

Certificate of Quality

(YYYY-MM-DD)

This product has been manufactured, processed and packaged in accordance with Quality Systems Regulation, 21 CFR Part 820. Representative samples were tested per Remel Inc., a part of Thermo Fisher Scientific Quality Control specifications and were found to meet performance criteria for this product.

Organism Challenge	Strain	Results
Maintenance:		
Chlamydia trachomatis	VR-880	Pass
Herpes simplex type 2	VR-734	Pass
Cytomegalovirus	VR-977	Pass
Respiratory syncytial virus	VR-1540	Pass
Toxicity:		
MRC5 Cells	CCL-171	Pass
VERO Cells	CCL-81	Pass
McCoy Cells	CRL-169	6 Pass

Physical Characteristics:

Appearance: Orange-Pink to Pink-Orange Clear Broth

pH @ 20-25°C: 7.3 +/- 0.2

Microbial Load Evaluation:

Manufactured lot has been statistically sampled. Samples were acceptable for microbial content and aesthetic value following half of the samples incubated at a minimum of 72 hours at 33-37°C, subcultured to Blood Agar, and incubated at an additional 72 hours at 33-37°C, and the other half of the samples incubated at a minimum of 48 hours at 20-25°C, subcultured to Sabouraud Dextrose Agar, and incubated at an additional 5 days at 20-25°C.

Signed

Quality Assurance Supervisor