

TEST	DESCRIPTION	STATUS	METHOD OR REFERENCE		ACCEPTABLE	
			PREFERRED	ALTERNATIVE(S)	SPECIFICATIONS	UNITS
<b>Bacteria and Fungi/Sterility</b>	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.	Mandatory	EP 2.6.1, USP <71>, 21CFR610.12	<ul style="list-style-type: none"> <li>• 9CFR113.26</li> <li>• JP 4.06</li> </ul>	<ul style="list-style-type: none"> <li>• Not Detected</li> <li>• No Growth</li> </ul>	N/A
<b>Biochemical Profile</b>	Composition of serum. An independent profile can be determined by an inexpensive, large animal chemistry panel from a veterinary diagnostic facility to ensure validity of COA.	Mandatory	Chem. Analyzer	<ul style="list-style-type: none"> <li>• Colorimetric</li> <li>• EP Bovine Serum</li> </ul>	Various	Various
<b>Electrophoretic Pattern</b>	Characteristic of bovine animal age. FBS has a very low gamma globulin fraction compared to other serum types.	Recommended	Capillary Electrophoresis	<ul style="list-style-type: none"> <li>• Cellulose Acetate</li> </ul>	<ul style="list-style-type: none"> <li>• Characteristic</li> <li>• Normal</li> <li>• Typical</li> </ul>	N/A
<b>Endotoxin</b>	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.	Mandatory	USP <85>, EP 2.6.14, EP 5.1.10, JP 4.01	<ul style="list-style-type: none"> <li>• Chromogenic LAL</li> </ul>	FBS..... <10 NBCS..... <100 BCS ..... <100 ABS ..... <10	EU/mL or IU/mL  <b>NOT</b> ng/mL
<b>Hemoglobin (Hb)</b>	Lower Hb indicates greater care during collection and serum processing. Higher Hb indicates cell lysis and may result in virus release.	Mandatory	Three-Wavelength Polychromatic Analysis	<ul style="list-style-type: none"> <li>• USP &lt;90&gt;, Fleming and Wolf</li> <li>• Three- Wavelength polychromatic - Allen correction</li> </ul>	FBS..... <30 NBCS..... <30 BCS ..... <30 ABS..... <30	mg/dL
<b>Gamma-Glutamyl Transferase (GGT)</b>	A high level of GGT is an identifying marker for non-fetal serum.	Mandatory	Chem Analyzer	None	FBS ≤ 10 NBCS 157 – 989 BCS 8 – 23 ABS 16 - 63	U/L (IU/L)

<b>Immunoglobulin G (IgG)</b>	Type of antibody. Generally, IgG greater than 300µg/mL is associated with serum other than FBS.	Mandatory	ELISA	<ul style="list-style-type: none"> <li>• RID</li> <li>• Refractometry</li> <li>• EP 2.7.1</li> </ul>	FBS..... <300 (30) NBCS..... >5,000 BCS ..... >10,000 ABS ..... >25,000	µg/mL (or mg/dL)
<b>Mycoplasma</b>	A potential cell culture contaminant that can create metabolic problems in cell cultures. Capable of passing through 0.2µm pore size filters.	Mandatory	Barile, MF and Kern J (1971)	<ul style="list-style-type: none"> <li>• 9CFR 113.28</li> <li>• EP 2.6.7</li> <li>• JP Mycoplasma</li> </ul>	<ul style="list-style-type: none"> <li>• Not Detected</li> <li>• No Growth</li> </ul>	N/A
<b>Osmolality</b>	Reflects electrolyte and solute concentration. Ensures material is not diluted.	Mandatory	USP <785>	<ul style="list-style-type: none"> <li>• EP 2.2.35</li> <li>• Vapor Pressure</li> </ul>	FBS..... 270-330 NBCS.... 270-330 BCS ..... 260-320 ABS ..... 260-300	mOsm/kg
<b>pH</b>	Serum is part of a physiological environment supporting cell viability. pH range also confirms the serum has not been adulterated.	Mandatory	USP <791>	<ul style="list-style-type: none"> <li>• EP 2.2.3</li> <li>• pH Meter</li> </ul>	FBS..... 7.0-8.0 NBCS..... 7.0-8.0 BCS ..... 7.5-8.5 ABS ..... 7.5-8.5	N/A
<b>Specific Gravity</b>	Specific gravity serves as an excellent indicator of serum adulteration and/or dilution	Recommended	Hydrometer		FBS 1.018 – 1.024	N/A
<b>Total Protein</b>	Characteristic of bovine animal age. FBS has the lowest protein concentration of the bovine serum types.	Mandatory	Biuret	<ul style="list-style-type: none"> <li>• Chem. Analyzer</li> <li>• BCA protein assay</li> </ul>	FBS..... 3.0-4.5 (30-45) NBCS..... 4.0-6.5 BCS ..... 5.5-7.5 ABS ..... 6.3-8.8	g/dL (or mg/mL)
<b>Geographic Origin Verification</b>	Allows serum identification by geographic origin of source animal.	Strongly Recommended	Trace element analysis by Oritain	Not Available	Characteristic of geography	N/A

<b>Adventitious Virus Testing</b>	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.	Mandatory	9CFR 113.53, 113.46 and 113.47	<ul style="list-style-type: none"> <li>• CVMP/743</li> <li>• EP 5.2.4</li> <li>• EP 5.2.5</li> <li>• CHMP/BWP/4579 20</li> </ul>	<ul style="list-style-type: none"> <li>• Tested (BVDV)</li> <li>• Not Detected</li> </ul>	N/A
<b>Virus Testing- Cytopathic Agents</b>	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.	Mandatory	9CFR 113.46	<ul style="list-style-type: none"> <li>• CVMP/743</li> <li>• EP 5.2.5</li> <li>• CHMP/BWP/4579 20</li> </ul>	<ul style="list-style-type: none"> <li>• Not Detected</li> </ul>	N/A
<b>Virus Testing- Hemadsorbing Agents</b>	Detection of hemagglutinin producing virus such as PI3. Is dependent upon selective attachment of erythrocytes onto the monolayer surface of tissue cultured cells.	Mandatory	9CFR 113.46	<ul style="list-style-type: none"> <li>• CVMP/743</li> <li>• EP 5.2.5</li> <li>• CHMP/BWP/4579 20</li> </ul>	<ul style="list-style-type: none"> <li>• Not Detected</li> </ul>	N/A
<b>Virus Testing- SN</b>	Test to detect and quantify antibodies specific for BVDV type 1 and type 2 as well as other bovine viruses.	Optional	9CFR 113.215		<ul style="list-style-type: none"> <li>• As Reported</li> </ul>	SN Titers