

Certificate of Analysis

PRODUCT: Human Serum Sample**CODE NO:** 34015 -1**LOT NO:** 25740**DATE OF
MANUFACTURE:** 18September2018**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.

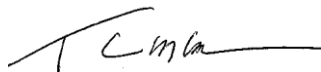
SAFETY: Each donor unit was tested prior to pooling according to FDA guidelines for the detection of Hepatitis B Surface Antigen, Antibodies to HIV and HVC, HIV-1 RNA, HBV DNA, HCV RNA, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). All units yielded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

25740.0282	25740.0310	25740.0268	25740.2296
25740.0283	25740.0311	25740.0361	25740.2299
25740.0289	25740.0317	25740.0363	25740.8292
25740.3817	25740.0322	25740.0364	25740.8274
25740.3818	25740.0326	25740.0365	25740.8285
25740.3832	25740.0327	25740.4289	25740.8283
25740.3840	25740.0130	25740.4302	25740.0176
25740.3844	25740.0134	25740.0374	25740.0173
25740.3846	25740.0663	25740.1502	25740.4294
25740.0309	25740.0259	25740.2292	25740.4295

QUALITY ASSURANCE

Quality Control Release Date: September 20, 2018

Theresa Kwasny
Quality Systems ManagerNOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES