



## CERTIFICATE OF ANALYSIS

### Human Serum AB

### Off-the-Clot

(Catalog Number 100-318-100, 100-318-005)

Lot Number: H424011

Date of Manufacture: Apr2024

Product Expiry: Apr2029

Origin: United States

Storage Temperature:  $\leq -10^{\circ}\text{C}$

For Cell Culture, further Manufacturing or Research use only. Not for direct Therapeutic use.

**Product Description:** Human Serum AB Off-the-Clot is collected from healthy male donors of the AB serotype at FDA-licensed facilities located in the United States. Donor units are tested for infectious disease markers prior to processing and found to be non-reactive. Human Serum AB Off-the-Clot is sterile-filtered through a 0.1  $\mu\text{m}$  filter prior to freezing.

| Test                           | Methodology                      | Specification     | Analysis     |
|--------------------------------|----------------------------------|-------------------|--------------|
| <b>Biological Testing</b>      |                                  |                   |              |
| Endotoxin                      | USP<85>, EP 2.6.14               | <10.0EU/mL        | <0.750 EU/mL |
| Hemoglobin                     | Fleming, AF and Woolf, AJ (1965) | <20.0 mg/dL       | 2.3 mg/dL    |
| <b>Microbiological Testing</b> |                                  |                   |              |
| Sterility                      | USP<71>, EP 2.6.1                |                   |              |
| Bacteria                       |                                  | No Growth         | No Growth    |
| Fungi                          |                                  | No Growth         | No Growth    |
| Mycoplasma                     | USP<63>                          | Not Detected      | Not Detected |
| <b>Viral Testing</b>           | 21CFR 610.40                     |                   |              |
| HBsAg                          | ABBOTT ChLIA                     | Non-Reactive      | Non-Reactive |
| Anti-HCV                       | ABBOTT ChLIA                     | Non-Reactive      | Non-Reactive |
| Anti-HIV-1/ HIV-2              | ABBOTT ChLIA                     | Non-Reactive      | Non-Reactive |
| Syphilis                       | ASI RPR                          | Negative          | Negative     |
| HBV-NAT                        | ROCHE NAT/ PCR                   | Not Detected      | Not Detected |
| HIV-NAT                        | ROCHE NAT/ PCR                   | Not Detected      | Not Detected |
| HCV-NAT                        | ROCHE NAT/ PCR                   | Not Detected      | Not Detected |
| West Nile Virus NAT            |                                  | Not Detected      | Not Detected |
| Chagas                         |                                  | Not Detected      | Not Detected |
| <b>Physical Testing</b>        |                                  |                   |              |
| Osmolality                     | USP<785>, EP 2.2.35              | 260 – 350 mOsm/kg | 287 mOsm/kg  |
| pH                             | USP<791>                         | Test and Report   | 7.69         |
| <b>Biochemistry Testing</b>    |                                  |                   |              |
| Albumin                        |                                  | Test and Report   | 4.2 g/dL     |
| ALT (SGPT)                     |                                  | Test and Report   | 8 U/L        |
| AST (SGOT)                     |                                  | Test and Report   | 15 U/L       |



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|------------------|-------------|-----------------|------------|
| Bilirubin, Total |             | Test and Report | 0.2 mg/dL  |
| BUN              |             | Test and Report | 13 mg/dL   |
| Calcium          |             | Test and Report | 9.1 mg/dL  |
| Chloride         |             | Test and Report | 104 mmol/L |
| Cholesterol      |             | Test and Report | 152 mg/dL  |
| Creatinine       |             | Test and Report | 1.03 mg/dL |
| Glucose          |             | Test and Report | 101 mg/dL  |
| Phosphorus       |             | Test and Report | 3.3 mg/dL  |
| Potassium        |             | Test and Report | 4.2 mmol/L |
| Protein, Total   |             | Test and Report | 7.2 g/dL   |
| Sodium           |             | Test and Report | 140 mmol/L |
| Triglycerides    |             | Test and Report | 71 mg/dL   |
| Uric Acid        |             | Test and Report | 5.4 mg/dL  |

*All blood products are collected from stringently screened male donors at FDA-licensed collection centers located in the United States. Viral testing is performed on the individual donor units. All other testing is performed on the final product pool prior to release. Universal precautions should be used when handling this material. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance. Precipitates may develop in this product upon freezing and/or thawing; this occurrence does not impact culture performance.*

The testing that has been performed as part of this lot release has been reviewed by Quality Assurance personnel and has confirmed that the testing meets the specifications presented on this Certificate of Analysis.

Karen Zuniga

Name

30MAY2024

Date

QA Associate II

Title