



Certificate of Analysis

**AIM-V(R) Medium CTS (TM)
Serum Free Medium 1X
Single Use Container
Sterile Filtered - 0.1 micron**

Catalog Number: 87-0112
Lot Number: 2036791

Storage Temperature: 2 to 8C
Storage Instructions: Protect from light
Expiration Date: 2019-12

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
¹ AIM-V QC Performance Assay	Pass	Pass	
² Endotoxin Testing (LAL Method)	≥ 0 to ≤ 1	<0.05	EU/mL
³ HCV Antibody Screening	Non Reactive	Non Reactive	
⁴ Hepatitis B Surface Antigen Screening	Non Reactive	Non Reactive	
⁵ HIV 1 & 2 Antibody Screening	Non Reactive	Non Reactive	
⁶ Mycoplasma, Supplemental (H-Stain)	Negative	Negative	
⁷ Mycoplasma Testing (Barile)	Negative	Negative	
⁸ Osmolality	≥ 310 to ≤ 340	327	mOsm/kg
⁹ pH	≥ 6.8 to ≤ 7.3	7.0	
¹⁰ Sterility Testing (USP 71)	Negative	Negative	

Read SDS

CAUTION: Human origin materials are non-reactive (donor level) for anti-HIV 1 & 2, anti-HCV and HBsAg. Handle in accordance with established bio-safety practices.

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.

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/celltherapyresearchsupport, email our technical support team at: techsupport@lifetech.com or contact us by phone at: 1-800-955-6768 extension 46501.

Maria J. Micale

Quality Systems Department

Date: 29-Nov-2018

REFERENCES:

- 1 Thermo Fisher Scientific Specifications. Cell Line Used: J. Kat clone E6-1 (ATCC No. TIB-152). Each lot of AIM-V is evaluated for its ability to support acceptable human lymphoid cell expansion. For each test or control sample, five wells of a 24-well plate are inoculated at 4×10^5 viable cells/mL. Viable cell counts are determined on day 7 and averaged. Both test and control samples must achieve a minimum of 1.75×10^6 viable cells/mL.
- 2 Current United States Pharmacopeia, <85> Bacterial Endotoxins Test.
- 3 FDA Licensed / Approved blood screening tests.
- 4 FDA Licensed / Approved blood screening tests.
- 5 FDA Licensed / Approved blood screening tests.
- 6 Hoechst H Stain Chen, T.R. (1977) Exp. Cell Res., 104, 255 Thermo Fisher Scientific Modified.
- 7 Barile, M.F. and Kern, J. (1971) P.S.E.M.B. 138, 432, Thermo Fisher Scientific Modified.
- 8 Thermo Fisher Scientific Specifications.
- 9 Thermo Fisher Scientific Specifications.
- 10 Current edition of USP.