

Certificate of Analysis

Product Name: ARC Rubella IgG Reagent (1x100)	Abbott List Number: 06C17-28
OEM Part Number: 06C17-28	Abbott Commodity Number: 39-6790
OEM Lot Number: 03491UN15	Expiration Date: 2016-07-31
Storage: 2 - 8°C	Package Insert No./Rev. 840627 / R3
Qty Manufactured: 5,063 Kits	Test Date 2015-01-23

Description	Lot Number	Expiration Date
Microparticles	03491UN15G	2016-07-31
Conjugate	03491UN15H	2016-07-31
ASD Reagent	03491UN15J	2016-07-31

Specification	Specification Limit	Result
Negative Control	<3.0 IU/mL	0.0 Pass
Negative Control	Lot Number	V41094
Positive Control 1	21.0 - 29.0 IU/mL	27.2 Pass
Positive Control 1	Lot Number	V41095
Positive Control 2	237.0 - 363.0 IU/mL	314.2 Pass
Positive Control 2	Lot Number	V41096
Panel 5	104.0 - 156.0 IU/mL	127.9 Pass
Panel 5	Lot Number	V30353
Panel 7	8.2 - 11.8 IU/mL	10.5 Pass
Panel 7	Lot Number	493369
Calibrator	Lot Number(s)	V41082-V41087

For in-vitro diagnostic use.

Rubella IgG Reagents contain animal source material.

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

This product has been manufactured in compliance with Fisher Diagnostic's operating procedures.



Quality Representative

Date: 2015-02-02