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 (serum) and intended as aid to diagnosis and prognosis of Rheumatoid Arthritis and autoimmune diseases[1].
The IVD devie can be used both in manual or on automatic analyzers. The product is intended for professional use in clinical laboratories.

TEST PRINCIPLE

Rheumatoid Factor (RF) reacts, via antigen-antibody reaction, with aggregated human IgG. The turbidity produced in this reaction is proportional to the concentration of RF in the sample, and it can be measured at the wavelenght of 340 nm[2-4].

MATERIALS PROVIDED AND COMPOSITION

RF R1 **0050: 1 x 45 ml (liquid) white cap**
0100: 2 x 45 ml (liquid) white cap

Composition: Good's buffer, stabilizers and preservatives.

RF R2 **0050: 1 x 9 ml (liquid) red cap**
0100: 2 x 9 ml (liquid) red cap

Composition: Heat-aggregated human IgG ≤ 0.5 mg/ml, stabilizers and preservatives.

Standard RF* ST001: 2 x 1 ml
Composition: RF solution, stabilizers and preservatives.

* Traceability: this method has been standardized against 1st British Standard NIBSC code : 64/002.

NOT SUPPLIED REQUIRED MATERIALS

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

REAGENT PREPARATION

Use ready-to-use reagents.

Calibration curve: prepare dilutions of RF Standard with saline solution, as per instructions below. The RF value of each calibrator can be calculated usign the RF Standard value according to the reported calculations.

Dilution	**Calibrator value**
Cal 0: 200 µl saline solution	(0 value)
Cal 1: 25 µl St. + 175 µl sal. sol.	(RF St. value / 8)
Cal 2: 50 µl St. + 150 µl sal. sol.	(RF St. value / 4)
Cal 3: 100 µl St. + 100 µl sal. sol.	(RF St. value / 2)
Cal 4: 200 µl Standard	(RF St. value)

STABILITY AND STORAGE

Store all kit components at 2-8°C.
Stability of reagents: up to expiration date claimed on label storing at 2-8°C;
Stability after first opening of reagent bottle: preferably within 60 days storing at 2-8°C.

PRECAUTIONS

RF R1: It is not classified as hazardous.

RF R2: It is not classified as hazardous.

Standard: It is not classified as hazardous.

Follow required safety procedures when handling all laboratory reagents.

SPECIMEN

Serum.
Samples are stable for 8 days when stored at 2-8°C and for 3 months at -20°C[5].

TEST PROCEDURE

Wavelength: 340 nm
Lightpath: 1 cm
Temperature: 37°C

dispense:	blank	calibrator	sample
reagent R1	1000 µl	1000 µl	1000 µl
water	64 µl	-	-
calibrator	-	64 µl	-
sample	-	-	64 µl

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

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

Mix, incubate at 37°C for 5 minutes.
Read the absorbances of calibrator (Ac_2) and sample (Ax_2) against reagent blank.

RESULTS CALCULATION

For calibrators and samples, calculate $\Delta A = A_2 - A_1$.
A calibration curve is plotted by using calibrators with an increasing RF concentrations.
Subsequently, the sample RF concentration can be calculated by interpolation of the absorbance value on the calibration curve.

REFERENCE INTERVALS

Adults[1] < 20 IU/ml

Each laboratory should establish its own reference ranges based on its population.

QUALITY CONTROL AND CALIBRATION

Calibrate again when reagent lot has changed. It is recommended to verify calibration with at least one level of an internal quality control. If control results do not meetacceptable criteria, recalibration may be necessary. The following human based control sera are available for this purpose:
RHEUMATOID FACTOR CONTROL SET

Please contact Customer Care for further information.

TEST PERFORMANCE

Sensitivity / Limit of Detection (LOD)
The method is able to detect up to 3.0 IU/ml.

Analytical specificity:
Interferences
interference does not occur with the following:

Heparin:	≤ 50 mg/l
Natrium Citraat	≤ 1000 mg/dl
Hemoglobin	≤ 1000 mg/dl
Bilirubin	≤ 30 mg/dl
Intralipid	≤ 2500 mg/dl
Ascorbic Acid	≤ 50 mg/dl
EDTA	≤ 5 mg/d

Veridicity[6]
BIAS% < 6.36

Accuracy:
Trueness[6]
Total observed error% < 13.50 (allowable total error)

Precision
Repeatability (intra-assay)

n = 20	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	29.2	1.06	3.65
sample 2	105.7	2.85	2.69
sample 3	204.0	3.13	1.54

Reproducibility (inter-assay)

days = 12	mean (IU/ml)	SD (IU/ml)	CV%
sample 1	24.6	0.88	3.57
sample 2	102.2	1.37	1.34
sample 3	190.2	3.63	1.91

Measurement range
The lower limit is 10.0 mg/l[7].
Measure interval depends on the concentration of the highest standard used for calibration.
If the limit value is exceeded, it is suggested to dilute the sample 1+4 with distilled water and repeat the test, multiplying the result by 5.

Linearity
The immunoturbidimetric method is not linear. However, after a 5-point non-linear calibration using a high standard at a concentration of 203 IU/ml, the test proves to be linear up to 203 IU/ml.

Hook effect
No Hook effect is observed with concentrations lower than 990 IU/ml.

Methods comparison[8]
A comparison between Chema and a commercially available product gave the following results:

RF competitor = x
RF Chema = y
n = 25

Linear regression
y = 1.033x + 0.670 IU/ml r = 0.9900

Passing-Bablok[9-10]
y = 1.066x - 0.915 IU/ml

WASTE DISPOSAL

P501: Dispose of product according to national/international regulations.

NOTICE TO THE USER

Any serious accident involving the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is located.

REFERENCES

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SYMBOLS

Chema Diagnostica uses symbols listed in the ISO 15223-1 (see www.chema.com - Section "Products" for definition of symbols used).

Addition, deletions or changes are indicated with a vertical line on the side of the affected paragraph.

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