

Technical Bulletin

Quality Control Test Methods

Test	Brief Description	Reference
Adventitious Viral Agents	Culture, Stain	Code of Federal Regulations, Title 9, "Animal and Animal Products".
Bacteriophage	Agar Overlay	Adams, M.H., <u>Bacteriophages</u> , Interscience Publishers, Inc. NY, 1959.
Bovine IgG	ELISA	Measure Bovine IgG content. The IgG concentration of the test sample is extrapolated from a standard curve.
Electrophoretic Profile	Serum Electrophoresis (Mylar Supported Cellulosic Medium)	Morris, C.J.O.R. and P. Morris, eds. <u>Separation Methods in Biochemistry</u> , Interscience Publishers, NY, 1963.
Endotoxin	Kinetic LAL	United States Pharmacopeia, Current Edition.
Growth Promotion/ Cytotoxicity	Cellular Proliferation	Growth promotion and cytotoxicity characteristics are measured by the cellular uptake of tetrazolium salt in a MTT assay. Cells propagated in a test sample are compared to cells propagated in an established control.
	Cloning Efficiency	Measured by inoculating 1 cell/well in a 96-well plate. The number of wells that give rise to colonies is measured and compared to the total number of wells inoculated.
	Plating Efficiency	Measured by inoculating a low number of cells into culture vessels. The percentage of cells that give rise to colonies is measured and compared to the number of cells inoculated.
Hemoglobin	Colorimetric	Nauman, H.N., "The Measurement of Hemoglobin; in Hemoglobin, Its Precursors and Metabolites", F.W. Sunderman and F.W. Sunderman. Eds (J.B. Lippincott Co., Philadelphia, PA 1964) PP 40-48.
Mycoplasma	Culture	Code of Federal Regulations, Title 9, "Animal and Animal Products". Barile, M.F. and J. Kern: Isolation of <u>M. arginini</u> from commercial bovine sera and its implication in contaminated cell culture (35913), Proc. Soc. Exp. Biol. And Med. 138:432-437 (1971). European Pharmacopeia, V.2.1.3.6 Test for Non-avian Mycoplasmas and Ureaplasmas, 1991.
	DNA-fluorochrome (Hoescht) stain	Del Giudice, R.A. and H.E. Hopps. Microbiological methods and fluorescent microscopy for the direct demonstration of mycoplasma infection of cell cultures. In <u>Mycoplasma Infection of Cell Cultures</u> , eds. G.J. McGarrity, D.G. Murphy and W.W. Nichols. Plenum press, NY 1978.

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Test	Brief Description	Reference
Osmolality	Freeze-point depression	Manual for Advanced Instrument, Inc. Model 3MO Micro-Osmometer.
Ouchterlony	Species Identification	Species of origin is determined by a double immunodiffusion assay method.
pH	Potentiometric	Manual for Corning pH meter, Model 125.
Sterility	Membrane filtration	United States Pharmacopeia, Current Edition.
Total Protein	Biuret	Gornall, A.G., C.J. Bardawill, M.M. David: Determination of serum proteins by means of the biuret reaction. J.Biol. Chem. 177:751-766 (1949).

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