

Certificate of Conformity

PRODUCT: Human Serum Sample**CODE NO:** 34015**LOT NO:** 21644**DATE OF
MANUFACTURE:** 04Aug2022**ORIGIN:** U.S.A.**STORAGE:** At or below -70 °C**VOLUME:** Varies. See attached list.

Statement of anonymity of donors: This product consists of samples from individual units of human serum 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.

SAFETY:

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. 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.

LOT NUMBERS: See attached list**QUALITY ASSURANCE**

Quality Control Release Date: August 22, 2022

Theresa Kwasny
Quality Director**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**

Human Serum Summary

Donor information of reserved human serum unit volumes

Human Serum Code: 34015 -1

Reserve Human Serum Unit Code: 14285

Customer: SD Medical System

Sales Order: 20220821001SO

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LOT #	DONOR IDENTIFICATION #	UNIT VOLUME (mL)	SERUM COLLECTION DATE
21644-2682	22PPAA2682	383	04/28/2022
21644-2686	22PPAA2686	365	04/28/2022
21644-1952	22MBFA1952	379	07/08/2022
21644-1283	22MFTA1283	371	07/08/2022
21644-1146	22BMDA1146	369	07/08/2022
21644-0451	22JMSA0451	369	07/08/2022
21644-1973	22MAFA1973	363	07/08/2022
21644-1280	22MFTA1280	363	07/08/2022
21644-2143	22MCTA2143	361	07/08/2022
21644-1148	22BMDA1148	361	07/08/2022