

Quality Control Matrix for Test Methods and Specifications

| Test | Reason |
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| pH | Serum is part of a physiological environment supporting cell viability. pH range also confirms the serum has not been adulterated. |
| Osmolality | Reflects electrolyte and solute concentration. Ensures material is not diluted. |
| Total Protein | Characteristic of bovine animal age. FBS has the lowest protein concentration |
| Endotoxin | Quantifies Gram-negative bacterial contamination of raw serum. Low endotoxin concentration indicates care in collection and processing. Endotoxin is not removed by filtration and, as a mutagen, can affect cell growth characteristics. |
| Hemoglobin (Hb) | Lower Hb indicates greater care during collection and serum processing. Higher Hb indicates cell lysis and may result in virus release. |
| Electrophoretic Pattern | Characteristic of bovine animal age. FBS has a very low gamma globulin fraction compared to other serum types. |
| Bacteria and Fungi/Sterility | Assurance that bacteria and fungi have been removed during manufacturing process. Serum filtered through 0.1µm pore sized filters, will remove bacteria and fungi and provide a product suitable for cell culture applications. |
| Mycoplasma | A potential cell culture contaminant that can create metabolic problems in cell cultures. Capable of passing through 0.2µm pore size filters. |
| Virus Testing - Cytopathic Agents | Test for animal viruses such as IBR that produce a cytopathic effect in the host cell. Evidence of cytopathic effect include: inclusion bodies, abnormal number of giant cells, or other cytopathology indicative of cell abnormalities attributable to an extraneous agent. |
| Virus Testing - Hemadsorbing Agents | Detection of hemagglutinin producing virus such as PI3. Is dependent upon selective attachment of erythrocytes onto the monolayer surface of tissue cultured cells. |
| Adventitious Virus Testing | BVDV exists as a common adventitious agent in bovine serum. Viruses are generally not removed by filtration. Gamma irradiation can provide good log reduction while maintaining serum functionality. Assay consists of growth in cell culture followed by IFA for several types of bovine viruses. |
| Immunoglobulin G (IgG) | Type of antibody. Generally, IgG greater than 300µg/mL is associated with serum other than FBS. |
| Gamma Glutamyl Transferase (GGT) | A high level of GGT is an identifying marker for non-fetal serum. |