

ISIA/USP specification comparison

| Test | Method | Units | Recommended ISIA Specification | Result | USP | USP method if different |
|-------------------------|--|---------|--------------------------------|-----------------------|---|-------------------------|
| Bacteria and Fungi | USP <71> | N/A | Not Detected | Not Detected | Not Detected | Same |
| Mycoplasma | Barille, MF and Kern, J (1971) | N/A | Not Detected | Not Detected | Not Detected | Same |
| Virus Testing: | | | | | | same |
| Cytopathogenic Agents | 9 CFR Part 113.53 c [113.46, 113.47] | N/A | Not Detected | Not Detected | Not Detected | |
| Hemadsorbing Agents | | N/A | Not Detected | Not Detected | | |
| BVD Virus | | N/A | Tested | Tested | | |
| pH at RT | USP<791> | N/A | 7.0 – 8.0 | (Result) | 7.0 – 8.0 | Same |
| Osmolality | USP<785> | mOsm/kg | 270 - 330 | (Result) | 280 - 360 | Same |
| Endotoxin | USP <85> | EU/ml | Test and Record | (Result) | 10 or less | same |
| Hemoglobin | Fleming, AF and Woolf AJ (1965) Clin. Chem. 12, 67 | gm/dl | Test and Record | (Result) | 30 or less | See USP <851> |
| Total Protein | Biuret Method; Dumas et al (1975) Clin Chem 21. 1159 | gm/dl | 3.0 – 4.5 | (Result) | 3.0 – 4.0 | USP <1057i> |
| Electrophoretic Pattern | Cellulose Acetate Electrophoresis | N/A | Normal | Normal | NA | Not recommended |
| Performance Testing | (Company specific method) | N/A | Tested and Acceptable | Tested and Acceptable | Tested and Acceptable | USP methodology <90> |
| Radial Immundiffusion | | | | | Positive for Bovine Contains no more than 500mg/L IgG | USP methodology <90> |