

CERTIFICATE OF ANALYSIS

Product Human Gamma Globulin Lyophilized Reagent Grade
Master Lot No. 111RM-XXA24
Item No. IGIVD-100G
Filled Volume 100 g
Storage Condition ≤ 8 degree Celsius or colder
Preservative(s) <Product Specific>
D.O.M. <Lot Specific>
Expiration Date 10 Years from the date of manufacture (D.O.M.)
Manufacturer Monobind Inc. ISO: 13485 Certified Company
Bleed Testing All Units in this serum pool were found negative or non-reactive to HIV 1/2 Antibodies, HBsAg, HCV Antibodies, and HIV,HBV, and HCV by NAT, and Syphilis by FDA approved methods.
Fractionation Method Cohn-Oncley Cold Alcohol Procedure
Caution Not for use in human or clinical diagnosis. For use in research, or manufacturing non-injectable products only.
Note **Results based on 5 % solution**

Test	Results	Methodology
Appearance	Off White Powder	Visual
Optical Density	TBD	@450nm
pH	TBD	ph Meter
Solubility	TBD minutes	Manual Stirring
Total Protein	#REF!	Biuret
Purity	TBD %	Protein Electrophoresis
Ash	TBD %	550°C, 3 hours incineration
Microbial	TBD cfu/mL	Pour Plate, 30-35 degree C, 48 hrs.
Moisture	TBD %	Thermogravimetric

Prepared by _____ (Biomatrix Dept.)
 Verified by _____ (QC Dept.)

Date: _____
 Date: _____

