



CERTIFICATE OF ANALYSIS

DESCRIPTION: Human Gamma Globulin, 5% Liquid

Lot Number: 00GEA00241
Manufacturing Date: 07 Oct 2016
Storage: 2-8°C

TEST	SPECIFICATION	RESULTS
Appearance	Liquid	Complies
Total Protein	Report Value	48 mg/ml
Protein Composition (IgG Purity)	≥92.0%	99.4%
pH	Report Value	5.6

Individual donor units used in the preparation of this product have been tested and found negative by tests for antibodies to HIV 1/2, HCV and non-reactive for HBsAg. Pooled samples were found non-reactive for HIV-1 RNA, HBV DNA and HCV RNA by Nucleic Acid Test. All testing performed with kits approved by the FDA. Each donor has been tested and found negative for syphilis according to FDA guidelines.

All donor units were collected at FDA approved donor centers located in the United States.

The pool of source plasma for fractionation from which the product comes from has been tested and found non-reactive for virological markers HBsAg, anti-HIV 1/2 and anti-HCV using validated serological tests, and for HCV RNA, HIV-1 RNA and HBV DNA using validated techniques.

ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS

QA J. Goodman

Date 08/23/18

CAUTION:

Not for use in humans or clinical diagnosis. These products are intended for research or diagnostic manufacturing use only.