

Certificate of Analysis

Mesenchymal Stem Cell Growth Medium

Catalog No. GUXMX-90011

Lot Number: T150418G001

Preparation Date: 2015-04-18

Size: 500 ml

Kit Components

Containing 440 ml of Mesenchymal Stem Cell Basal Medium (Cat. No. GUXMX-03011-440), 50 ml of Mesenchymal Stem Cell-Qualified Fetal Bovine Serum (Cat. No. GUXMX-05001-50), 5 ml of L-Glutamine, 5 ml of Penicillin-Streptomycin Solution, pH7.2. Store at 4°C.

Sterility

Bacterial and Fungal Contamination: Samples are inoculated and cultured on blood agar plate, thioglycolate broth, tryptocase soy broth and sabouraud dextrose agar.

Specification: No growth must be observed.

Mycoplasma: Samples are tested for mycoplasma contamination using a PCR-based assay and direct culture.

Specification: Results must be negative.

Endotoxin: Samples are tested for endotoxin contamination with LAL test.

Specification: Results must show a concentration of $\leq 25\text{EU/ml}$.

Cell culture testing

Each batch of growth medium is tested for its ability to support in vitro growth of mesenchymal stem cells. When are cultured in growth medium, cells must demonstrate a doubling time of 18-24 h, can proliferate for ≥ 5 passages, and that $\leq 5\%$ of cells exhibit spontaneous differentiation in each passage.

Results:

All specifications have been met.



Jane Chen

QA Manager

May 11, 2015