



## Certificate of Analysis

Cell Therapy Systems  
CELLstart (TM) CTS (TM)  
Humanized Substrate for Cell Culture

Catalog Number: A10142  
Lot Number: 2004454

Storage Temperature: 2 to 8C  
Storage Instructions: Protect from light  
Expiration Date: 2020-01

For Research Use or Non-Commercial Manufacturing of Cell-Based Products for Clinical Research. Caution: Not intended for direct administration into humans or animals.

TEST	SPECIFICATION	RESULT	UNITS
<sup>1</sup> Endotoxin Testing (LAL Method)	0 to 32	4.80	EU/mL
<sup>2</sup> HCV Antibody Screening	Non Reactive	Non Reactive	
<sup>3</sup> Hepatitis B Surface Antigen Screening	Non Reactive	Non Reactive	
<sup>4</sup> HIV 1 & 2 Antibody Screening	Non Reactive	Non Reactive	
<sup>5</sup> Mycoplasma qPCR Detection Assay	Negative	Negative	
<sup>6</sup> Protein Determination	Acceptable	Acceptable	
<sup>7</sup> Sterility Testing (USP 71)	Negative	Negative	

Read SDS

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

For support related to CTS (TM) products, please visit us at: [www.lifetechnologies.com/celltherapysupport](http://www.lifetechnologies.com/celltherapysupport), 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: 14-Feb-2019

### **REFERENCES:**

- 1 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 2 FDA Licensed / Approved blood screening tests.
- 3 FDA Licensed / Approved blood screening tests.
- 4 FDA Licensed / Approved blood screening tests.
- 5 Thermo Fisher Scientific Specifications. The Mycoplasma qPCR Detection Assay uses Power SYBR® Green detection technology and a Real-Time Polymerase Chain Reaction to amplify a target DNA sequence common to a wide variety of mycoplasmas.
- 6 Thermo Fisher Scientific Specifications.
- 7 Current edition of USP.

EXAMPLE