

Certificate of Analysis**PRODUCT:** Human IgM, 1mg/mL Azide-free**CODE NO:** 34035**LOT NO:** 18045**DATE OF** 6/29/2023**MANUFACTURE:****STORAGE:** -20 °C**ORIGIN:** U.S.A.

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

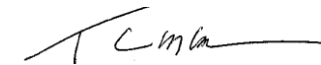
NOTES: This product consists of IgM antibodies that have been isolated from human serum using affinity chromatography. It undergoes precipitation steps to increase purity and is solubilized in 0.425% NaCl, filtered through a 0.2µm filter, lyophilized and reconstituted with no preservative.

ASSAYS:

Test	Specification	Result
Protein Determination by OD 280	1.18 to 1.24 AU	1.21 AU
SDS-PAGE	>80% Pure by densitometry	96.7 %
Immunoelectrophoresis	Single arc of detection for IgM against antisera	Pass

QUALITY ASSURANCE

Quality Control Release Date: June 30, 2023

Theresa Kwasny
Director of Quality**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**Product in development** ☒NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES