

Certificate of Analysis

PRODUCT: Human IgM, Affinity Purified, Liquid
CODE NO: 34032
DATE OF MANUFACTURE: 12/5/2022
ORIGIN: U.S.A.
LOT NO: 33944
STORAGE: -20°C
SAFETY: *Statement of anonymity of donors:* This product consists of human serum, either single units or 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 HIPAA 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, WNV RNA, and Syphilis. Each donor has been tested according to FDA guidelines for T. Cruzi (Chagas). 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.

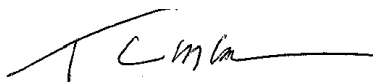
PROCESS NOTES: This product consists of human IgM antibodies isolated from human serum using affinity chromatography. Human IgM is supplied in buffer containing 50 mM Tris-HCl and 200 mM NaCl with 0.1% sodium azide as a preservative.

ASSAYS:

Test	Specification	Result
Absorbance 280 nm	1.12 – 1.24	1.2
SDS-PAGE purity	>95% Pure by densitometry	96%
Immunoelectrophoresis	Single arc of detection for IgM against anti-whole human serum	Pass

QUALITY ASSURANCE

Quality Control Release Date: December 18, 2022



Meets or exceeds specifications ☒
Does not meet specifications ☐
Product under development ☒

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