



13

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.

Analytes

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

Description	Size	Cat No.	Type
COVID-19 Anitgen 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 Toxoplasma Gondii IgG Rubella IgG CMV IgG HSV-1 IgG	HSV -2 IgG VZV IgG EBV IgG Syphilis IgG	IgM Toxoplasma Gondii IgM Rubella IgM CMV IgM HSV-1 IgM	HSV-2 IgM 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