

Certificate of Analysis

Name: Recombinant Rheumatoid Factor

Product Code: NAT41677-1000

Batch #: 25050249P

Date of Manufacture: 02-MAY-2025

Product Description: Recombinant rheumatoid factor (rRF) in human plasma. The monoclonal rRF was expressed in HEK293 cells as a J-chain stabilized pentameric human IgM molecule and diluted in human plasma. The antibody demonstrated reactivity consistent with native rheumatoid factor on Abbott Alinity c System (Rheumatoid Factor), Abbott ARCHITECT c System (Rheumatoid Factor), Beckman Coulter Unicel DxC 600/800 System (K-ASSAY RF v2), Roche cobas® 6000 c 501 (RF-II) and Roche cobas® pure c 303 (RF-II) clinical analyzer and assay platforms. However, platform-specific variation in recovery was observed.

Amount: 1.0 mL

rRF content: 6.4 mg/mL

Presentation: Liquid

Buffer: Human plasma (LGC Basematrix BM5 #1805-0040)

Usage Guidelines

Health and Safety: All local guidelines for handling human-derived material should be observed when working with this product.

Short-term Storage: 4 °C

Longterm Storage: -20 °C. Avoid multiple freeze-thaw cycles.

General: We recommend testing recovery/reactivity of this product in individual assays. Once thawed, if the product is excessively hazy or precipitated, incubate at 39 °C under gentle mixing until precipitates solubilize. Precipitates do not interfere with RF recovery.

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Usage Guidelines (continued)

Stability: Accelerated stability at 37 °C, 22 °C and 4 °C showed no loss in RF recovery after 6 weeks.

03/07/2025

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QC

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03/07/2025

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QA

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Products are for Research Use or for Further Manufacturing Use only. Not for Diagnostic or Therapeutic Use.