

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.: 21140

Date of Manufacture: 07/02/2020

Expiration Date: 12/29/2021

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> | Lot No. | Exp. Date |
|------------|----------------------|--------------|------------|
| Container: | CDC6378 | 05/20/2020 | N/A |
| Cap: | CAP-1 Gal- RMS-38 | 202004572023 | N/A |
| Spigot: | COM4401-IW | 1078477 | N/A |
| Chemical: | ES1244-1000 | 0F21110 | 2021-12-29 |

QC Testing:

| LOT NUMBER: 0F21110 | | | | |
|---------------------------------|---------------------------------------------|----------|-------------|--|
| ATTRIBUTE | SPECIFICATION | RESULTS | PASS / FAIL | |
| Appearance | Clear, colorless, no observable particulate | Pass | PASS | |
| рН | 6.5 - 7.0 | 6.6 | PASS | |
| Assay | 0.85% to 0.90% | 0.87% | PASS | |
| Isotonicity (Macro observation) | No hemolysis | Pass | PASS | |
| Isotonicity (Micro observation) | No RBC aggregates | Pass | PASS | |
| ТАМС | < 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: Fernando Fana Quality Associate