

Certificate of Analysis

PRODUCT: Rabbit Gamma Globulin**CODE NO:** 21008**LOT NO:** 06341**DATE OF
MANUFACTURE:** March 4, 2019**EXPIRATION:** 2 years from date of
receipt**STORAGE:** 2-8 °C**SHIPPING
CONDITIONS:** Ambient temperature**ORIGIN:** U.S. Origin. Blood was collected from normal, clinically healthy rabbits at ARTEC-0007. This material has not been pooled or blended with material from another country or with any other ingredient.**HEALTHY
ANIMAL
STATEMENT:** This product is made from raw materials that were collected from animals found free from obvious signs of infectious and contagious disease.**EU
REQUIREMENTS:** Product meets European Union requirements for production of technical blood products.**APPEARANCE:** Off-white, fine flaky powder.**PROCEDURE:** Rabbit gamma globulin is purified from normal rabbit serum (either sex, healthy animals) using different fractionation procedures established in our laboratory.

ASSAYS:	Required Assays	Specification	Result
	Serum Protein Electrophoresis	≥ 95%	99%
	Protein by Weight, O.D. 280 nm E ^{1%} 1.39	≥ 85%	96%
	Moisture Content	For information only	1.8%
	Immunoelectrophoresis	Test confirms major band as IgG	Pass
	Additional Assays		
	Bioburden	≤ 1000 cfu/g	60 cfu/g

QUALITY ASSURANCE

Quality Control Release Date:

April 18, 2019

Doug Stocker
Quality Systems Technician**Meets or exceeds specifications** ☒**Does not meet specifications** ☐**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**