

## **Certificate of Analysis**

Revised January 10, 2019

**Product:** 

**GemCell™ Donor Horse Serum** 

0.2µm sterile-filtered

Catalog #: 100-508 Lot #: E55H00J

Origin: United States (100%)

Manufacture Date: Jun 2018

Expiration Date: Jun 2023

| TEST                    | <b>M</b> ETHODOLOGY              | SPECIFICATION | RESULTS      |
|-------------------------|----------------------------------|---------------|--------------|
| Biological Testing      |                                  |               |              |
| Endotoxin               | USP<85>                          | Report        | 0.769 EU/mL  |
| Hemoglobin              | Fleming, AF and Woolf, AJ (1965) | Report        | 4.08 mg/dL   |
| Microbiological Testing |                                  |               |              |
| Sterility               | USP<71>                          |               |              |
| Bacteria                |                                  | Not Detected  | Not Detected |
| Fungi                   |                                  | Not Detected  | Not Detected |
| Mycoplasma              | Barile, MF and Kern, J (1971)    | Not Detected  | Not Detected |
| Viral Testing           | 9 CFR 113.53c (113.46, 113.47)   |               |              |
| EIA (Coggins)           |                                  | Not Detected  | Not Detected |
| EVA                     |                                  | Not Detected  | Not Detected |
| EHV-1/ERV               |                                  | Not Detected  | Not Detected |
| BVDV                    |                                  | Not Detected  | Not Detected |
| Reo                     |                                  | Not Detected  | Not Detected |
| Rabies virus            |                                  | Not Detected  | Not Detected |
| Physical Testing        |                                  |               |              |
| Osmolality              | USP<785>                         | Report        | 282 m0sm/kg  |
| pH @ RT                 | USP<791>                         | Report        | 7.97         |
| Biochemical Testing     |                                  |               |              |
| Protein, Total          | Biuret                           | Report        | 6.0 g/dL     |

For Cell Culture, further Manufacturing and Research use only. Not for direct Therapeutic use. Product meets European Union Requirements for Production of Technical Blood Products.

Created by/ date

Verified by/ date

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