



Rocky Mountain Biologicals, Inc

# Certificate of Analysis

## Donor Equine Serum- 0.2 µm Filtered, US Origin

Product Number: DES-BBT-5XM  
 DES-BBT-01L  
 DES-BBT-SMP  
 DES-BBT-CSP

Lot Number: 20160915ES  
 Date of Manufacture: 09/2016  
 Expiration Date: 09/2021  
 Storage Temperature: ≤ -10 °C

BASIS FOR RELEASE

NOT FOR HUMAN OR ANIMAL CONSUMPTION

### CHEMICAL ANALYSIS

| Test          | Method             | Specification   | Result      |
|---------------|--------------------|-----------------|-------------|
| Albumin       | Chemistry Analyzer | As Reported     | 2.8 g/dL    |
| ALT           | Chemistry Analyzer | As Reported     | 10 U/L      |
| AST           | Chemistry Analyzer | As Reported     | 305 U/L     |
| Bilirubin     | Chemistry Analyzer | As Reported     | 0.8 mg/dL   |
| Calcium       | Chemistry Analyzer | As Reported     | 10 mg/dL    |
| Cholesterol   | Chemistry Analyzer | As Reported     | 78 mg/dL    |
| Creatinine    | Chemistry Analyzer | As Reported     | 1 mg/dL     |
| Globulin      | Chemistry Analyzer | As Reported     | 4 g/dL      |
| Glucose       | Chemistry Analyzer | As Reported     | 70 mg/dL    |
| Osmolality    | Osmometer          | 206-345 mOsm/kg | 277 mOsm/kg |
| pH            | pH Meter           | 6.0 - 8.5       | 8.1         |
| Phosphorus    | Chemistry Analyzer | As Reported     | 4.2 mg/dL   |
| Potassium     | Chemistry Analyzer | As Reported     | 4.4 mEq/L   |
| Sodium        | Chemistry Analyzer | As Reported     | 133 mEq/L   |
| Total Protein | Chemistry Analyzer | 6.0 - 9.5 g/dL  | 6.8 g/dL    |

### MICROBIOLOGICAL ANALYSIS

| Test       | Method      | Specification | Result       |
|------------|-------------|---------------|--------------|
| Endotoxin  | LAL         | ≤ 50 EU/mL    | 2.4 EU/mL    |
| Mycoplasma | 9CFR 113.28 | Not Detected  | Not Detected |
| Sterility  | 9CFR 113.26 | No Growth     | No Growth    |

### VIRAL ANALYSIS

| Test         | Method      | Specification | Result       |
|--------------|-------------|---------------|--------------|
| BVD          | 9CFR 113.53 | Not Detected  | Not Detected |
| CPE          | 9CFR 113.53 | Not Detected  | Not Detected |
| EHV          | 9CFR 113.53 | Not Detected  | Not Detected |
| EIA          | 9CFR 113.53 | Not Detected  | Not Detected |
| EVA          | 9CFR 113.53 | Not Detected  | Not Detected |
| Hemadsorbing | 9CFR 113.53 | Not Detected  | Not Detected |
| Rabies       | 9CFR 113.53 | Not Detected  | Not Detected |
| REO Virus    | 9CFR 113.53 | Not Detected  | Not Detected |

### IDENTITY ANALYSIS

| Test       | Method | Specification        | Result |
|------------|--------|----------------------|--------|
| Appearance | Visual | Clear Amber Solution | Pass   |

**Rocky Mountain Biologicals, Inc.**  
 6015 Greg's Way | Missoula, MT 59808 | USA  
 Tel: 406-541-7624 | Fax: 406-541-7615  
 www.rmbio.com

**Donor Equine Serum- 0.2 µm Filtered, US Origin**

**Product Number:** DES-BBT-5XM  
DES-BBT-01L  
DES-BBT-SMP  
DES-BBT-CSP

**Lot Number:** 20160915ES  
**Date of Manufacture:** 09/2016  
**Expiration Date:** 09/2021  
**Storage Temperature:** ≤ -10 ° C

ADDITIONAL LOT INFORMATION

NOT FOR HUMAN OR ANIMAL CONSUMPTION

## Additional Testing

| GROWTH PROMOTION/CYTOTOXICITY |               |               | CUSTOMER SPECIFIC |        |               |        |
|-------------------------------|---------------|---------------|-------------------|--------|---------------|--------|
| Test                          | Specification | Result        | Test              | Method | Specification | Result |
| CHO                           | As Reported   | Not Requested | Not Requested     |        |               |        |
| CHO Cell Cytotoxicity         | As Reported   | Not Requested | Not Requested     |        |               |        |
| Vero                          | As Reported   | Not Requested | Not Requested     |        |               |        |
| Vero Cell Cytotoxicity        | As Reported   | Not Requested | Not Requested     |        |               |        |


### STATEMENT OF ORIGIN

Raw serum used in the manufacture of this product was obtained from approved suppliers collecting from traceable animals originating from the United States. Full health, traceability, and required regulatory documentation are maintained under RMBIO's quality systems. The serum was processed, filtered, and finished in the United States.

### EUROPEAN UNION ELIGIBILITY

Product meets European Union Requirements of Technical Blood Products.

### Approval

|                                       |   |              |
|---------------------------------------|---|--------------|
| <b>Quality Assurance- Print Name:</b> | <b>Quality Assurance- Sign Name:</b>  | <b>Date:</b> |
| <b>Terri Sorensen</b>                 |  | 10/25/14     |