

Certificate of Analysis

PRODUCT: Human Gamma Globulin, Lyophilized Powder**CODE NO:** 34060**LOT NO:** 21070535**ORIGIN:** U.S.A.**Expiration Date:** 29SEP2026**STORAGE:** Ambient (short term), 2-8°C or colder (long term)**SAFETY:** 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 has been tested and found non-reactive for virological markers HBsAg, anti HIV 1/2 and anti HCV using validated serological test and for HCV RNA, HIV-1 RNA and HBV DNA using validated techniques.

All blood products should be handled and treated as potentially infectious.

PROCESS**NOTES:**

This product consists of human gamma globulin that has been purified from human plasma via salt fractionation methods.

ASSAYS:

Test	Specification	Result
Appearance	White to Yellow Powder	Complies
Total Protein	Report Result	5.8 g/dL
Protein Composition (IgG Purity)	≥ 97%	97%
Moisture	Report Result	3.0%

QUALITY ASSURANCE

Quality Control Release Date:

June 2, 2025

Kendra Graham
Quality Systems Lead**Meets or exceeds specifications** ☒**Does not meet specifications** ☐

NOT FOR USE IN PRODUCTS SUBJECT TO LICENSE UNDER SECTION 351 OF THE PUBLIC SERVICE ACT
SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES