

## Certificate of Analysis

**PRODUCT:** Goat Gamma Globulin

**CODE NO:** 22005

**LOT NO:** 22441

**DATE OF MANUFACTURE:** August 12, 2019

**STORAGE:** 2-8 °C

**ORIGIN:** U.S.A.

**EU 142/2011:** AR-TEC-0007

**EU REQUIREMENTS:** Product meets EU requirements for production of treated technical blood products.

**PROCEDURE:** The goat serum was obtained from USDA approved facility TX-TEC- 0004. The processing of the serum was performed at AR-TEC 0007. Goat gamma globulin is purified from normal goat serum using different fractionation procedures followed by extensive dialysis against low ionic strength buffer and finally lyophilization. To help eliminate diseases that might be carried in animal blood products, the pH of the gamma globulin is adjusted to <5.0 for a minimum of 3 hours during one of the fractionation processes.

**RECONSTITUTION:** Reconstitute in at least 0.2% NaCl solution.

**ASSAYS:**

| Required Assays                                     | Specification        | Result |
|---|----------------------|--------|
| Serum Protein Electrophoresis                       | ≥ 98%                | >99%   |
| Protein by Weight, O.D. 280 nm E <sup>1%</sup> 1.39 | ≥ 85%                | 85%    |
| Moisture Content                                    | For information only | 4.2 %  |

**QUALITY ASSURANCE**

Quality Control Release Date: October 3, 2019



Doug Stocker  
 Quality Systems Technician

**Meets or exceeds specifications**

**Does not meet specifications**

**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**