

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.: 25291

Date of Manufacture: 2021-06-22

Expiration Date: 2022-12-21

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 10 Liter Cubetainers (Manufactured by Hedwin Corporation.)

Materials:

	<u>Part No.</u>	<u>Lot No.</u>	<u>Exp. Date</u>
Container:	CDC5894	05/26/2021	N/A
Cap:	CAP-1 Gal- RMS-38	202105607877	N/A
Spigot:	COM4401-IW	1345820	N/A
Chemical:	ES1244-1000	1F25285	2022-12-21

QC Testing:

LOT NUMBER: 1F25285			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	6.5 - 7.0	6.77	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	< 1 CFU/ml	PASS
TYMC	< 10 CFU/ml	< 1 CFU/ml	PASS

Country of Origin: United States of America

Latex Free: This product contains no latex

Created By:
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Director of Operations & Quality