

Certificate of Analysis

Product Name: C3 Clinical Chemistry
OEM Part Number: 09D9622
OEM Lot Number: 97992UN22
Storage: 2 - 8°C
Qty Manufactured: 156 Kits

Abbott List Number: 09D9622
Abbott Commodity Number: 09D9622
Expiration Date: 2023-02-19
Package Insert No./Rev. G96024 / R02

Specification	Specification Limit	Result
Barcode Scan	Acceptable verification on c8000	Complies Pass
Bio-Rad L1	72 - 87 mg/dL	78 Pass
Bio-Rad L1	Lot Number	68971
Bio-Rad L2	156 - 190 mg/dL	172 Pass
Bio-Rad L2	Lot Number	68972
Bio-Rad L3	222 - 272 mg/dL	244 Pass
Bio-Rad L3	Lot Number	68973
Control Level 4 % Difference	-10 - 10 %	0 Pass
Micro: Beg Sample (R1)	<30 CFU/mL	0 Pass
Micro: End Sample (R1)	<30 CFU/mL	0 Pass
Micro: Beg Sample (R2)	<30 CFU/mL	0 Pass
Micro: End Sample (R2)	<30 CFU/mL	0 Pass

For in-vitro diagnostic use.

This product contains animal source material. The caprine material used in the manufacture of this product is derived from goat antiserum collected from U.S. sourced goats.

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.

This product contains R1 and R2 components. The component name, lot number, and expiration date matches the kit name, lot number, and expiration date listed on this COA.



Quality Representative

Date: 2022-02-25