

Certificate of Analysis

PRODUCT: Goat Gamma Globulin**CODE NO:** 22005**LOT NO:** 33338**DATE OF****MANUFACTURE:** November 28, 2016**STORAGE:** 2-8 °C**ORIGIN:** U.S.A.**EU 142/2011:** AR TEC 0007

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 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.

APPEARANCE: White to off-white powder

ASSAYS:

Required Assays	Specification	Result
Serum Protein Electrophoresis	≥ 96%	97%
Protein by Weight, O.D. 280 nm E ^{1%} 1.39	≥ 85%	90%
Moisture Content	For information only	1.40%

QUALITY ASSURANCE

Quality Control Release Date:

December 19, 2016

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