

Certificate of Analysis

Product Name: Immunoglobulin M Clinical Chemistry
OEM Part Number: 01E0122
OEM Lot Number: 97985UN22
Storage: 2 - 8°C
Qty Manufactured: 188 Kits

Abbott List Number: 01E0122
Abbott Commodity Number: 01E0122
Expiration Date: 2023-02-24
Package Insert No./Rev. G96022 / R02

| Specification | Specification Limit | Result |
|-------------------------|----------------------------------|---------------|
| Barcode Scan | Acceptable verification on c8000 | Complies Pass |
| Bio-Rad L1 | 48 - 59 mg/dL | 55 Pass |
| Bio-Rad L1 | Lot Number | 68971 |
| Bio-Rad L2 | 112 - 136 mg/dL | 127 Pass |
| Bio-Rad L2 | Lot Number | 68972 |
| Bio-Rad L3 | 159 - 194 mg/dL | 178 Pass |
| Bio-Rad L3 | Lot Number | 68973 |
| Control 4: % Difference | -10 - 10 % | -2 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 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 animal source material. The caprine material used in the manufacture of this product is derived from goat antiserum collected from U.S. sourced goats. It does not originate from or pass through countries affected by BSE/TSE as per 9 CFR 94.18 (a) in effect at the time of shipment of the material.

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: 2022-03-25