

Certificate of Analysis

Product Name: C4 Kit
OEM Part Number: 09D971T21
OEM Lot Number: 14600UN15
Storage: 2 - 8°C
Qty Manufactured: 677 Kits

Abbott List Number: 09D971T21
Abbott Commodity Number: 39-6831
Expiration Date: 2016-09-10
Package Insert No./Rev. 304990 / R03
Test Date 2015/09/21

Description	Lot Number	Expiration Date
C4 R1	14600UN15	2016-09-10
C4 R2	14600UN15	2016-09-10

Specification	Specification Limit	Result
Barcode Scan	Acceptable verification on c8000	Complies Pass
Bio-Rad L1	13.1 - 16.0 mg/dL	14.6 Pass
Bio-Rad L1	Lot Number	66301
Bio-Rad L2	32.5 - 39.8 mg/dL	36.0 Pass
Bio-Rad L2	Lot Number	66302
Bio-Rad L3	49.9 - 60.9 mg/dL	55.4 Pass
Bio-Rad L3	Lot Number	66303
Control Level 4: % Difference	-10 - 10 %	1 Pass
Micro: Beg Sample (R1) Result	<30 CFU/mL	1 Pass
Micro: End Sample (R1) Result	<30 CFU/mL	0 Pass
Micro: Beg Sample (R2) Result	<30 CFU/mL	0 Pass
Micro: End Sample (R2) Result	<30 CFU/mL	0 Pass

For in-vitro diagnostic use.

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

The above product has been manufactured in compliance with Quality Systems Regulations, passed all Thermo Fisher final release specifications, and has met all Abbott acceptance requirements.



Quality Representative

Date: 2015-09-22