

Quality Testing

Quality is at the core of everything we do, and BIOLOGOS is pleased to offer a wide range of standard tests across our product lines, as well as numerous specialty tests available upon your request. As an ISO 13485 and GMP certified facility, BIOLOGOS is well equipped to provide these tests across our product line, as well as offering a long-established partnerships with external testing providers.

Test	Description	Lead Time	Typical Product Categories	In House Test
Sterility (USP 71 or 9 CFR 113.26)	Sterility testing confirms that products are free from the presence of viable microorganisms. Sterility testing is very important for medical devices, pharmaceuticals, preparations, tissue materials and other materials that claim to be sterile or free from viable microorganisms. 9 CFR is the sterility testing method descrived by the FDA for liquid products, other than live vaccine, and is primarily used for non FDA regulated processes, such as reagent use USP-71 is the compendium standard for pharmaceutical and medical device testing of sterility.	3 Weeks	All Products	
Mycoplasma Assay (9 CFR 113.28)	Sterility testing confirms that products are free from the presence of viable microorganisms. Sterility testing is very important for medical devices, pharmaceuticals, preparations, tissue materials and other materials that claim to be sterile or free from viable microorganisms. 9 CFR is the sterility testing method descrived by the FDA for liquid products, other than live vaccine, and is primarily used for non FDA regulated processes, such as reagent use USP-71 is the compendium standard for pharmaceutical and medical device testing of sterility.	6 Weeks	All Serum, Select Liquid Media	
Viral Assay (9 CFR 113.47) Cytopathic/ Hemadsorbing Agents (9 CFR 113.46)	The combination of these two tests satisfy the requirements of 9 CFR 113.53, which outlines the requirement for animal origin blood products to be verified free of any viral contaminants. Viral testing is performed to the specific species of origin of the sample (i.e. porcine, equine, bovine).	5 Weeks	Serum, Trypsin	
рН	PH stands for Potential of Hydrogen. It refers to the hydrogen ion concentration in a solution. It is the measure of the acidity or alkalinity of a solution. The PH value ranges from 0 to 14 on a pH scale.	1 Day	All Products	Χ
Osmolality	Osmolality is a measure of how much one substance has dissolved in another substance. The greater the concentration of the substance dissolved, the higher the osmolality. Very salty water has higher osmolality than water with just a hint of salt.	1-2 Days	Serum, liquid media, salines, buffers	X
Hydrogen Peroxide Assay	A measure of the hydrogen peroxide content in a solution	7 days	Hydrogen Peroxide solutions	
Normality	Normality is a measure of concentration equal to the gram equivalent weight per liter of solution. Gram equivalent weight is the measure of the reactive capacity of a molecule. The solute's role in the reaction determines the solution's normality. Normality is also known as the equivalent concentration of a solution.	7 days	Hydrochloric Acid Solutions	X
Chemistry Profile	Blood chemistry package that provides data on key metabolic tests, such as protein, glucose, and metals analysis.	1-2 Days	All serum products	
Endotoxin	The Bacterial Endotoxins Test (BET) is an in vitro assay for detection and quantitation of bacterial endotoxins, a component of the cell wall of gram-negative bacteria Routine monitoring of water systems and incoming materials can help to ensure that the process does not contribute endotoxins to the final product.	1-2 Days (in-house)	Serum, liquid media, some salines (based on customer request)	X
Hemoglobin	A hemoglobin test measures the levels of hemoglobin in a serum sample. Hemoglobin is an indicator of quality of serum in regard to ruptured red blood cell components in the material.	1 Day	Serum	Х



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Specialty Tests	Description	Lead Time	Typical Products	In House Test
Particulate Analysis	Particulate analysis is a microscopic analysis of foreign particles within a solution. There are two thresholds of particulate sizes – 10 micrometers and 25 micrometers.	7-10 Days	Reagents	
Species ID	DNA Species identification of blood plasma used in serum.	7-10 Days	Serum	
M. Hyo Assay	Antibody test that detects the presence of Mycoplasma hyopneumoniae in a serum.	7 Days	Porcine Serum	
Seneca Valley A Viral Assay	Screen for the Seneca Valley A Virus	4 Weeks	Porcine Serum	
Porcine Circovirus Assay	Screen for Circiovirus	4 Weeks	Porcine Serum	