

PRODUCT DATA SHEET

HUMAN COMPLEMENT, IgG/IgM DEPLETED, POOLED SERUM (LIQUID OR LYOPHILIZED)

Product Codes

Liquid:

34010 -0

34010 -1; -2; -5; -10; -100

Lyophilized:

34010L -1; -2; -5; -10

Pack size:

Variable

1; 2; 5; 10 and 100 mL

1; 2; 5 and 10 mL

Description:

This product consists of human serum that has been depleted of IgG and IgM antibodies. Depleted serum is filtered through a 0.2 µm membrane filter, aliquoted and frozen. For lyophilized material, product is aliquoted and lyophilized.

Physical State:

Frozen liquid or lyophilized powder

Testing:

CH50: Complement hemolytic titer

HPLC or ELISA: Residual IgG & IgM concentration

For lyophilized product only: Gravimetric moisture determination

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. 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.

Packaging, shipping/storage:

Packaging:

Liquid: Poly bottles or cryogenic tubes

Lyophilized: Glass vials

Storage Temperature:

Liquid: -70 °C or below

Lyophilized: -20°C or below for long term storage; for shipping and short-term storage, 2-8°C is acceptable

Shipping Conditions:

Liquid: Dry ice

Lyophilized: Cool packs

Guarantee:

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 functional antibody assays (SBA-Serum Bactericidal Assay, OPA-Opsonophagocytic Assay) for vaccine evaluation. Complement components are heat-sensitive; complement activity may be reduced with extended time at elevated temperatures or following multiple freeze-thaw cycles. For best results, freeze in smaller working aliquots for repeated use.

For lyophilized material, resuspend the powder in the appropriate volume of water (i.e. for 34010L -1, use 1 mL of water; for 34010L -2, use 2 mL of water; for 34010L -5, use 5 mL of water; for 34010L -10, use 10 mL of water). Once resuspended, freeze any unused material in smaller aliquots at -80°C.

References:

McIntosh ED, Broker M, Wassil J, Welsch JA, Borrow R. 2015. Serum bactericidal antibody assays - the role of complement in infection and immunity. *Vaccine*. 33:4414-4421.

Santos GF, Deck RR, Donnelly J, Blackwelder W, Granoff DM. 2001. Importance of complement source in measuring meningococcal bactericidal titers. *Clin Diagn Lab Immunol*. 8:616-623.

Bash MC, Lynn F, Mocca B, Borrow R, Findlow H, Hassan-King M, Preziosi MP, Idoko O, Sow S, Kulkarni P, LaForce FM. 2014. Development and use of a serum bactericidal assay using pooled human complement to assess responses to a meningococcal group A conjugate vaccine in african toddlers. *Clin Vaccine Immunol*. 21:755-761.