

Certificate of Analysis

Product Name: ARC TNI Rgt(1x100)
OEM Part Number: 02K41-28
OEM Lot Number: 36311UN14
Storage: 2 - 8°C
Qty Manufactured: 9,991 Kits

Abbott List Number: 02K41-28
Abbott Commodity Number: 39-6729
Expiration Date: 2015-08-31
Package Insert No./Rev. 840653 / R08
Test Date 2014-09-04

Description	Lot Number	Expiration Date
Microparticles	36311UN14G	2015-08-31
Conjugate	36311UN14H	2015-08-31
ASD Reagent	36311UN14J	2015-08-31

Specification	Specification Limit	Result
Calibrator B/A Ratio	>=8.0	10.9 Pass
LOD: Result	<=0.01 ng/mL	0.00 Pass
Panel 1 N >= 3	0.33 (0.26 - 0.39) ng/mL	0.34 Pass
Panel 1: %CV	Report	3.0 % FIO
Panel 1	Lot number	244215
Control L N >= 3	0.16 (0.12 - 0.20) ng/mL	0.14 Pass
Control L: %CV	Report	2.5 % FIO
Control L	Lot number	TNI16081
Control M N >= 3	0.59 (0.47 - 0.71) ng/mL	0.57 Pass
Control M: %CV	Report	2.5 % FIO
Control M	Lot number	TNI16082
Control H N >=3	16.10 (12.88 - 19.32) ng/mL	15.67 Pass
Control H: %CV	Report	2.0 % FIO
Control H	Lot number	TNI16083
Master Calibrator	Lot number(s)	170941 170943-170947

For in-vitro diagnostic use.

Troponin-I Reagents contain animal source material.

This lot meets all current release specifications per quality document MS.MASTER342.

The above product has been manufactured in compliance with Fisher Diagnostics' operating procedure.



Quality Representative

Date: 2014-09-12