RHEUMATOID FACTOR FL

RF 0050 CH	1 x 50 ml
RF 0100 CH	2 x 50 ml

INTENDED USE

Reagent for quantitative in vitro determination of rheumatoid factor in biological fluids.

SUMMARY OF TEST

Rheumatoid Factor (RF) is an autoantibody directed against the Fc fragment of immunoglobulin G. Being also IgA and IgG, IgM component of rheumatoid factor is mainly assayed in clinical practice. Associated since its discovery to rheumatoid arthritis, high levels of RF have been identified in Sjogren syndrome and in case of connective tissue diseases.

PRINCIPLE OF THE METHOD

Rheumatoid Factor (RF) selectively reacts with IgGs coated to latex, thus producing particle agglutination. The produced turbidity is proportional to the concentration of RF in the sample, and can be measured at the wavelenght of 660 nm.

KIT COMPONENTS

For in vitro diagnostic use only.
The components of the kit are stable until expiration date on the label.
Keep away from direct light sources.

RF R1 **0050: 1 x 40 ml (liquid) white cap**
0100: 2 x 40 ml (liquid) white cap

Composition: Buffer pH 8.2, stabilizers and preservatives.

RF R2 **0050: 1 x 10 ml (liquid) red cap**
0100: 2 x 10 ml (liquid) red cap

Composition: suspension of latex particles coated with human IgG, stabilizers and preservatives.

Standard: RF solution - 2 ml

Store all components at 2-8°C.

REAGENT PREPARATION

Use separate reagents ready to use.
Kindly shake R2 vial before use.
Stability: up to expiration date on labels at 2-8°C.
Stability since first opening of vials: use preferably within 60 days at 2-8°C.

Calibration curve: prepare dilutions of RF Standard with physiological solution, according to the following indications. RF value of each calibrator can be calculated from RF Standard value with the reported operation.

Dilution	Calibrator value
Cal 0: 80 µl physiological solution	(0)
Cal 1: 10 µl St. + 70 µl phys. sol.	(RF St. value x 0.125)
Cal 2: 20 µl St. + 60 µl phys. sol.	(RF St. value x 0.25)
Cal 3: 40 µl St. + 40 µl phys. sol.	(RF St. value x 0.5)
Cal 4: 60 µl St. + 20 µl phys. sol.	(RF St. value x 0.75)
Cal 5: 80 µl Standard	(RF St. value)

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

MATERIALS REQUIRED BUT NOT SUPPLIED

Current laboratory instrumentation. Spectrophotometer UV/VIS with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

SPECIMEN

Serum, plasma.
Keep specimens away from direct light sources.
Samples are stable 7 days when stored at 2-8°C and 1 month at -20°C.

TEST PROCEDURE

Wavelength: 660 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	800 µl	800 µl	800 µl
water	10 µl	-	-
calibrator	-	10 µl	-
sample	-	-	10 µl

Mix, incubate at 37°C for 3 minutes.
Read against reagent blank the absorbances of calibrator (Ac_1) and sample (Ax_1).

dispense:	blank	calibrator	sample
reagent R2	200 µl	200 µl	200 µl

Mix, incubate at 37°C for 2 minutes.
Read against reagent blank the absorbances of calibrator (Ac_2) and sample (Ax_2).

RESULTS CALCULATION

For calibrators and samples, calculate $\Delta A=A_2-A_1$.
A calibration curve is plotted by the use of calibrators with increasing RF concentrations.
Successively, RF concentration of a sample can be calculated by interpolating its absorbance value on the calibration curve.

EXPECTED VALUES

Adults < 30 IU/ml

Each laboratory should establish appropriate reference intervals related to its population

QUALITY CONTROL AND CALIBRATION

It is suggested to perform an internal quality control.
For this purpose the following human based control serum is available:
RHEUMATOID FACTOR CONTROL SET

Please contact Customer Care for further information.

TEST PERFORMANCE

Measure interval
Measure interval depends on the concentration of the highest standard used for calibration.
If such a limit value is exceeded, it is suggested to dilute sample 1+4 with distilled water and to repeat the test, multiplying the result by 5.

Hook effect
No Hook effect is observed with concentrations lower than 800 IU/ml.

Sensitivity/limit of detection
The limit of detection is 7 IU/ml.

Interferences
No interference was observed by the presence of:

hemoglobin	≤ 400 mg/dl
bilirubin	≤ 40 mg/dl
lipids	≤ 500 mg/dl

Precision

intra-assay (n=10)	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	24.8	0.60	2.44
sample 2	79.6	0.55	0.69

inter-assay (n=10)	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	25.2	2.39	9.48
sample 2	79.4	2.37	2.98

Methods comparison
A comparison between CHEMA and a commercially available product gave the following results:

RF competitor = x
RF FL CHEMA = y
n = 48

$y = 0.92x + 1.85$ IU/ml $r^2 = 0.97$

WASTE DISPOSAL

This product is made to be used in professional laboratories.
P501: Dispose of contents according to national/international regulations.

REFERENCES

Ameratunga R., Musaad S., Sugrue C., Kyle C. *Clin. Rheumatol.* 2011, 30(9), 1215-1220
Tietz Textbook of Clinical Chemistry, Fourth Edition, Burtis-Ashwood-Bruns (2006), 366.

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SYMBOLS

IVD	*in vitro* diagnostic medical device
LOT	batch code
REF	catalogue number
	temperature limit
	use by date
	caution
	consult instructions for use

CE