

Certificate of Analysis

PRODUCT: Human Serum Sample

CODE NO: 34015 -1

LOT NO: 22740

**DATE OF
MANUFACTURE:** 15August2018

ORIGIN: U.S.A.

STORAGE: At or below -70 °C

VOLUME: Approximately 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.

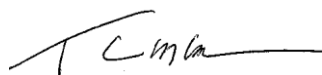
SAFETY: Each donor unit was tested prior to pooling according to FDA guidelines for the detection of Hepatitis B Surface Antigen, Antibodies to HIV and HVC, HIV-1 RNA, HBV DNA, HCV RNA, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded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

22740.3582	22740.1241	22740.1333	22740.3486	22740.1869	22740.1328	22740.0520	22740.1454
22740.3587	22740.1331	22740.1335	22740.3497	22740.3500	22740.1250	22740.0849	22740.1266
22740.1452	22740.1264	22740.3489	22740.1870	22740.1258	22740.1456	22740.3589	22740.3490
22740.1255	22740.1263	22740.1880	22740.1881	22740.0855	22740.1868	22740.1256	22740.1260
22740.3491	22740.1334	22740.1329	22740.3588	22740.0848	22740.3480	22740.3499	22740.1249
22740.0853	22740.6831	22740.3581	22740.0515	22740.1261	22740.1265	22740.1257	22740.3487
22740.1882	22740.3506	22740.3566	22740.3507	22740.3510	22740.3567	22740.0852	22740.3495
22740.1001	22740.1327	22740.3484	22740.1251	22740.3572	22740.3573	22740.1460	22740.0850
22740.6853	22740.1248	22740.1245	22740.0851	22740.1326	22740.1243	22740.6818	22740.3492
22740.6849	22740.3488	22740.3577	22740.3494	22740.3493	22740.1242	22740.3498	22740.3509

QUALITY ASSURANCE

Quality Control Release Date: August 15, 2018



Theresa Kwasny
 Quality Systems Manager

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 SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES