

Certificate of Analysis

PRODUCT: Human Serum, IgG/IgM Antibody Depleted

CODE NO: 34014

LOT NO: 11442

DATE OF
MANUFACTURE: April 23, 2020

STORAGE: At or below -70 °C

ORIGIN: U.S.A.

SAFETY: *Statement of anonymity of donors:* This product consists of human serum, either single units or pooled from single units, obtained from anonymous donors who are required to sign an informed consent. Donors acknowledge that their donation is made voluntarily and in consideration of the fee, and the blood and derivatives from it may be used in any manner decided by the corporation. The collection facilities strictly adhere to HIPAA regulations and donor's identities will never be revealed to end users of their blood or any components manufactured from it. No information is provided to Pel-Freez that would give any indication as to the identity of any donor(s) at any time. Pel-Freez has further processed this material as identified solely as "human serum" and has made no attempt to ascertain the identity of any donor from which the raw material was collected.

Each donor unit was tested prior to pooling according to FDA guidelines for the detection of Hepatitis B Surface Antigen, Antibodies to HIV and HVC, HIV-1 RNA, HBV DNA, HCV RNA, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded NON-REACTIVE/NEGATIVE results for each test performed. Units were tested with an investigational nucleic acid test (NAT) for ZIKA VIRUS RNA and found to be NON-REACTIVE. All blood is collected in the United States of America from human donors in FDA licensed centers and tested with FDA approved test kits. 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 blood products should be handled at the Bio-Safety Level 2 as recommended by the CDC/NIH manual: BIO-SAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FOR POTENTIALLY INFECTIOUS HUMAN SERUM OR BLOOD SPECIMENS.

PROCESS
NOTES: This product consists of human serum that has been depleted of IgG and IgM antibodies.

ASSAYS:

	Calculated Hemolytic Titer, CH50		IgG concentration, HPLC		IgM concentration, HPLC	
	Specification	Result	Specification	Result	Specification	Result
Donor Feed Serum	Report Result	302	Report Result	12 mg/mL	Report Result	1.5 mg/mL
IgG/IgM depleted serum	Report Result	64	Report Result ¹	1.6% ¹	Report Result ¹	10% ¹

¹ Assay value as % of starting donor feed serum.

QUALITY ASSURANCE

Quality Control Release Date: June 12, 2020



 Sarah Graves
 Quality Systems Technician

Meets or exceeds specifications ☐
Does not meet specifications ☒

Amended 05Jul2023 TK

NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
 SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES