



## Certificate of Analysis

**STEMPRO® MSC SFM Basal Medium CTS(TM)**  
**For Mesenchymal Stem Cells**  
**– L-Glutamine**

**Catalog Number:** A10334  
**Lot Number:** 2093111

**Storage Temperature:** 2 to 8C  
**Storage Instructions:** Protect from light  
**Expiration Date:** 2021-03

For human ex vivo tissue and cell culture processing applications. CAUTION: When used as a medical device, Federal Law restricts this device to sale by or on the order of a physician.

TEST	SPECIFICATION	RESULT	UNITS
<sup>1</sup> Endotoxin Testing (LAL Method)	<1.0	<0.03	EU/mL
<sup>2</sup> Osmolality	>=290 to <=320	304	mOsm/kg
<sup>3</sup> pH	>=6.9 to <=7.6	7.3	
<sup>4</sup> STEMPRO® MSC SFM Performance Assay	Acceptable	Acceptable	
<sup>5</sup> Sterility Testing (USP 71)	Negative	Negative	

Read SDS.

The manufacturing facility is in compliance with 21 CFR Part 820 Quality Systems Regulation and is certified to ISO 13485.

GIBCO brand, Thermo Fisher Scientific cell culture liquid products are prepared by an aseptic process for which each step has been validated to ensure that all products meet the industry standard sterility assurance level of  $10^{-3}$ ; i.e. product that demonstrates a contamination level of no more than 1 of 1,000 units during the manufacturing process. The highest level of sterility assurance (equal to or greater than  $10^{-6}$ ) cannot be achieved without terminal sterilization which is harmful to the performance of cell culture products.

For support related to CTS(TM) products, please visit us at: [www.lifetechnologies.com/celltherapyresearchsupport](http://www.lifetechnologies.com/celltherapyresearchsupport), email our technical support team at: [celltherapysupport@lifetech.com](mailto:celltherapysupport@lifetech.com), or contact us by phone at: 1-800-955-6288 extension 46501.

Quality Systems Department

Date: 10-Apr-2019

### **REFERENCES:**

- 1 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 2 Thermo Fisher Scientific Specifications.
- 3 Thermo Fisher Scientific Specifications.
- 4 Each lot of STEMPRO® MSC SFM Basal Medium and Supplement are tested as a complete medium for its ability to expand human bone marrow derived Mesenchymal Stem Cells (MSC). Early passage MSC from four normal bone marrow donors were pooled and cryopreserved. Cells are seeded into 96-well plates and incubated. On day 5, the cells are assayed using the CyQUANT® NF fluorescent assay, and read on a Gemini EM fluorescent plate reader. Cell expansion in test and control media conditions are measured by the relative fluorescence units and are found to be acceptable according to GIBCO internal specifications.
- 5 Current edition of USP.

EXAMPLE