

CERTIFICATE OF ANALYSIS

PRODUCT: HUMAN GAMMA GLOBULIN 5%

LOT NUMBER(S):

LOT #	VOLUME
B122A8482	100 mL

PURITY: 100%

pH VALUE: 5.2

TOTAL PROTEIN: 5.0 g/100 mL

PROTEIN COMPOSITION: 100%

STERILITY: Sterile- Passed Test

CHLORIDE: < 10 mmol/l

SODIUM: < 2 mmol/l

MALTOSE: 100 mg/ml

SOURCE: HUMAN DONOR(S)

STORAGE: 2-25° C

Individual donor units used in the preparation of this product have been tested and found Negative by tests for antibodies to HIV 1, HIV 2 and HCV and Non-reactive for HBsAg and Non-reactive for HIV 1 and HCV by Nucleic Acid Test performed on pooled samples 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.

ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS

Signature: 

Print Name: Mariela Moreno

Date: 7/16/14