

Certificate of Analysis
HUMAN PLASMA NAHEP GENDER POOLED

Product Information

Product #: HUMANPLNH-0000325
Lot# / Sample ID#: HMN1197009
Storage temperature: -20°C OR COLDER
Lot(s) Release Date: 17NOV2023

Quality Control

THE DONOR(S) USED IN THE MANUFACTURING OF THIS PRODUCT HAVE BEEN TESTED WITH FDA CBER LICENSED SCREENING TESTS (TITLE 21 - CFR PART 610.40) TO SHOW THE FOLLOWING:

HEPATITIS B SURFACE ANTIGEN NEGATIVE, HBV NAT NEGATIVE, HIV 1 & 2 ANTIBODY NEGATIVE, HIV NAT NEGATIVE, HCV ANTIBODY NEGATIVE, HCV NAT NEGATIVE, SYPHILIS NEGATIVE, WEST NILE VIRUS NAT NEGATIVE, DONOR HAS TESTED NEGATIVE BY A LICENSED TEST FOR ANTIBODIES TO T.CRUIZII EITHER ON THE CURRENT DONATION OR AT LEAST ONE PREVIOUS DONATION.

Regulatory

APPROVED BY:



Wini Luty
Sr Director, Biologic Operations

DATE: 17NOV2023

DOCUMENT # WES-FRM-001

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

PRODUCT DATA SHEET

SHIP DATE: 17NOV2023

HUMAN PLASMA NAHEP GENDER POOLED

Product Number: HUMANPLNH-0000325

Lot Number(s): HMN1197009
Expiration Date: 30NOV2028
Storage Conditions: -20°C OR COLDER
Anticoagulant: NaHep

PROJECT DETAILS

Purchase Order:	BJ20298
Sales Order Number:	S10023019160
Total Volume Shipped:	200 ML
Presentation:	1 LOT OF 200 ML (40 X 5 ML) OF HUMAN PLASMA NAHEP GENDER POOLED RECOVERED FROM WHOLE BLOOD DONATIONS Pooled from 4 males and 4 females
Filtration:	None

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.

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