

## Certificate of Analysis

**Product Name: Blood Bank Saline – Buffered Solution**

**Description: Isotonic Saline Solution, 0.85% w/v, Buffered**

**Product No.: ES124320L**

**Lot. No.: 21805**

**Date of Manufacture: 08/27/2020**

**Expiration Date: 02/24/2022**

**Product Specifications:**

Ingredients: Sodium Chloride, USP Grade  
 Disodium Phosphate, Food Grade  
 Monosodium Phosphate, Food Grade  
 Deionized Water, NCCLS Type I Reagent Grade

Packaging: Product undergoes a two-phase sub-micron filtration process as well as UV Sterilization before filling process begins.  
 Packaged in 20 Liter Cubetainers (Manufactured by Hedwin Corporation.)

**Materials:**

|            | <u>Part No.</u>      | <u>Lot No.</u> | <u>Exp. Date</u> |
|------------|----------------------|----------------|------------------|
| Container: | CDC6378              | 07/21/2020     | N/A              |
| Cap:       | CAP-1 Gal-<br>RMS-38 | 202006577973   | N/A              |
| Spigot:    | COM4401-IW           | 1078477        | N/A              |
| Chemical:  | ES1243-1000          | 0H21783        | 2022-02-24       |

**QC Testing:**

| <b>LOT NUMBER: 0H21783</b>      |   |                |                    |
|---------------------------------|---|----------------|--------------------|
| <b>ATTRIBUTE</b>                | <b>SPECIFICATION</b>                        | <b>RESULTS</b> | <b>PASS / FAIL</b> |
| Appearance                      | Clear, colorless, no observable particulate | Pass           | <b>PASS</b>        |
| pH                              | 7.0-7.2                                     | 7.06           | <b>PASS</b>        |
| Assay                           | 0.85% to 0.90%                              | 0.88%          | <b>PASS</b>        |
| Isotonicity (Macro observation) | No hemolysis                                | Pass           | <b>PASS</b>        |
| Isotonicity (Micro observation) | No RBC aggregates                           | Pass           | <b>PASS</b>        |
| TAMC                            | < 10 CFU/ml                                 | 0 CFU/ml       | <b>PASS</b>        |
| TYMC                            | < 10 CFU/ml                                 | 0 CFU/ml       | <b>PASS</b>        |

**Country of Origin:** United States of America

**Latex Free:** This product contains no latex

Created By:  
 Fernando Fana  
 Quality Associate