

Certificate of Analysis

Product Name: ALINITY RHEUMATOID FACTOR REAGENT	Abbott List Number: 04R9921
OEM Part Number: 04R9921	Abbott Commodity Number: 04R9921
OEM Lot Number: 22156UN20	Expiration Date: 2022-01-01
Storage: 2 - 8°C	Package Insert No./Rev. G90849 / R03
Qty Manufactured: 193 Kits	Test Date 2020-11-24

Description	Lot Number	Expiration Date
Rheumatoid Factor R1	22156UN20	2022-01-01
Rheumatoid Factor R2	22156UN20	2022-01-01

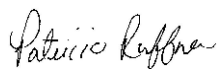
Specification	Specification Limit	Result
Barcode Scan	Acceptable verification on ALINITY (ICQ)	Complies Pass
Technopath S Control L2	18.8 - 24.0 IU/mL	23.1 Pass
Technopath S Control L2	Lot Number	18610182
Technopath S Control L3	31.1 - 37.2 IU/mL	34.1 Pass
Technopath S Control L3	Lot Number	18610183
Control 3 % Difference	-16 - 16 %	1 Pass
Control 5 % Difference	-16 - 16 %	3 Pass
Microbial Content: R1 BEG	<30 CFU/mL	0 Pass
Microbial Content: R1 END	<30 CFU/mL	0 Pass
Microbial Content: R2 BEG	<100 CFU/mL	0 Pass
Microbial Content: R2 END	<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: 2020-12-03