

Certificate of Analysis

Product Information & Quality Control

PRODUCT: Human Mononuclear Cells (PBMC)
CATALOG # HUMANPBMC-0002021
SAMPLE TYPE: INDIVIDUAL, MALE
AGE: 34
RACE: AFRICAN AMERICAN
CRYOPRESERVATIVE: CryoStor CS10
SHORT TERM STORAGE: -70 °C OR COLDER (UP TO 2 WEEKS)
LONG TERM STORAGE: LIQUID NITROGEN VAPOR PHASE (-140 °C)
LOT#: W462823001877
DONOR ID: RG4486
COLLECTION DATE: 14-JUN-2023

QA/QC Post-Thaw Results

Concentration per Vial	10M
Viable Cell Count	16.0 x 10 ⁶
Cell Viability, (>70%)	92.0%

HLA TYPE

HLA-A	A*30:01:01 ; A*68:02:01
HLA-B	B*15:03:01 ; B*57:02:01
HLA-C	C*02:10:01 ; C*18:02:01
HLA-DP	DPA1*02:01:01 ; DPA1*03:01:01 ; DPB1*105:01:01 ; DPB1*13:01:01
HLA-DQ	DQA1*05:01:01 ; DQA1*05:02 ; DQB1*02:01:01 ; DQB1*03:19:01
HLA-DR	DRB1*03:01:01 ; DRB1*11:01:02 ; DRB3*02:02:01 ; DRB3*02:02:01

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 (-140 °C)" OF A LIQUID NITROGEN TANK.

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, AND STS.

UNLESS OTHERWISE AGREED IN A DULY EXECUTED CONTRACT BETWEEN THE PARTIES, THIS DOCUMENT IS GOVERNED BY THE TERMS AND CONDITIONS LOCATED AT www.bioivt.com WHICH IS HEREBY INCORPORATED HEREIN.

Regulatory

APPROVED BY:



Wini Luty
Sr Director, Biologic Operations

DATE:

26-OCT-2023

DOCUMENT #

WES-FRM-001

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