

PRODUCT FOR EVALUATION CERTIFICATE OF ANALYSIS

PRODUCT DESCRIPTION:	Human Complement IgG/IgM/IgA Depleted Pooled, Lyophilized																															
CODE:	34041L	LOT:	18247	STORAGE:	-20° C or below																											
DATE OF MANUFACTURE:	01JUL2025			ORIGIN:	U.S.A.																											
SAFETY:	<i>Statement of anonymity of donors:</i> 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: <u>BIO-SAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, FOR POTENTIALLY INFECTIOUS HUMAN SERUM OR BLOOD SPECIMENS.</u>																															
DESCRIPTION:	Human serum is depleted of IgG, IgM, and IgA. After depletion and filtration, material is lyophilized.																															
ASSAYS/TEST RESULTS:	<table border="1"> <thead> <tr> <th>Required Assays</th> <th>Specification</th> <th>Result</th> </tr> </thead> <tbody> <tr> <td>IgG – feed serum</td> <td>Report</td> <td>15 mg/mL</td> </tr> <tr> <td>IgG – pre-lyophilization</td> <td>≤ 3.5%¹</td> <td>0.028%</td> </tr> <tr> <td>IgM – feed serum</td> <td>Report</td> <td>1.02 mg/mL</td> </tr> <tr> <td>IgM – pre-lyophilization</td> <td>≤ 3.5%¹</td> <td>2.2%</td> </tr> <tr> <td>IgA – feed serum</td> <td>Report</td> <td>3.0 mg/mL</td> </tr> <tr> <td>IgA – pre-lyophilization</td> <td>≤ 3.5%¹</td> <td>0.53%</td> </tr> <tr> <td>CH50</td> <td>Report</td> <td>88</td> </tr> <tr> <td>Moisture</td> <td>< 5%</td> <td>2.7%</td> </tr> </tbody> </table> ¹⁾ Assay value as % of starting donor feed serum.					Required Assays	Specification	Result	IgG – feed serum	Report	15 mg/mL	IgG – pre-lyophilization	≤ 3.5% ¹	0.028%	IgM – feed serum	Report	1.02 mg/mL	IgM – pre-lyophilization	≤ 3.5% ¹	2.2%	IgA – feed serum	Report	3.0 mg/mL	IgA – pre-lyophilization	≤ 3.5% ¹	0.53%	CH50	Report	88	Moisture	< 5%	2.7%
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SIGNATURE



Bartholomew Rothrauff
Quality Systems Technician
Release date: 11JUL2025

PRODUCT FOR EVALUATION
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES
NOT FOR USE IN HUMANS