

Certificate of Analysis

PRODUCT: Human Serum, IgG/IgM Depleted Single Donor
CODE NO: 34099 **LOT NO:** 10846A
DATE OF MANUFACTURE: 17Apr2024 **STORAGE:** At or below -70°C
ORIGIN: U.S.A.

SAFETY: Serum of human origin collected only from US FDA plasma/serum collection centers and have been tested according to the FDA guideline for serological test for syphilis (STS) and found to be nonreactive. The individual units comprising the lot or lots have been tested for HBSAG, HCV (PCR), HIV-1 AG (HIV-PCR/HIV Genomic test) and antibodies to HIV 1/ 2 and HCV and found negative/Non-reactive by an approved FDA test.

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.

ASSAYS:

	Calculated Hemolytic Titer, CH50		IgG concentration, HPLC		IgM concentration, HPLC	
	Specification	Result	Specification	Result	Specification	Result
Donor Feed Serum	Report Result	219	Report Result	16 mg/mL	Report Result	1.7 mg/mL
IgG/IgM depleted serum	Report Result	89	Report Result	0.69% ¹	Report Result	1.6% ¹

¹ Assay value as % of starting donor feed serum.

QUALITY ASSURANCE

Quality Control Release Date: 23Apr2024



Kendra Graham
Quality Systems Technician / Clerk

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