Pel-Freez® BIOLOGICALS

205 North Arkansas Street
Rogers, AR 72756

PRODUCT DATA SHEET

HUMAN IGG AFFINITY PURE LIQUID – 1 MG/ML

Product Codes:
34030 -0
34030 -1; -5; -10

Pack size:
Variable
1; 5; and 10 mL

Description:
This product consists of human IgG antibodies that have been isolated from human serum using Affinity Chromatography. It undergoes precipitation steps to increase purity and is solubilized in PBS pH 7.4 with 0.1% sodium azide. The product is filtered through a 0.2µm filter and packaged under sterile conditions.

IgG concentration is verified using HPLC. Additionally, immunoelectrophoresis confirmed the presence of a single precipitin arc between IgG and antisera specific to human serum. IgG was also shown to react with antiserum specific to IgG heavy and light chains.

Physical State:
Liquid

Packaging, shipping/storage:
Packaging:
HDPE Diagnostic Bottle

Storage Temperature:
2-8 °C

Shipping Conditions:
Ice

Expiration:
Product quality is guaranteed to meet Pel-Freez Biologicals' specifications for 1 year from the date of receipt by the customer as long as the product is stored in accordance with the indicated storage conditions.

Application Notes:
Suitable for use in HPLC. Also suitable for use in immunoassays.

Testing of Human Serum Source:
Statement of anonymity of donors: This product consists of pooled human serum 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, 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. Units were tested with an investigational nucleic acid test (NAT) for ZIKA VIRUS RNA and found to be NON-REACTIVE. 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. NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT. SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES.

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