



Certificate of Analysis

PRODUCT: Human Complement Sterile Immunodepleted/Activated

CODE NO: R&D

LOT NO: 06238

DATE OF March 2, 2016

MANUFACTURE:

ORIGIN: U.S.A.

STORAGE: At or below -70 °C

INSTRUCTIONS This product consists of human serum that has been pooled, immunodepleted, and had
FOR USE: the addition of a complement factor designed to recover the complement activity lost during immunodepletion. The serum was filtered following immunodepletion and the activator was added under aseptic conditions, though the product was not re-filtered so as to preserve complement activity.

1. For use, prepare a 37°C water bath.
2. Thaw the serum on ice and maintain on ice until ready for use.
3. Incubate serum for a minimum of 15 minutes in the 37°C water bath just prior to performing titer assay. The serum may be incubated up to 30 minutes at 37°C with no increase or decrease in activity.
4. Mix serum gently following incubation and place on ice.
5. Proceed immediately with complement titer assay.

Complement activity may be lost upon re-freezing, therefore re-freezing/thawing is not recommended.

SAFETY: *Statement of anonymity of donors:* This product consists of serum 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 HIPPA 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, and Syphilis. All units yielded NON-REACTIVE/NEGATIVE results for each test performed. 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.

ASSAYS:

Required Assays	Result
ELISA, IgG	0.0008 mg/mL (>14000X depletion compared to precursor)

QUALITY ASSURANCE

Quality Control Release Date:

March 3, 2016

Chris Lyle
Director of TechnologyNOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES