Certificate of Analysis

PRODUCT: Human Serum, Off the Clot, Pooled

CODE NO: 34019 **LOT NO:** **EXAMPLE**

DATE OF MANUFACTURE: ---------- **STORAGE:** At or below -20 ˚C

ORIGIN: U.S.A.

SAFETY: *Statement of anonymity of donors:* This product consists of human serum, either single units or pooled from single units, 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.

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.

PROCESS NOTES: This product consists of human serum that has been pooled and filtered to 0.4 µm.

ASSAYS:

Required Assays	Specification	Result
Complement Activity (CH50)	>100	243

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

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