

Certificate of Analysis

Product Name: Diluent/Sheath
OEM Part Number: 01H731H01
OEM Lot Number: 75938UN14
Storage: 15 - 30°C
Qty Manufactured: 1,760 Kits

Abbott List Number: 01H73-01
Abbott Commodity Number: 39-6991
Expiration Date: 2015-12-31
Package Insert No./Rev. N/A / N/A

Specification	Specification Limit	Result
pH: Beg Sample-Value 1	7.2 - 7.6	7.4 Pass
pH: Beg Sample-Value 2	7.2 - 7.6	7.4 Pass
pH: End Sample-Value 1	7.2 - 7.6	7.4 Pass
pH: End Sample-Value 2	7.2 - 7.6	7.4 Pass
Osmolality: Beg Sample-Value 1	310 - 320 mOsmol/Kg	318 Pass
Osmolality: Beg Sample-Value 2	310 - 320 mOsmol/Kg	317 Pass
Osmolality: End Sample-Value 1	310 - 320 mOsmol/Kg	318 Pass
Osmolality: End Sample-Value 2	310 - 320 mOsmol/Kg	317 Pass
Microbial (Pooled Sample)	<=10 CFU	0 Pass
Background: Beg Sample-WBC (x10 ³ /μL)	<=0.10	0.00 Pass
Background: Beg Sample-RBC (x10 ⁶ /μL)	<=0.02	0.00 Pass
Background: Beg Sample-PLTo (x10 ³ /μL)	<=3.00	0.07 Pass
Background: Beg Sample-PLTi (x10 ³ /μL)	<=5.00	0.31 Pass
Background: End Sample-WBC (x10 ³ /μL)	<=0.10	0.00 Pass
Background: End Sample-RBC (x10 ⁶ /μL)	<=0.02	0.00 Pass
Background: End Sample-PLTo (x10 ³ /μL)	<=3.00	0.03 Pass
Background: End Sample-PLTi (x10 ³ /μL)	<=5.00	0.10 Pass
RBC: Beg Sample (10 ⁶ /μL)	-0.15 - 0.15	-0.04 Pass
MCV: Beg Sample (fL)	-2.0 - 2.0	-0.7 Pass
RDW: Beg Sample (%)	-0.60 - 0.60	-0.10 Pass
PLT: Beg Sample (10 ³ /μL)	-25 - 25	1 Pass
RBC: End Sample (10 ⁶ /μL)	-0.15 - 0.15	0.02 Pass
MCV: End Sample (fL)	-2.0 - 2.0	-0.4 Pass
RDW: End Sample (%)	-0.60 - 0.60	-0.10 Pass
PLT: End Sample (10 ³ /μL)	-25 - 25	4 Pass
Date of Manufacture of Bulk	Report	2014-12-09
Test Date	Report	2014-12-12

1 Kit = 1 cubie

This product has been manufactured in compliance with Quality System Regulations, passed all Fisher Diagnostics final release specifications, and has met all Abbott acceptance requirements and current release specifications per applicable quality documents.

The product name, lot number, and expiration date matches the product name, lot number, and expiration date listed on this Certificate of Analysis.



Quality Representative

Date: 2014-12-19