CAMBRIDGE Life Sciences

Autoimmunity Reagents: Rheumatology

AUTOZYME™ RF

KEY POINTS:

- **Antigen: horse IgG**
- **Calibration: 5 calibrators (quantitative), related to WHO W1066 for Rheumatoid Factor which replaced the 1st British Standard 64/2.**
- **Serum samples, Dilution: 1/100 (10µl sample+ 990µl diluent)**
- **No interference from Bilirubin, Haemoglobin, Lipids, Ascorbic Acid**
- **Assay Time: 30', 30' 30'**

INDICATION:

Quantitative detection of IgA, IgM or IgG Rheumatoid Factors in human sera or plasma to aid the diagnosis of rheumatoid arthritis in conjunction with other laboratory tests and clinical findings.

PRINCIPLE OF THE ASSAY:

The presence of rheumatoid factors (auto-antibodies directed against the Fc region of IgG molecules) is a common feature of rheumatoid arthritis. Rheumatoid factors have been found among the IgM, IgA and IgG classes of immunoglobulin. Most agglutination methods detect 19S (pentameric) IgM rheumatoid factor (Rf) only. Using ELISA technology, all major immunoglobulin classes can be measured.
The IgM Rf shows a strong correlation with the onset of an erosive disease state. However, IgM Rf is also present in patients with SLE and bacterial endocarditis. Recent literature suggests that 75% of patients with chronic polyarthritis have IgM Rf whereas only 30% of patients with other connective tissue diseases have raised levels. IgM Rf is also seen in other diseases such as viral hepatitis, liver cirrhosis, sarcoiditis and tuberculosis.
IgG Rf has been reported to be significantly increased in patients with rheumatoid vasculitis and correlate with disease activity. Moreover, IgG Rf may contribute to the tissue damage by activating complement.
The presence of IgA Rf is indicative of a more severe and erosive outcome of the disease. The detection of IgA Rf can give an early indication of an underlying rheumatic disease and is considered to be more specific than IgM Rf.

ORDERING INFORMATION	CONFIGURATION	PART NUMBER
AUTOZYME™ RF IgA	1 x Microplate 6 x 1.5mL Calibrators 1 x 1.5mL Negative Control 1 x 1.5mL Positive Control 2 x 50mL Sample Diluent 1 x 100mL Wash Buffer Conc (X20) 1 x 15mL Conjugate 1 x 15mL ABTS Substrate 1 x 15mL Stop Solution	Z9196
AUTOZYME™ RF IgM		Z9296
AUTOZYME™ RF IgG		Z9396

CE IVD 98/79/EC
For in vitro diagnostic use and Professional Use only.

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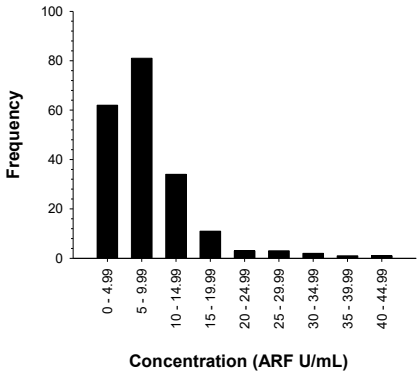
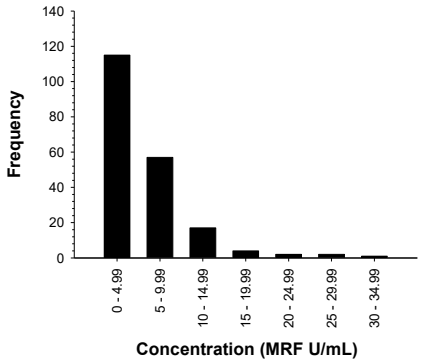
PERFORMANCE:

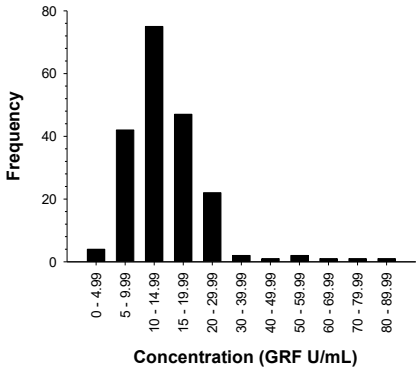
Reference Values

AUTOZYME™ RF was used to determine the RF IgA, IgM and IgG levels of 100 serum samples (tested in duplicate) from normal blood donors with no apparent abnormalities. The data was evaluated and the following ranges obtained:

	Z9196 RF IgA	Z9296 RF IgM	Z9396 RF IgG
Normal Range	≤ 21.4 ARF U/mL	≤ 15.3 MRF U/mL	≤ 35.9 GRF U/mL
Positive	> 21.4 ARF U/mL	> 15.3 MRF U/mL	> 35.9 GRF U/mL







Precision

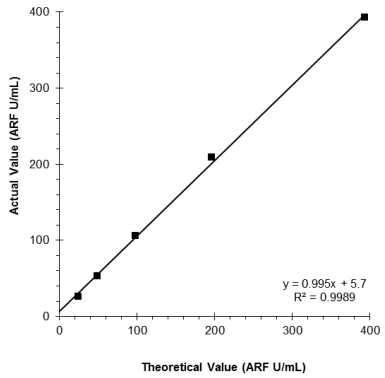
Intra-assay (n=20)	ARF U/mL	CV %	MRF U/mL	CV %	GRF U/mL	CV %
Sample 1	10.3	5.0	14.2	3.3	9.0	3.2
Sample 2	50.7	2.3	41.3	4.6	36.5	2.3
Sample 3	104.9	4.0	281.2	4.3	164.9	3.2
Inter-assay (n=10)	**ARF U/mL**	**CV %**	**MRF U/mL**	**CV %**	**GRF U/mL**	**CV %**
Sample 1	6.1	16.0	3.8	16.7	16.9	14.4
Sample 2	184.0	11.1	195.2	11.0	102.3	11.6
Sample 3	330.6	11.1	361.6	12.3	287.7	15.8

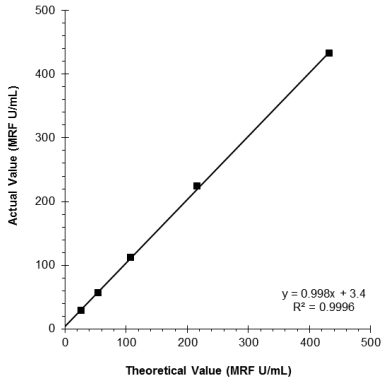
Interference

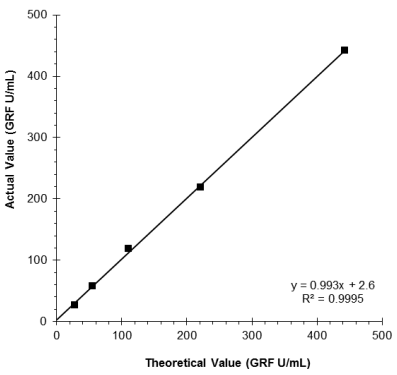
Interferent	Concentration
Ascorbic Acid	2.0 g/L
Bilirubin	500mg/L
Haemoglobin	5.0g/L
Intralipids	10% (w/v)

No significant interference observed.

Linearity







Measuring Range

Z9196 RF IgA: 2.9 - 600.0 ARF U/mL
Z9296 RF IgM: 1.1 - 600.0 MRF U/mL
Z9396 RF IgG: 1.7 - 600.0 GRF U/mL
The minimum detectable concentration is defined as the concentration equal to 2 standard deviations from the mean of 20 replicate determinations of the sample diluent,.