

Fisher Diagnostics a division of Fisher Scientific Company, LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike Middletown, VA (USA) 22645-1905

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Certificate of Analysis

Product Name: WBC Reagent - Part A

OEM Part Number: 01H771H01

OEM Lot Number: 94354UN15

Storage: Room Temp

Abbott List Number: 01H77-01

Abbott Commodity Number: G4-0019

Expiration Date: 2016-07-31

Package Insert No./Rev. N/A / N/A

Qty Manufactured: 576 Kits

Specification	Specification Limit	Result
pH: Beg Sample-Value 1	8.0 - 8.6	8.4 Pass
pH: Beg Sample-Value 2	8.0 - 8.6	8.4 Pass
pH: Beg Sample Dilution-Value 1	6.8 - 7.4	7.3 Pass
pH: Beg Sample Dilution-Value 2	6.8 - 7.4	7.3 Pass
pH: End Sample-Value 1	8.0 - 8.6	8.4 Pass
pH: End Sample-Value 2	8.0 - 8.6	8.4 Pass
Osmolality: Beg Sample-Value 1	61 - 69 mOsmol/Kg	63 Pass
Osmolality: Beg Sample-Value 2	61 - 69 mOsmol/Kg	63 Pass
Osmolality: End Sample-Value 1	61 - 69 mOsmol/Kg	63 Pass
Osmolality: End Sample-Value 2	61 - 69 mOsmol/Kg	64 Pass
Background: Beg Sample-WBC (x 10 ³ /μL)	<=0.10	0.00 Pass
Background: Beg Sample-RBC (x 10^6/µL)	<=0.02	0.00 Pass
Background: Beg Sample-PLT (x 10 [^] 3/μL)	<=5.00	0.02 Pass
Background: End Sample-WBC (x 10 ³ /μL)	<=0.10	0.00 Pass
Background: End Sample-RBC (x 10^6/µL)	<=0.02	0.00 Pass
Background: End Sample-PLT (x 10 [^] 3/μL)	<=5.00	0.03 Pass
Date of Manufacture of Bulk	Report	2015-07-06
Test Date	Report	2015-07-09

1 Kit = 4 bottles of 01H75-01A

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: 2015-07-14