

PRODUCT: CHANG Amnio
with: Gentamicin Sulfate (50 µg/mL),
L-Glutamine

LOT #0000025922

CATALOG #99473

MFR DATE: 02/04/2025

STORAGE: Below -10°C

EXPIRES: 11/18/2026

CERTIFICATE OF ANALYSIS

Products manufactured by FUJIFILM Irvine Scientific, Inc. are produced in accordance with *in vitro* diagnostic guidelines and the Good Manufacturing Practices Act, utilizing detailed production protocols, formulation and test procedures. FUJIFILM Irvine Scientific, Inc. is licensed by both Federal and State agencies and is inspected regularly for compliance.

Sterility	No evidence of bacterial or fungal contamination after incubation in fluid thioglycollate and soybean-casein digest media per Current USP <71>; 21 CFR, Part 610.12.
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Mycoplasma ¹	None detected by the DNA fluorochrome stain.
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Growth Support	Supports the growth of early passage normal human amniotic fluid cells. The passaged cells were allowed to proliferate for 5 days in parallel with a control lot of tissue culture medium. No evidence of toxicity, cytopathic effects or nutritional deficiencies were observed.
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	<u>Specification</u>	<u>Result</u>
pH	Report Results	7.15
Osmolality	Report Results	307 mOsm/Kg H ₂ O
Endotoxin	≤2.4 EU/ml	Less than 0.12 EU/ml gel clot assay. LAL sensitivity 0.03 EU/ml.

¹Select components tested at raw material level.

Released By: 

Date: 03/06/2025

Title: QA Product Release Coordinator

Rev 2