

FBS Quality Control Matrix for Test Methods

(For specifications, see the FBS section of the USP/EP)

Test	Reason
pH	This is part of the physiological environment (<i>reflects acidic or alkaline</i>) supporting cell viability, extremes in pH will affect cell growth and could result in cell death.
Osmolality	Reflects electrolyte and solute concentration. Numbers out of range can indicate material adulteration.
Total Protein	Quantity can be characteristic of bovine animal age. FBS has the lowest protein concentration
Endotoxin	Quantifies pyrogens from gram-negative bacterial contamination of raw serum. Low endotoxin concentration indicates care in collection and processing. Endotoxin is typically not removed by filtration and, as a mutagen, can affect cell growth characteristics.
Hemoglobin	Lower hemoglobin (Hb) indicates greater care during collection and serum processing. Higher Hb indicates cell lysis.
Electrophoretic Pattern	A qualitative test that shows the relationship of various globulins in serum.
Bacteria and Fungi/Sterility	Assurance that bacteria and fungi have been removed during manufacturing process. Bacteria and fungi are removed through filtration using 0.1µm pore sized filters providing a product suitable for cell culture applications.
Mycoplasma	A potential cell culture contaminant that can create metabolic problems in cell cultures. Serum filtered through triple 0.1µm pore sized filters will provide a high level of assurance of mycoplasma removal.
Virus Testing - Cytopathic Agents	Test for animal viruses such as Infectious Bovine Rhinotracheitis (IBR) that produce a cytopathic effect in the host cell. Evidence of cytopathic effect may include inclusion bodies, abnormal number of giant cells, or other cytopathologies indicative of cell abnormalities attributable to an extraneous agent.
Virus Testing - Hemadsorbing Agents	Detection of a hemagglutinin producing virus such as Parainfluenza Type 3 (PI3) is dependent upon selective attachment of erythrocytes onto the monolayer surface of infected tissue cultured cells.
Adventitious Virus Testing	Test consists of growth in cell culture followed by Immunofluorescent Assay (IFA) for several types of common bovine viruses such as Bovine Viral Diarrhea Virus (BVDV). Viruses are generally not removed by filtration. Gamma irradiation can provide good log reduction for certain adventitious agents while maintaining serum functionality.
Immunoglobulin G (IgG)	Immunoglobulin G (IgG) is a type of antibody characteristic of bovine animal age. Generally, IgG greater than 300µg/mL is associated with serum other than FBS. FBS has a very low gamma globulin fraction compared to other serum types.
Gamma Glutamyl Transferase (GGT)	A high level of Gamma Glutamyl Transferase (GGT) is an identifying marker for non-fetal serum. Anything over 10 IU is generally indicative of a non-fetal product.