

Certificate of Analysis

Product Name: Blood Bank Saline – Standard Solution

Description: Isotonic Saline Solution, 0.85% w/v, Non-buffered

Product No.: ES124420L

Lot. No.: 24673

Date of Manufacture: 05/05/2021

Expiration Date: 11/03/2022

Product Specifications:

Ingredients: Sodium Chloride, USP 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 | 04/21/2021 | N/A |
| Cap: | CAP-1 Gal- RMS-38 | 202102599242 | N/A |
| Spigot: | COM4401-IW | 1345815 | N/A |
| Chemical: | ES1244-1000 | 1E24674 | 2022-11-03 |

QC Testing:

| LOT NUMBER: 1E24674 | | | |
|---------------------------------|---|----------------|--------------------|
| ATTRIBUTE | SPECIFICATION | RESULTS | PASS / FAIL |
| Appearance | Clear, colorless, no observable particulate | Pass | PASS |
| pH | 6.5 - 7.0 | 6.92 | PASS |
| Assay | 0.85% to 0.90% | 0.88% | PASS |
| Isotonicity (Macro observation) | No hemolysis | Pass | PASS |
| Isotonicity (Micro observation) | No RBC aggregates | Pass | PASS |
| TAMC | < 10 CFU/ml | 0 CFU/ml | PASS |
| TYMC | < 10 CFU/ml | 0 CFU/ml | PASS |

Country of Origin: United States of America

Latex Free: This product contains no latex

Created By:
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Quality Associate