

Certificate of Analysis

Product Name: ADVIA OPTIpoint
Product Numbers: 10312283/T03368254
Lot Number: OP41114

Date of Manufacture: 07-OCT-14
Expiration Date: 2015-04-30
Storage: 2 - 8°C

Specification	Specification Limit	Result
Appearance	Light, brownish-red liquid which has a clear supernatant after settling	Complies
Microbial Growth	No growth allowed	Complies
RBC: CV	<= 5.0 %	1.2
MCV: Mean	83.0 - 99.0 fL	98.9
MCV: CV	<= 1.0 %	0.2
MCV: Result Agreement	-3.5 - 3.5 fL	-1.6
CHCM: Mean	32.0 - 40.0 g/dL	34.2
CHCM: CV	<= 1.0 %	0.1
CHCM: Result Agreement	-1.3 - 1.3 g/dL	0.4
RDW: Mean	11.0 - 15.0 %	12.7
RDW: CV	<= 2.5 %	0.6
RDW: Result Agreement	-1.0 - 1.0 %	0.4
HDW: Mean	2.00 - 3.00 g/dL	2.53
HDW: CV	<= 2.0 %	0.6
HDW: Result Agreement	-0.2 - 0.2 g/dL	0.0
Mean X: Mean	20.0 - 32.0	26.1
Mean X: CV	<= 1.0 %	0.3
Mean X: Result Agreement	-0.6 - 0.6	-0.1
Mean Y: Mean	22.0 - 33.0	30.0
Mean Y: CV	<= 1.0 %	0.2
Mean Y: Result Agreement	-0.6 - 0.6	-0.5
PLT:Mean	<= 50000 Cells per microliter	6950
Package Insert No.	Report	03867526
Package Insert Rev.	Report	H
Test Date	Report	10-22-14
Quantity Manufactured	Report	816

For in-vitro diagnostic use.

* This product contains animal and human source material. Human source material has been tested and found nonreactive for HBsAg, HCV, HIV 1, HIV 2, and Syphilis.

* The above lot number was manufactured in compliance with Quality Systems Regulations, has met all product specifications and has been released.

* This product was manufactured by Fisher Diagnostics for Siemens Healthcare Diagnostics.



Quality Representative

Date: 2014-10-28