

Certificate of Analysis

HUMAN PLASMA NAHEP FEMALE

Product Information

HUMANPLNH-0000321 Product #:

Lot# / Sample ID#: HMN1162025

Storage temperature: -20°C OR COLDER

Lot(s) Release Date: 18AUG2023

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.CRUZI EITHER ON THE CURRENT DONATION OR AT LEAST ONE PREVIOUS DONATION.

Regulatory

APPROVED BY:

Sr Director, Biologic Operations

DATE:

18AUG2023

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: 18AUG2023

HUMAN PLASMA NAHEP FEMALE Product Number: HUMANPLNH-0000321

HMN1162025 Lot Number(s): **Expiration Date:** 31AUG2028

-20°C OR COLDER **Storage Conditions:**

PROJECT DETAILS

Purchase Order:	REPLACE/BJ19878
Sales Order Number:	\$10023013183
Total Volume Shipped:	10 ML
Presentation:	1 INDIVIDUAL OF 10 ML (10 X 1 ML)
	OF HUMAN PLASMA NAHEP FEMALE
Filtration:	None

THIS MATERIAL SHOULD BE HANDLED AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS. PLEASE USE UNIVERSAL BIOHAZARD INFO: 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 BIOLYT, 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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FOR UPDATED EXPIRATION DATE INFORMATION, CLICK HERE