

Certificate of Analysis

Product Information & Quality Control

<p>PRODUCT: HUMAN MONONUCLEAR CELLS (PBMC) CATALOG #: HUMANPBMC-0002021 SAMPLE TYPE: INDIVIDUAL, MALE AGE: 34 RACE: BLACK OR AFRICAN AMERICAN ANTICOAGULANT: ACD CRYOPRESERVATIVE: CRYOSTOR CS10 SHORT TERM STORAGE: -70 °C OR COLDER (UP TO 2 WEEKS) LONG TERM STORAGE: LIQUID NITROGEN VAPOR PHASE (-140 °C) LOT#: HMN621837 (198001488) DONOR ID: RM10237 COLLECTION DATE: 11-NOV-2021</p>
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QA/QC Post-Thaw Results	
Concentration per Vial	10M
Viable Cell Count	18.7 x 10 ⁶
Cell Viability, (>70%)	98.0%

BIOIVT RECOMMENDS CRYOPRESERVED CELLS BE STORED FOR NO MORE THAN 2 WEEKS AT -70 °C OR COLDER. FOR LONG TERM STORAGE, THIS PRODUCT MUST BE STORED IN THE "VAPOR PHASE" OF A LIQUID NITROGEN TANK. THE EXPIRATION DATE PROVIDED IS CONTINGENT UPON USE OF LIQUID NITROGEN FOR LONG-TERM STORAGE.

BIOHAZARD INFO: THIS MATERIAL SHOULD BE HANDLED AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS. PLEASE USE UNIVERSAL PRECAUTIONS. NO TEST METHOD CAN PROVIDE TOTAL ASSURANCE THAT HEPATITIS B VIRUS, HEPATITIS C VIRUS, HUMAN IMMUNODEFICIENCY VIRUS, OR OTHER INFECTIOUS AGENTS ARE ABSENT. THUS, ALL BIOLOGICAL PRODUCTS THAT WE PROVIDE SHOULD BE HANDLED AT THE BIO-SAFETY LEVEL 2 AS RECOMMENDED BY THE CDC/NIH MANUAL "BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FROM POTENTIALLY INFECTIOUS HUMAN SERUM OR BLOOD SPECIMENS"

THIS PRODUCT IS BEING SOLD FOR RESEARCH AND/OR MANUFACTURING PURPOSES ONLY. THE BIOLOGICAL SAMPLES SUPPLIED BY BIOIVT, OR ANY MATERIAL ISOLATED FROM THE SAMPLES, ARE FOR IN-VITRO RESEARCH USE ONLY AND ARE NOT TO BE USED AS A SOURCE OF MATERIAL FOR CLINICAL THERAPIES. HUMAN MATERIAL MAY BE USED IN VIVO IN ANIMALS. THE USER ASSUMES ALL RESPONSIBILITY FOR ITS USAGE AND DISPOSAL, IN ACCORDANCE WITH ALL REGULATIONS.

THE MATERIAL LISTED ON THIS CERTIFICATE OF ANALYSIS HAS BEEN TESTED IN ACCORDANCE WITH FDA REGULATIONS AND FOUND TO BE NEGATIVE FOR HIV 1/2 AB AND HCV AB AND NON-REACTIVE FOR HBSAG, HIV-1 RNA, HCV RNA, HBV DNA, WNV RNA, ANTI-T. CRUZI, ZIKA VIRUS RNA AND STS.

BIOIVT WARRANTS THAT AT THE TIME OF SHIPMENT THE PRODUCT IS FREE FROM DEFECTS IN MATERIAL AND WORKMANSHIP AND CONFORMS TO SPECIFICATIONS WHICH ACCOMPANY THE PRODUCT. BIOIVT MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR PERFORMANCE.

Regulatory

APPROVED BY:



Wini Luty
Sr Director, Biologic Operations

DATE:

27-DEC-2024

DOCUMENT #

WES-FRM-001

BioIVT is committed to sourcing human and animal biological material in accordance with the highest ethical and regulatory standards.