

Certificate of Analysis

PRODUCT: Human Complement Antibody Depleted**CODE NO:** R&D**LOT NO:** 35336**DATE OF
MANUFACTURE:** December 19, 2014**ORIGIN:** U.S.A.**STORAGE:** At or below -20 °C

SAFETY: This product consists of serum pooled from single units obtained from anonymous donors that has been depleted of IgG antibodies by affinity chromatography. Depleted serum is filtered through a 0.2 µm membrane filter, aliquoted and frozen. 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
CH50	1:64
ELISA, IgG	0.0008 mg/mL (>14000X depletion compared to precursor)

QUALITY ASSURANCE

Quality Control Release Date: February 19, 2015

Chris Lyle
Quality Systems Manager and Scientist, Operational Technical Support

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