



## Certificate of Conformity

**PRODUCT:** Human Serum, Off Clot, Single Donor

**CODE NO:** 34011

**LOT NO:** EXAMPLE

**DATE OF MANUFACTURE:** =-----

**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:

21242-0750	21242-1539	21242-2371	21242-1308	21242-2315
21242-0751	21242-1540	21242-2372	21242-1310	21242-2316
21242-0752	21242-1170	21242-2373	21242-1311	21242-2317
21242-2011	21242-3241	21242-2374	21242-1313	21242-2319
21242-2012	21242-3242	21242-2375	21242-1314	21242-2320
21242-2013	21242-3243	21242-2376	21242-1315	21242-5562
21242-2014	21242-0891	21242-0510	21242-1316	21242-5563
21242-2015	21242-0892	21242-0512	21242-1317	21242-5564
21242-0777	21242-2369	21242-0513	21242-2312	21242-5565
21242-1538	21242-2370	21242-1307	21242-2313	21242-5566

### QUALITY ASSURANCE

Quality Control Release Date: -----

Meets or exceeds specifications   
Does not meet specifications

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