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DATA SHEET

Reagent:	Anti-HIV Immune Globulin (HIVIG)
Catalog Number:	3957
Lot Number:	070002
Provided:	50 mg protein (1 ml)
Description:	HIVIG (Human Immunodeficiency Virus Immune Globulin) is a 5% protein solution in 0.9% NaCl. The preparation contains no preservatives, buffers or stabilizing agents. Each ml contains 50 mg of protein, not less than 95% of which has the electrophoretic mobility of gamma globulin. Greater than 90% of the gamma globulin is monomeric. The product is prepared from pooled plasma of asymptomatic, HIV antibody positive donors with CD4+ counts above 400/µL. All donors must be negative for HBsAg and anti-HCV. The donors are selected for high titer p24 antibody and test negative for HIV antigen when plasma units are tested by EIA. The initial pools are chemically inactivated by treatment with 1% Tween 80 and 1% Tri-N-Butyl Phosphate and heated at 30°C for four hours. This step inactivates at least 3 $\log_{10}$ units of infectious HIV. The treated plasma is then fractionated using the cold alcohol Cohn-Oncley process, which inactivates at least 12 $\log_{10}$ units of infectious HIV. Additional purification and inactivation is provided when IgG is purified by QAE Sephadex gel, an ion exchange resin, which yields monomeric, unfragmented, and undenatured IgG. The final product is formulated as a sterile, non-pyrogenic solution suitable for intravenous injection. Product safety is evaluated by testing each lot of HIVIG for negative results on p24 antigen by EIA, HIV culture and HIV DNA PCR.
Recommended Storage:	4-8°C
Contributor:	NABI and National Heart Lung and Blood Institute (Dr. Luiz Barbosa).
NOTE:	Acknowledgment for publications should read "The following reagent was obtained through the NIH AIDS Reagent Program, Division of AIDS, NIAID, NIH: Anti-HIV Immune Globulin (HIVIG) from NABI and NHLBI."
Research	

Research Chart:

Certificate of Analysis
PRODUCT: Human Immunodeficiency Virus Immune Globulin (Human) I.V.

Batch Analysis

Test	**Specification:**	**Result**:
Potency, anti-p24 titer	> 1/20,000	1/80,000
Product Identity	Positive, Human Negative, Bovine Negative, Ovine Negative, Porcine	Pass
Product Identity	Gamma Globulin by Electrophoresis	Pass
Purity	≥ 95% by Electrophoresis	100%
Total Protein	4.5 – 5.5 g/dL, Biuret Method	4.8 g/dL (Pass)
Chromatographic Purity	≤ 2% Fragments > 90% Monomer <10% Dimer ≤ 3% Aggregate	< 0.3% (Pass) 97.1% (Pass) 2.7% (Pass) < 0.3% (Pass)
Heat Stability	No Gelation (4 Hrs. @ 57°C)	Pass
Appearance	Solution Transparent to Translucent and Free of Extraneous Material	Pass
Safety	USP XXIII, 21 CFR 610.11	Pass
Sterility	USP XXIII, 21 CFR 610.12	Pass
pH	6.4 - 7.2	6.7 (Pass)
Pyrogen	Non-Pyrogenic, 21 CFR 610.13	Pass
Neutralization	> 1:160	Pass
Lymphocyte Infectivity	Negative	Pass
HIV Ag	Negative	Pass

Product prepared from human plasma tested and certified negative for HBsAg, HIV-1 Ag and anti-HCV by FDA Licensed methods. Product tested for Hepatitis C Virus RNA by PCR and none was detected. Product tested for HIV-1 DNA and HIV-1 RNA by PCR and none was detected.