

Certificate of Analysis

Product Name: Blood Bank Saline – Buffered Solution

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

Product No.: ES124320L

Lot. No.: 20863

Date of Manufacture: 05/27/2020

Expiration Date: 11/26/2021

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	04/17/2020	N/A
Cap:	CAP-1 Gal- RMS-38	202003565141	N/A
Spigot:	COM4401-IW	1078477	N/A
Chemical:	ES1243-1000	0E20835	2021-11-26

QC Testing:

LOT NUMBER: 0E20835			
ATTRIBUTE	SPECIFICATION	RESULTS	PASS / FAIL
Appearance	Clear, colorless, no observable particulate	Pass	PASS
pH	7.0-7.2	7.05	PASS
Assay	0.85% to 0.90%	0.89%	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:
 Fernando Fana
 Quality Associate