

Certificate of Analysis

PRODUCT: Rabbit Gamma Globulin**CODE NO:** 21008**LOT NO:** 16042**DATE OF
MANUFACTURE:** June 8, 2020**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 AR TEC 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%	100%
Protein by Weight, O.D. 280 nm E ^{1%} 1.39	≥ 85%	92%
Moisture Content	For information only	3.25%
Immunoelectrophoresis	Test confirms major band as IgG	Pass
Additional Assays		
Bioburden	≤ 1000 cfu/g	20 cfu/g

QUALITY ASSURANCE

Quality Control Release Date:

July 20, 2020

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