

Biologicals Division

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**Pel-Freez®**

## Certificate of Analysis

**PRODUCT:** Rabbit Gamma Globulin, U.S. Origin

**CODE NO:** 21008      **LOT NO:** 35636

**STORAGE:** 2-8 °C      **SHIPPING CONDITIONS:** Ambient temperature

**PROCEDURE:** Rabbit gamma globulin is purified from normal rabbit serum (either sex, healthy animals) using fractionation procedures established in our laboratory.

**ORIGIN:** U.S. Origin. Blood was collected from normal, clinically healthy rabbits at plant AR-TEC-0007. This material has not been pooled or blended with material from another country or with any other ingredient.

**APPEARANCE:** Off-white, fine flaky powder.

### EU

**REQUIREMENT:** Product meets European Union requirements for production of technical blood products.

**EXPIRATION:** 2 years from date of receipt

### ASSAYS:

| Required Assays                                        | Specification                   | Result                                    |
|--------------------------------------------------------|---------------------------------|-------------------------------------------|
| Serum Protein Electrophoresis                          | ≥ 95%                           | > 99%                                     |
| Protein by Weight, O.D. 280 nm<br>E <sup>1%</sup> 1.39 | ≥ 85%                           | 87%                                       |
| Moisture Content                                       | FIO                             | 3.46%                                     |
| Immunoelectrophoresis                                  | Test confirms major band as IgG | Major band confirmed as IgG (at 10 mg/mL) |
| Additional Assays                                      |                                 |                                           |
| Bioburden                                              | < 1000 cfu/g                    | 60 cfu/g                                  |

### QUALITY ASSURANCE

**Quality Control Release Date:** January 2, 2015



Sarah Graves  
Quality Systems Technician

**Meets or exceeds specifications ✓**  
**Does not meet specifications**

**SUITABLE FOR FURTHER MANUFACTURE OR RESEARCH PURPOSES**