

Certificate of Conformity

PRODUCT: Human Serum, Off Clot, Single Donor
CODE NO: 34011
LOT NO: 13341
DATE OF MANUFACTURE: 13May2019
ORIGIN: U.S.A.
STORAGE: At or below -70 °C

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.

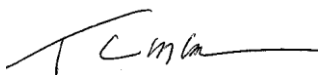
SAFETY: Each donor unit was tested prior to pooling according to FDA guidelines for the detection of Hepatitis B Surface Antigen, Antibodies to HIV and HVC, HIV-1 RNA, HBV DNA, HCV RNA, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded NON-REACTIVE/NEGATIVE results for each test performed. 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.

LOT NUMBERS:

13341.0853	13341.1003	13341.2503	13341.2525
13341.2275	13341.1006	13341.2505	13341.2526
13341.0427	13341.1007	13341.2506	13341.2527
13341.0428	13341.1008	13341.2510	13341.2528
13341.1085	13341.1009	13341.2512	13341.A1012
13341.0639	13341.1010	13341.2513	13341.1013
13341.0640	13341.1012	13341.2515	13341.A1016
13341.0641	13341.1016	13341.2516	13341.1716
13341.0645	13341.2501	13341.2519	13341.1050
13341.1147	13341.2502	13341.2521	13341.0500

QUALITY ASSURANCE

Quality Control Release Date: July 12, 2020



Theresa Kwasny
Quality Systems Manager

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