

## *Certificate of Analysis*

Product Name: RF Kit  
OEM Part Number: 08G661T21  
OEM Lot Number: 87906UN11  
Storage: 2 - 8°C  
Qty Manufactured: 446 Kits

Abbott List Number: 08G661T21  
Abbott Commodity Number: 39-6806  
Expiration Date: 2012-12-15  
Package Insert No./Rev. 304369 / R1  
Test Date 11/9/11

Description	Lot Number	Expiration Date
RF R1	87906UN11	2012-12-15
RF R2	87906UN11	2012-12-15

Specification	Specification Limit	Result
Barcode Scan	Acceptable verification on c8000	Complies Pass
Bio-Rad Control L1	Lot Number	11721
Bio-Rad Control L2	Lot Number	11722
Bio-Rad Control L3	Lot Number	11723
Control 4	83.0 - 105.6 IU/mL	90.9 Pass
Control 3 % Difference	-16 - 16 %	1 Pass
Control 5 % Difference	-16 - 16 %	2 Pass
Micro: Beg Sample (R1)	<30 CFU/mL	0 Pass
Micro: End Sample (R1)	<30 CFU/mL	0 Pass
Micro: Beg Sample (R2)	<100 CFU/mL	1 Pass
Micro: End Sample (R2)	<100 CFU/mL	0 Pass

For in-vitro diagnostic use.

This product contains animal source material. The bovine material used in the manufacture of this product is derived from bovine blood collected from U.S. sourced cattle slaughtered at a USDA licensed establishment.

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: 2011-11-14