

# **Certificate of Analysis**

### **HUMAN PLASMA K2EDTA**

### **Product Information**

**HUMANPLK2-0000285** Product #:

Lot# / Sample ID#: HMN1167271

Storage temperature: -20°C OR COLDER

Lot(s) Release Date: 29AUG2023

### **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:

29AUG2023

**DOCUMENT #** 

WES-FRM-001

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

Hicksville, NY 11802-0770



### PRODUCT DATA SHEET

SHIP DATE: 29AUG2023

**HUMAN PLASMA K2EDTA** 

Product Number: HUMANPLK2-0000285

HMN1167271 Lot Number(s): 30SEP2028 **Expiration Date:** 

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

K2EDTA **Anticoagulant:** 

### **PROJECT DETAILS**

Purchase Order:	BJ19909
Sales Order Number:	\$10023012632
Total Volume Shipped:	200 ML
Presentation:	1 INDIVIDUAL OF 200 ML (20 X 10 ML) OF HUMAN PLASMA K2EDTA RECOVERED FROM WHOLE BLOOD DONATIONS
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 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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FOR UPDATED EXPIRATION DATE INFORMATION, CLICK HERE