

Rheumatoid Factor (RF) Calibrators Kit

✓ **REFERENCE**



RF 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)			
Batch number :	22D14		
Expiry date :	01/2024		
Control date :	19/04/22		
Quality control report :	DGM-QAC-REP-22081		
Document prepared and signed by :	L.Ginneberge		

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.

✓ **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 (RCON-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>



RFREK 22D14 IFU EN v04 20/04/22

✓ **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.


	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^*
Rheumatoid Factor	7.5	0.4	15	0.8	30	1.5	60	3.0	120	6.0

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.

Symbols

The following symbols may appear on the packaging and labelling :

	<i>Batch code</i>		<i>Buffer</i>
	<i>Use by</i>		<i>Calibrator</i>
	<i>Manufacturer</i>		<i>High</i>
	<i>In Vitro Diagnostics Medical Device</i>		<i>Medium</i>
	<i>Temperature limitation (store at)</i>		<i>Low</i>
	<i>Catalogue number</i>		<i>4 levels</i>
	<i>Consult instructions for use</i>		<i>5 levels</i>
	<i>Reagent</i>		<i>6 levels</i>
	<i>Kit</i>		<i>Control</i>
	<i>Contents</i>		<i>This product meets the requirements of European Directive 98/79 CE concerning diagnostic medical devices in vitro</i>
	<i>Antibody or Antiserum</i>		<i>Track version changes</i>

	<i>DiAgam Belgium: Rue du Parc Industriel 40, 7822 Ghislenghien, Belgium</i>
<i>DiAgam Headquarters</i>	<i>Avenue Louis Lepoutre 70, 1050 Bruxelles, Belgique</i>
<i>Distributed by</i>	<i>DiAgam France: Boulevard de la Liberté 130, 59000 Lille, France</i>

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