Rheumatoid Factor (RF) Calibrators KIT

✓ ***REFERENCE.***

5 calibrators KIT	RFREK-000	5 x 1 ml	2-8°C
Human RF in synthetic biological fluid standardised from the first International Standard WHO W1066, sodium azide (< 1g/l)			

✓ ***SAMPLES AND REFERENCE VALUES.***
See the corresponding reagents technical sheet.

✓ ***COMPOSITION.***
RF calibrators are synthetic biological fluids containing human RF at fixed value diluted in HEPES pH 7.4 buffer containing stabilisers and sodium azide (<1g/l) as preservative.

✓ ***PRINCIPLE OF TEST.***
The human RF reacts upon colloidal gold coated with human IgG. In the presence of IgM rheumatoid factor, the particles agglutinate, which induces a red shift in the visible spectrum of the colloid. This induces an increase in optical density at 600 nm, which is directly proportional to the rheumatoid factor concentration in the RF calibrator which can be used for the quantitative determination of RF in immunocolorimetry.

✓ ***PRECAUTIONS.***
For in vitro single diagnostic use. To be handled by entitled Personnel.
Products from human source were tested and found free from HBsAg and antibodies to HCV and HIV but this material should be treated just as carefully as potentially infective.
Products containing sodium azide have to be handled with care; avoid ingestion and contact with skin and mucous membranes. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides.

✓ ***ANALYTICAL PERFORMANCES.***
See the corresponding reagents technical sheet.

✓ ***PREPARATION AND REAGENTS STABILITY.***
The calibrators are ready for use; once opened, they are stable until expiry date if stored stoppered in appropriate temperature conditions and without any contamination (avoid pipetting and decantation).

✓ ***METHOD OF ANALYSIS AND CALCULATION.***
See the corresponding reagents technical sheet.

✓ ***QUALITY CONTROL.***
Accuracy and reproducibility: analytical performances can be checked with the internal quality control serum of the laboratory or with the Liquichek™ (BIO-RAD) Rheumatoid Factor Control sera (see the values range obtained with DiAgam reagents and indicated on the accompanying BIO-RAD sheet).
Calibration: calibration curve and stability of calibration curve can be validated with the DiAgam calibration control (RFCON-002).
In case of analytical performances modification, calibrate the method again and contact the manufacturer if modifications are subsisting.

✓ ***BIBLIOGRAPHY.***
WHO Reference Reagent Rheumatoid Arthritis Serum, Human NIBSC code: W1066. http://www.nibsc.ac.uk/documents/ifu/W1066.pdf

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RFREKFTEN 26/02/2013 v03

Rheumatoid Factor	CAL 1		CAL 2		CAL 3		CAL 4		CAL 5	
	kIU/l		kIU/l		kIU/l		kIU/l		kIU/l	
	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**	certified val.	*U**
	7.5	***0.4***	**15**	***0.8***	**30**	***1.5***	**60**	***3***	**120**	***6***

U : The certified uncertainty is the half-width of the 95 % confidence interval of the mean.*
Values assigned from the first International Standard WHO W1066.

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