



QUALITY CONTROLS CATALOGUE



Fortress
Diagnostics



Fortress Diagnostics

How To Order

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Advancing Global Diagnostics

Fortress Diagnostics is a well-established, multi award-winning IVD manufacturer based in the United Kingdom, supplying an extensive portfolio of products to over 100 countries worldwide.

We have been providing our distributors and end users with high quality products for over 20 years. The objective of Fortress Diagnostics is to provide the highest level of diagnostic solutions, globally, through continued investment in research and development.

Why choose Fortress Diagnostics?



Our proven product performance, matched with our selection of reputable distribution partners, has been instrumental in our continued success and growth. Built on a culture of quality and performance, we are committed to providing our customers with a reliable service and results they can trust.



Our ISO 13485:2016 certification for the design, development, manufacturing and distribution of in vitro diagnostics (IVD) medical reagents and instrumentation endorses our product range and ensures that the highest quality standards are constantly maintained.



Through our global distribution network, we provide highly accurate medical testing solutions to immunology, haematology and serological laboratories in hospitals, medical centres, clinics, blood banks and research institutions in over 100 international markets.



Hosting an in-house Research and Development team, we are committed to creating the next innovative IVD solutions to exceed our customer's requirements and advance the healthcare industry. We reinvest over 30% of our turnover in R&D every year.

Fortress Quality Controls & Calibrators

Quality controls and calibrators play a vital role in clinical diagnostics by ensuring the accuracy and reliability of test results. Quality controls are designed to monitor the performance of diagnostic assays and reagents, helping to detect any variations or issues that may arise during testing. This ongoing assessment ensures that laboratories maintain high standards and can identify problems before they affect patient care. Calibrators, on the other hand, are used to establish the measurement accuracy of diagnostic instruments by providing a known reference point against which test results can be compared.

Together, these elements contribute to standardisation and consistency in laboratory testing, fostering confidence in the results provided to healthcare professionals. Ultimately, robust quality control and calibration processes are essential for delivering precise diagnoses, guiding effective treatment decisions, and ensuring patient safety in clinical practice.

Fortress Quality Controls (**Seraqual**) are supplied with instrument and method specific assigned values. We can also provide quality control solutions, tailor-made to customer specification and requirements, enabling laboratories to be more efficient and reduce costs. We also work with many universities, research institutions and laboratories to develop quality control and calibration solutions for unique and novel biomarkers.

The Seraqual Portfolio

Fortress Diagnostics Seraqual Controls and Calibrators are available for:

Antioxidants
Aqueous Standards
Blood Gas & Electrolytes
Cardiac
Clinical Chemistry
Coagulation/Haemostasis
Diabetes

Drugs of Abuse
Haematology
Immunoassay/ Infectious
Immunology/Proteins
Lipids
Maternal Screening
Neonatal Screening
Paediatric Screening

Speciality Controls
Thalassaemia
Therapeutic Drugs
Torch
Paediatric
Urine
Xanthochromia

Why Choose Fortress Quality Controls & Calibrators?

1



Customer Support

Fortress Diagnostics employ a highly-skilled team of technical support staff to assist customers with all their needs and technical questions. We are always on-hand to help.



2



Cost Saving

Our Quality Controls Range have a wide-ranging analyte content, enabling laboratories to consolidate their quality control purchases and therefore benefit from cost savings.



3



Accurate

Manufactured by Fortress Diagnostics in our ISO 13485:2016 accredited labs, Seraqual products are designed to provide highly accurate target values mimicking human samples, with minimal matrix effects being observed.



4



Reliable

Our fully in-house logistics team enables us to ship orders globally and our customer support team are available to assist with any labs' special requirements or custom orders to ensure customer satisfaction is always exceeded.



5



Third Party Controls Suitable For Global Market

We manufacture a wide range of third party controls which are value-assigned, without bias, towards any methods or instrumentation, enabling labs to meet their ISO accreditations through accurate and robust training.



6



High Quality

Seraqual products are manufactured without the use of preservatives or stabilisers, utilising human-based material, which have undergone stringent quality checks for HIV, HBsAg, HCV, HTLV, and Syphilis for FDA approved methods. Products of animal origin are not added in the Fortress controls, therefore eliminating the lack of specificity in antibody-based tests.





Flexible

As well as offering an extensive range of controls, Fortress Diagnostics has the ability to manufacture custom quality control products to meet any customer requirements providing a fully flexible solution.



Long Shelf Life

Fortress Diagnostics offer quality controls in two different formats - lyophilised (stable for up to 4 years) and liquid (stable with a shelf life of up to 18 months) - enabling labs to utilize lot supply and save costs.



Traceability

Fortress Controls and Calibrators are CE marked and fully traceable to the reference material according to ISO 17511 and ISO 18153 directives.



Consolidation

Fortress Quality Controls offer a wide parameter range allowing more analyte coverage with a single control.



Value Assignment

The Fortress value assignment involves six European Reference Laboratories, (chosen on the basis of the analytes performed in these laboratories), each of which performs five independent runs.



Compatibility

Fortress Controls are made from human derived material, with minimal matrix effects being observed.



Find Out More



Website

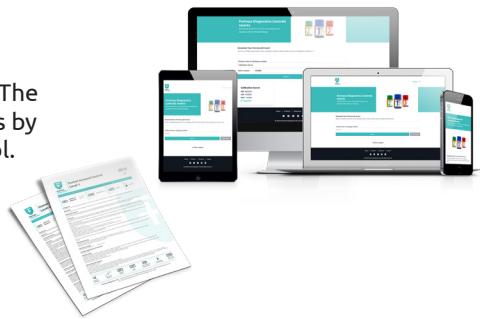
fortressdiagnostics.com

The Fortress Diagnostics website details our full product range, allowing users to add products of interest to a "Quote Request" which is sent directly to our sales team. We regularly post blogs, event information, resources and company updates.

Quality Control Inserts Portal

insert.fortressdiagnostics.com

Fortress Diagnostics are excited to launch the new Fortress QC Inserts Portal. The portal allows customers to easily search our database of quality control inserts by product name, catalogue number or batch number in our easy-to-use filter tool. Inserts can be viewed online or downloaded in PDF format.



Brochures & Catalogues

fortressdiagnostics.com/resources

All Fortress Diagnostics brochures and catalogues can be viewed and downloaded on the Fortress Resource Hub in PDF format.

Videos

youtube.com/@fortressdiagnostics

Subscribe to our YouTube channel to explore information videos, tutorial guides for Seraqual 365, interviews for World Awareness Days and more.



Social Media

Explore and follow our social media pages across **Instagram**, **LinkedIn**, **Facebook** and **Twitter**. We regularly post updates on product launches, events Fortress are exhibiting at, news from the world of diagnostics and company developments.

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SECTION 1

ANTIOXIDANTS

Antioxidant Controls

Antioxidant quality controls in diagnostics are crucial for ensuring the accuracy and reliability of tests that measure oxidative stress and antioxidant levels in biological samples. These quality controls are used to validate the performance of diagnostic assays, ensuring that the test results are consistent and accurate. Positive controls, which contain known quantities of antioxidants, help confirm that the assay is working correctly, while negative controls, without antioxidants, ensure there is no false detection of antioxidant activity.

By using antioxidant controls, laboratories can detect any potential issues with the assay, such as reagent degradation or equipment malfunction. In addition to positive and negative controls, diagnostic assays may also use blank and solvent controls to account for any potential interference from other substances or experimental factors. Consistent use of antioxidant quality controls helps to standardize the measurement of oxidative stress biomarkers, ensuring that results are comparable across different laboratories and studies. These controls are critical in clinical diagnostics, where accurate measurements of antioxidant levels can be used for disease risk assessment, monitoring therapeutic responses, and guiding treatment decisions, particularly in conditions like cardiovascular diseases, diabetes, and neurodegenerative disorders.

The Fortress Seraqual Antioxidant Quality Controls are lyophilised for enhanced stability, offer excellent accuracy and precision and cover a range of key antioxidants in clinical practice. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Glutathione Peroxidase Control



- This control is presented in a Lyophilised format stable to expiry date at 2-8 °C.
- Reconstituted stability 3 days at 2-8 °C.
- 100% Human serum based.

| Description | Size | Cat No. | Type |
|--------------------------------|----------|----------|------|
| Glutathione Peroxidase Control | 5 x 1 ml | BXC0556A | Lyo |

Glutathione Reductase Calibrator & Control



- Fortress Glutathione Reductase Controls are intended for monitoring accuracy and precision.
- Calibrators and Controls are supplied in a Lyophilised format stable up to expiry at 2-8 °C.
- Reconstituted stability 7 day at 2-8°C or 3 days at 25 °C.
- 100% Human serum based.

| Description | Size | Cat No. | Type |
|----------------------------------|----------|----------|------|
| Glutathione Reductase Calibrator | 5 x 1 ml | BXC0999A | Lyo |
| Glutathione Reductase Control | 5 x 1 ml | BXC0460A | Lyo |

Superoxide Dismutase Control



- The Control is presented in Lyophilised format stable to expiry date at 2-8 °C.
- Reconstituted stability of 7 days at 2-8 °C.
- 100% Human serum based.

| Description | Size | Cat No. | Type |
|------------------------------|----------|----------|------|
| Superoxide Dismutase Control | 5 x 1 ml | BXC0433A | Lyo |

Total Antioxidant Status Calibrator & Control



- 100% Human serum based.
- Reconstituted stability of 7 days at 2-8 °C.

| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| Total Antioxidant Status (TAS) Calibrator | 1 x 1 ml | BXC0555A | Lyo |
| Total Antioxidant Status (TAS) Control | 5 x 5 ml | BXC0554A | Lyo |



?

SECTION 2
AQUEOUS
STANDARDS

Aqueous Standards

Aqueous standards in diagnostics are reference solutions used to calibrate and validate diagnostic assays, ensuring accurate measurement of analytes in biological fluids such as blood, urine, and saliva. These standards consist of known concentrations of target molecules dissolved in water, closely mimicking the physiological environment.

By using aqueous standards, laboratories can calibrate instruments and establish a baseline for comparison with patient samples. This allows for precise detection and quantification of biomarkers, essential for diagnosing diseases and monitoring health conditions. Aqueous standards are especially important in ensuring consistency across different diagnostic platforms and laboratories. They help identify any variation or drift in instrument performance over time and confirm that the reagents used in tests are functioning properly. In clinical diagnostics, the use of well-prepared aqueous standards ensures that test results are reliable and reproducible, which is critical for making informed medical decisions, particularly in areas such as metabolic monitoring, hormone assays, and infection diagnostics.

The Fortress Aqueous Standards are available in a liquid stable format for convenience and ease-of-use, with a long shelf life, and are traceable to reference standard material.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided



Aqueous Standards

- Liquid stable (ready-to-use).
- Long shelf life.
- Traceable to reference standard material.

| Description | Method | Size | Cat No. | Type |
|---------------------------------------|---|---------------|----------|------|
| Albumin | 45 g/L (4.5g/dL) | 10 x 5 ml | BXCSTD01 | LS |
| Calcium | Referenced against NIST 909b (2.5mmol/L 10mg/dL) | 10 x 5 ml | BXCSTD02 | LS |
| Chloride | Referenced against NIST 909b (75mmol/L) | 10 x 5 ml | BXCSTD03 | LS |
| Chloride | Referenced against NIST 909b (100mmol/L) | 10 x 5 ml | BXCSTD04 | LS |
| Cholesterol | Referenced against NIST 909b (5.17mmol/L 200mg/dL) | 10 x 5 ml | BXCSTD05 | LS |
| Creatinine | Referenced against NIST 909b (177 µmol/L 2 mg/dL) | 10 x 5 ml | BXCSTD06 | LS |
| Creatine/Glucose/Urea Standard | Referenced against NIST 965a / 909b (5.55 mmol/L 100mg/dL/ 177 µmol/L / 8.33mmol/L) | 10 x 5 ml | BXCSTD24 | LS |
| Glucose | Referenced against NIST 965a (5.55 mmol/L 100mg/dL) | 10 x 5 ml | BXCSTD07 | LS |
| Glucose-Fructose Standard | | 5 x 1 ml | BXCSTD26 | LS |
| Haemoglobin Standard | For Drabkin's Method (18g/dL) | 5 x 10 ml | BXCSTD08 | LS |
| Haemoglobin Standard Set | For Drabkin's Method (8, 10, 12, 15 & 18g/dL) | 5 x 1 x 10 ml | BXCSTD09 | LS |
| Iron | 35.8 µmol/L (0.2 mg/dL) | 10 x 5 ml | BXCSTD10 | LS |
| Iron | 107.4 µmol/L (0.6 mg/dL) | 10 x 5 ml | BXCSTD11 | LS |
| Lactate | 4.44mmol/L (40mg/dL) | 10 x 5 ml | BXCSTD12 | LS |
| Magnesium | Referenced against NIST 909b (1.0 mmol/l/2.43mg/dL) | 10 x 5 ml | BXCSTD13 | LS |
| Phosphorus | 1.61 mmol/L (5 mg/dL) | 10 x 5 ml | BXCSTD14 | LS |
| Potassium | Referenced against NIST 909b (0.5 mmol/L) | 10 x 5 ml | BXCSTD15 | LS |
| Potassium | Referenced against NIST 909b (5 mmol/L) | 10 x 5 ml | BXCSTD16 | LS |
| Pyruvate | 2 mmol/L | 10 x 5 ml | BXCSTD17 | LS |
| Sodium | Referenced against NIST 909b (150.0 mmol/L 150 mEq/L) | 10 x 5 ml | BXCSTD18 | LS |
| Total Protein | Referenced against NIST 927d (60g/L (6.0 g/dL) | 10 x 5 ml | BXCSTD19 | LS |
| Triglycerides | Referenced against NIST 909b (2.28 mmol/L 200mg/dL) | 10 x 5 ml | BXCSTD20 | LS |
| Urea | Referenced against NIST 909b (8.33 mmol/L 50mg/dL) | 10 x 5 ml | BXCSTD21 | LS |
| Uric Acid | Referenced against NIST 909b (595 µmol/L 10mg/dL) | 10 x 5 ml | BXCSTD22 | LS |
| Urinary Copper Standard | Referenced against NIST-SE 3114 (1.6mol/L) | 10 x 5 ml | BXCSTD25 | LS |
| Urinary/CSF Protein Standard | Referenced against NIST 927d (1g/L) | 10 x 5ml | BXCSTD23 | LS |



3

SECTION 3
BLOOD GAS
& ELECTROLYTES

Blood Gas & Electrolyte Controls

Blood gas and electrolyte controls in diagnostics are essential for ensuring the accuracy and reliability of tests that measure critical parameters like pH, oxygen (PaO₂), carbon dioxide (PaCO₂), and key electrolytes such as sodium, potassium, chloride, and bicarbonate. These controls, typically pre-prepared solutions with known concentrations, are used to calibrate and validate diagnostic equipment, such as blood gas analyzers.

By regularly running these controls, laboratories can detect any inaccuracies in the testing process, ensuring that instruments and reagents are functioning correctly and that test results are precise. In clinical settings, the proper use of blood gas and electrolyte controls helps prevent diagnostic errors, which are crucial in high-stakes situations such as critical care and emergency medicine. Any variation in these tests can significantly impact patient management, from adjusting ventilation settings to correcting electrolyte imbalances.

The Fortress Blood Gas & Electrolytes Quality Controls contain values for ten parameters, with values assigned by European Reference Laboratories, covering pH, pCO₂, pO₂ and electrolytes. Available in a liquid stable format for convenience and ease-of-use. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Blood Gas & Electrolyte Controls



- Liquid stable controls with a shelf life of 1 year when stored, unopened at 2-8 °C.
- Values are assigned by European reference laboratories.
- Store at 2-8 °C. Do not freeze or expose to temperatures greater than 30 °C.
- When opened, analyse immediately for Blood Gas parameters and use within 1 hour for electrolytes.

Analytes

| Calcium Chloride Glucose | Lactate Potassium Sodium | pCO ₂ pH pO ₂ | Total CO ₂ |
|--------------------------------|--------------------------------|---|-----------------------|
|--------------------------------|--------------------------------|---|-----------------------|

| Description | Size | Cat No. | Type |
|---|-----------|----------|------|
| Blood Gas & Electrolyte Control (Level 1) | 1 x 2 ml | BXC0108A | LS |
| Blood Gas & Electrolyte Control (Level 1) | 10 x 2 ml | BXC0108D | LS |
| Blood Gas & Electrolyte Control (Level 2) | 1 x 2 ml | BXC0108B | LS |
| Blood Gas & Electrolyte Control (Level 2) | 10 x 2 ml | BXC0108E | LS |
| Blood Gas & Electrolyte Control (Level 3) | 1 x 2 ml | BXC0108C | LS |
| Blood Gas & Electrolyte Control (Level 3) | 10 x 2 ml | BXC0108F | LS |
| Blood Gas & Electrolyte Control (Tri-Level) | 30 x 2 ml | BXC0108G | LS |

Electrolyte Controls



- Liquid stable format with a shelf life of 2 years when stored at 2-8 °C.
- Values are assigned by European reference laboratories.
- Store at 2-8 °C. Do not freeze or expose to temperatures greater than 30 °C.
- When opened the analytes are stable for a period of 15 days when stored at 2-8 °C.

Analytes

| Chloride (ISE & Colorimetry) | Potassium (ISE & Colorimetry) | pH | Sodium (ISE & Colorimetry) |
|------------------------------|-------------------------------|----|----------------------------|
|------------------------------|-------------------------------|----|----------------------------|

| Description | Details | Size | Cat No. | Type |
|--------------------------------|--------------------|----------|----------|------|
| Electrolytes Calibrator | | 5 x 5 ml | BXC0140A | LS |
| Electrolytes Control (Level 1) | Low (Na, K, Cl) | 5 x 5 ml | BXC0143A | LS |
| Electrolytes Control (Level 2) | Normal (Na, K, Cl) | 5 x 5 ml | BXC0144A | LS |
| Electrolytes Control (Level 3) | High (Na, K, Cl) | 5 x 5 ml | BXC0145A | LS |



SECTION 4

BLOOD GROUPING

Blood Grouping Controls

Blood grouping controls in diagnostics are vital for ensuring the accuracy of blood type determination, which is essential for safe blood transfusions, organ transplants, and pregnancy management. These controls are standardised samples with known blood types (A, B, AB, O, and Rh factor) used to verify the performance of blood typing assays and equipment. By including both positive and negative controls in the testing process, laboratories can ensure that reagents are reacting correctly with antigens and antibodies, reducing the risk of errors in identifying a patient's blood group.

Using blood grouping controls regularly helps maintain the reliability of diagnostic tests, preventing potentially life-threatening transfusion reactions caused by incorrect blood typing. It also ensures consistency across different testing environments, whether in routine clinical laboratories or emergency settings. These controls allow for early detection of any technical issues with reagents, equipment, or the procedure itself, ensuring accurate and dependable blood group determination, which is critical for patient safety.

The Fortress Seraqual ABO-Rhesus Blood Grouping Quality Control Set is available in a liquid stable format for convenience and ease-of-use and covers all major blood types. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

ABO-Rhesus Blood Grouping Control Set



- Ready-to-Use
- Covers all major blood types.
- Total Blood Kit.

Analytes

| A | B | Rhesus Rh | Kell Phenotype |
|----|---|-----------|----------------|
| AB | O | | |

| Description | Details | Size | Cat No. | Type |
|--|---|-----------|----------|------|
| ABO-Rhesus Blood Grouping Control Set | For use Rh-reagents and Anti-K Monoclonal | 4 x 4 ml | BXC0070A | LS |
| Monoclonal Anti-D Negative Control | | 1 x 10 ml | BDNC0010 | LS |
| Precise Weak Anti-D Control | Sensitivity Control for AHG | 1 x 5 ml | BGWD0005 | LS |



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SECTION 5
Bone Markers

Bone Markers

Bone marker controls play a critical role in ensuring the accuracy and reliability of diagnostic tests that assess bone metabolism. These standardized samples contain known levels of key markers such as osteocalcin, PINP, CTX, and alkaline phosphatase, and are used to verify the performance of assays and analytical instruments. Including both high and low concentration controls in routine testing helps detect issues with reagents, equipment, or procedures early, reducing the risk of inaccurate results that could impact clinical decisions in conditions like osteoporosis, bone cancer, or metabolic bone disorders.

The Fortress Bone Marker Control Set is available in a liquid stable format for convenience and ease of use. Each control comes with method- and instrument-specific assigned values, ensuring compatibility across various testing platforms. Regular use of these controls supports consistent, high-quality diagnostics and enhances patient safety by maintaining the integrity of bone health assessments across clinical settings.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Bone Marker Controls (Serum)



| Description | Size | Cat No. | Type |
|---------------------------------------|----------|----------|------|
| Bone Markers Control Level 1 | 2 x 1 ml | BXC0707A | Lyo |
| Bone Markers Control Level 2 | 2 x 1 ml | BXC0707B | Lyo |
| Bone Markers Control Level 3 | 2 x 1 ml | BXC0707C | Lyo |
| Bone Markers Control Tri-level | 2 x 1 ml | BXC0707D | Lyo |

| Analytes | | |
|-------------|----------|----------------------|
| Osteocalcin | Bone ALP | Procollagen Type - 1 |

Reconstituted Stability: 2 weeks

| Description | Size | Cat No. | Type |
|---------------------------------------|----------|----------|------|
| CTX Serum Bone Control Level 1 | 3 x 1 ml | BXC0706A | Lyo |
| CTX Serum Bone Control Level 1 | 3 x 1 ml | BXC0706B | Lyo |

Bone Marker Controls (Urine)

Reconstituted Stability: 2 weeks

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| CTX Control Level 1 (C-Terminal Telopeptide) | 3 x 1 ml | BXC0706A | Lyo |
| CTX Control Level 1 (C-Terminal Telopeptide) | 3 x 1 ml | BXC0706B | Lyo |



SECTION 6

CARDIAC

Cardiac Controls

Cardiac controls are essential in diagnostics for ensuring the accuracy and reliability of tests that measure key cardiac biomarkers, such as troponin and B-type natriuretic peptide (BNP), which are critical for diagnosing heart attacks, heart failure, and other cardiovascular conditions. These controls, which contain known concentrations of these biomarkers, help validate the performance of diagnostic assays, ensuring that testing equipment and reagents are working properly. By using these controls, laboratories can identify potential issues early, minimising the risk of inaccurate test results that could lead to misdiagnosis or inappropriate treatment.

The role of cardiac controls is particularly crucial in emergency and critical care settings, where timely and precise biomarker measurements are vital for guiding immediate medical interventions. Reliable cardiac diagnostics help physicians make informed decisions about treatment strategies, such as initiating therapies for acute coronary syndromes or adjusting treatments for chronic heart conditions. Regular use of cardiac controls ensures consistency across tests, supporting better patient outcomes by enabling accurate diagnosis and monitoring of cardiovascular health.

The Fortress Seraqual Cardiac Quality Controls have been designed to cover several cardiac analytes. Available in a lyophilised format for enhanced stability and manufactured from 100% human based serum to negate matrix effect. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Cardiac Controls



- Values are assigned by European reference laboratories.
- Lyophilised format stable up to expiry at 2-8 °C.
- Reconstituted stability of 5 days at 2-8 °C or 4 weeks at -20 °C.
- 100% Human serum base.

Analytics

| Homocysteine CK Total | CK MB Activity CK MB Mass | Digoxin Troponin I | Troponin T Myoglobin |
|--------------------------|------------------------------|-----------------------|-------------------------|
|--------------------------|------------------------------|-----------------------|-------------------------|

| Description | Details | Size | Cat No. | Type |
|---------------------------|---|-------------|----------|------|
| Cardiac Control (Level 1) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 2 ml | BXC0455A | Lyo. |
| Cardiac Control (Level 1) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 1 ml | BXC0455B | Lyo. |
| Cardiac Control (Level 2) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 2 ml | BXC0456A | Lyo. |
| Cardiac Control (Level 2) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 1 ml | BXC0456B | Lyo. |
| Cardiac Control (Level 3) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 2 ml | BXC0464A | Lyo. |
| Cardiac Control (Level 3) | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 5 x 1 ml | BXC0464B | Lyo. |
| Cardiac Control Set | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 3 x 1 x 2ml | BXC0450A | Lyo. |
| Cardiac Control Set | CK Total, CKMB Activity, CKMB Mass, Tni,TnT, Digoxin, Homocysteine, Myoglobin | 3 x 1 x 1ml | BXC0450B | Lyo. |



CK/CK MB Calibrators & Controls

- Lyophilised format stable up to expiry at 2-8 °C.
- Values are assigned by European Reference Laboratories.
- 100% Human serum base.
- Reconstituted stability 5 days at 2-8 °C, 8 hours at +25 °C and 4 weeks at -20 °C.

Analytes

| | CK Total | CK MB Activity | |
|-----------------------------------|-----------|----------------|------|
| Description | Size | Cat No. | Type |
| CK/CK MB Calibrator | 1 x 2 ml | BXC0454A | Lyo. |
| CK/CK MB Calibrator | 5 x 2 ml | BXC0454B | Lyo. |
| CK/CK MB Control (Level 1) | 1 x 2 ml | BXC0453A | Lyo. |
| CK/CK MB Control (Level 1) | 5 x 2 ml | BXC0453B | Lyo. |
| CK/CK MB Control (Level 1) | 10 x 2 ml | BXC0453C | Lyo. |
| CK/CK MB Control (Level 2) | 1 x 2 ml | BXC0459A | Lyo. |
| CK/CK MB Control (Level 2) | 5 x 2 ml | BXC0459B | Lyo. |
| CK/CK MB Control (Level 2) | 10 x 2 ml | BXC0459C | Lyo. |

D-DIMER Calibrators & Controls

- Lyophilised format stable up to expiry at 2-8°C.
- Prepared from human serum.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---|------------|----------|------|
| D-Dimer Calibrator Set | 5 x 1 x1ml | BXC0788A | Lyo. |
| D-Dimer Control Set (Level 1 & Level 2) | 2 x 1 x1ml | BXC0789A | Lyo. |

Homocysteine Calibrators & Controls

- Fortress Homocysteine controls are intended for monitoring accuracy and precision.
- The Calibrators & controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- 100% Human serum based.

| Description | Size | Cat No. | Type |
|---|--------------|----------|------|
| Homocysteine Calibrator (2 Levels) | 2 x 1 x 1ml | BXC0691B | Lyo. |
| Homocysteine Control (2 Levels) | 2 x 1 x 1 ml | BXC0692A | Lyo. |

Myoglobin Calibrators & Controls

- Lyophilised to achieve long shelf life.
- Reconstituted stability of 30 days at 2-8°C and 12 months at -20°C.

| Description | Size | Cat No. | Type |
|------------------------------------|---------------|----------|------|
| Myoglobin Calibrator Series | 5 x 1 x 0.5ml | BXC0486A | Lyo. |
| Myoglobin Control | 1 x 0.5ml | BXC0487A | Lyo. |

NTProBNP Calibrators & Controls

- Lyophilised format stable to expiry at 2-8 °C.
- Prepared from human serum.
- Reconstituted stability of 8 hours at 2-8°C.

| Description | Details | Size | Cat No. | Type |
|---|---|--------------|----------|------|
| NTProBNP Calibrator Set (6 Levels) | Reconstituted Stability 8 hours at 2-8°C | 6 x 1 x 1 ml | BXC0355A | Lyo. |
| NTProBNP Control Series (2 Levels) | Reconstituted Stability 8 hours at 2-8°C | 2 x 1 x 1 ml | BXC0356A | Lyo. |
| BNP Calibrator Level 1 | human Serum Base, Reconstituted Stability 8 hours at 2-8°C | 1 x 0.5ml | BXC0455S | Lyo. |
| BNP Calibrator Level 2 | human Serum Base, Reconstituted Stability 8 hours at 2-8°C | 1 x 0.5ml | BXC0456S | Lyo. |



Troponin-T (High Sensitivity) Controls

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Cut-off value of 13.5ng/L for automated systems.
- Suitable for use in point-of-care testing.
- Open vial stability of 1 week, at 2-8°C.

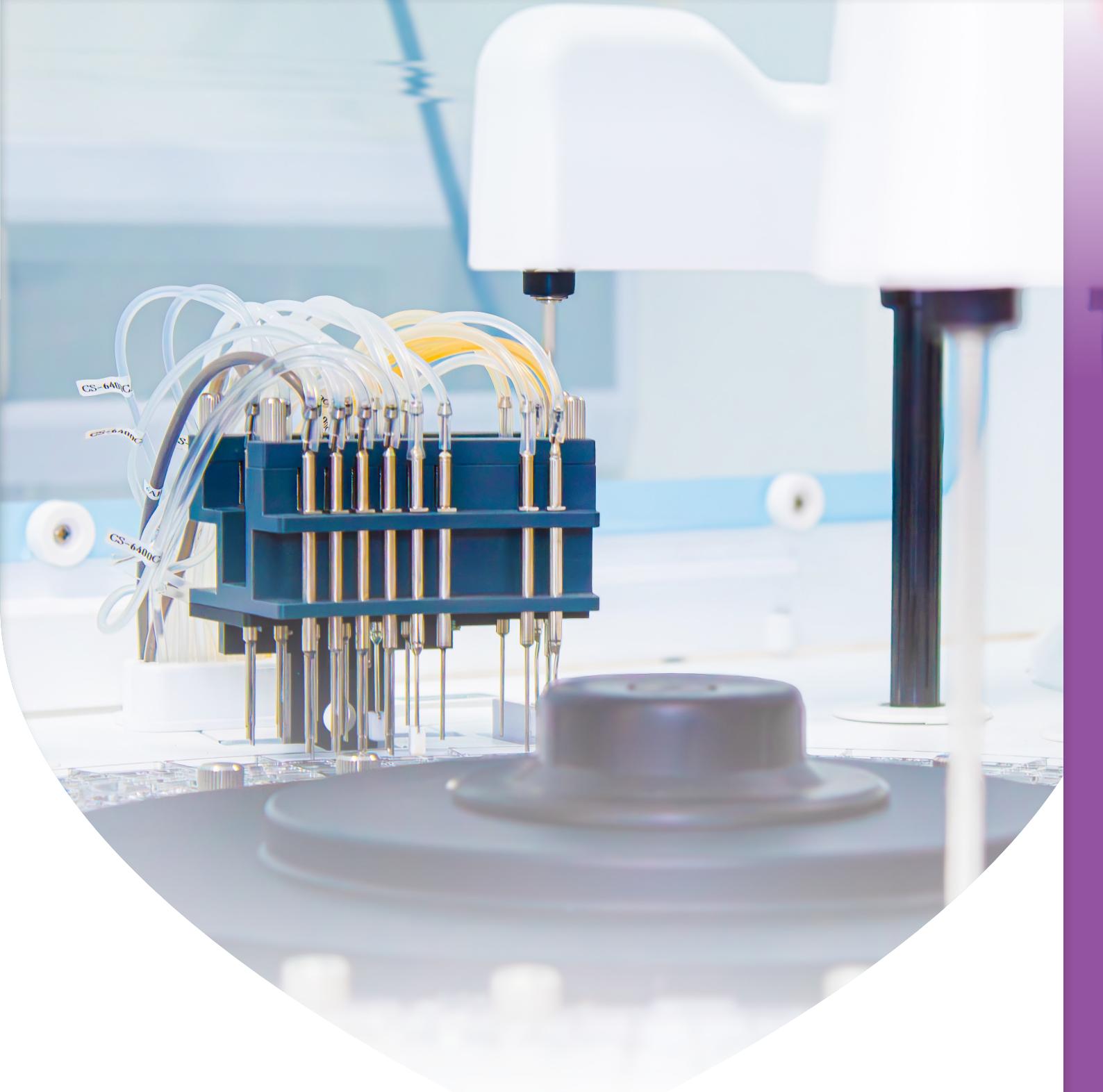
| Description | Details | Size | Cat No. | Type |
|--|-------------------------------------|----------|----------|------|
| Troponin-T High Sensitivity Control | For use on all major systems | 3 x 1 ml | BXC0457A | LS |

Troponin-I Controls & Calibrators



- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 5 days at 2-8°C.

| Description | Details | Size | Cat No. | Type |
|----------------------------------|-------------------------------------|--------------|----------|------|
| Troponin-I Control Set | For use on all major systems | 2 x 1 x 1 ml | BXC0470A | Lyo. |
| Troponin-I Calibrator Set | For use on all major systems | 6 x 1 x 1 ml | BXC0473A | Lyo. |



7

SECTION 7
CLINICAL
CHEMISTRY

Clinical Chemistry Controls

Clinical chemistry controls are vital for ensuring the accuracy, reliability, and validity of laboratory tests that analyze bodily fluids, such as blood and urine. These controls, which include both positive and negative samples with known concentrations of analytes, help validate the performance of diagnostic assays and ensure that testing equipment and reagents are functioning correctly. By routinely using these controls, laboratories can detect any inconsistencies or errors in the testing process, thereby minimizing the risk of false positives or negatives that could lead to misdiagnosis or inappropriate treatment.

The role of clinical chemistry controls is particularly important in maintaining quality assurance in laboratory settings. They help ensure that the results are consistent and reproducible across different tests and patient samples, supporting accurate clinical decision-making. In critical situations, such as emergency medicine or monitoring chronic conditions, reliable laboratory data is essential for guiding treatment plans and assessing patient outcomes. Overall, clinical chemistry controls are integral to enhancing the overall quality of healthcare by providing dependable diagnostic information that informs patient management and care strategies.

The Fortress clinical chemistry range of controls are suitable for a range of clinical chemistry analysers, offering flexibility for your laboratory. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Featured Product

Human Assayed Controls



Multi-Analyte Human Assayed Controls are essential tools in clinical laboratories for ensuring the accuracy and reliability of diagnostic tests. These controls contain a blend of multiple analytes—such as hormones, proteins, and other biomarkers—mimicking human samples.

They are used to validate and monitor the performance of assays, which are tests designed to measure the presence or concentration of specific substances in a sample. By incorporating a range of analytes, these controls help laboratories simultaneously assess the precision and accuracy of various diagnostic assays under a single test run. This comprehensive approach not only enhances the efficiency of quality control procedures but also ensures consistency in test results, ultimately contributing to better patient care by maintaining high standards in laboratory diagnostics.

Why Choose Fortress Human Assayed Controls?



Human serum based: Same matrix as samples.



Lyophilised format: Fortress Human Assayed Controls are stable to expiry at 2-8°C.



Custom levels tailored to specific requirements available: Adaptable to perfectly suit unique experimental conditions, analytical needs, and regulatory standards.



0.2μ filtered: Helps remove particulate contaminants and potential microbial contaminants, leading to more accurate and reproducible outcomes in various assays.



Method based values with reference traceability provided.



Reconstituted stability of 7 days at 2-8°C, or 4 weeks at -20°C.

Analytes

| Enzymes | Substrates | Iron/TIBC | Immunoassays |
|----------------------------|--------------------|-----------------------|--------------|
| Alkaline Phosphatase | Albumin | Inorganic Phosphorous | Cortisol |
| ALT (GPT) | APO A1 | LDL Cholesterol | Folate |
| Amylase | APO B | NEFA | FT3 |
| AST (GOT) | Bicarbonate | Osmolality | FT4 |
| Cholinesterase | Bile Acids | Total Protein | Total T3 |
| CK (Total) | Bilirubin Direct | Transferrin | Total T4 |
| Gamma GT | Bilirubin Total | Triglycerides | Total PSA |
| GLDH | Calcium | UIBC | TSH |
| HBDH | Cholesterol | Urea | Vitamin B12 |
| LDH | Copper | Uric Acid | Drugs |
| Lipase | Creatinine | Zinc | Digoxin |
| Pancreatic Amylase | D3-Hydroxybutyrate | Electrolytes | Gentamicin |
| Total Acid Phosphatase | Glucose | Bicarbonate | Paracetamol |
| Prostatic Acid-Phosphatase | HDL Cholesterol | Chloride | Salicylate |
| Total Amylase | IGA | Lithium | Theophylline |
| | IGG | Magnesium | Tobramycin |
| | IGM | Potassium | |
| | Iron | Sodium | |

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Human Assayed Control (Level 1) | 10 x 5ml | BXC0312A | Lyo. |
| Human Assayed Control (Level 2) | 10 x 5ml | BXC0312B | Lyo. |
| Human Assayed Control (Level 1) | 5 x 5ml | BXC0312C | Lyo. |
| Human Assayed Control (Level 2) | 5 x 5ml | BXC0312D | Lyo. |
| Human Assayed Control (Level 1) | 1 x 5ml | BXC0312E | Lyo. |
| Human Assayed Control (Level 2) | 1 x 5ml | BXC0312F | Lyo. |

GenChem UltraQC TR



Analytes

| | | | |
|---------------------------|--------------------------------|---------------------------|----------------|
| Alkaline Phosphatase | Carcinoembryonic Antigen (CEA) | α-HBDH | Prolactin |
| Albumin | Chloride | Iron | Protein, Total |
| Alkaline Phosphatase | Cholesterol | Haptoglobin | PSA Total |
| Alpha-1-Acid Glycoprotein | Cholinesterase | HDL Cholesterol (Direct) | Sodium |
| Alpha-1-Antitrypsin | CK-NAC | IgA | T Uptake |
| Alpha-Fetoprotein | Complement C3 | IgE | Testosterone |
| ALT (GPT) | Complement C4 | IgG | TSH |
| Amylase (Pancreatic) | Copper | IgM | TIBC |
| Amylase (Total) | Cortisol | Lactate | Total Beta hCG |
| Apo-A1 | Creatinine | LDH LACTATE DEHYDROGENASE | Total T3 |
| Apo-B | D3-Hydroxybutyrate | LDL Cholesterol Direct | Total T4 |
| AST (GOT) | DHEA-S | Leutinising Hormone (LH) | Transferrin |
| Beta-2-Macroglobulin | Ethanol (alcohol) | Lipase | Triglycerides |
| Bicarbonate | Ferritin | Lipoprotein (a) | Troponin T |
| Bile Acids | Folate | Lithium | UIBC |
| Bilirubin, Direct | Free T3 | Magnesium | Urea |
| Bilirubin, Total | Free T4 | Myoglobin | Uric Acid |
| C-Reactive Protein | FSH | Osmolality | Vitamin B12 |
| Ceruloplasmin | Gamma-GT | Phosphate Inorganic | Zinc |
| Calcium | GLDH | Potassium | |
| | Glucose | Prealbumin | |
| | | Progesterone | |

| Description | Size | Cat No. | Type |
|--|----------|----------|--------------|
| Assayed Chemistry Control (Level-1) | 6 x 5 ml | BXC0365A | LS (Frozen). |
| Assayed Chemistry Control (Level-2) | 6 x 5 ml | BXC0365B | LS (Frozen) |
| Assayed Chemistry Control (Level-3) | 6 x 5 ml | BXC0365C | LS (Frozen) |



Calibration Serum

- Approximately 40 parameters are value assigned by reference laboratories in Europe.
- Method based values with reference traceability provided.
- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8 °C, or 4 weeks at -20 °C.

Analytes

| Enzymes | Pancreatic Amylase Prostatic Phosphatase | Creatinine D3- Hydroxybutyrate Glucose | Uric Acid Zinc |
|----------------------------|---|--|---------------------|
| ALP ALT (GPT) | | HDL Cholesterol Iron Iron/TIBC | Electrolytes |
| Total Amylase AST (GOT) | Albumin Bicarbonate | Inorganic Phosphorous | Chloride Lithium |
| Cholinesterase CK NAC | Bile Acids Bilirubin Direct | Lactate | Magnesium |
| Gamma GT GLDH | Bilirubin Total Calcium | LDL Cholesterol Total Protein | Potassium |
| HBDH LDH | Cholesterol | Triglycerides | Osmolality |
| Lipase | Copper | Urea | Sodium |

| Description | Size | Cat No. | Type |
|--------------------------|-----------|----------|------|
| Calibration Serum | 1 x 3 ml | BXC0321K | Lyo. |
| Calibration Serum | 5 x 3 ml | BXC0321L | Lyo. |
| Calibration Serum | 10 x 3 ml | BXC0321M | Lyo. |

ADA Calibrators & Controls



- Liquid Stable version (Ready-to-use) stable to expiry at 2-8 °C & Open vial stability of 30 days, at 2-8°C.
- Lyophilised version reconstituted stability of 30 days at 2-8°C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|------------------------------|----------|----------|------|
| ADA Calibrator | 1 x 1 ml | BXC0209A | LS |
| ADA Control (Level 1) | 1 x 1 ml | BXC0210A | LS |
| ADA Control (Level 2) | 1 x 1 ml | BXC0216A | LS |
| ADA Calibrator | 1 x 1 ml | BXC0217A | Lyo. |
| ADA Control (Level 1) | 1 x 1 ml | BXC0218A | Lyo. |
| ADA Control (Level 2) | 1 x 1 ml | BXC0219A | Lyo. |

Alcohol, Ammonia, Carbonate Calibrators & Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 24 hours at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Alcohol, Ammonia, Carbonate Calibrator | 1 x 2 ml | BXC0492A | LS |
| Alcohol, Ammonia, Carbonate Control (Level 1) | 1 x 2 ml | BXC0493A | LS |
| Alcohol, Ammonia, Carbonate Control (Level 2) | 1 x 2 ml | BXC0494A | LS |

Aldolase Calibrators & Controls



- Lyophilised product with a 3 year shelf life when stored at 2-8 °C.
- Reconstituted stability of 5 days at 2-8°C.
- Values assigned by reference laboratories in Europe

| Description | Size | Cat No. | Type |
|----------------------------------|----------|----------|------|
| Aldolase Calibrator | 3 x 1 ml | BXC0394A | Lyo. |
| Aldolase Control Elevated | 3 x 1 ml | BXC0393A | Lyo. |
| Aldolase Control Normal | 3 x 1 ml | BXC0392A | Lyo. |



Alpha-1-Acid Glycoprotein Calibrators & Controls

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| Alpha-1-Acid Glycoprotein Calibrator | 2 x 1 ml | BXC0892A | LS |
| Alpha-1-Acid Glycoprotein Control | 2 x 1 ml | BXC0891A | LS |

Alpha-1-Antitrypsin Calibrators & Controls

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Details | Size | Cat No. | Type |
|--|---------------------|-------------|----------|------|
| Alpha-1-Antitrypsin Calibrator | Immunoturbidimetric | 1 x 2 ml | BXC0711A | LS |
| Alpha-1-Antitrypsin Control (Level 1 & Level 2) | Immunoturbidimetric | 2 x 1 x 2ml | BXC0712A | LS |
| Alpha-1-Microglobulin Calibrator | | 1 x 1 ml | BXC0887A | LS |
| Alpha-1-Microglobulin Control (Level 1 & Level 2) | | 2 x 1 x 1ml | BXC0889A | LS |

Aluminium Calibrators & Controls

- Liquid Stable (Ready-to-Use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|----------------------------------|----------|----------|------|
| Aluminium Control Level 1 | 1 x 1 ml | BXC0696A | LS |
| Aluminium Control Level 2 | 1 x 1 ml | BXC0697A | LS |
| Aluminium Control Level 3 | 1 x 1 ml | BXC0698A | LS |

Ammonia Controls & Calibrators

- Liquid stable Calibrator and Control with a 2 year shelf life.
- Values are assigned in house using Enzymatic UV method.
- Storage at 2-8 °C.
- One month open vial stability at 2-8 °C.

| Description | Size | Cat No. | Type |
|-----------------------------|----------|----------|------|
| Ammonia Calibrator | 3 x 2 ml | BXC0373A | LS |
| Ammonia Control High | 3 x 2 ml | BXC0375A | LS |
| Ammonia Control Low | 3 x 2 ml | BXC0374A | LS |

Angiotensin Converting Enzyme (ACE) Controls & Calibrators

- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Angiotensin Converting Enzyme (ACE) Calibrator | 3 x 1 ml | BXC0177A | Lyo. |
| Angiotensin Converting Enzyme (ACE) Control (Level 1) | 3 x 1 ml | BXC0178A | Lyo. |
| Angiotensin Converting Enzyme (ACE) Control (Level 2) | 3 x 1 ml | BXC0179A | Lyo. |

Anti-CCP Controls & Calibrators

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- When vial opened it must be used immediately, store at 2-8°C.

| Description | Size | Cat No. | Type |
|-----------------------------------|-------------|----------|------|
| Anti-CCP Calibrator | 1 x 1 ml | BXC0379D | LS |
| Anti-CCP Calibrator Series | 6 x 1 x 1ml | BXC0379B | LS |
| Anti-CCP Control Set | 2 x 1 x 1ml | BXC0379C | LS |

Anti-Mullerian Hormone (AMH) Calibrators & Control Set



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- When vial opened it must be used immediately, store at 2-8°C.

| Description | Size | Cat No. | Type |
|--|--|----------|------|
| Anti-Mullerian Hormone (AMH) Calibrators & Control Set | Calibrator Set: 2 x 1x0.5ml ; Control Set: 2x1x0.5ml | BXC0999A | LS |

APO A1/B Calibrator Series



| Description | Size | Cat No. | Type |
|----------------------------|--------------|----------|------|
| APO A1/B Calibrator Series | 6 x 1 x 1 ml | BXC0413A | LS. |

ASO (Single Point) Calibrators



- Values are assigned by in house methods and instruments
- 100% human material designed for matrix conformity.
- The liquid stable ASO Single point calibrator has a shelf life of 2 years when stored at 2-8 °C.
- Once opened the calibrator is stable for a period of 30 days when stored without contamination at 2-8 °C.

| Description | Details | Size | Cat No. | Type |
|-------------------------------|---------------------|----------|----------|------|
| ASO (Single Point) Calibrator | Immunoturbidimetric | 1 x 1 ml | BXC0323A | LS |
| ASO (Single Point) Calibrator | Immunoturbidimetric | 3 x 1 ml | BXC0323B | LS |

ASO, CRP, RF Control



- This control is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The values are assigned in European Reference Laboratories.
- 100% Human serum designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.
- This material is presented in a liquid stable format and is stable up to expiry at 2-8 °C.

| Description | Details | Size | Cat No. | Type |
|----------------------|---------------------|----------|----------|------|
| ASO, CRP, RF Control | Immunoturbidimetric | 3 x 1 ml | BXC0645A | LS |

Beta-2- Microglobulin Calibrators & Controls



| Description | Size | Cat No. | Type |
|---|--------------|----------|------|
| Beta-2- Microglobulin Calibrator | 1 x 1 ml | BXC0647A | LS |
| Beta-2- Microglobulin Control (Level 1 & Level 2) | 1 x 2 x 1 ml | BXC0648A | LS |

Bile Acid Controls & Calibrators



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|-------------------------------------|--------------|----------|------|
| Bile Acid Calibrator | 1 x 1 ml | BXC0582A | LS |
| Bile Acid Control Set (Level 1 & 2) | 2 x 1 x 1 ml | BXC0583A | LS |



Blood Alcohol Controls & Calibrators

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- When vial opened it must be used immediately, store at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Blood Alcohol Calibrator | 1 x 2 ml | BXC0488A | LS |
| Blood Alcohol Control (Level 1) | 1 x 2 ml | BXC0489A | LS |
| Blood Alcohol Control (Level 2) | 1 x 2 ml | BXC0490A | LS |



Bilirubin Controls & Calibrators

- Human Serum based Controls simulating the human serum matrix.
- Values assigned by reference laboratories in Europe.
- Typical levels: Total Bilirubin around 350 umol/l (around 20 mg/dl) & Direct Bilirubin around 100 umol/l (around 6.0 mg/dl).
- Lyophilised product and Liquid Stable version ready-to-use stable up to expiry at 2-8 °C.
- Storage at 2-8 °C.
- Reconstituted stability of 5 days at 2-8 °C.
- Values for Total and Direct Bilirubin.
- Ideal for laboratories measuring Neonatal Bilirubin.
- Open vial stability for liquid 3 months.

| Description | Size | Cat No. | Type |
|--|-------------|----------|------|
| Bilirubin Calibrator | 3 x 1ml | BXC0319A | Lyo. |
| Bilirubin Control (Elevated) | 1 x 1ml | BXC0318A | Lyo. |
| Bilirubin Control (Elevated) | 5 x 1ml | BXC0318B | Lyo. |
| Bilirubin Calibrator | 2 x 1ml | BXC0303A | LS |
| Bilirubin Control Set | 2 x 1 x 1ml | BXC0304A | LS |
| Bilirubin Control Set, Paediatric | 2 x 1 x 1ml | BXC0305A | LS |
| Bilirubin Control (Normal) | 1 x 1ml | BXC0306A | LS |
| Bilirubin Control (Normal) | 3 x 1ml | BXC0306B | LS |
| Bilirubin Control (Elevated) | 1 x 1 ml | BXC0307A | LS |
| Bilirubin Control (Elevated) | 3 x 1 ml | BXC0307B | LS |

Citrate (Urinary) Calibrators & Controls

- The controls are presented in a Liquid format and are stable up to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Citrate (Urinary) Calibrator [200mg/L] | 2 x 1 ml | BXC0136A | LS |
| Citrate (Urinary) Control (Level 1) [50mg/L] | 2 x 1 ml | BXC0137A | LS |
| Citrate (Urinary) Control (Level 2) [600mg/L] | 2 x 1 ml | BXC0139A | LS |



CO₂ (Bicarbonate) Controls & Calibrators

- Values are assigned by in house methods using Enzymatic CO₂ kits.
- The CO₂ (Bicarbonate) calibrator is intended for calibrating the Fortress CO₂ (Bicarbonate) kit.
- CO₂ (Bicarbonate) Calibrator & Controls are Liquid Stable.
- Stable to expiry at 2-8 °C.
- Five hours open vial stability at 2-8 °C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| CO₂ (Bicarbonate) Calibrator | 3 x 2 ml | BXC0155A | LS |
| CO₂ (Bicarbonate) Control Low | 3 x 2 ml | BXC0156A | LS |
| CO₂ (Bicarbonate) Control High | 3 x 2 ml | BXC0157A | LS |



CSF Controls

- Human CSF based controls.
- Method based values with reference traceability provided.
- Liquid stable (Ready-to-Use) - Stable to expiry at 2-8 °C.
- Once opened, the control is stable for a period of 30 days when stored at 2-8 °C without contamination.

| Analytes | | | | |
|------------------------------------|---|-------------------------------|--------------------|------|
| Proteins | | Electrolytes | Substrates | |
| IgA IgG IgM Total Protein | | Chloride Lactate Sodium | Albumin Glucose | |
| Description | Details | Size | Cat No. | Type |
| CSF Control (Level 1) | Albumin, Chloride, Glucose, IgA, IgG, IgM, Lactate, Sodium, Total Protein | 1 x 1 ml | BXC0673A | LS |
| CSF Control (Level 2) | Albumin, Chloride, Glucose, IgA, IgG, IgM, Lactate, Sodium, Total Protein | 1 x 1 ml | BXC0673B | LS |

CSF Diff Control

| Description | Size | Cat No. | Type |
|----------------------------|----------|----------|------|
| CSF Diff Control (Level 1) | 5 x 2 ml | BXC0080A | LS. |
| CSF Diff Control (Level 2) | 5 x 2 ml | BXC0081A | LS. |
| CSF Diff Control (Level 3) | 5 x 2 ml | BXC0082A | LS. |

CRP Controls & Calibrators


- Fortress CRP controls are intended for monitoring accuracy and precision of CRP turbidimetric, Immunoturbidimetric and Nephelometric assays.
- This control is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The values are assigned in European Reference Laboratories.
- 100% Human serum designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.

| Description | Details | Size | Cat No. | Type |
|------------------------------------|---------------------|----------------|----------|------|
| CRP (Single Point) Calibrator | Immunoturbidimetric | 3 x 1 ml | BXC0324A | LS |
| CRP (Multi Point) Calibrator | Immunoturbidimetric | 6 x 1 x 1 ml | BXC0324B | LS |
| CRP (Ultra Sensitive) Low Control | Immunoturbidimetric | 3 x 1 ml | BXC0325A | LS |
| CRP (Ultra Sensitive) Standard Set | Immunoturbidimetric | 5 x 1 x 0.5 ml | BXC0327A | LS |
| CRP Control (Level 1) | | 5 x 1 ml | BXC0326A | LS |
| CRP Control (Level 2) | | 5 x 1 ml | BXC0326B | LS |
| CRP Control Set | | 2 x 1 x 1 ml | BXC0326C | LS |

Cyanmethaemoglobin Standard Set


- Typical concentrations 8,10,12,15,18 g/dL.
- The standard set comprises of 5 standards.
- Values are assigned using in house methods.
- Store the standard set at 2-8 °C. The Standard set is stable up to expiry when stored unopened at 2-8 °C.
- Once opened the standard set is stable for a period of 1 month when stored at 2-8°C without contamination.
- Do not freeze

| Description | Size | Cat No. | Type |
|---------------------------------|---------------|----------|------|
| Cyanmethaemoglobin Standard Set | 5 x 1 x 10 ml | BXC0483A | LS |

Cystatin C Controls & Calibrators


- Values are assigned using in house methods.
- These controls and calibrators are supplied in liquid stable format with a shelf life of 2 years when stored at 2-8 °C.
- When opened and stored at 2-8 °C, without contamination, the controls and calibrators are stable for a period of 1 month.
- Mix gently before use.
- The calibrator set and controls are liquid stable.
- Human serum based to ensure matrix compatibility.
- Do not freeze.



| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| Cystatin C Calibrator Set (6 Levels) | 6 x 1 ml | BXC0334A | LS |
| Cystatin C Control (Level 1) | 2 x 1 ml | BXC0333A | LS |
| Cystatin C Control (Level 2) | 2 x 1 ml | BXC0333B | LS |

D3-Hydroxybutyrate Controls & Calibrators



- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted Stability of 7 Days at 2-8°C.

| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| D3-Hydroxybutyrate Calibrator | 1 x 3 ml | BXC0544A | Lyo |
| D3-Hydroxybutyrate Control (Level 1) | 1 x 5 ml | BXC0543A | Lyo |
| D3-Hydroxybutyrate Control (Level 2) | 1 x 5 ml | BXC0543B | Lyo |

D-Dimer Calibrators & Controls



- Liquid Stable (Ready-to-use)
- Prepared from human serum.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| D-Dimer Calibrator Set (5 Levels) | 5 x 1 ml | BXC0788A | LS |
| D-Dimer Control Set (Level 1 & Level 2) | 5 x 1 ml | BXC0789A | LS |

ESR Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Details | Size | Cat No. | Type |
|------------------------------|---|-----------|----------|------|
| ESR Control (Level 1) | To be used with all routine ESR instruments | 2 x 10 ml | BXC0631A | LS |
| ESR Control (Level 2) | To be used with all routine ESR instruments | 2 x 10 ml | BXC0632A | LS |

Ferritin Controls & Calibrators



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|-----------------------------------|--------------|----------|------|
| Ferritin Calibrator | 1 x 1 ml | BXC0445A | LS |
| Ferritin Calibrator Set | 6 x 1 x 1 ml | BXC0445B | LS |
| Ferritin Control (Level 1) | 3 x 1 ml | BXC0443A | LS |
| Ferritin Control (Level 2) | 3 x 1 ml | BXC0444A | LS |

Fructosamine Controls & Calibrators



- Values are assigned using both in house and reference laboratory values.
- 100% Human Serum designed for matrix conformity.

| Description | Size | Cat No. | Type |
|---------------------------------------|---------------|----------|------|
| Fructosamine Calibrator | 1 x 1 ml | BXC0592A | LS |
| Fructosamine Control (Level 1) | Low 3 x 1 ml | BXC0593A | LS |
| Fructosamine Control (Level 2) | High 3 x 1 ml | BXC0594A | LS |



G-6-PDH Controls

- Values assigned by reference Laboratories in Europe.
- Stable to expiry at 2-8 °C.
- Reconstituted stability of 5 days at 2-8 °C.
- Lyophilised for enhanced stability.
- Typical Levels:
G-6-PDH Deficient Control : 100 - 200 U/l
G-6-PDH Normal Control : 900 - 1400 U/l

| Description | Size | Cat No. | Type |
|----------------------------------|-----------|----------|------|
| G-6-PDH Control Normal | 3 x 1.0ml | BXC0573B | Lyo. |
| G-6-PDH Control Deficient | 3 x 1.0ml | BXC0572B | Lyo. |

Glucose-Fructose Control



| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| Glucose-Fructose Control (Level 1) | 1 x 1 ml | BXC0099A | LS |
| Glucose-Fructose Control (Level 2) | 1 x 1 ml | BXC0099B | LS |

Glutathione Peroxidase Calibrator & Control



| Description | Size | Cat No. | Type |
|--|------------|----------|------|
| Glutathione Peroxidase Control | 5 x 1 ml | BXC0556A | LS |
| Glutathione Peroxidase Control | 5 x 0.5 ml | BXC0556B | LS |
| Glutathione Peroxidase Calibrator | 5 x 1 ml | BXC0557A | LS |

Glycerol Control



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|-------------------------|----------|----------|------|
| Glycerol Control | 2 x 5 ml | BXC0278A | LS |

HDL/LDL Calibrators



- Fortress HDL/LDL Cholesterol Calibrator is presented in a Lyophilised format for enhanced stability. Stable up to expiry at 2-8 °C.
- Once opened and reconstituted the control is stable for 7 days at 2-8 °C, or 30 days at -20 °C.
- 100% human material designed for matrix conformity.

Analytes

| | |
|--------------------------|--------------------------|
| HDL Cholesterol (Direct) | LDL Cholesterol (Direct) |
|--------------------------|--------------------------|

| Description | Size | Cat No. | Type |
|--|----------------|----------|------|
| HDL/LDL Calibrator | 3 x 1 ml | BXC0315D | LS. |
| HDL/LDL Calibrator | 1 x 1 ml | BXC0315E | LS. |
| IgG Sub Classes Control Set | 2 x 1 x 0.5 ml | BXC0726A | LS. |
| IgG Sub Classes Calibrator (IgG 1, 2, 3) | 1x1 ml | BXC0727A | LS. |
| IgG Sub Classes Calibrator (IgG 4) | 1 x 1 ml | BXC0728A | LS. |

IgE Calibrators & Controls



- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.
- Reconstituted stability of 30 days at -20°C.

| Description | Size | Cat No. | Type |
|--|--------------|----------|------|
| IgE Calibrator | 1 x 1 ml | BXC0752A | Lyo. |
| IgE Control Set (Level 1 & Level 2) | 2 x 2 x 1 ml | BXC0753A | Lyo. |



Immunoglobulin Calibrator

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.
- Prepared from Human Serum.

Analytes



| IgA | IgG | IgM | |
|----------------------------------|----------|----------|------|
| Description | Size | Cat No. | Type |
| Immunoglobulin Calibrator | 3 x 1 ml | BXC0040A | LS |

Lipase Calibrator



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|--------------------------|----------|----------|------|
| Lipase Calibrator | 3 x 1 ml | BXC0510A | LS |

Lipoprotein (a) Calibrators & Controls



- The controls are supplied in two levels.
- 100% Human serum designed for matrix conformity.
- Liquid stable controls and calibrators stable up to expiry at 2-8 °C.
- Once opened the calibrator and controls are stable for a period of 30 days when stored at 2-8 °C.
- Lipoprotein Low and High controls typically have the following the levels:
 - Lipoprotein Control Low around 20mg/dl.
 - Lipoprotein Control High around 50mg/dl.
- Do not freeze.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Lipoprotein (a) Calibrator High | 1 x 1 ml | BXC0134A | Lyo |
| Lipoprotein (a) Control Low | 1 x 1 ml | BXC0131A | Lyo |
| Lipoprotein (a) Control High | 1 x 1 ml | BXC0133A | Lyo |

Lithium Calibrator



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Details | Size | Cat No. | Type |
|--------------------------------|----------------------------|--------------|----------|------|
| Lithium 3000 Calibrator | 3000 mmol/L | 2 x 1 ml | BXC0106A | LS |
| Lithium Calibrator | Only for Enzymatic Lithium | 1 x 2 x 1 ml | BXC0141A | LS |

Methanol Calibrators & Controls



| Description | Size | Cat No. | Type |
|-----------------------------------|---------|----------|------|
| Methanol Calibrator | 1 x 2ml | BXC0497A | LS |
| Methanol Control (Level 1) | 1 x 2ml | BXC0498A | LS |
| Methanol Control (Level 2) | 1 x 2ml | BXC0499A | LS |

Microalbumin Calibrators & Controls

- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---------------------------------------|----------|----------|------|
| Microalbumin Calibrator Series | 5 x 1 ml | BXC0329A | LS |
| Microalbumin Control | 2 x 1 ml | BXC0328A | LS |
| Microalbumin Control | 2 x 1 ml | BXC0328B | LS |



Myoglobin Calibrators & Controls

- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted stability of 30 days at 2-8°C.

| Description | Size | Cat No. | Type |
|------------------------------------|---------------|----------|------|
| Myoglobin Calibrator Series | 1 x 1 x 0.5ml | BXC0486A | Lyo. |
| Myoglobin Control | 1 x 0.5ml | BXC0487A | Lyo. |

Oxalate Calibrators & Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---|---------|----------|------|
| Oxalate (Urinary) Calibrator [0.5 mmol/L] | 1 x 5ml | BXC0147A | LS |
| Oxalate (Urinary) Control (Level 1) [0.2 mmol/L] | 1 x 5ml | BXC0148A | LS |
| Oxalate (Urinary) Control (Level 2) [0.7 mmol/L] | 1 x 5ml | BXC0149A | LS |

RF (Multi-Point) Calibrators



- This Calibrator is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The Calibrator is presented as a single level calibrator which can be diluted as necessary for calibrating RF Turbidimetric Assays.
- Values are assigned by in house methods and instruments.
- 100% human material designed for matrix conformity.
- Once opened the control is stable for a period of 30 days. when stored without contamination at 2-8 °C.

| Description | Details | Size | Cat No. | Type |
|-----------------------------|---------------------|---------|----------|------|
| RF (Multi-Point) Calibrator | Immunoturbidimetric | 1 x 2ml | BXC0612A | LS |
| RF (Multi-Point) Calibrator | Immunoturbidimetric | 3 x 2ml | BXC0612B | LS |

TIBC Calibrator



- Lyophilised Stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---------------------------------------|----------|----------|------|
| TIBC Calibrator (Single Level) | 2 x 1 ml | BXC0238A | Lyo. |

Vitamin D Control & Calibrator



| Description | Size | Cat No. | Type |
|---------------------------------|--------------|----------|------|
| Vitamin D Control Set | 2 x 1 x 1 ml | BXC0474A | LS |
| Vitamin D Calibrator Set | 5 x 1 x 1ml | BXC0475A | LS |

Zinc & Copper Calibrator

- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted stability of 30 days at 2-8°C.

| Description | Size | Cat No. | Type |
|-------------------------------------|----------|----------|------|
| Zinc & Copper Calibrator | 2 x 1 ml | BXC0463A | Lyo. |





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SECTION 8

COAGULATION/ HAEMOSTASIS

Coagulation / Haemostasis Controls

Coagulation and haemostasis controls are essential in diagnostics for accurately assessing a patient's ability to form blood clots and maintain haemostasis. These controls include standardized samples with known coagulation properties used to validate laboratory tests that measure parameters like prothrombin time (PT), activated partial thromboplastin time (aPTT), and platelet counts. By employing these controls, laboratories can ensure the accuracy and reliability of test results, which are critical for diagnosing bleeding disorders, monitoring anticoagulant therapy, and guiding treatment decisions in various clinical scenarios, such as surgery or trauma care.

The importance of coagulation and haemostasis controls extends to maintaining quality assurance within laboratory settings, allowing for consistent and reproducible results across different testing environments. Reliable coagulation diagnostics are crucial for preventing complications related to abnormal bleeding or thrombosis, ultimately improving patient outcomes. Regular use of these controls helps identify any technical issues with reagents or instrumentation, ensuring that healthcare providers have accurate information to make informed decisions regarding patient management and treatment strategies.

The Fortress Haemostasis Plasma Controls are provided in a lyophilised format for enhanced stability and are 100% human serum based to negate matrix effects. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Plasma Calibrator & Controls



For Coagulation Series only, PT, aPTT, Fibrinogen, Thrombin Time

- The calibrator and controls are supplied in lyophilised format and stable to expiry when stored at 2-8 °C.
- Once opened and reconstituted, the calibrators and controls are stable for a period of 24 hours at 2-8 °C.
- 100% Human plasma to mimic human samples.
- Do not Freeze

| Description | Size | Cat No. | Type |
|--|--------------|----------|------|
| Plasma Calibrator | 5 x 1 ml | COAG125A | Lyo. |
| Plasma Control (Level 1) | 1 x 1 ml | COAG108A | Lyo. |
| Plasma Control (Level 1) | 5 x 1 ml | COAG108B | Lyo. |
| Plasma Control (Level 2) | 1 x 1 ml | COAG109A | Lyo. |
| Plasma Control (Level 2) | 5 x 1 ml | COAG109B | Lyo. |
| Plasma Control Set (Level 1 & Level 2) | 2 x 5 x 1 ml | COAG112A | Lyo. |



SECTION 9
CUSTOMISED
QUALITY CONTROLS

Customised Quality Controls

Fortress Diagnostics has extensive experience and expertise in the production of customised quality controls for EQA programmes, and manufacturing custom made QC solutions for laboratories throughout the global market.

Over 200 analytes can be customized in the required matrix, with concentrations, levels and volumes. The following list of quality controls can be customised by Fortress Diagnostics:

Antioxidant Controls
Clinical Chemistry
Cardiac Controls
Haemostasis Controls
Diabetes Controls
Immunoassay Controls

Immunology / Specific Protein Controls
Lipids
Tumor Markers
TDM and DOA
Urine Assayed
Urine Strip Controls

Why Customise Fortress Controls?



Cost Effective

Fortress Diagnostics operate throughout the global market. Over 200 analytes can be customized in the required matrix, with concentrations, levels and volumes, leading to cost savings.



Customised

The customised advantage helps in getting the laboratory's requirement in analytes and levels in one control. High usage controls can be manufactured in higher volumes.



Quality

All controls are CE marked and manufactured according to the ISO13485 specifications.



Choice of Matrix

Controls are available in different matrices, like Serum, Plasma, Whole Blood, Urine and aqueous material.



Fast Lead Time

The total order, testing and manufacturing time is 60 days. This cuts the ordering of customised control to half the time that is required by other companies to manufacture customised controls.



Our Process

Time Frame of 90 Days

1**Customer Provides a Specification****3****Customer Places Order****Specification Reviewed & Agreed****2****5****Customer Returns Pilot Results (2 Weeks)****Pilot Samples Sent to Customer****7****Despatch of Samples to Customer for Approval/Testing****Manufacture of Controls****9****Material is Labelled, Packaged & Despatched to Customer****Customer Accepts Material**



SECTION 10 DIABETES

Diabetes

Diabetes controls are crucial in diagnostics for ensuring the accuracy and reliability of tests that measure blood glucose levels and other related biomarkers, enabling timely diagnosis, effective monitoring of glycemic control, and informed treatment decisions to manage diabetes and prevent complications.

The Fortress Diabetes Controls are lyophilised for enhanced stability, and are ideal for both clinical and research use. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided



Fructosamine Controls & Calibrators

- Values are assigned using both in house and reference laboratory values.
- 100% Human Serum designed for matrix conformity.
- Lyophilised Controls and Calibrators stable to expiry at 2-8 °C.
- Reconstituted stability of 28 days at -20 °C.

| Description | Size | Cat No. | Type |
|--------------------------------|---------------|----------|------|
| Fructosamine Calibrator | 1 x 1 ml | BXC0592A | LS |
| Fructosamine Control (Level 1) | low 3 x 1 ml | BXC0593A | LS |
| Fructosamine Control (Level 2) | high 3 x 1 ml | BXC0594A | LS |



HbA1c Calibrators

- 100% human blood designed for matrix conformity.
- The Calibrator is supplied in a Lyophilised format with a 2 year shelf life when stored at 2-8 °C.
- Reconstituted stability of 5 days at 2-8 °C.
- HbA1c Calibrator Set: Typical levels:
 - HbA1c Calibrator Level 1: 5-6%
 - HbA1c Calibrator Level 2: 11-13%
- Do not freeze.

| Description | Size | Cat No. | Type | |
|--|----------------------|-----------------|----------|------|
| HbA1c Calibrator Series | For use with BXC0670 | 2 x 1 x 0.5 ml | BXC0668A | Lyo. |
| HbA1c Calibrator Set (2 Levels) | | 2 x 1 x 0.5 ml | BXC0678A | Lyo. |
| HbA1c (HPLC) Calibrator Set (2 Levels) | For HPLC Method Only | 2 x 1 x 0.25 ml | BXC0780A | Lyo. |



HbA1c Controls

- Controls are supplied in a Lyophilised format stable to expiry at 2-8 °C.
- The controls are value assigned in European Reference Laboratories.
- The Control carries values for methods such as Immunoturbidimetry, Micro-column, HPLC and Enzymatic HbA1c & point of care devices.
- Values are provided for both NGSP DCCT and IFCC methodologies.

| Description | Size | Cat No. | Type | |
|-------------------------------------|----------------------|----------------|----------|------|
| HbA1c (HPLC) Control Set (2 Levels) | For HPLC Method Only | 2 x 1 x 0.5 ml | BXC0779A | Lyo. |
| HbA1c Control High | 2 x 0.5 ml | BXC0677A | Lyo. | |
| HbA1c Control Low | 2 x 0.5 ml | BXC0676A | Lyo. | |
| HbA1c Control Set | 2 x 2 x 0.5 ml | BXC0675A | Lyo. | |
| HbA1c Control Set (2 Levels) | For use with BXC0670 | 2 x 1 x 0.5 ml | BXC0669A | Lyo. |



Thalassaemia (Alpha & Beta) Control

For use on all major systems and methods including HPLC, Immunoassay, HbA2, HbF, HbS.

- Designed for monitoring accuracy and precision of Haemoglobin Variants measurements associated with Thalassaemia.
- The controls are supplied in a Lyophilised format stable up to expiry at 2-8 °C.
- 100% Human blood.

| Description | Size | Cat No. | Type |
|---|------------|----------|------|
| Thalassaemia (Alpha & Beta) Control (Level 1) | 2 x 0.5 ml | BXC0665A | Lyo. |
| Thalassaemia (Alpha & Beta) Control (Level 2) | 2 x 0.5 ml | BXC0665B | Lyo. |



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SECTION 11
DRUGS
OF ABUSE

Drugs of Abuse

Drugs of abuse controls are vital in diagnostics for accurately detecting and monitoring the use of illicit substances, prescription medications, and other psychoactive drugs in patients. These controls consist of standardized samples with known concentrations of specific drugs or their metabolites, used to validate the performance of drug testing assays, such as immunoassays and gas chromatography. By implementing these controls, laboratories ensure the reliability and accuracy of test results, which are crucial for effective patient management in various settings, including addiction treatment, pain management, and legal cases.

The role of drugs of abuse controls extends beyond accuracy; they are essential for maintaining quality assurance in drug testing laboratories. Regular use of these controls helps identify potential errors, such as reagent degradation or instrument malfunction, thus preventing false positives or negatives that could impact patient care or legal outcomes. Moreover, reliable drug testing plays a critical role in public health initiatives, workplace drug screening, and monitoring compliance with treatment programs, ultimately contributing to safer and more effective healthcare practices.

The Fortress Drugs of Abuse Controls, are available in a liquid stable (ready-to-use) format for convenience and ease-of-use, offer an independent assessment of performance for Drugs of Abuse Immunoassays, and are suitable for semi-quantitative and quantitative use. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Drugs of Abuse Controls



- Fortress Drugs of Abuse controls are intended for checking assay performance of Drugs of Abuse Immunoassays.
- These controls are urine based and have concentrations 25% above and below the SAMHSA (Substance Abuse And Mental Health Services Administration) recommended cut off levels.
- Liquid stable controls (ready-to-use).
- Suitable for semi-quantitative and quantitative use.
- 2 years shelf life.
- 30 days open vial stability when stored at 2-8 °C.

Typical Values in Drugs of Abuse Control Levels

| Analyte | DOA Level (ng/ml) | DOA Level 2 (ng/ml) | DOA Level 3 (ng/ml) |
|-----------------|-------------------|---------------------|---------------------|
| Amphetamines | 600 | 900 | 1350 |
| Barbiturates | 100 | 400 | 1000 |
| Benzodiazepines | 102 | 250 | 600 |
| Cannabinoids | 50 | 90 | 150 |
| Cocaine | 300 | 275 | 400 |
| LSD | 0.05 | 0.1 | 0.2 |
| Methadone | 200 | 300 | 800 |
| Opiates | 1000 | 1500 | 6000 |
| Phencyclidine | 15 | 25 | 100 |
| Propoxyphene | 60 | 100 | - |
| TCA | 50 | 90 | 180 |

Analytes

| | | | |
|------------------------------|----------------------------|-----------------------------|-------------------------------|
| Amphetamines Barbiturates | Benzodiazepines Cocaine | LSD Methadone Opiates | Phencyclidine Propoxyphene |
|------------------------------|----------------------------|-----------------------------|-------------------------------|

| Description | Size | Cat No. | Type |
|---|--------------|----------|------|
| Drugs of Abuse Control (Level 1) | 10 x 10 ml | BXC0784A | LS |
| Drugs of Abuse Control (Level 1) | 10 x 3 ml | BXC0784B | LS |
| Drugs of Abuse Control (Level 2) | 10 x 10 ml | BXC0785A | LS |
| Drugs of Abuse Control (Level 2) | 10 x 3 ml | BXC0785B | LS |
| Drugs of Abuse Control (Level 3) | 10 x 10 ml | BXC0786A | LS |
| Drugs of Abuse Control (Level 3) | 10 x 3 ml | BXC0786B | LS |
| Multi DOA Calibrator/Control | 6 x 1 x 1 ml | BXC0989A | LS |
| Tricyclic Anideressan Calibrator/Control | 3 x 3 x 3 ml | BXC0996C | Lyo. |



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SECTION 12 HAEMATOLOGY

Haematology

Hematology controls are crucial in diagnostics for ensuring the accuracy and reliability of tests that analyse blood components, including red and white blood cells, platelets, and hemoglobin levels. These controls consist of standardised samples with known cell counts and characteristics, used to validate laboratory instruments and procedures for tests like complete blood counts (CBC) and coagulation profiles. By implementing these controls, laboratories can detect any discrepancies in test results, which is essential for diagnosing conditions such as anemia, leukemia, and other blood disorders, as well as for monitoring patient response to treatment.

The role of hematology controls extends to maintaining quality assurance within laboratory settings, allowing for consistent and reproducible results across different testing environments. Reliable hematology diagnostics are vital for guiding clinical decision-making and ensuring appropriate patient management. Regular use of these controls helps identify potential issues with reagents or equipment, thereby minimising the risk of misdiagnosis or inappropriate treatment. Overall, hematology controls play a significant role in enhancing the quality of healthcare by providing accurate diagnostic information that informs treatment strategies and improves patient outcomes.

The Fortress Haematology Controls combines 14 analytes, covering the most commonly tested blood profiles in a single control. With 3-part differential technology an unbiased, independent assessment of analytical performance. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid
Frozen



Liquid
Stable



100% Human
Serum



Assayed Target
Values Provided

Haematology Controls & Calibrators



- Fortress Haematology calibrators are intended for calibrating 3 part differential analysers.
- The controls are intended for monitoring accuracy and precision in 3 part differential analysers.
- The product is supplied as a liquid stable material with storage at 2-8 °C.
- When opened, this product is stable for a period of 21 days, when stored at 2-8 °C.

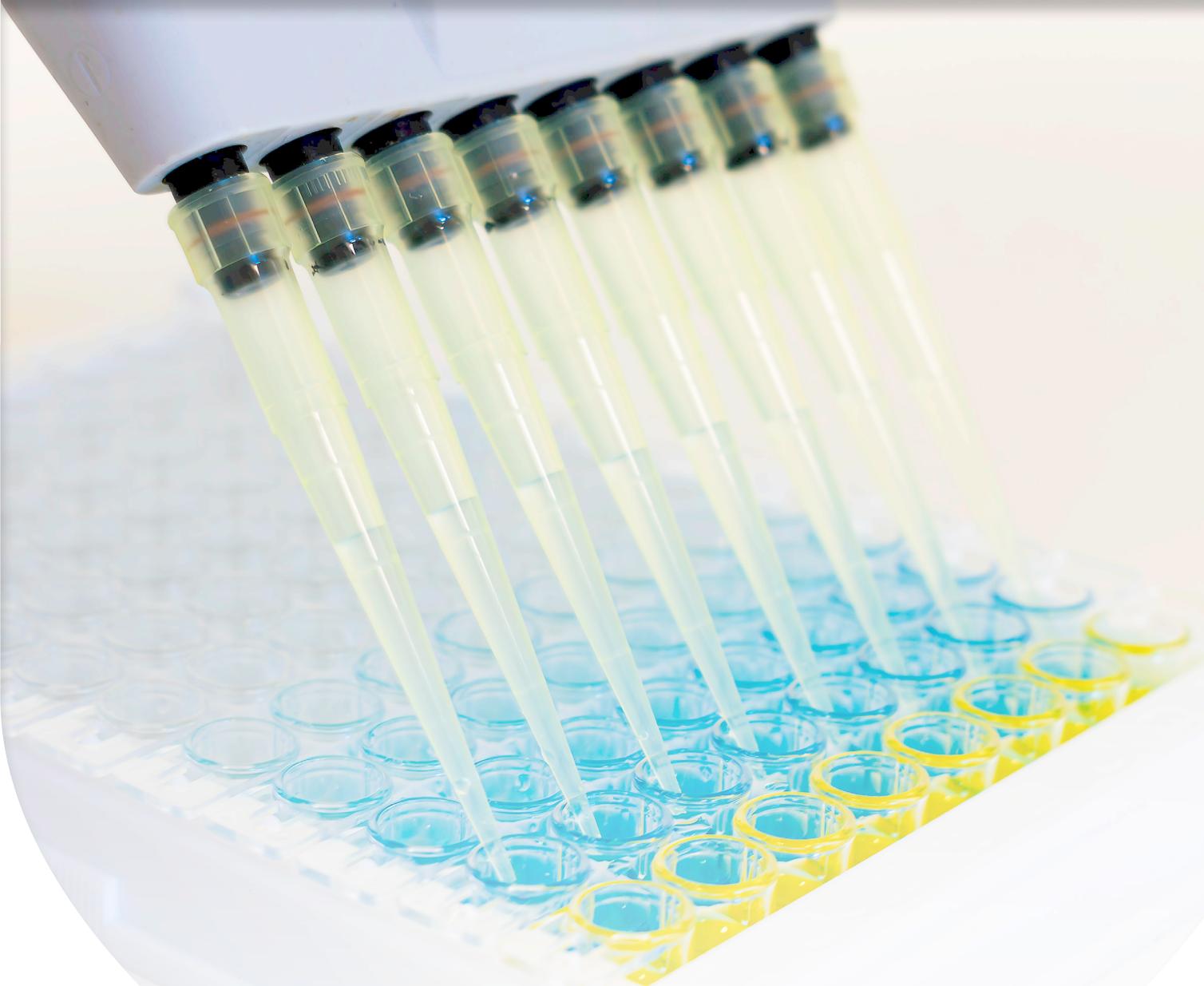
Values Available for the Following Analysers:

Abbott Cell Dyn 1600/1700/1800, ABX Micros 60, 80/80XL, Coulter ACT 5 Diff, Coulter ACT Diff/ACT Diff 3, Coulter STKS/MAXM/HMX, Coulter T890/T660/T540, Danam DATACELL 16CP/11800/18/18MS/18MS Plus, Siemens ADVIA 120/2120/1210i, Sysmex XE2100/XE5000/XT1800i/XT2000i/XS1000i, Sysmex KX21/K1000, ERMA PCE210, Merck Medonic CA620, Mindray BC1800/BC3000/BC-3000CT/BC3200/BC3000 Plus/BC2600/BC2800, Nihon Kohden CELLTAC Alpha MEK 6318, MEK 6410K, Fortress CellDiff 3, Swelab AC920, Medonic CA610, Abacus Junior.

Analytes

| | | | |
|-----------------------------------|-----------------------------------|--|--------------------------|
| Haemoglobin HCT MCH MCHC | MCV MPV Platelets RDW CV | RDW SD Total RBC Total WBC Granulocytes | Lymphocytes Mid Cells |
|-----------------------------------|-----------------------------------|--|--------------------------|

| Description | Size | Cat No. | Type |
|--------------------------------|--------------|----------|------|
| Haematology Calibrator | 3 x 3 ml | HAEMC005 | LS |
| Haematology Control (Level 1) | 3 x 3 ml | HAEMC001 | LS |
| Haematology Control (Level 2) | 3 x 3 ml | HAEMC002 | LS |
| Haematology Control (Level 3) | 3 x 3 ml | HAEMC003 | LS |
| Haematology Control (3 Levels) | 3 x 3 x 3 ml | HAEMC004 | LS |



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SECTION 13 IMMUNOASSAY/ INFECTIOUS DISEASES

Immunoassay

Immunoassay controls are essential in diagnostics for ensuring the accuracy and reliability of tests that detect and quantify specific proteins, hormones, drugs, and antibodies in biological samples. These controls consist of standardised samples with known concentrations of analytes, which are used to validate the performance of immunoassay methods such as enzyme-linked immunosorbent assays (ELISA) and radioimmunoassays. By incorporating these controls, laboratories can monitor assay precision, sensitivity, and specificity, thus minimising the risk of false-positive or false-negative results that could lead to incorrect diagnoses or inappropriate treatment decisions.

The role of immunoassay controls extends to maintaining quality assurance in laboratory operations, ensuring that test results are consistent and reproducible across different assays and testing platforms. Reliable immunoassay diagnostics are critical for guiding clinical decisions, such as monitoring hormone levels, diagnosing infectious diseases, and screening for autoimmune disorders. Regular use of these controls helps identify any technical issues with reagents, instrumentation, or assay protocols, ultimately supporting accurate and timely patient management. Overall, immunoassay controls significantly enhance the quality of healthcare by providing trustworthy diagnostic information that informs treatment strategies and improves patient outcomes.

The Fortress Immunoassay Controls Range have been designed to cover a variety of the most comprehensive markers, including: thyroid hormones, fertility hormones, tumour markers, growth deficiency, allergy, diabetes, anaemia and steroids. All Fortress controls in the Immunoassay range are manufactured from 100% human serum to negate matrix effects. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid
Frozen



Liquid
Stable



100% Human
Serum



Assayed Target
Values Provided

Immunoassay Controls



- Fortress Immunoassay Controls are intended for monitoring accuracy and precision.
- Controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8 °C or 4 week at -20 °C.
- Values are assigned in European reference laboratories.
- 28 analytes.

Analytics

| Thyroid | Tumor Markers | Allergy | Steroids |
|--------------------|----------------------|-----------|----------------------|
| Hormones | CEA | IgE | 17-OH |
| Total T3 | AFP | | Progesterone |
| Total T4 | PSA | | Cortisol |
| Free T3 | fPSA | | Unconjugated Estriol |
| Free T4 | | | Progesterone |
| TSH | | | Testosterone |
| T-uptake | | | DHEA-S |
| Fertility Hormones | Cardiac Markers | Diabetes | |
| LH | Digoxin | C-peptide | |
| FSH | | Insulin | |
| Prolactin | | | |
| HCG | | | |
| | Growth Deficiency | Anaemia | |
| | Human Growth Hormone | Ferritin | |

| Description | Size | Cat No. | Type |
|-------------------------------|--------------|----------|------|
| Immunoassay Control (Level 1) | 4 x 3 ml | BXC0363A | Lyo. |
| Immunoassay Control (Level 2) | 4 x 3 ml | BXC0363B | Lyo. |
| Immunoassay Control (Level 3) | 4 x 3 ml | BXC0363C | Lyo. |
| Immunoassay Tri-Level Control | 3 x 4 x 3 ml | BXC0363D | Lyo. |

Immunoassay Speciality



- Lyophilised stable to expiry at 2-8 °C
- 100% Human serum
- Reconstituted stability of 7 days at 2-8 °C or 28 days stored at -20 °C.

Analytes

| | | |
|---|-------------------------------|----------------------------------|
| 1-25 (OH) Vitamin D Anti TG Anti TP | C Peptide IgF-I Insulin | Osteocalcin PTH Calcitonin |
|---|-------------------------------|----------------------------------|

| Description | Size | Cat No. | Type |
|--|--------------|----------|------|
| Immunoassay Speciality (Level 1) | 1 x 2 ml | BXC0364A | Lyo. |
| Immunoassay Speciality (Level 2) | 1 x 2 ml | BXC0364B | Lyo. |
| Immunoassay Speciality (Level 3) | 1 x 2 ml | BXC0364C | Lyo. |
| Immunoassay Speciality Tri-Level Control | 3 x 1 x 2 ml | BXC0364D | Lyo. |

Anti-Mullerian Hormone (AMH) Calibrators & Controls



- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.
- Comparable with all AMH assays.

| Description | Size | Cat No. | Type |
|---|---|----------|------|
| Anti-Mullerian Hormone (AMH) Calibrators & Controls | Cal A: 1 x 0.5ml; Cal B-G: 6 x 0.5ml; Ctl L1: 1 x 0.5ml; Ctl L2: 1 x 0.5ml | BXC0999A | Lyo. |

hCG Serum Control



- Fortress hCG Serum controls are intended for monitoring the accuracy and precision of hCG assays in both quantitative and qualitative formats.
- Controls are supplied as lyophilised materials stable up to expiry at 2-8 °C.
- The controls are available in two levels – positive and negative.
- Value assignment of the Positive Controls is performed in European reference laboratories.
- 100% Human serum based for matrix conformity.
- Positive control has a hCG concentration of >/= 20 IU/ml, making it ideal for sensitivity testing of qualitative assays.

| Description | Size | Cat No. | Type | |
|-------------------|----------|----------|----------|-----|
| hCG Serum Control | Positive | 1 x 1 ml | BXC0681A | LS. |
| hCG Serum Control | Negative | 1 x 1 ml | BXC0682A | LS. |
| hCG Serum Control | Positive | 1 x 5 ml | BXC0683A | LS. |

H-Pylori Control



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|-----------------------------|--------------|----------|------|
| H-Pylori Control (2 Levels) | 2 x 1 x 1 ml | BXC0684A | LS |

Tumour Marker Controls



For use on all major systems & methods including Immunoassay Instruments

- Fortress Tumour Marker controls are multi analyte controls designed for monitoring accuracy.
- The controls are supplied in a Lyophilised format for enhanced stability.
- 100% human serum.
- Reconstituted stability of 10 days at 2-8 °C and 30 days at 20 °C.
- Stable up to expiry at 2-8 °C.

Analytes

| | | | |
|---|--|--|------------------------------|
| AFP Beta-2-microglobulin CA 15-3 CA 19-9 | CA 72-4 CA 125 Calcitonin CEA | Cyfra 21 Ferritin HCG Neuron Specific Enolase | PSA fPSA Thyroglobulin |
|---|--|--|------------------------------|

| Description | Size | Cat No. | Type |
|--------------------------------------|-------------|----------|------|
| Tumour Marker Control (Level 1) | 5 x 2 ml | BXC0792A | Lyo. |
| Tumour Marker Control (Level 2) | 5 x 2 ml | BXC0792B | Lyo. |
| Tumour Marker Control SET (2-Levels) | 2 x 1 x 2ml | BXC0793A | Lyo |

Vitamin-D Calibrators & Controls



- Liquid Stable product stable to expiry at 2-8 °C.
- Reconstituted stability of 30 days at 2-8°C.

| Description | Size | Cat No. | Type |
|-------------------------------------|-------------|----------|------|
| Vitamin-D Calibrator Set (5 Levels) | 5 x 1 x 1ml | BXC0475A | LS. |
| Vitamin-D Control Set (2 levels) | 2 x 1 x 1ml | BXC0474A | LS. |

SAA Control



- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.

| Description | Size | Cat No. | Type |
|-------------|----------|----------|------|
| SAA Control | 3 x 1 ml | BXC0703A | Lyo. |

Infectious Diseases

Infectious diseases controls are crucial in diagnostics for ensuring the accuracy and reliability of tests that identify and quantify pathogens, such as bacteria, viruses, fungi, and parasites, in biological samples. These controls consist of standardised samples containing known concentrations of specific pathogens or their genetic material, which are used to validate the performance of diagnostic assays like polymerase chain reaction (PCR) tests and enzyme immunoassays. By incorporating these controls, laboratories can monitor the sensitivity and specificity of tests, thereby reducing the risk of false-negative or false-positive results that could impact patient management and public health responses.

The role of infectious diseases controls extends to maintaining quality assurance in laboratory settings, ensuring consistent and reproducible results across different testing environments and methodologies. Reliable diagnostics for infectious diseases are essential for timely treatment, outbreak control, and infection prevention strategies. Regular use of these controls helps identify potential issues with reagents, equipment, or testing protocols, which is critical for maintaining the integrity of diagnostic results. Overall, infectious diseases controls significantly enhance the quality of healthcare by providing accurate diagnostic information that informs treatment decisions and public health initiatives, ultimately improving patient outcomes and community health safety.

The Fortress Infectious Diseases Controls are available in a liquid stable format for convenience and ease-of-use, being made from 100% human serum to negate matrix effects. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

COVID-19 Antigen Controls



| Description | Size | Cat No. | Type |
|---|---------------|----------|------|
| COVID-19 Antigen Control Pair (Positive and Negative Control) | 2 x 1 x 0.5ml | COVIDNPC | LS |

HBsAb Control Panel



- 100% Human serum from single donors.
- The panel is supplied in 5 levels.
- Open vial stability of 60 days when stored at 2-8 °C without contamination.
- HBsAg Controls have the following concentrations; L1 0.2IU/ml, L2 0.5IU/ml, L3 1.0IU/ml, L4 2.0IU/ml, L5 4.0IU/ml.

| Description | Size | Cat No. | Type |
|--------------------------------|---------------|----------|------|
| HBsAb Control Panel (2 Levels) | 2 x 1 x 0.5ml | BXC0805A | LS |
| HBsAb Control Panel (5 Levels) | 5 x 1 x 0.5ml | BXC0800A | LS |



HCV Antibody Control Panel

- The control panel is supplied as a liquid panel stable up to expiry at 2-8 °C.
- 100% Human serum
- The panel is supplied in 4 levels.
- Open vial stability: 30 days at 2-8 °C without contamination.

| Description | Size | Cat No. | Type |
|---------------------------------------|---------------|----------|------|
| HCV Antibody Control Panel (4 Levels) | 4 x 1 x 0.5ml | BXC0804A | LS |

HE4



| Description | Size | Cat No. | Type |
|---------------|------------|----------|------|
| HE4 (Level 1) | 1 x 0.25ml | BXC0425A | Lyo. |
| HE4 (Level 2) | 1 x 0.25ml | BXC0425B | Lyo. |

HIV-I Antibody Control Panel



- The control panel is supplied as a liquid panel stable up to expiry at 2-8 °C.
- 100% Human serum
- The panel is supplied in 4 levels.
- Open vial stability: 30 days at 2-8 °C without contamination.

| Description | Size | Cat No. | Type |
|---|-------------|----------|------|
| HIV-I Antibody Control Panel (4 Levels) | 4 x 1 x 1ml | BXC0802A | LS |

HIV-I Antigen (p24) Control Panel



- The Control Panel is supplied as a liquid panel stable up to expiry at 2-8 °C.
- 100% Human serum from single donors.
- The panel is supplied in 4 levels.
- Open vial stability: 30 days when stored at 2-8 °C without contamination.

| | |
|---------|-----------|
| Level 1 | 1.25U/ml |
| Level 2 | 2.50U/ml |
| Level 3 | 5.00U/ml |
| Level 4 | 10.00U/ml |

| Description | Size | Cat No. | Type |
|--|----------------|----------|------|
| HIV-I Antigen (p24) Control Panel (4 Levels) | 4 x 1 x 0.5 ml | BXC0803A | LS |

IFN-γ Control



| Description | Size | Cat No. | Type |
|---------------|----------|----------|------|
| IFN-γ Control | 3 x 1 ml | BXC0702A | Lyo. |

Procalcitonin Control



| Description | Size | Cat No. | Type |
|--------------------------------------|-------------|----------|------|
| Procalcitonin Control Set (2 Levels) | 2 x 1 x 1ml | BXC0590B | LS. |

Protein Control



- This control is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- Values are assigned by reference laboratories based in Europe.
- Values for Immunoglobulin, Inflammatory proteins, Complements, Carrier and Storage proteins are available in the control.
- 100% Human material designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.
- Liquid Ready to Use.

| Description | Size | Cat No. | Type |
|-----------------------------------|-------------|----------|------|
| Protein Control (Level 1) | 1 x 1 ml | BXC0638A | LS |
| Protein Control (Level 2) | 1 x 1 ml | BXC0639A | LS |
| Protein Control Set (Level 3) | 1 x 1 ml | BXC0640A | LS |
| Protein Control Set (L1, L2 & L3) | 3 x 1 x 1ml | BXC0641A | LS |

Retinol Binding Protein Control



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---------------------------------|----------|----------|------|
| Retinol Binding Protein Control | 1 x 1 ml | BXC0995A | LS |

Syphilis Control Panel



- The Control Panel is supplied as a liquid panel stable up to expiry at 2-8 °C.
- 100% Human serum from single donors.
- The panel is supplied in 6 levels.
- Open vial stability: 30 days when stored at 2-8 °C without contamination.

| Description | Size | Cat No. | Type |
|-----------------------------------|---------------|----------|------|
| Syphilis Control Panel (6 Levels) | 6 x 1 x 0.5ml | BXC0806A | LS |

Torch Controls Negative



- The Fortress TORCH Control Negative is intended for use in monitoring the specificity of TORCH Assays to rule out false positive reactions.
- The Control is supplied in a liquid stable format stable up to expiry at 2-8 °C.
- For use on all major systems

| Description | Size | Cat No. | Type |
|------------------------|----------|----------|------|
| TORCH Control Negative | 3 x 1 ml | BXC0799A | LS |

Torch Controls Positive



- The Fortress TORCH Control Positive is intended for use in monitoring precision of TORCH Assays.
- The control is supplied in a liquid stable format.
- The control is stable up to expiry at 2-8 °C.
- Values are assigned in European Reference Laboratories.
- TORCH-IgM controls are supplied individually to prevent cross-reactivity.
- TORCH-IgG controls are supplied together / vial.
- For use on all major systems

Analytes

| IgG | HSV-2 IgG VZV IgG EBV IgG Syphilis IgG | IgM | HSV-2 IgM Toxoplasma Gondii IgM Rubella IgM CMV IgM HSV-1 IgM |
|--|---|-----|---|
| Toxoplasma Gondii IgG Rubella IgG CMV IgG HSV-1 IgG | | | Syphilis RPR |

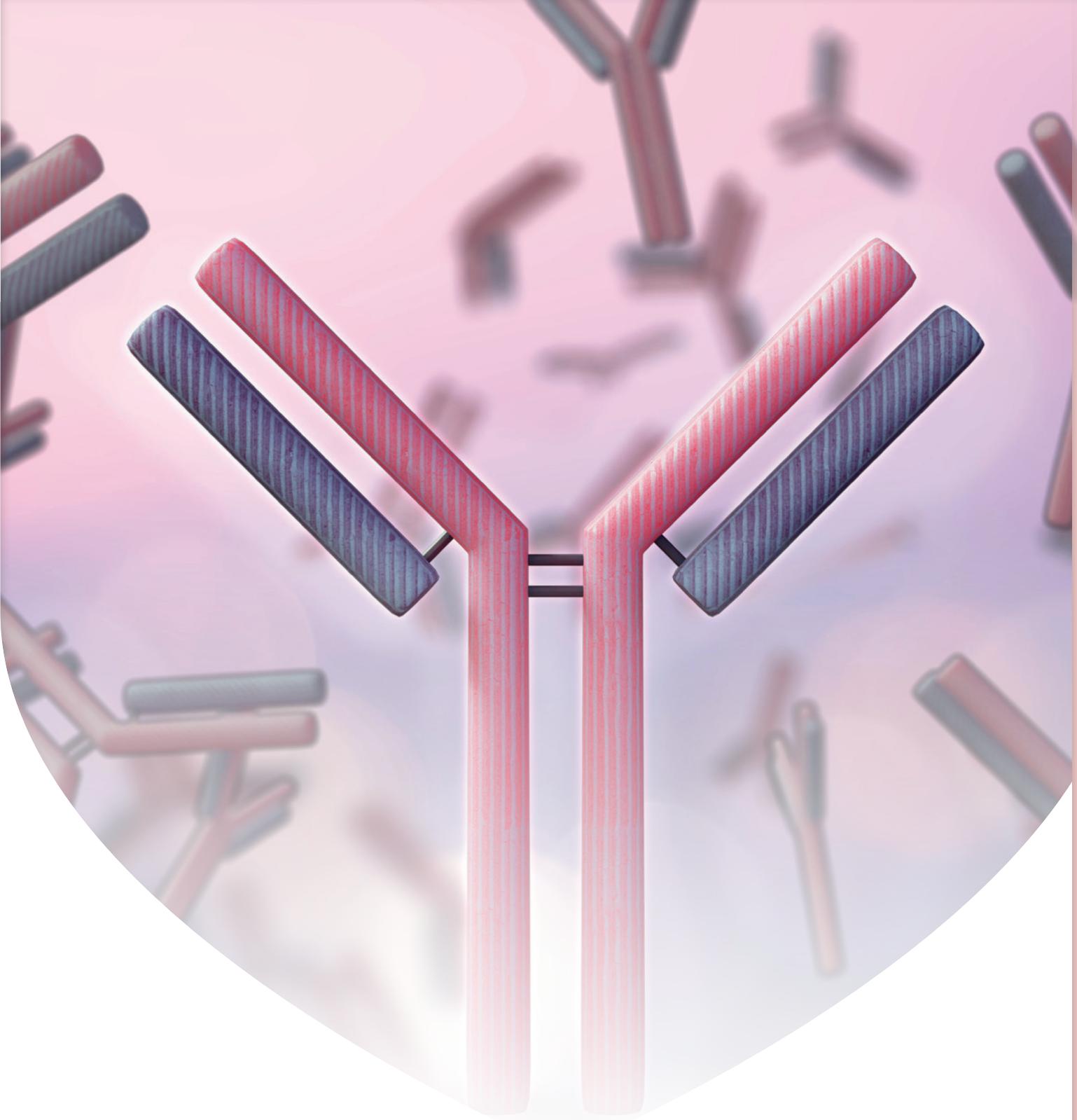
| Description | Size | Cat No. | Type |
|----------------------------|--------------|----------|------|
| TORCH IgG Control Positive | 3 x 1 ml | BXC0799B | LS |
| TORCH IgM Control Positive | 5 x 1 x 1 ml | BXC0799C | LS |

Xanthochromia Quality Control



- Lyophilised format for convenience and longer shelf life.
- Human Based Material.
- True Third Party control providing unbiased assessment of performance.
- Open reconstituted Vial stability of 2 days at 2° to 8°C. Stable for 1 year when stored unopened at 2° to 8°C.

| Description | Size | Cat No. | Type |
|--------------------------------|----------|----------|------|
| Xanthochromia Positive Control | 3 x 1 ml | BXC0355A | Lyo |



SECTION 14
**IMMUNOLOGY/
PROTEINS**

Immunology Controls

Immunology and protein controls are essential in diagnostics for ensuring the accuracy and reliability of tests that assess various immune responses and protein levels in biological samples. These controls consist of standardised samples with known concentrations of specific proteins or antibodies, utilised to validate the performance of assays such as enzyme-linked immunosorbent assays (ELISA) and Western blots. By incorporating these controls, laboratories can evaluate assay precision, sensitivity, and specificity, thus reducing the risk of incorrect results that could lead to misdiagnoses or inappropriate treatment decisions.

Immunology and protein controls play a key role in maintaining quality assurance in laboratory processes, ensuring consistent and reproducible test results across various assays. Reliable diagnostics are crucial for diagnosing autoimmune disorders, allergies, and infections, as well as monitoring treatment responses. Regular use of these controls helps identify potential issues with reagents or equipment, facilitating accurate and timely patient management. Overall, they significantly enhance healthcare quality by providing dependable diagnostic information that informs clinical decisions and improves patient outcomes.

The majority of the Fortress Immunology/Protein Controls are available in a liquid stable format for convenience and ease-of-use and are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

APO A1/B Calibrator Series



- Liquid Stable, long shelf life, stable to expiry at 2-8 °C. (Unopened)
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|-----------------------------------|----------------------------------|----------|------|
| APO A1/B Calibrator Series | Immunoturbidimetric 6 x 1 x 1 ml | BXC0413A | LS. |

ASO (Single Point) Calibrators



- Values are assigned by in house methods and instruments.
- 100% human material designed for matrix conformity.
- The liquid stable ASO Single point calibrator has a shelf life of 2 years when stored at 2-8 °C.
- Once opened the calibrator is stable for a period of 30 days when stored without contamination at 2-8 °C.

| Description | Size | Cat No. | Type |
|--------------------------------------|------------------------------|----------|------|
| ASO (Single Point) Calibrator | Immunoturbidimetric 1 x 1 ml | BXC0323A | LS |
| ASO (Single Point) Calibrator | Immunoturbidimetric 3 x 1 ml | BXC0323B | LS |

ASO, CRP, RF Control



- This control is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The values are assigned in European Reference Laboratories.
- 100% Human serum designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.
- This material is presented in a liquid stable format and is stable up to expiry at 2-8 °C.

| Description | Size | Cat No. | Type |
|-----------------------------|------------------------------|----------|------|
| ASO, CRP, RF Control | Immunoturbidimetric 3 x 1 ml | BXC0645A | LS |

CRP Controls & Calibrators



- This control is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The values are assigned in European Reference Laboratories.
- 100% Human serum designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.

| Description | Size | Cat No. | Type |
|---|---|----------|------|
| CRP (Single Point) Calibrator | <i>Immunoturbidimetric</i> 3 x 1 ml | BXC0324A | LS |
| CRP (Multi Point) Calibrator | <i>Immunoturbidimetric</i> 6 x 1 x 1 ml | BXC0324B | LS |
| CRP (ULTRA SENSITIVE) Low Control | <i>Immunoturbidimetric</i> 3 x 1 ml | BXC0325A | LS |
| CRP (ULTRA SENSITIVE) Standard Set | <i>Immunoturbidimetric</i> 5 x 1 x 0.5 ml | BXC0327A | LS |
| CRP Control (Level 1) | 5 x 1 ml | BXC0326A | LS |
| CRP Control (Level 2) | 5 x 1 ml | BXC0326B | LS |
| CRP Control Set | 2 x 1 x 1 ml | BXC0326C | LS |

ESR Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.
- To be used with all routine ESR instruments

| Description | Size | Cat No. | Type |
|------------------------------|-----------|----------|------|
| ESR Control (Level 1) | 2 x 10 ml | BXC0631A | LS |
| ESR Control (Level 2) | 2 x 10 ml | BXC0632A | LS |

IgE Calibrators & Controls



- Lyophilised product stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.
- Reconstituted stability of 30 days at -20°C.

| Description | Size | Cat No. | Type |
|--|-------------|----------|------|
| IgE Calibrator | 1 x 1 ml | BXC0752A | Lyo. |
| IgE Control Set (Level 1 & Level 2) | 2 x 1 x 1ml | BXC0753A | Lyo. |

Protein Control



- This control is presented in a liquid stable format (Ready-to-use) and is stable up to expiry when stored at 2-8 °C.
- Values are assigned by reference laboratories based in Europe.
- Values for Immunoglobulin, Inflammatory proteins, Complements, Carrier and Storage proteins are available in the control.
- 100% Human material designed for matrix conformity.
- Once opened the control is stable for a period of 30 days when stored without contamination at 2-8 °C.

| Analytes | | | |
|--------------------------|-----------------------|-------------------------|-------------------------|
| Albumin | CRP | IgA | Lambda Light Chains |
| Alpha-1 Acidglycoprotein | C1q Inactivator | IgG | Prealbumin |
| Alpha-1 Antitrypsin | C1 Esterase Inhibitor | IgM | Free Lambda Light Chain |
| Alpha-2 Macroglobulin | Ceruloplasmin | IgE | Transferrin |
| ASO | Complement C3 | Kappa Light Chains | Total Protein |
| Antithrombin-III | Complement C4 | Retinol Binding Protein | |
| Beta-2-Microglobulin | Ferritin | Free Kappa Light Chain | |
| | Haptoglobin | Rheumatoid Factor | |

| Description | Size | Cat No. | Type |
|--|-------------|----------|------|
| Protein Control (Level 1) | 1 x 1 ml | BXC0638A | LS |
| Protein Control (Level 2) | 1 x 1 ml | BXC0639A | LS |
| Protein Control Set (Level 3) | 1 x 1 ml | BXC0640A | LS |
| Protein Control Set (L1, L2 & L3) | 3 x 1 x 1ml | BXC0641A | LS |

Retinol Binding Protein Control



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Retinol Binding Protein Control | 1 x 1 ml | BXC0995A | LS |

SAA Control

- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.

| Description | Size | Cat No. | Type |
|--------------------|----------|----------|------|
| SAA Control | 3 x 1 ml | BXC0703A | Lyo. |

RF (Multi-Point) Calibrators



- This Calibrator is presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- The Calibrator is presented as a single level calibrator which can be diluted as necessary for calibrating RF Turbidimetric Assays.
- Values are assigned by in house methods and instruments.
- 100% human material designed for matrix conformity.
- Once opened the control is stable for a period of 30 days. when stored without contamination at 2-8 °C.

| Description | Size | Cat No. | Type |
|------------------------------------|-----------------------------|----------|------|
| RF (Multi-Point) Calibrator | Immunoturbidimetric 1 x 2ml | BXC0612A | LS |
| RF (Multi-Point) Calibrator | Immunoturbidimetric 3 x 2ml | BXC0612B | LS |

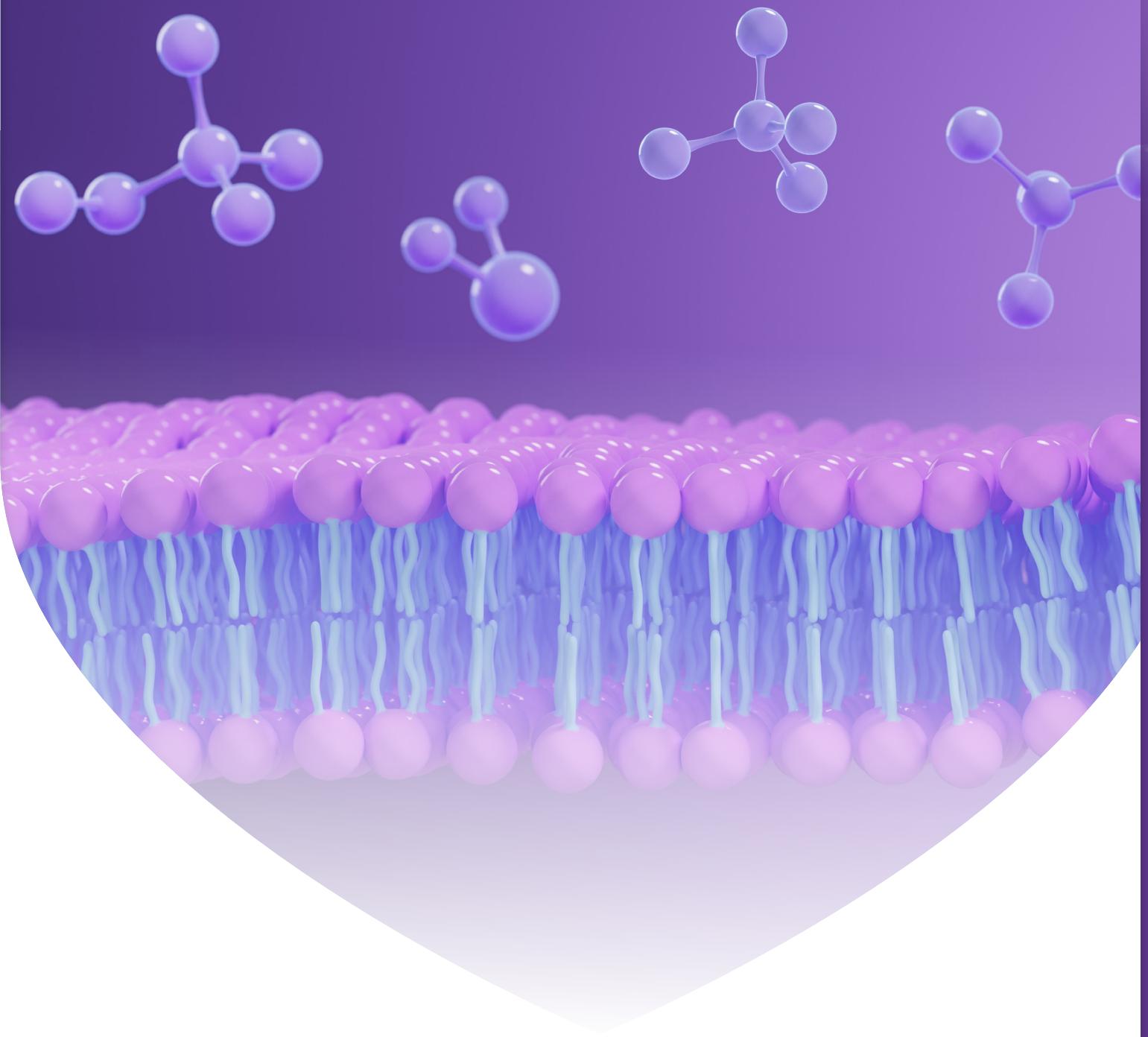
Specific Protein Calibrators



- Fortress Specific Protein Calibrator is a single level multi-analyte calibrator for use in automated systems with auto dilution facility.
- Fortress Specific Protein Calibrator set is a multi analyte multi level calibrator set for calibrating protein assays.
- Both the Calibrators are presented in a liquid stable format and is stable up to expiry when stored at 2-8 °C.
- 100% Human material designed for matrix conformity.
- Once opened, the calibrator is stable (Ready-to-use) for a period of 30 days when stored without contamination at 2-8 °C.

| Analytes | | | |
|--------------------------|-----------------------|-------------------------|-------------------------|
| Albumin | CRP | IgA | Lambda Light Chains |
| Alpha-1 Acidglycoprotein | C1q Inactivator | IgG | Prealbumin |
| Alpha-1 Antitrypsin | C1 Esterase Inhibitor | IgM | Free Lambda Light Chain |
| Alpha-2 Macroglobulin | Ceruloplasmin | IgE | Transferrin |
| ASO | Complement C3 | Kappa Light Chains | Total Protein |
| Antithrombin-III | Complement C4 | Retinol Binding Protein | |
| Beta-2-Microglobulin | Ferritin | Free Kappa Light Chain | |
| | Haptoglobin | Rheumatoid Factor | |

| Description | Size | Cat No. | Type |
|--|--------------|----------|------|
| Specific Protein Calibrator | 1 x 1 ml | BXC0644A | LS |
| Specific Protein Calibrator Set | 6 x 1 x 1 ml | BXC0646A | LS |



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SECTION 15
LIPIDS

Lipid Controls

Lipid controls are essential in diagnostics for accurately measuring lipid levels, such as cholesterol and triglycerides, in biological samples. These controls consist of standardized samples with known lipid concentrations, which validate the performance of assays used in lipid testing.

By incorporating lipid controls, laboratories ensure the reliability and precision of test results, which are crucial for diagnosing and managing conditions like hyperlipidemia and cardiovascular diseases. Regular use of these controls helps identify potential issues with reagents or instruments, ultimately supporting effective patient management and enhancing the overall quality of healthcare through accurate lipid profiling. The Fortress Lipid Controls are lyophilised for enhanced stability and are suitable for automated and semi-automated systems. The multi-analyte controls offer test menu consolidation. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Glycerol Control



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|------------------|----------|----------|------|
| Glycerol Control | 2 x 5 ml | BXC0278A | LS. |

HDL/LDL Calibrators



- Fortress HDL/LDL Cholesterol Calibrator is presented in a Lyophilised format for enhanced stability, stable up to expiry at 2-8 °C.
- Once opened and reconstituted the control is stable for 7 days at 2-8 °C, or 30 days at -20 °C.
- 100% human material designed for matrix conformity.

| Analytes | | | |
|--------------------------|----------|--------------------------|------|
| HDL Cholesterol (Direct) | | LDL Cholesterol (Direct) | |
| Description | Size | Cat No. | Type |
| HDL/LDL Calibrator | 3 x 1 ml | BXC0315D | Lyo. |
| HDL/LDL Calibrator | 1 x 1 ml | BXC0315E | Lyo. |

Lipid Controls



- The Fortress Lipid Controls are intended for monitoring accuracy and precision.

| Analytes | | | |
|---|--------------|---|--|
| Apolipoprotein A1 Apolipoprotein B Cholesterol | | HDL Cholesterol (Precipitation) HDL Cholesterol (Direct) LDL Cholesterol (Direct) | LDL Cholesterol (Precipitation) & Triglycerides |
| Description | Size | Cat No. | Type |
| Lipid Control Level 1 (Cholesterol, Triglycerides, APO A1, APO B, HDL, LDL) | 3 x 1 ml | BXC0317A | Lyo. |
| Lipid Control Level 2 (Cholesterol, Triglycerides, APO A1, APO B, HDL, LDL) | 3 x 1 ml | BXC0330A | Lyo. |
| Lipid Control Level 3 (Cholesterol, Triglycerides, APO A1, APO B, HDL, LDL) | 3 x 1 ml | BXC0316A | Lyo. |
| Lipid Control Set (TRI-LEVELS) (Cholesterol, Triglycerides, APO A1, APO B, HDL, LDL) | 3 x 1 x 1 ml | BXC0350A | Lyo. |



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SECTION 16
MATERNAL
SCREENING

Maternal Screening Controls

Maternal screening controls are essential in diagnostics for accurately assessing the health of pregnant individuals and identifying potential risks to the developing fetus. These controls consist of standardised samples with known concentrations of biomarkers, such as hormones and proteins, used to validate the performance of screening assays. By incorporating these controls, laboratories ensure the reliability and accuracy of test results, which are crucial for detecting conditions like gestational diabetes, preeclampsia, and chromosomal abnormalities, thereby informing timely clinical interventions.

The role of maternal screening controls also extends to maintaining quality assurance in laboratory processes, ensuring consistent and reproducible results across different tests. Reliable maternal diagnostics are critical for guiding prenatal care and enabling informed decision-making for expectant parents. Regular use of these controls helps identify any potential issues with reagents or equipment, ultimately supporting effective patient management and improving health outcomes for both mothers and their babies. The Fortress Maternal Screening Controls are available in a lyophilised format offering enhanced stability and are 100% human serum based to negate matrix effects.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Anti-Mullerian Hormone (AMH) Calibrators & Controls

- Lyophilised for long shelf life, stable to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8°C.
- Compatable with all AMH assays.

| Description | Size | Cat No. | Type |
|--|--|----------|------|
| Anti-Mullerian Hormone (AMH) Calibrators & Control Set | Calibrator Set: 2 x 1x0.5ml ; Control Set: 2x1x0.5ml | BXC0999A | Lyo. |

Maternal Screening Control

For screening of Down's syndrome & Spina Bifida compatible for use on most clinical chemistry systems including immunoassay systems.

- Screening Controls are multi analyte controls intended for use in monitoring accuracy and precision for assays used in first and second trimester screening of Downs Syndrome and Spina Bifida.
- The Controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- Reconstituted stability of 7 days at 2-8 °C.
- 100% human serum.

| Analytes | | |
|----------------------|---------------------|-----------------------------------|
| AFP Free beta hCG | Inhibin A PAPP-A | Total hCG Unconjugated Estriol |

| Description | Size | Cat No. | Type |
|--------------------------------------|--------------|----------|------|
| Maternal Screening Control (Level 1) | 2 x 1 ml | BXC0695A | Lyo. |
| Maternal Screening Control (Level 2) | 2 x 1 ml | BXC0695B | Lyo. |
| Maternal Screening Control (Level 3) | 2 x 1 ml | BXC0695C | Lyo. |
| Maternal Screening Control Tri-Level | 3 x 1 x 1 ml | BXC0699A | Lyo. |

PAPP-A & f-beta-hCG Controls

- The Controls are provided in a Lyophilised format stable up to expiry at 2-8 °C.
- 100% human serum.
- Reconstituted stability of 7 days at 2-8 °C.

| Description | Size | Cat No. | Type |
|---------------------------------------|------------|----------|------|
| PAPP-A & f-beta-hCG Control (Level 1) | 1 x 0.5 ml | BXC0337A | Lyo. |
| PAPP-A & f-beta-hCG Control (Level 2) | 1 x 0.5 ml | BXC0338A | Lyo. |
| PAPP-A & f-beta-hCG Control (Level 3) | 1 x 0.5 ml | BXC0339A | Lyo. |
| PAPP-A Control | 1 x 0.5 ml | BXC0240A | Lyo. |



Pediatric Control

- L
- R
- C

| Description | Details | Size | Cat No. | Type |
|--------------------|--|---------|----------|------|
| Paediatric Control | ALP, Bilirubin, Calcium, Chloride, Magnesium, In, Phosphorous, Potassium, Sodium | 3 x 1ml | BXC0807A | Lyo. |

Pre-eclampsia

Pre-eclampsia is a disorder of pregnancy that is associated with new-onset hypertension most often after 20 weeks' gestation and frequently near term. During the 2nd and 3rd trimesters soluble fms-like tyrosine kinase 1 and Placental Growth Factor (sFlt-1/PIGF) are both predictive and diagnostic for pre-eclampsia. It has been shown that increased levels of sFlt-1 and decreased levels of PIGF in maternal serum can predict the subsequent onset of pre-eclampsia..

Determining serum PIGF concentration, used as a single marker, or sFlt-1 and PIGF, used as a ratio, improve the clinical management and decision making (risk stratification) with women showing signs and symptoms of pre-eclampsia.

PIGF Testing will be valuable:

- For testing women with signs and symptoms of pre-eclampsia after week 20 of gestation
- To help Rule-out and Rule-in suspected pre-eclampsia
- To monitor women that are at high risk for pre-eclampsia
- To confirm clinical suspicion of pre-eclampsia with symptomatic women and/or to confirm unclear diagnosis of pre-eclampsia
- Serum concentrations of sFlt-1 and PIGF can differentiate healthy women from women with pre-eclampsia. Changes in sFlt-1 and PIGF levels reflect the severity of the disease.

PIGF as a single marker or sFlt-1/PIGF ratio. PIGF alone compared to sFlt-1/PIGF ratio for pre-eclampsia rule-in and rule-out has a comparable performance, and both options are equally recommended for clinical use. In addition to sFlt-1/PIGF ratio, PIGF alone, with concentration based cut-offs, could provide more simpler and affordable alternative to dual biomarker testing. Using PIGF has additional advantages. Studies have shown that PIGF is a good marker (decreased serum PIGF level) for identifying pregnancies with placental insufficiency including fetal growth restriction and/or stillbirth

PIGF Controls



For screening of Down's syndrome & Spina Bifida compatible for use on most clinical chemistry systems including immunoassay systems.

| Description | Details | Size | Cat No. | Type |
|--|------------------|----------|----------|------|
| Placental Growth Factor (PIGF) Control Level-1 | Target: 30pg/ml | 3 x 2 ml | BXC0700A | LS. |
| Placental Growth Factor (PIGF) Control Level-2 | Target: 100pg/ml | 3 x 2 ml | BXC0700B | LS. |
| Placental Growth Factor (PIGF) Control Level-3 | Target: 600pg/ml | 3 x 2 ml | BXC0700C | LS. |

Pre-eclampsia Control



| Description | Details | Size | Cat No. | Type |
|-------------------------------|--|----------|----------|------|
| Pre-eclampsia Control Level-1 | s-FLT-1 (soluble fms-like tyrosine Kinase-1) | 3 x 1 ml | BXC0704A | Lyo. |
| Pre-eclampsia Control Level-2 | s-FLT-1 (soluble fms-like tyrosine Kinase-1) | 3 x 1 ml | BXC0704B | Lyo. |



SECTION 17

Pre-Eclampsia Controls

Pre-Eclampsia Controls

Pre-eclampsia is a disorder of pregnancy that is associated with new-onset hypertension most often after 20 weeks' gestation and frequently near term. During the 2nd and 3rd trimesters sFlt-1 and PLGF are both predictive and diagnostic for pre-eclampsia. It has been shown that increased levels of sFlt-1 and decreased levels of PLGF in maternal serum can predict the subsequent onset of pre-eclampsia.

Determining serum PLGF concentration, used as a single marker, or sFlt-1 and PLGF, used as a ratio, improve the clinical management and decision making (risk stratification) with women showing signs and symptoms of pre-eclampsia. (Lecarpentier et al 2016; Annals of Endocrinology; Zeisler et al, 2016; New England Journal of Medicine)

PLGF Testing will be valuable:

- For testing women with signs and symptoms of pre-eclampsia after week 20 of gestation
- To help Rule-out and Rule-in suspected pre-eclampsia
- To monitor women that are at high risk for pre-eclampsia
- To confirm clinical suspicion of pre-eclampsia with symptomatic women and/or to confirm unclear diagnosis of pre-eclampsia
- Serum concentrations of sFlt-1 and PLGF can differentiate healthy women from women with pre-eclampsia. Changes in sFlt-1 and PLGF levels reflect the severity of the disease.

PLGF as a single marker or sFlt-1/PLGF ratio. PLGF alone compared to sFlt-1/PLGF ratio for pre-eclampsia rule-in and rule-out has a comparable performance, and both options are equally recommended for clinical use. In addition to sFlt-1/PLGF ratio, PLGF alone, with concentration based cut-offs, could provide more simpler and affordable alternative to dual biomarker testing. Using PLGF has additional advantages. Studies have shown that PLGF is a good marker (decreased serum PLGF level) for identifying pregnancies with placental insufficiency including fetal growth restriction and/or stillbirth. (Giblin et al 2020; Pregnancy Hypertension; Sherrell et al 2018; Eur. J. Obstet Gynecol Reprod Biol.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

PRE-ECLAMPSIA CONTROLS



- Liquid Frozen format for convenience and longer shelf life.
- Human Based Material.
- True Third Party control providing unbiased assessment of performance.
- Open Vial stability of 14 days at 2° to 8°C. Stable for 1 year when stored unopened at 2° to 8°C.
- Placental Growth Factor (PLGF) CONTROLS LEVEL-2 & LEVEL-3
- SHORT-TERM PREDICTION and AID IN THE DIAGNOSIS OF PRE-ECLAMPSIA MANAGEMENT (11-13 Week Gestation)

| HIGH Concentration | MEDIUM Concentration | LOW Concentration |
|------------------------|-----------------------|-----------------------|
| ≥ 150pg/ml | 50-150 pg/ml | <50pg/ml |
| RULE OUT PRE-ECLAMPSIA | SHORT-TERM PREDICTION | RULE-IN PRE-ECLAMPSIA |

| Description | Size | Cat No. | Type |
|-------------------------------|----------|----------|---------------|
| PRE-ECLAMPSIA CONTROL LEVEL-2 | 5 x 2 ml | BXC0700B | Liquid Frozen |
| PRE-ECLAMPSIA CONTROL LEVEL-3 | 5 x 2 ml | BXC0700C | Liquid Frozen |



18

SECTION 18
**NEONATAL
SCREENING**

Neonatal Screening Controls

Neonatal screening controls are essential in diagnostics for ensuring the accuracy and reliability of tests that detect metabolic and genetic disorders in newborns, enabling timely interventions that can prevent serious health issues and improve long-term outcomes.

The Fortress Neonatal Screening Controls are dried blood spot (DBS) which ensures accurate, reliable and repeatable results.

BCAA (Leucine) Calibrators & Controls

| Description | Size | Cat No. | Type |
|---|----------------|----------|------|
| BCAA (Leucine) Calibrator | 2 x 1 Disc | BXC0067A | Disc |
| BCAA (Leucine) (Level 1) | 2 x 1 Disc | BXC0068A | Disc |
| BCAA (Leucine) (Level 2) | 2 x 1 Disc | BXC0068B | Disc |
| BCAA (Leucine) (Level 3) | 2 x 1 Disc | BXC0068C | Disc |
| BCAA (Leucine) (Level 4) | 2 x 1 Disc | BXC0068D | Disc |
| BCAA (Leucine) (Control Set) (4 Levels) | 4 x 1 x 2 Disc | BXC0069A | Disc |

Dried Bloodspot Calibrators on Filter Paper for Neonatal Screening

| Description | Size | Cat No. | Type |
|--|----------------|----------|------|
| Dried Bloodspot Calibrators on filter paper for Neonatal Screening | 4 x 1 x 1 Disc | BXC0059A | Disc |

G-6-PDH Controls



- Values assigned by reference Laboratories in Europe.
- Stable to expiry at 2-8 °C.
- Reconstituted stability of 5 days at 2-8 °C.
- Typical Levels:
G-6-PDH Deficient Control : 100 - 200 U/L.
G-6-PDH Normal Control : 900 - 1400 U/L.

| Description | Size | Cat No. | Type |
|-----------------------------|----------|----------|------|
| G-6-PDH Control (Normal) | 1 x 1 ml | BXC0573B | Lyo. |
| G-6-PDH Control (Deficient) | 1 x 1 ml | BXC0572B | Lyo. |

PKU Calibrators & Controls

4 Levels of Phenylalanine.

| Description | Size | Cat No. | Type |
|----------------------------|----------------|----------|------|
| PKU Calibrator | 2 x 1 Disc | BXC0064A | Disc |
| PKU Control (Level 1) | 2 x 1 Disc | BXC0065A | Disc |
| PKU Control (Level 2) | 2 x 1 Disc | BXC0065B | Disc |
| PKU Control (Level 3) | 2 x 1 Disc | BXC0065C | Disc |
| PKU Control (Level 4) | 2 x 1 Disc | BXC0065D | Disc |
| PKU Control Set (4 Levels) | 4 x 1 x 2 Disc | BXC0066A | Disc |

Total Galactose Calibrators & Controls

| Description | Size | Cat No. | Type |
|--|---------|----------|------|
| Total Galactose Calibrator | 1 x 1ml | BXC0060A | LS. |
| Total Galactose Control (Level 1) | 1 x 1ml | BXC0061A | LS. |
| Total Galactose Control (Level 2) | 1 x 1ml | BXC0061B | LS. |
| Total Galactose Control (Level 3) | 1 x 1ml | BXC0061C | LS. |
| Total Galactose Control (Level 4) | 1 x 1ml | BXC0061D | LS. |
| Total Galactose Control Set (4 Levels) | 1 x 1ml | BXC0062A | LS. |



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SECTION 19
PAEDIATRIC
SCREENING

Paediatric Screening Control

Paediatric screening controls are crucial in ensuring early detection of health conditions and developmental issues in children, which allows for timely interventions that can significantly improve long-term outcomes. By identifying potential problems before symptoms appear, screenings provide an opportunity to prevent complications and enable treatments that can mitigate the impact of various disorders.

Early detection is particularly important for conditions like metabolic disorders, which, if untreated, can lead to severe consequences, but are manageable when caught early. The importance of paediatric screening also lies in its ability to support families in understanding and addressing their child's health needs. Regular screenings provide parents with reassurance and guidance, helping them monitor their child's development and identify any potential issues early on. This proactive approach reduces the risk of delayed diagnosis, which can lead to more complex and costly treatments in the future. By focusing on preventive care and early intervention, paediatric screening controls contribute to better health outcomes, reduced healthcare burdens, and improved quality of life for both children and their families.

The Fortress Paediatric Control is lyophilised for enhanced stability and ensures accuracy and precision. The controls are supplied with instrument and method specific assigned values.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Paediatric Control



- The Control is supplied in a Lyophilised format with a shelf life of 2 years when stored at 2-8°C.
- Reconstituted stability of 5 days at 2-8 °C.
- Excellent for clinical decision making.

Analytes

| | | | |
|-----------------------------------|---------------------|-----------------------------------|---------------------|
| ALP Bilirubin (Total & Direct) | Calcium Chloride | Inorganic Phosphorus Magnesium | Potassium Sodium |
|-----------------------------------|---------------------|-----------------------------------|---------------------|

| Description | Size | Cat No. | Type |
|--------------------|----------|----------|------|
| Paediatric Control | 3 x 1 ml | BXC0807A | Lyo. |



20

SECTION 20
SPECIALITY
CONTROLS

Speciality Controls

Serum indices are crucial in diagnostics for providing valuable information about the concentrations of various substances in the blood, such as proteins, enzymes, and electrolytes, which are essential for evaluating overall health and diagnosing specific conditions. These indices, which often include measures like albumin, globulin, and total protein levels, help assess organ function, nutritional status, and the presence of inflammatory or pathological processes. By accurately measuring serum indices, healthcare providers can gain insights into a patient's health status, facilitating timely diagnosis and effective treatment planning.

The role of serum indices in diagnostics extends to maintaining quality assurance in laboratory practices, ensuring that test results are consistent and reliable across different assays and patient samples. Regularly utilising controls and standardised methods in serum index testing helps identify potential discrepancies, such as issues with reagents or instruments, thereby supporting accurate clinical decision-making. Overall, serum indices significantly enhance the quality of healthcare by providing essential diagnostic information that guides treatment strategies and improves patient outcomes.

The Fortress Serum Indices Controls are designed to monitor the ability of an instrument to accurately measure lipaemia, icterus and haemolysis (LIH) in specimens. The controls are 100% human serum based to negate matrix effects and are compatible with a variety of clinical chemistry analysers.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Serum Indices (LIH)



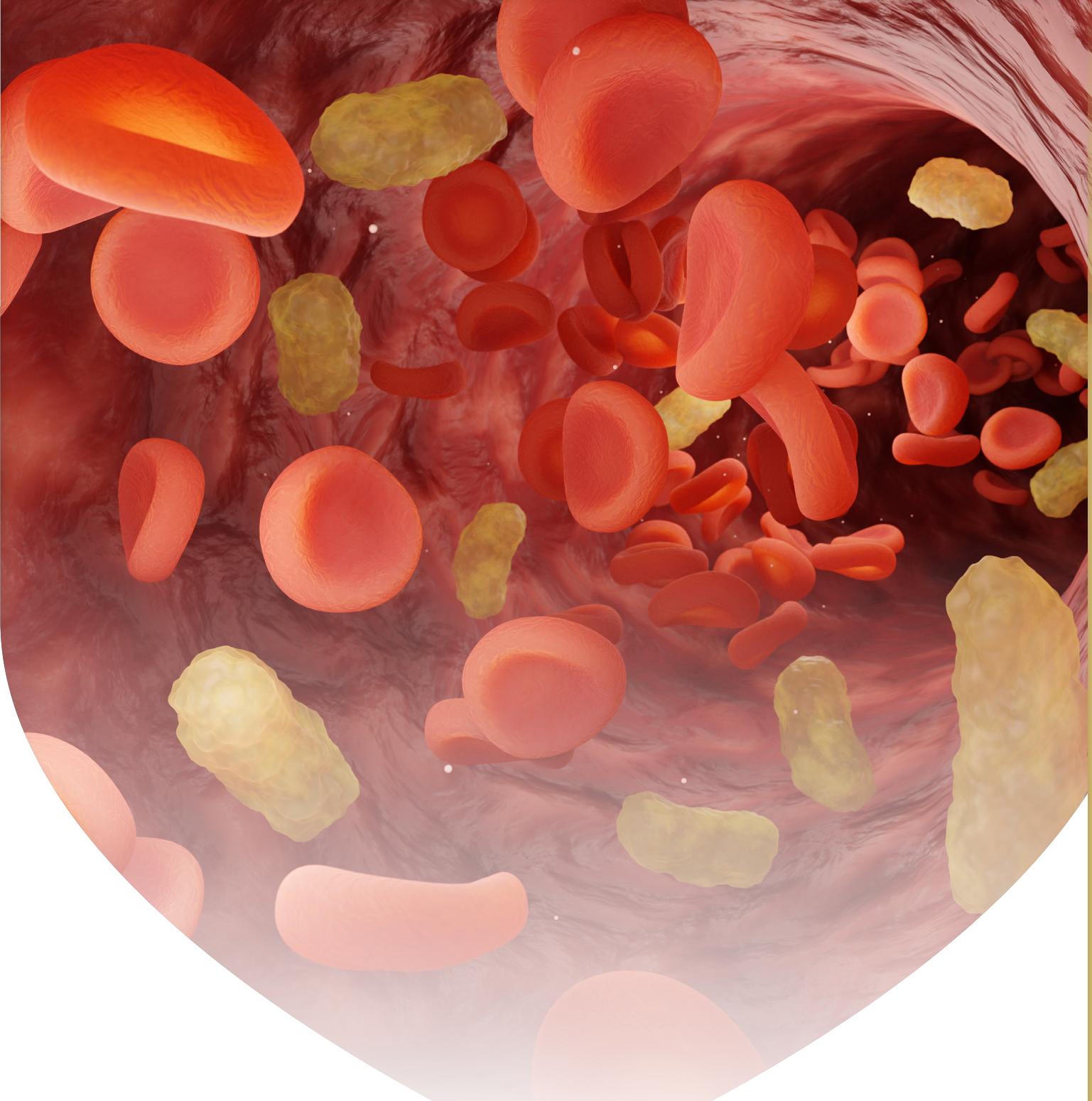
- Available in lyophilised and liquid stable formats.
- 100% Human based
- Stable to expiry date at 2-8°C.
- Reconstituted stability of 14 days at 2-8 °C.
- 4 levels available.

Analytes

| Lipemia | Icterus | Haemolysis | |
|----------------------------|--|------------|--------------|
| Description | Details | Cat No. | Size |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599E | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599D | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599C | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599B | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised For Beckman Coulter Series | BXC0599A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600E | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600D | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600C | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600B | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Beckman Coulter Series | BXC0600A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604E | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604D | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604C | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604B | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Roche Series | BXC0604A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605F | 3 x 4 x 5 ml |

| Description | Details | Cat No. | Size |
|---------------------|---------------------------------|----------|--------------|
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605E | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605D | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605C | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605B | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Roche Series | BXC0605A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606E | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606D | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606C | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606B | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Abbott Series | BXC0606A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607E | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607D | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607C | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607B | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Abbott Series | BXC0607A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608E | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608D | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608C | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608B | 4 x 5 ml |
| Serum Indices (LIH) | Lyophilised for Vitros Series | BXC0608A | 4 x 1 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609F | 3 x 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609E | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609D | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609C | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609B | 4 x 5 ml |
| Serum Indices (LIH) | Liquid Frozen For Vitros Series | BXC0609A | 4 x 1 x 5 ml |





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SECTION 21

THALASSAEMIA

Thalassaemia Controls

Thalassemia controls are essential in diagnostics for accurately detecting and managing thalassemia, a group of inherited blood disorders characterised by abnormal hemoglobin production. These controls consist of standardised samples with known hemoglobin patterns and genetic markers, utilised to validate the performance of diagnostic assays such as hemoglobin electrophoresis and molecular testing. By incorporating these controls, laboratories can ensure the reliability and accuracy of test results, facilitating early diagnosis and appropriate management of thalassemia to prevent complications like anemia and organ damage.

Additionally, thalassemia controls play a crucial role in maintaining quality assurance within laboratory testing processes, ensuring that results are consistent and reproducible across different assays and platforms. Reliable diagnostics are critical for guiding treatment decisions, including the need for blood transfusions or iron chelation therapy, and for providing informed family planning options for affected individuals. Regular use of these controls helps identify any potential issues with reagents or instruments, ultimately supporting effective patient management and enhancing health outcomes for those with thalassemia and their families.

The Fortress Thalassaemia Controls are designed to monitor the accuracy and precision of haemoglobin variant measurements associated with thalassaemia.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Thalassaemia Controls



- Designed for monitoring accuracy and precision of Haemoglobin Variant measurements associated with Thalassaemia.
- The controls are supplied in a Lyophilised format stable up to expiry at 2-8 °C.
- 100% Human blood.

Analytes

| Heamoglobin F | HPLC Haemoglobin A2 | Haemoglobin S | | |
|---|--|---------------|----------|------|
| Description | Details | Size | Cat No. | Type |
| Thalassaemia (Alpha & Beta) Control (Level 1) | For use on all major systems & Methods including HPLC & Immunoassay , HbA2, HbF, HbS | 2 x 0.5ml | BXC0665A | LS. |
| Thalassaemia (Alpha & Beta) Control (Level 2) | For use on all major systems & Methods including HPLC & Immunoassay , HbA2, HbF, HbS | 2 x 0.5ml | BXC0665B | LS. |
| HbA2 Control Set | HPLC Haemoglobin A2, Haemoglobin F, Haemoglobin S (HPLC SYSTEMS) | 2 x 2 x 0.5ml | BXC0778A | LS. |



22

SECTION 22
THERAPEUTIC
DRUGS

Therapeutic Drug Controls

Therapeutic drug controls are crucial in diagnostics for ensuring the accuracy and reliability of tests that measure drug levels in the bloodstream, which is essential for optimising pharmacotherapy and ensuring patient safety. These controls consist of standardised samples with known concentrations of specific therapeutic drugs, used to validate the performance of assays such as immunoassays and chromatography. By incorporating these controls, laboratories can monitor assay precision and detect any discrepancies, thereby minimising the risk of subtherapeutic or toxic drug levels that could lead to ineffective treatment or adverse reactions.

Furthermore, the role of therapeutic drug controls extends to maintaining quality assurance in laboratory practices, ensuring consistent and reproducible results across different testing environments. Reliable therapeutic drug monitoring is vital for guiding clinical decisions, adjusting medication dosages, and preventing drug interactions. Regular use of these controls helps identify potential issues with reagents or equipment, ultimately supporting effective patient management and improving health outcomes. Overall, therapeutic drug controls significantly enhance the quality of healthcare by providing accurate diagnostic information that informs treatment strategies and optimises patient care.

The Fortress Therapeutic Drug Controls are manufactured from 100% human serum to negate matrix effects and are lyophilised for enhanced stability.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Therapeutic Drug Monitoring



- The Fortress Therapeutic Drug Monitoring controls are intended for checking accuracy and precision.
- The controls are presented as multi analyte, lyophilised controls stable up to expiry at 2-8 °C.
- Reconstituted stability of 14 days when stored at 2-8 °C or 60 days at -20 °C.
- 100% Human serum designed for matrix conformity.

Analytes

| | | | | |
|---|--|--|---|-----------------------------|
| Amikacin Caffeine Carbamazepine Cyclosporine | Digoxin Ethosuxamide Gentamicin Lithium | Methotrexate Paracetamol Phenobarbitone Phenytoin | Primidone Salicylate Theophylline Tobramycin | Valproic Acid Vancomycin |
|---|--|--|---|-----------------------------|

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Therapeutic Drug Monitoring (Level 1) | 5 x 5 ml | BXC0781A | Lyo. |
| Therapeutic Drug Monitoring (Level 2) | 5 x 5 ml | BXC0782A | Lyo. |
| Therapeutic Drug Monitoring (Level 3) | 5 x 5 ml | BXC0783A | Lyo. |



23

SECTION 23
URINE

Urine Controls

Urine controls are vital in diagnostics for ensuring the accuracy and reliability of tests that analyse urine samples, which are commonly used to evaluate kidney function, identify metabolic disorders, and screen for drugs or other substances. These controls include standardised samples with known concentrations of various analytes, such as glucose, protein, and specific gravity, which are utilised to validate the performance of assays like dipstick tests and urinalysis. By incorporating these controls, laboratories can monitor assay precision and identify inconsistencies, thereby reducing the risk of incorrect results that could lead to misdiagnosis or inappropriate treatment.

Moreover, urine controls are crucial for maintaining quality assurance in laboratory procedures, ensuring consistent and reproducible results across different assays and platforms. Reliable urine diagnostics are essential for guiding clinical decision-making, particularly in diagnosing conditions such as urinary tract infections, diabetes, and renal diseases. Regular use of these controls helps detect potential issues with reagents or equipment, ultimately promoting effective patient management and improving health outcomes. Overall, urine controls significantly contribute to healthcare quality by providing reliable diagnostic information that informs treatment strategies and enhances patient care.

The Fortress Urine Controls are manufactured from 100% human serum to negate matrix effects and are available in both lyophilised and liquid stable formats offering flexibility to laboratories.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Citrate (Urinary) Calibrators & Controls



- The controls are presented in a Liquid format and are stable up to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|---|----------|----------|------|
| Citrate (Urinary) Calibrator [200mg/L] | 2 x 1 ml | BXC0136A | LS |
| Citrate (Urinary) Control (Level 1) [50mg/L] | 2 x 1 ml | BXC0137A | LS |
| Citrate (Urinary) Control (Level 2) [600mg/L] | 2 x 1 ml | BXC0139A | LS |

Microalbumin Calibrators & Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.
- 100% Human urine

| Description | Size | Cat No. | Type |
|--------------------------------|----------|----------|------|
| Microalbumin Calibrator Series | 5 x 1 ml | BXC0329A | LS |
| Microalbumin Control (Level 1) | 2 x 1 ml | BXC0328A | LS |
| Microalbumin Control (Level 2) | 2 x 1 ml | BXC0328B | LS |

Oxalate Calibrators & Controls



- Liquid Stable (Ready-to-use) stable to expiry at 2-8 °C.
- Open vial stability of 30 days, at 2-8°C.

| Description | Size | Cat No. | Type |
|--|----------|----------|------|
| Oxalate (Urinary) Calibrator [0.5 mmol/L] | 1 x 5 ml | BXC0147A | LS |
| Oxalate (Urinary) Control (Level 1) [0.2 mmol/L] | 1 x 5 ml | BXC0148A | LS |
| Oxalate (Urinary) Control (Level 2) [0.7 mmol/L] | 1 x 5 ml | BXC0149A | LS |



Urine Assayed Controls

- Fortress Urine assayed controls are intended for monitoring precision and accuracy for Urine chemistry assays.
- The controls are presented as Lyophilised materials for increased stability, stable up to expiry at 2-8 °C.
- Values are assigned by reference laboratories in Europe.
- Reconstituted stability of 5 days 2-8 °C or 15 days at -20 °C.
- 100% human urine designed for matrix conformity.

Analytes

| | | | |
|----------|--------------|-----------------------|-----------|
| 5HIAA | Creatinine | Microalbumin | Potassium |
| Amylase | Dopamine | Norepinephrine | Protein |
| Calcium | Epinephrine | Normetanephrine | Sodium |
| Chloride | Glucose | Osmolality | Urea |
| Copper | Magnesium | Oxalate | Uric Acid |
| Cortisol | Metanephrine | Inorganic Phosphorous | VMA |

| Description | Size | Cat No. | Type |
|--|------------|----------|------|
| Urine Assayed Control (Level 1) | 10 x 10 ml | BXC0661A | Lyo. |
| Urine Assayed Control (Level 2) | 10 x 10 ml | BXC0661B | Lyo. |

Urine Strip Controls



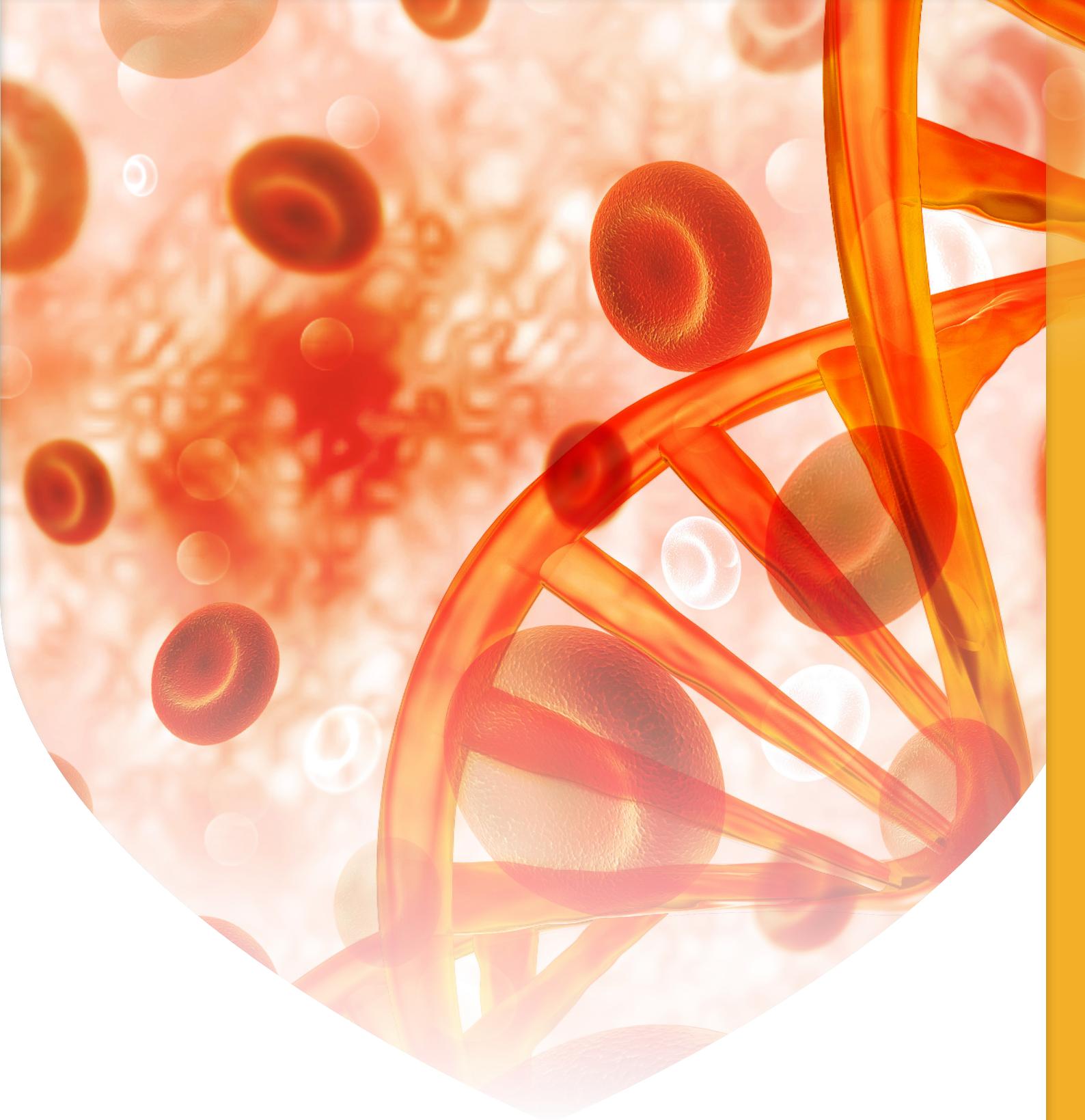
For Urine and hCG Strips Only

- Fortress urine Strip controls are designed for Urine and hCG Strips Only
- Values are assigned by in house methods.
- The Fortress Urine Strip controls are provided in a liquid stable format with a increased stability, stable up to expiry at 2-8 °C.
- Open vial stability of 30 days when stored without contamination at 2-8 °C.
- Compatible with all urine strips from a variety of manufacturers.
- Reconstituted stability of 5 days 2-8 °C or 15 days at -20 °C.
- 100% human urine designed for matrix conformity.

Analytes

| | | | |
|------------|------------|------------------|--------------|
| Albumin | Glucose | Nitrites | Urobilinogen |
| Bilirubin | hCG | pH | |
| Creatinine | Ketones | Protein | |
| Blood | Leukocytes | Specific Gravity | |

| Description | Size | Cat No. | Type |
|--|---------------|----------|------|
| Urine Strip Control (Level 1 & Level 2) | 2 x 3 x 12 ml | BXC0663A | LS |



24

SECTION 24
XANTHOCHROMIA

Xanthochromia Quality Controls

Xanthochromia is derived from the Greek word “xanthos,” meaning yellow. The term was first used to describe the pink or yellow pigmentation of cerebrospinal fluid (CSF). This colour change is attributed to varying concentrations of pigmented compounds such as oxyhaemoglobin, bilirubin, and methaemoglobin, which are typically the by-products of red blood cell degradation.

The term is now more widely accepted to represent the yellow colour created by the presence of bilirubin in the CSF. The presence of bilirubin, resulting in yellow discolouration of the CSF, is the contemporary definition of xanthochromia. It can be diagnosed by 2 methods: the traditional visualization or eye test, and the more sensitive and specific spectrophotometry. Detection of Xanthochromia has been facilitated since the 1950s by the spectrophotometric analysis of CSF but is usually possible by simple visual inspection of a sample held in front of a white piece of paper. Heme pigments can be found in CSF within 12 hours of subarachnoid bleeding, reach peak levels after 36–48 hours, and typically disappear over the next 7–10 days.

Bilirubin accumulation in CSF may occur via intrathecal conversion from haemoglobin-heme within macrophages and other leptomeningeal cells, or by passive diffusion from the circulation during periods of severe jaundice. In this latter setting, CSF is not usually stained until the total plasma bilirubin reaches 10–15 mg/dl. The presence of bilirubin in CSF is the main cause of xanthochromia associated with high spinal fluid protein content, usually found above levels of 150 mg/dl.

Fortress Diagnostics has been manufacturing Xanthochromia Controls for a number of years intended for use as a true third party control in monitoring the performance of Bilirubin and Oxyhaemoglobin in Cerebrospinal Fluid. Xanthochromia Controls are supplied as unassayed and are suitable for use as IQC with various UV spectrophotometers. It is designed to deliver a cost-effective control to users.



Lyophilised



Liquid Frozen



Liquid Stable



100% Human Serum



Assayed Target Values Provided

Xanthochromia Quality Control



- Lyophilised format for convenience and longer shelf life.
- Human Based Material.
- True Third Party control providing unbiased assessment of performance.
- Open reconstituted Vial stability of 2 days at 2° to 8°C. Stable for 1 year when stored unopened at 2° to 8°C.

Analytes

Bilirubin

Oxyhaemoglobin

| Description | Size | Cat No. | Type |
|--------------------------------|----------|----------|------|
| Xanthochromia Positive Control | 3 x 1 ml | BXC0355A | Lyo. |



25

SECTION 25

IQC & EQA PROGRAMMES



Seraqual 365: IQC Management Software

The Seraqual 365 IQC Management Software is a peer data QC programme designed for use with Seraqual Controls. It provides a cost effective and comprehensive package for labs who need to manage their daily QC activities on a centralized platform in real time.



SERAQUAL 365

IQC Management Software



**Simple, Easy to Use
Peer Comparison
Tool**



**Real Time Data
on a Centralised
Platform**

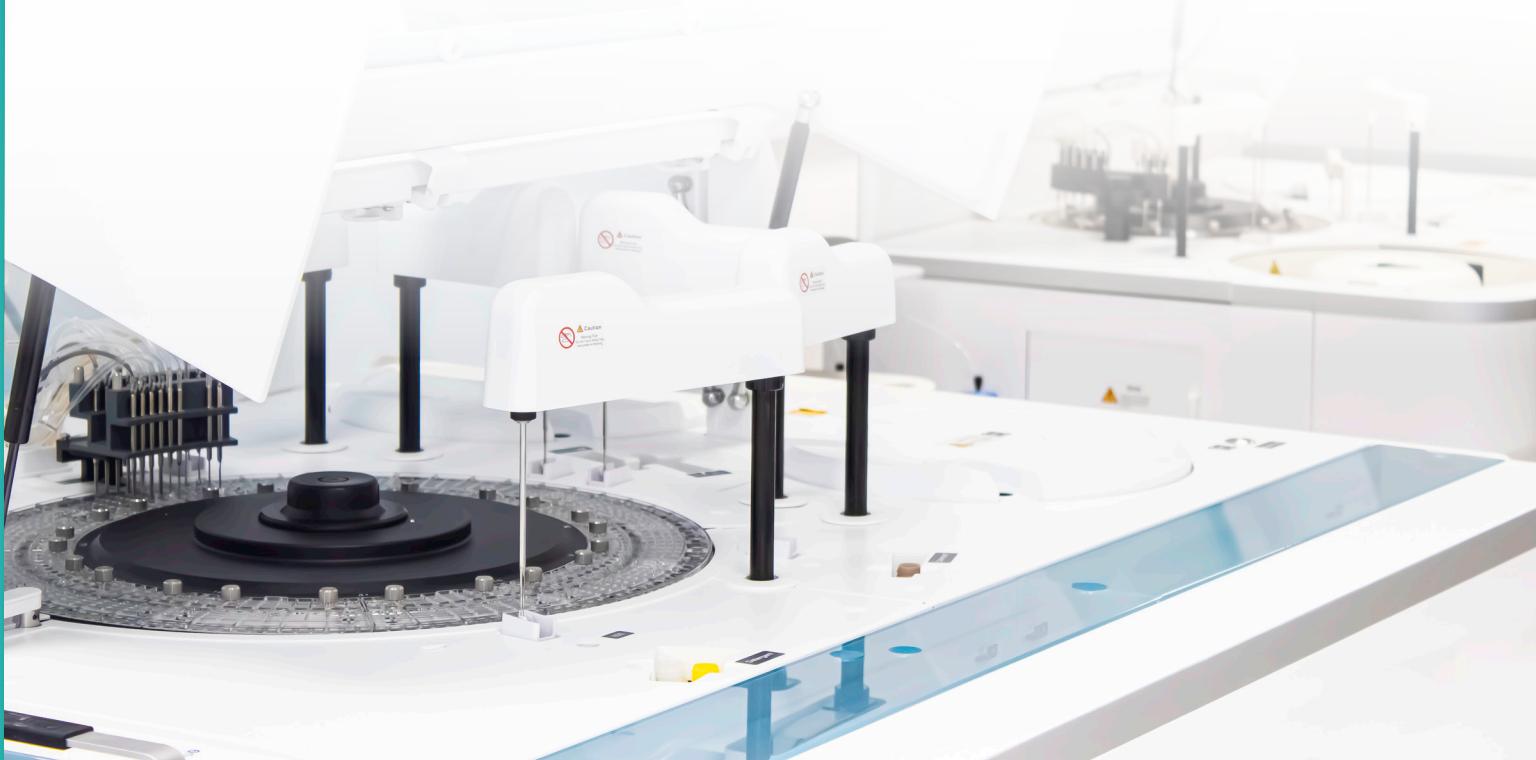


**Cost Effective &
Comprehensive QC Data Management
Software**

The system has a number of features to enhance data review and trouble shooting within a lab to include:

- **A dashboard interface** that presents a condensed panel of the features of the system showing options most frequented. It also flags any exceptions for review
- **A simple easy to use interface** that allow labs to configure and enter results easily with a need for minimal training
- **Interactive charts** for quick and easy performance review including Histogram and Levey –Jennings

- **Exceptions reports** so data from a specified date range can be reviewed quickly
- **Statistical Comparison Report** can be specified by date range at the instrument, method or all method level.
- **Peer Group Statistics** allowing you to compare your results with other labs using the same QC material
- **Advanced Statistical Analysis** that includes performance indicators such as Uncertainty of Measurement (UM), Bias, Total Error (TE) and Sigma Scores.





Ordering Information

| Description | Cycle | Cat No. | Size |
|--|--------------------------------------|----------|------|
| Seraqual 365 Internal Quality Assessment Programme | 1 Cycle = 12 Months (1 Year License) | SERAQ00P | |

Software Overview

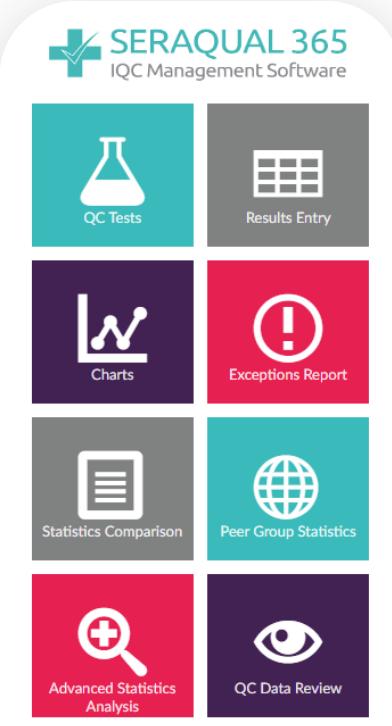
1

Dashboard

Presents a condensed panel of the features of the system showing options most frequented.

A full list of features that the system offers is available from the drop down at the top left hand corner.

It also flags any exceptions for review to allow rapid identification of any QC problems and allow quick and effective corrective action.



[Instructions for Use \(English Only\)](#)

2

QC Tests

| | | | | |
|----------------------------|---|----------------------------------|---------------------------|------------------|
| Instrument ID | Cobas | | | |
| Location | Chemistry Lab | | | |
| Instrument Name | Roche Cobas c311 | | | |
| Control Type | Clinical Chemistry | | | |
| Lots | HSN029 - HSE029 | | | |
| Show | <input checked="" type="radio"/> Current Assays | <input type="radio"/> All Assays | Add Assay | |
| Analyte | Method | Reagent Supplier | Unit | Temperature (°C) |
| Acid Phosphatase Prostatic | Naphthyl with Pentandiol | Roche Diagnostics | U/L | 37 |
| Bilirubin Direct | DCA | 3P Bioservice S.R.L. | μmol/L | 0 |
| CK | CK-NAC | ABX Horiba | U/L | 37 |

This option allows a lab to quickly see the instruments registered, the programmes and lots associated with these instruments and then the associated QC test.

Here a lab can also set the Target mean and SD of a test (cumulative, user defined or Seraqual 365 (targets available for selected assayed lots)).

3

Result Entry

A simple feature to allow easy manual addition of results.

An alarm is activated if a result entered violates a multi rule set.

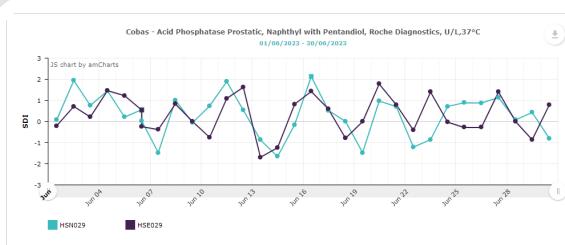
There are also indicators to show when a result has been edited, commented upon or reviewed.

| | | | |
|---|--|--|-----------------------------------|
| Assay | Acid Phosphatase Prostatic, Naphthyl with Pentandiol, Roche Diagnostics, U/L, 37°C | | <input type="checkbox"/> Current? |
| Target Mean/SD | HSN029 | Mean 0.0000 SD 0.000 | Mean 0.0000 SD 0.000 |
| Your Statistics | Results 192 | Results 192 | |
| | Mean 14.9812 SD 1.268 CV% 8.46 Bias% 0.00 | Mean 35.2177 SD 2.643 CV% 7.51 Bias% 0.00 | |
| Add Result | | | |
| ! Rule violation * Edited record ^ Comment ✓ Reviewed | | | |



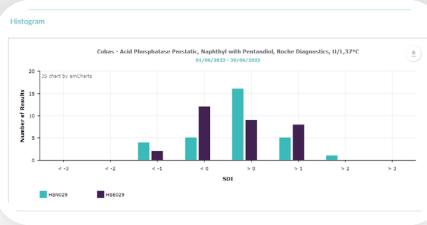
4

Charts



The Levey Jennings and Histograms interactive charts can be generated within a specific date range proving invaluable for identifying data shifts and trends.

The charts can be downloaded, saved, annotated and printed for the users convenience.



5

Exceptions Report

The Exceptions Report presents all results that have violated the multi rules set in a date range that can be specified.

Through colour coding it identifies the violated rules that are 'Alert' and those that are 'Reject'.

Any comments associated with a result are also detailed.

Exceptions Report

Cobas - Chemistry Lab - Roche Cobas c311

Acid Phosphatase Prostatic, Naphthyl with Pentandiol, Roche Diagnostics, U/L, 37°C

| DATE | TIME | OPERATOR | RESULT | SDI | RESULT | SDI |
|------------|----------|----------|---------------|--------|---------------|--------|
| 06/06/2023 | 11:06:38 | FD | 15.4000 10:x+ | 0.5583 | 36.4000 10:x+ | 0.5382 |

Bilirubin Direct, DCA, 3P Bioservice S.R.L., µmol/L

| DATE | TIME | OPERATOR | RESULT | SDI | RESULT | SDI |
|------------|----------|----------|-------------|--------|---------|--------|
| 07/06/2023 | 14:20:48 | FD | 8.2000 1.2s | 2.0474 | 25.5000 | 1.8610 |

6

Statistics Comparison Report

A worldwide and country comparison of statistics at either the Instrument, Method or All Method level is available in this report.

A date range can be specified.

This report includes performance indicators such as Mean, SD, CV%, Bias %, SDI and CVI.

Statistics Comparison Report

Comparison Level: Instrument

| LOT | INSTRUMENT | NO. OF RESULTS | | | MEAN | | | SD | | | CV% | | | MAPS | | | SDI | | | CVI | | |
|------------|------------------------------------|----------------|--------|--------|---------|---------|---------|-------|------|---------|-------|------|---------|-------|-----|---------|-------|-----|---------|-------|-----|---------|
| | | TYPE | NUMBER | NUMBER | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY |
| 198-01-008 | Roche Cobas c311 - Chemistry Lab 2 | 100 | 100 | 100 | 14.186 | 14.184 | 0.03 | 0.83 | 0.83 | 4.42 | 4.42 | 4.42 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| 198-02-008 | Roche Cobas c311 - Chemistry Lab 2 | 100 | 100 | 100 | 72.623 | 72.620 | 1.15 | 1.15 | 1.15 | 1.58 | 1.58 | 1.58 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| 198-03-006 | Roche Cobas c311 - Chemistry Lab 2 | 100 | 100 | 100 | 233.267 | 233.264 | 3.41 | 3.41 | 3.41 | 1.46 | 1.46 | 1.46 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |

Clinical Chemistry, Acid Phosphatase Prostatic, Naphthyl with Pentandiol, Roche Diagnostics, U/L, 37°C

| LOT | INSTRUMENT | NO. OF RESULTS | | | MEAN | | | SD | | | CV% | | | MAPS | | | SDI | | | CVI | | |
|--------|------------------------------------|----------------|--------|--------|--------|--------|---------|-------|------|---------|-------|------|---------|-------|-------|---------|-------|------|---------|-------|------|---------|
| | | TYPE | NUMBER | NUMBER | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY | WORLD | YOU | COUNTRY |
| HSE029 | Roche Cobas c311 - Chemistry Lab | 102 | 243 | 243 | 35.218 | 35.230 | 35.230 | 2.64 | 2.64 | 2.64 | 7.48 | 7.48 | 7.48 | -0.54 | -0.54 | 0.00 | 1.00 | 1.00 | 1.00 | 1.00 | 1.00 | |
| HSE029 | Roche Cobas c311 - Chemistry Lab 2 | 142 | 243 | 243 | 35.106 | 35.230 | 35.230 | 2.33 | 2.64 | 6.63 | 7.48 | 7.48 | 7.48 | -0.35 | -0.35 | -0.05 | 0.89 | 0.89 | 0.89 | 0.89 | 0.89 | |



7

Peer Group Statistics

A lab can select World or Country Statistics for a chosen Control Type and Lot.

The peer group can be at a number of different levels as seen in the image.

The report includes Mean, SD, CV% and the number of labs.

The screenshot shows a search interface for 'Show Statistics For' with 'World' selected. Below are filters for 'Control Type' (Clinical Chemistry) and 'Lot' (HSN055). To the right is a 'Peer Group' legend: Analyte (blue circle), Analyte/Method (orange circle), Analyte/Method/Instrument (green circle), Analyte/Method/Reagent Supplier (red circle), and Analyte/Method/Instrument/Reagent Supplier (purple circle). A table lists results for 'Peer Group' (ALT / GPT), 'SI Unit' (U/L), 'Results' (90, 87, 100), 'Mean' (27.9941, 17.0878, 146.7460), 'SD' (1.079, 17.252, 26.409), 'CV%' (3.94, 100.96, 18.00), and 'No. Labs' (2, 3, 2).

| Show Statistics For | | Peer Group | | | |
|--|--------------------|--|------|----------|--------|
| <input checked="" type="radio"/> World | | <input checked="" type="radio"/> Analyte | | | |
| <input type="radio"/> United Kingdom | | <input type="radio"/> Analyte/Method | | | |
| Control Type | Clinical Chemistry | Results | Mean | SD | CV% |
| Lot | HSN055 | U/L | 90 | 27.9941 | 1.079 |
| | | g/L | 87 | 17.0878 | 17.252 |
| | | U/L | 100 | 146.7460 | 26.409 |
| | | | | | 3.94 |
| | | | | | 100.96 |
| | | | | | 18.00 |
| | | | | | 2 |
| | | | | | 3 |
| | | | | | 2 |

8

Advanced Statistics Report

This report draws on a number of important statistical metrics that include Mean, SD, CV%, Uncertainty of Measurement (UM), Bias, TE, Sigma (BV) and Sigma (CLIA).

The report can be based at either the Instrument, Method or All Method Level and if required within a specified date range.

9

QC Data Review

A lab selects a date range (instrument, lot and assay selection is optional) and the report generated displays any results that have not yet been reviewed.

Results violating a multirule are highlighted according to their 'Alert' or 'Reject' status.

A reviewer has the ability to set all the results to reviewed or individually look at results and comment.

This function allow quick and easy identification of tests that may be problematic.

Additional Features

Programme available in English, Spanish, Chinese, Farsi and Arabic.

Co-ordinators have the ability to look at the Statistics Comparison Report and Advanced Statistical Analysis Report of the labs they are responsible for.

Instruction for Use available on the Software

Automatic deactivations of peer data to maintain the integrity of the data

For further information please contact admin@seraqual365.com



SEQAS: EQA Management Software

SEQAS is an EQA scheme that forms part of the Fortress Quality Control Platform. EQA helps to assure customers, such as physicians, patients, and health authorities, that the laboratory can produce reliable results. Individual laboratories can use EQA to identify problems in laboratory practices, allowing for appropriate corrective action. EQA participation will help to evaluate reliability of methods, materials, and equipment, and to evaluate and monitor training impact.



For laboratories performing public health-related testing, EQA can help to assure that results from different laboratories during surveillance activities are comparable. EQA participation is usually required for accreditation. Samples received for EQA testing, as well as the information shared by the EQA provider, are useful for conducting educational and professional development activities.

Participation in an external quality assessment program provides valuable data and information for the laboratory which:

- allows peer comparison of performance and results among different test sites;
- provides early warning for systematic problems associated with kits or operations;
- provides objective evidence of testing quality;
- indicates areas that need improvement;
- identifies training needs.



A fast easy-to-use data capture system



Data analysis that is easy to understand & interpret



Monthly cycles for a range of programmes



End of cycle reports



Certificates of registration

SEQAS Programmes

| Description | Cycle | Cat No. | Size |
|---|---------------------------------------|----------|----------------|
| SEQAS External Quality Assessment Programme | | SEQAS00P | |
| SEQAS Monthly Clinical Chemistry (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS001 | 1 x 12 x 5ml |
| SEQAS Monthly Immunoassay Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS002 | 1 x 12 x 1ml |
| SEQAS Haematology Programme (Apr-Mar) | 2 Cycles = 12 Months (1 Sample/Month) | SEQAS003 | 2 x 6 x 3ml |
| SEQAS Monthly HbA1c Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS004 | 1 x 12 x 0.5ml |
| SEQAS Monthly Coagulation Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS005 | 1 x 12 x 1ml |
| SEQAS Monthly Lipids Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS006 | 1 x 12 x 1ml |
| SEQAS Monthly Cardiac Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS007 | 1 x 12 x 2ml |
| SEQAS Monthly Blood Gas & Electrolytes Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS008 | 1 x 12 x 2ml |
| SEQAS Monthly Specific Protein Panel Programme (Jan-Dec) | 1 Cycle = 12 Months (1 Sample/Month) | SEQAS009 | 1 x 12 x 1ml |

Fortress Quality Control Inserts Portal

Download e-inserts for the Fortress Diagnostics Quality Controls & Calibrators range through our online portal.

Fortress Diagnostics are excited to launch the new Fortress QC Inserts Portal. The portal allows customers to easily search our database of inserts by product name, catalogue number or batch number in our easy-to-use filter tool. Inserts can be viewed online or downloaded in PDF format.

 insert.fortressdiagnostics.com



Terms & Conditions

1. General

All quotations made, all orders accepted, all goods sold, all service and advice rendered are subject to these conditions and to the exclusion of any previous conditions of purchase. Any variations to these must be expressly accepted by us in writing.

2. Specifications

We reserve the right to supply goods to the specification and/or design current at the date of dispatch. We cannot accept a request for goods as previously supplied as binding.

3. Admin & Handling Charge

An admin & handling charge of £25.00 will be added to all orders.

4. International Bank Charges

For international orders a £15.00 international bank charge will be added to all BACS payments unless the customer agrees to pay these charges at their end.

5. PayPal/Credit Card Transactions

We accept PayPal, credit card and debit card payments. There is a 3.5% PayPal processing fee added to all customer orders who choose to pay via PayPal this will be detailed on your invoice. This is the same charge that Fortress incur to receive this method of payment.

6. Prices

Although we take great care to ensure price stability, we reserve the right to change prices without notice. Goods will be invoiced at the prices valid on the date of confirmation of the Buyer's order. All prices given are exclusive of VAT unless otherwise stated.

Fortress Diagnostics cannot accept responsibility for typographical errors in pricing within our catalogues, advertising literature or quotations.

Prices quoted are "Ex Works" (Incoterms 2010). Freight, insurance and all other respective costs e.g. Certificate of origin, legalised and notarised documents will be invoiced separately.

7. Delivery

Goods are shipped or dispatched at Buyer's risk. Our standard dispatch dates are 21 days after orders are confirmed and paid in full (unless you have credit terms).

Delivery times quoted are to be treated as an estimate only and Fortress Diagnostics shall not be liable for any failure to deliver within such times whether a time for delivery be quoted or not. We shall not be held responsible for delays caused by anything beyond our reasonable control. Any special delivery requirements must be notified to us in writing at the time of placing the order.

We shall have the right at our discretion to make a reasonable charge for special handling and/or delivery.

The Seller is entitled to make delivery in instalments unless such delivery would be unreasonable or unless otherwise agreed upon and confirmed by the Seller in writing. In the case that a fixed period for delivery is agreed upon and the Seller is in default with the supply, the Buyer shall grant the Seller a reasonable additional period of time, normally of 4 weeks.

8. Order Additions

Any additions will result in a new order being created in line with our standard delivery terms. Where possible we will attempt to dispatch your order additions with your original order but cannot guarantee this.

9. Damage/Loss/Shortage

No claim for breakages or missing goods can be recognised unless notified to Fortress Diagnostics and the carriers within 72 hours of receipt of the goods. If damages or shortages are immediately apparent upon delivery please:

1. Notify the carrier when signing for receipt of the goods.
2. Advise Fortress Diagnostics customer services team as soon as possible.

In the case of non-delivery of a complete consignment notification must be received by us within 10 days of invoice date.

10. Return of Goods

Notification of returns must be made within 1 week of receipt of goods. Goods which have been received damaged or in error must be held in the correct storage conditions.

Do not return the goods until you contact our customer services team for a returned goods authorisation number. Clearly mark the authorisation number on the package to ensure your goods can be speedily processed.

You will appreciate that we cannot accept responsibility for loss or damage to goods being returned to us unless we arranged collection. If the mistake was ours there is of course no charge to you. However, if the goods were incorrectly ordered an administration and re-stocking charge of 25% of the invoice value excluding VAT is chargeable. Temperature controlled products incorrectly ordered will not normally be accepted for return.

11. VAT

We are required to charge VAT on all UK orders at the current VAT rate.

For organisations that are VAT exempt each order must be accompanied by an exemption certificate unless special arrangements have been made in writing. Under circumstances where a VAT exemption certificate does not accompany an order we are obliged by law to charge VAT. If subsequently you reclaim a VAT credit it must be completed within 30 days of invoice date.

12. Payment Terms

Payments are to be made within the agreed payment terms set with our customers. We may at our discretion charge interest at the rate of 5% above the base lending rate of Barclays Bank plc on all overdue accounts to the date of actual payment. Payment in advance or financial guarantees may be requested from customers who do not have an account.

13. Quotations

Quotations are valid for 30 days.

14. Cancellation

Orders may not be cancelled without our prior written agreement and may be subject to a cancellation charge. Standing orders must be cancelled in writing at least 8 weeks prior to what becomes the last shipment date.

15. Liability

Fortress Diagnostics' liability for any loss or damage suffered by you and arising by way of defects in the goods or otherwise, howsoever shall be limited to the invoice price of the goods in respect of or in relation to which loss or damage is claimed. Our liability under this clause shall be in lieu of any warranty or condition implied by law as to the quality or fitness for any particular purpose of the goods and save as provided.

16. Ownership

All goods remain the property of Fortress Diagnostics Limited until payment is received in full. The responsibility for insurance and care of goods, including 3rd party risks lies with the purchaser.

17. Health & Safety

All products sold by Fortress Diagnostics Limited, should be handled by qualified personnel, exercising care during handling, usage and disposal. For further information please contact Fortress Diagnostics Limited.

Control of Substances Hazardous to Health 2002 (COSHH)

All Fortress products are developed and designed for 'IN VITRO' use only.

COSHH safety data sheets are available for all products on request.



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