

Certificate of Conformity

PRODUCT: Human Serum Sample**CODE NO:** 34015**LOT NO:** 26643**DATE OF
MANUFACTURE:** 23Sep2021**ORIGIN:** U.S.A.**STORAGE:** At or below -70 °C**VOLUME:** > 1 mL per sample

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.

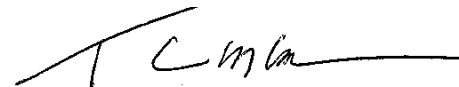
LOT NUMBERS:

26643-0879	26643-4557	26643-1017	26643-2580	26643-2231	26643-1056
26643-0909	26643-0703	26643-1228	26643-4561	26643-0296	26643-1050
26643-1837	26643-2395	26643-1120	26643-0678	26643-0972	26643-0088
26643-0528	26643-0705	26643-0617	26643-1960	26643-1095	26643-0808
26643-2100	26643-1832	26643-0618	26643-1324	26643-1912	26643-2977
26643-0788	26643-0319	26643-M0585	26643-2233	26643-2479	26643-0807
26643-1229	26643-2888	26643-B0585	26643-2234	26643-1053	26643-1326
26643-1013	26643-0595	26643-0586	26643-1094	26643-1049	26643-1323
26643-1840	26643-2101	26643-2388	26643-0966	26643-1462	26643-0526
26643-1270	26643-1106	26643-2245	26643-0964	26643-0811	26643-0335
26643-1269	26643-0584	26643-0331	26643-2756	26643-2972	26643-0625
26643-2887	26643-1514	26643-2098	26643-1055	26643-2981	26643-2754
26643-1122	26643-0704	26643-0317	26643-2482	26643-2603	26643-2753
26643-1100	26643-0676	26643-1230	26643-1054	26643-1069	26643-2005
26643-1101	26643-4573	26643-2097	26643-1149	26643-0965	26643-1274
26643-1099	26643-2599	26643-0377	26643-0809	26643-1093	26643-0812
	26643-2154	26643-0616	26643-2141	26643-1908	

QUALITY ASSURANCE

Quality Control Release Date:

September 24, 2021

Theresa Kwasny
Director of QualityNOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES