

Certificate of Conformity

PRODUCT: Human Serum, Off Clot, Single Donor
CODE NO: 34011
LOT NO: 19642
DATE OF MANUFACTURE: 14Jul2020
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.

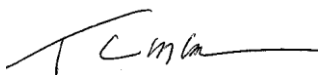
SAFETY: Each donor unit was tested prior to pooling according to FDA guidelines for the detection of Hepatitis B Surface Antigen, Antibodies to HIV and HVC, HIV-1 RNA, HBV DNA, HCV RNA, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded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

19642-0373	19642-0674	19642-2097	19642-1676	19642-0994
19642-0374	19642-0675	19642-2101	19642-1679	19642-0999
19642-0375	19642-1318	19642-4928	19642-1759	19642-1000
19642-0955	19642-1319	19642-4929	19642-1761	19642-1393
19642-0956	19642-1320	19642-4940	19642-0685	19642-1398
19642-0959	19642-1052	19642-4949	19642-1757	19642-1399
19642-0960	19642-1589	19642-4952	19642-1764	19642-2917
19642-0963	19642-1594	19642-4954	19642-1765	
19642-0964	19642-2163	19642-4956	19642-1768	
19642-0673	19642-1173	19642-4957	19642-1770	

QUALITY ASSURANCE

Quality Control Release Date: July 17, 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