

Certificate of Analysis

PRODUCT: Human Complement – IgG/IgM Antibody Depleted Human Complement**CODE NO:** R&D Samples**LOT NO:** 22438**DATE OF MANUFACTURE:** August 11, 2016**ORIGIN:** U.S.A.**STORAGE:** At or below -70 °C

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.

PROCESS NOTES: This product consists of human serum that has been depleted of IgG and IgM antibodies by affinity chromatography. Depleted serum is filtered through a 0.45 µm membrane filter, aliquoted and frozen. Antibody concentrations given below indicate IgG concentration after IgG depletion for the precursor lot (lot 18138-A). This precursor lot was then used for the depletion of IgM to produce the IgG/IgM depleted product (lot 22438). IgM concentration was measured in the precursor lot before and after IgM depletion, the results of which are shown below.

ASSAYS:

Required Assays	Result	
Calculated CH50, based on QCP 3800 Hemolytic Titer	Reference Sample: Lot 18138-A (IgG depleted precursor): 131	Lot 22438 (IgG/IgM depleted): 157
ELISA, Ig concentration	Reference Sample: Lot 18138-A (IgG depleted precursor): - IgG: 0.000322 mg/mL - IgM: 0.844548 mg/mL	Lot 22438 (IgG/IgM depleted): IgM: 0.000021 mg/mL

QUALITY ASSURANCE

Quality Control Release Date: August 15, 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