

Rheumatoid Factor (Ver.2) Assay

for Chemistry Analyzers

Introducing the **new, improved K-ASSAY® RF (Ver.2)** assay, a highly sensitive, latex-enhanced, quantitative assay for measuring Rheumatoid Factor in patient serum or plasma samples.

Features and Advantages:

- Quantitative latex immunoturbidimetric method
- Adaptable to most chemistry analyzers
- Very sensitive assay (LoQ = 6.65 IU/mL)
- Very wide assay range (up to 600 IU/mL)
4 times higher than other assays!
- No prozone effect up to the highest sample tested (1,700 IU/mL)
2 times higher than other assays!
- Excellent single-site and multi-site precision
- Liquid, ready-to-use reagents
- Standardized to the NIBSC Rheumatoid Arthritis Serum, 64/002 reference material

The K-ASSAY® RF (Ver.2) Assay is the assay you can trust!

CALL US
1-800-526-4925 x111
1-206-575-8068 x111

OR EMAIL US
diagnostics@k-assay.com



FDA 510(k) cleared for U.S.
CE registered for EU

KAMIYA BIOMEDICAL COMPANY
www.k-assay.com

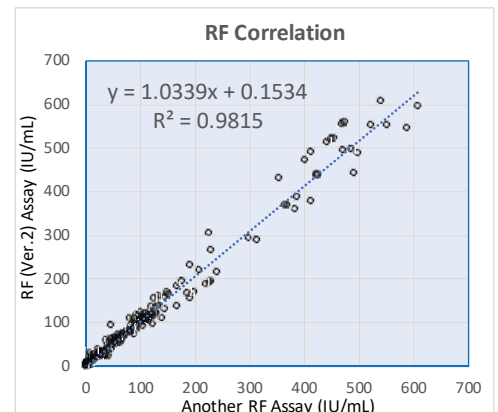
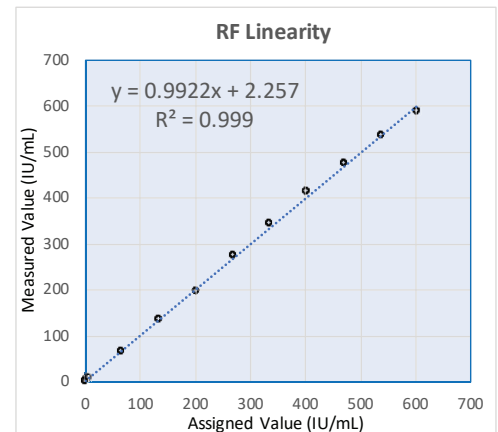
Clinical Information:

Rheumatoid arthritis (RA) is a chronic autoimmune disease that primarily affects the joints but can also affect other parts of the body. There is no one test to diagnose RA. Instead, rheumatologists review blood test results, examine the patient's joints, and look at X-rays or ultrasound images.

Rheumatoid factor (RF) is found in about 80% of patients with chronic RA. Detection of RF is one of the diagnostic criteria of the American College of Rheumatology for classifying rheumatoid arthritis.

Assay Characteristics:

Assay Format	Latex-enhanced immunoturbidimetric assay		
Sample Material	Serum or plasma Acceptable anticoagulants: citric acid, EDTA, lithium heparin		
Calibration	6-point		
Standardization	NIBSC Rheumatoid Arthritis Serum, 64/002		
Sample Volume	3.0 µL (may vary by analyzer)		
Expected Values	< 11 IU/mL		
Measuring Range	6.65 – 600 IU/mL		
Multi-Site Precision	<u>14.1 IU/mL</u>	<u>21.2 IU/mL</u>	<u>101.7 IU/mL</u>
Repeatability	4.5%	2.5%	0.7%
Reproducibility	7.2%	4.9%	1.6%
Detection Limit	LoB: 2.21 IU/mL LoD: 4.29 IU/mL LoQ: 6.65 IU/mL		
Prozone / Hook Effect	No effect observed up to highest concentration tested (1,700 IU/mL)		
On-Board Stability	30 days		
Regulatory	FDA cleared (U.S.) CE Mark (EU)		



Product Information:

	Cat. No.	Product Name	Kit Size
REAGENT	KAI-230	RF (Ver.2) Reagent Set	R1: 1 x 20 mL, R2: 1 x 20 mL (liquid)
CALIBRATOR	KAI-231C	RF Calibrator (Ver.2) Set	6 levels x 1 mL (liquid)
CONTROL	K55C-4M	ASO/CRP/RF Control Set	2 levels, 2 x 2 mL each level (lyophilized)

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