

Certificate of Analysis
HUMAN PLASMA K2EDTA POOLED GENDER

Product Information

Product #: HUMANPLK2PNN
Lot# / Sample ID#: HMN647813
Storage temperature: -20°C OR COLDER
Lot(s) Release Date: 30JUL2021

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: 30JUL2021

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: 30JUL2021

HUMAN PLASMA K2EDTA POOLED GENDER

Product Number: HUMANPLK2PNN

Lot Number(s): HMN647813
Expiration Date: 31JUL2026
Storage Conditions: -20°C OR COLDER
Anticoagulant: K2EDTA

PROJECT DETAILS

Purchase Order:	BJ16354
Sales Order Number:	S10021015284
Total Volume Shipped:	100 ML
Presentation:	1 LOT OF 100 ML (1 X 100 ML) OF HUMAN PLASMA K2EDTA POOLED GENDER RECOVERED FROM WHOLE BLOOD DONATIONS
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.

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.

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