNOPATH's service offering. We have a dedicated clinical engineering and service management team providing a comprehensive suite of preventative maintenance and repair service offerings covering our complete instrumentation portfolio.

Our team of highly trained engineers is supported by a dedicated Service Co-Ordinator who liaises directly with customers to schedule preventative maintenance and repair visits and manage any service related enquires.

Our services:

- ✔ Site Surveys and installation planning
- ✔ Suite of preventative maintenance programs
- ✔ Calibration services
- ✔ Breakdown and repair services
- ✔ Technical support and training
- ✔ 48 Hour response time
- ✔ Nationwide coverage throughout the U.K. and Ireland
- ✔ Certified engineers
- ✔ Certified reports, documentation and certification
- ✔ Telephone, in-House and on-site support



CONTACT US

For further information on any of the clinical pathology offerings from TECHNOPATH please contact us on the below details or check out our website: www.techno-path.com

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