

PRODUCT INFORMATION SUMMARY: ANTIBODY-DEPLETED HUMAN SERUM

Pel-Freez Biologicals offers a large scale commercial source of IgG and IgM depleted human serum for use as a negative matrix diluent in a variety of vaccine development assays and research applications.

Human serum is a critical reagent in a variety of clinical and research applications but often contains certain components that can disrupt these assays. Human serum is a source of complement proteins that are necessary for bacterial vaccine applications including serum bactericidal and opsonophagocytic assays, however complement activity may interfere with other applications such as tissue culture. Antibodies in human serum that protect the donor from disease may cause unwanted background activity when used as a diluent.

Antibody-depleted human serum (ADHS) can be used to prepare human serum test panels with titers that uniformly span the entire assay reporting range from the lower limit of detection to the upper limit of detection.

Our ADHS is a preparation of pooled, pathogen-free normal human serum that has been systematically treated to remove IgG and IgM antibodies. Following antibody depletion, the pooled serum is returned to its original concentration via diafiltration then sterile filtered. Over 96% of IgG and IgM are removed by our process while the remaining ADHS retains all critical serum proteins for your bioassays.

- Qualification panels that uniformly span the assay reporting range from the lower to the upper limits of quantitation (LLOQ/ULOQ).
- Creation of large volumes of quality control sera (QCS) that can be used for extended clinical testing timelines.
- Creation of proficiency panels to measure long-term assay performance.
- Preparation of samples for dilutional linearity testing.

| | Product Code | Aliquot Size | Specifications |
|--|--------------|--------------|---|
| IgG/IgM Depleted Human Serum Heat-Inactivated | 34020-1 | 1 mL | Residual IgG & IgM: <3.5% CH50: 0 Typical Lot Size: 5 L to 10 L |
| | 34020-5 | 5 mL | |
| | 34020-10 | 10 mL | |
| | 34020-100 | 100 mL | |
| | 34020-500 | 500 mL | |

Table 1. Pel-Freez Biologicals antibody-depleted human serum available pack sizes and specifications.

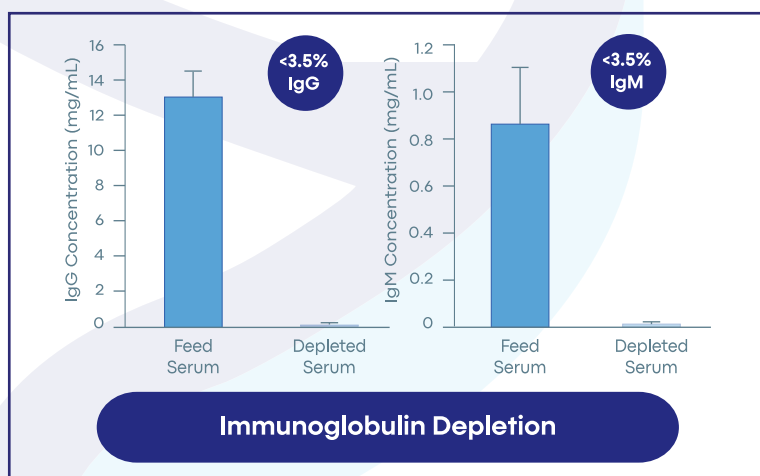


Figure 1. Analysis of pre- and post-depletion human serum by HPLC indicates < 3.5% residual IgG and IgM antibodies following depletion.

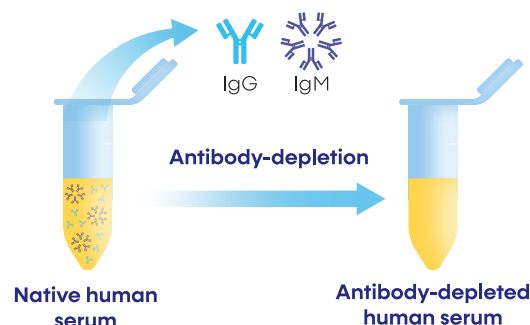
Human serum is processed from whole blood acquired from healthy donors in FDA-licensed facilities in the U.S. Donors provide informed consent prior to donation. Each unit of blood is tested according to FDA guidelines and found to be negative for all required viral markers.

ADHS is also used in a variety of laboratory qualification activities:

- Analyst training and qualification
- Complement serum screening and qualification
- Laboratory equipment and assay room qualification
- Media component qualification
- Filter membrane qualification
- Inter-laboratory assay transfer

The Antibody-Depletion Advantage

- ✓ Improved Lot-to-Lot Consistency
- ✓ Reduced Screening Time
- ✓ Liter+ Quantities Available



Manufacturing Process Overview

IgG and IgM immunoglobulins are depleted from pooled normal human serum using proprietary methods. Antibody-depleted serum is reconstituted to 1X concentration, 0.2 micron filtered, heat-inactivated at 56°C for 30 min, cooled, then frozen at -80°C. Quality control measures include residual IgG and IgM content and confirmation of complement inactivation via hemolytic titer (CH50). See Figure 2 below for an overview of the general manufacturing process.

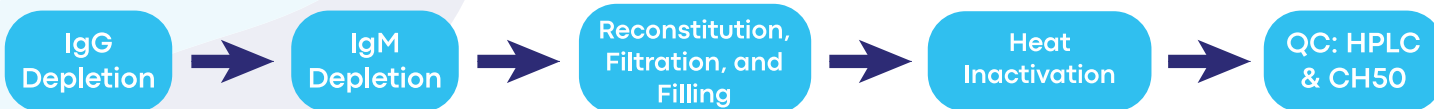
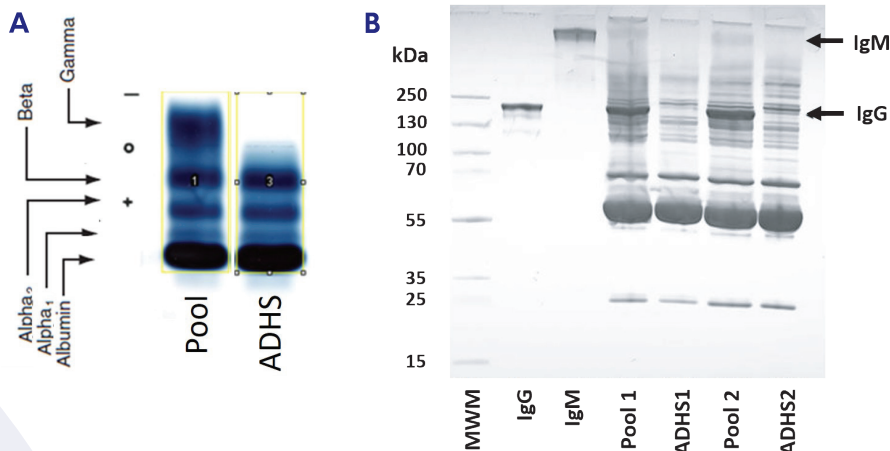


Figure 2. Flow chart for the manufacture of antibody-depleted human serum.

Figure 3. A) Our process of removing immunoglobulins from pooled human serum does not remove the other major serum fractions, such as serum albumin, alpha₁ globulins, alpha₂ globulins and beta globulins, as demonstrated by serum protein electrophoresis. B) Comparison of pre- and post-depletion preparations by SDS-PAGE demonstrate similar protein profiles with the exception of IgG and IgM which have been removed.



Pel-Freez Biologicals
antibody-depleted human serum is a viable diluent, low in residual IgG and IgM antibodies, retaining critical proteins necessary to perform as a serum matrix. Each lot is produced in accordance to standard operating procedures under our ISO 9001-certified quality management system.

| Accession Number | MW [kDa] | Description | Average # Peptides | |
|------------------|----------|--|--------------------|----------|
| | | | Pool | Depleted |
| P04114 | 515 | Apolipoprotein B-100 | 68 | 78* |
| P01024 | 187 | Complement C3 | 50 | 59† |
| P01023 | 163 | Alpha-2-macroglobulin | 39 | 44† |
| POCOL5 | 192 | Complement C4-B | 37 | 38* |
| P00450 | 122 | Ceruloplasmin | 22 | 26* |
| P02768 | 69 | Albumin | 23 | 25* |
| P01009 | 47 | Alpha-1-antitrypsin | 20 | 21* |
| P02787 | 77 | Serotransferrin | 19 | 21† |
| Q14624 | 103 | Inter-alpha-trypsin inhibitor heavy chain H4 | 17 | 18* |
| P02647 | 31 | Apolipoprotein A-1 | 19 | 19* |

Figure 4. Analysis of pre- and post-depletion human serum by mass spectrometry (8 M guanidine + 7K MWCO desalting and trypsin digestion) indicates minimal differences in levels of critical matrix proteins. Ten prominent proteins shown (n = 3, *p > 0.05, †p < 0.05 due to increased serum concentration following depletion and diafiltration).

Related Products

Code 34010 Antibody Depleted Human Complement
Code 34031 Human IgG, Affinity Purified, Lyophilized*
Code 34033 Human IgM, Affinity Purified, Lyophilized*
 *Also available in liquid preparations

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