

PRODUCT: Continuous Single Culture Complete (CSCM-C)
with Gentamicin and HSA

LOT #0000031454

CATALOG #90165

MFR DATE: 12/17/2024

STORAGE: 2°- 8°C

EXPIRES: 04/16/2025

CERTIFICATE OF ANALYSIS

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with the Guideline for Manufacture of In Vitro Diagnostic Products and the Good Manufacturing Practices (GMP's) for Medical Devices. FUJIFILM Irvine Scientific, Inc. is licensed by both Federal and State agencies and is inspected regularly for compliance.

All donors used to obtain the human albumin and human globulins were tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Human Immunodeficiency Virus (HIV), and Hepatitis C virus (HCV) by approved testing methods.

Assay	Specification	Result
Sterility ¹	Pass	Pass
pH ²	7.3 – 7.5	7.4
Osmolality	260 – 270 mOsm/Kg H ₂ O	263 mOsm/Kg H ₂ O
Endotoxin ³	≤0.25 EU/ml	<0.05 EU/ml
Albumin Recovery ⁴	≥85%	109%
Mouse Embryo Test (One-cell) ⁵		
-Control:		
% of embryos developing	≥ 80%	97% (90/93)
-This lot:		
% of embryos developing	≥ 80%	98% (91/93)
Human Sperm Survival Assay ⁶	≥ 70%	93%

¹In accordance with the Current USP <71>; 21 CFR, Part 610.12.

²With CO₂ equilibration at 5.5% CO₂ (+/- 0.2% CO₂) at 37°C

³Utilizes a Chromogenic Assay with a sensitivity of 0.005 EU/ml.

⁴Albumin concentration is determined by the BCG method. Formulation verification is conducted on bulk powder medium that is used to manufacture liquid lots. HPLC detection of glucose, lactic acid, pyruvic acid and amino acids verify concentrations within specifications of formulation.

⁵One cell mouse embryo testing is performed using mouse embryos. Test results indicate the percentage of mouse embryos developing to fully expanded blastocysts after 96 hours in culture.

⁶Human Sperm Survival Assay (HSSA) test results indicate the percent of original motility at 24 hours.

Released By: Dalia Ramirez

Date: 01/17/2025

Title: QA Product Release Coordinator

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