

Certificate of Analysis

PRODUCT: Human Complement – IgG/IgM Depleted

CODE NO: R&D Samples

LOT NO: 05038

DATE OF MANUFACTURE: May 13, 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.*

Infectious Disease Testing: 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: Sample Description: Lot 05038 tested previously and depleted of IgG was used as the precursor serum for IgM depletion using successive immunoprecipitation. Column numbering indicates the number of successive IP columns used in the IgM depletion step. Serum was filtered after IgG depletion but was not filtered again following IgM depletion.

Required Assays	Result
% Lytic Activity: Value given is relative percent lysis to Lot 05038 (IgG Depleted, Pre-IgM depletion) at the reciprocal dilution of serum giving 50% lysis	Lot 05038 (IgG Depleted, Pre-IgM depletion): Set at 100%, Recip dil. 50% lysis: 226 Column #1: 88.8% Recip dil. 50% lysis: 201 Column #2: 81.5% Recip dil. 50% lysis: 184 Column #3: 55.0% Recip dil. 50% lysis: 124 Column #4: 55.8% Recip dil. 50% lysis: 126
ELISA: Residual IgM concentration following successive IP	Lot 05038 (IgG Depleted, Pre-IgM depletion): 890 µg/mL Column #1: 522 µg/mL Column #2: 327 µg/mL Column #3: 288 µg/mL Column #4: 259 µg/mL (For reference: Concentration of IgG following initial IgG depletion: 0.716 µg/mL)

QUALITY ASSURANCE

Quality Control Release Date: May 16, 2016



Chris Lyle
 Director of Technology

NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
 SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES