BECKMAN COULTER CE

AU

Instructions For Use

RF (L)
RF Latex

REF OSR61105 4 x 24 mL R1, 4 x 8 mL R2

For *in vitro* diagnostic use only.

PRINCIPLE

INTENDED USE

Immuno-turbidimetric test for the quantitative determination of RF (rheumatoid factor) antibodies in human serum and plasma on Beckman Coulter AU analysers.

SUMMARY AND EXPLANATION

Reference[1,2]

Rheumatoid factors (RF) are antibodies directed against antigenic determinants on the Fc fragment of IgG. These are usually IgM antibodies, but may be IgG, IgA or IgE. Rheumatoid factor sensitivity in rheumatoid arthritis varies from 30% in population-based studies to 70 – 80% in hospital-based studies, where the disease tends to be more severe. Higher titres of RF are more specific for the diagnosis of RA and are more common in patients with rapidly progressive joint destruction and in those with extraarticular manifestations such as subcutaneous rheumatic nodules. However, RF is a non-specific test and a positive RF is observed in 1 – 5% of the healthy population at low titres and in 15 – 20% of elderly subjects with other chronic disease states. A positive RF is also seen in autoimmune rheumatic diseases and in non-rheumatic conditions with variable frequency e.g. SLE, Sjögren's syndrome, subacute bacterial endocarditis and other bacterial infections, infectious hepatitis, chronic liver diseases, chronic active pulmonary diseases, parasitic infections and viral infections.

METHODOLOGY

When a sample is mixed with R1 buffer and R2 IgG latex suspension, RF reacts specifically with IgG coated on the latex particles to yield insoluble aggregates. The absorbance of these aggregates is proportional to the RF concentration in the sample.

SPECIMEN

TYPE OF SPECIMEN

Serum and Li-/Na-heparin, Na-/K-EDTA and citric acid plasma.

Stable in serum and plasma for:[3]

1 day at 20…25°C

8 days at 2…8°C

3 months at -20°C (avoid repeated freezing and thawing)

Specimen storage and stability information provides guidance to the laboratory. Based on specific needs, each laboratory may establish alternative storage and stability information according to good laboratory practice or from alternative reference documentation.

REAGENTS

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents.

Biological materials of human origin contained in R2 were tested for Anti-HCV, HbsAg and Anti-HIV 1/2 on a single donor basis using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products derived from human blood will not transmit infectious agents, this product should be handled as a potentially infectious material.

Dispose of all waste material in accordance with local guidelines.

This product contains material of animal origin. The product should be considered as potentially capable of transmitting infectious diseases.

REACTIVE INGREDIENTS

Final concentration of reactive ingredients:

Glycine buffer (pH 8.0)	170 mmol/L
Latex coated with human IgG	< 0.5%
Preservative	0.09%

The concentrations of the reactive components of the reagents shown on the kit label are the actual concentrations in the individual R1/R2 vials. The reagent composition which is shown in the Instructions For Use is the final concentration of these components in the reaction cuvette after addition of R1, Sample, and R2.

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

RF Latex R1	WARNING	
		
	H317	May cause an allergic skin reaction.
	H402	Harmful to aquatic life.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		2-Methyl-4-isothiazolin-3-one < 0.06%

SDS	Safety Data Sheet is available at beckmancoulter.com/techdocs

REAGENT PREPARATION

R1 is ready for use and can be placed directly on board the instrument. R2 should be mixed by inversion 5 – 10 times before placing on board the instrument and at weekly intervals thereafter.

REAGENT STORAGE AND STABILITY

The reagents are stable, unopened, up to the stated expiry date when stored at 2…8°C. Once open, reagents stored on board the instrument are stable for 90 days.

CALIBRATION

CALIBRATOR REQUIRED

RF Latex Calibrator Cat. No.: ODC0028.

The calibrator RF value is traceable to WHO International reference material, NIBSC 64/2.[4]

Recalibrate the assay every 30 days or when the following occur:

Change in reagent lot or significant shift in control values;

Major preventative maintenance was performed on the analyzer or a critical part was replaced

Following calibration, the resulting curve should be visually reviewed, on the Beckman Coulter analyzer, for acceptability using the software options - Routine, Calibration Monitor, Calibration Curve. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice.

QUALITY CONTROL

ITA Control Sera ODC0014, ODC0015 and ODC0016 or other control materials with values determined by this Beckman Coulter system may be used.

Each laboratory should establish its own control frequency however good laboratory practice suggests that controls be tested each day patient samples are tested and each time calibration/blanking is performed.

The results obtained by any individual laboratory may vary from the given mean value. It is therefore recommended that each laboratory generates analyte specific control target values and intervals based on multiple runs according to their requirements. These target values should fall within the corresponding acceptable ranges given in the relevant product literature.

If any trends or sudden shifts in values are detected, review all operating parameters.

Each laboratory should establish guidelines for corrective action to be taken if controls do not recover within the specified limits.

TESTING PROCEDURE(S)

Refer to the appropriate Beckman Coulter AU analyser User Guide/Instructions For Use (IFU) for analyser-specific assay instructions for the sample type as listed in the Intended Use statement. Data check parameters are required. See Setting Sheet for specific instrument details.

CALCULATIONS

The Beckman Coulter analyzers automatically compute the RF concentration of each sample.

REPORTING RESULTS

REFERENCE INTERVALS

Reference[5]

Adults	≤ 14 IU/mL

This value is based on serum samples from 144 test subjects (97.5th percentile).

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should verify the transferability of the expected values to its own population, and if necessary determine its own reference interval according to good laboratory practice. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history, clinical examinations and other findings.

PROCEDURAL NOTES

LIMITATIONS

Samples with extremely abnormal optical characteristics, especially turbidity, may produce atypical results.

Samples with very high RF concentrations (> 1,500 IU/mL) can generate false low results without appropriate "Z" flags due to excess antigen in the sample.

INTERFERENCES

Results of studies conducted to evaluate the susceptibility of the method to interference were as follows:

Icterus:	Interference less than 5% up to 40 mg/dL or 684 µmol/L bilirubin
Haemolysis:	Interference less than 5% up to 5 g/L haemoglobin
Lipemia:	Interference less than 10% up to 750 mg/dL Intralipid

In very rare cases gammopathy, in particular type IgM (Waldenstrom’s macroglobulinemia), may cause unreliable results.

Refer to Young[6] for further information on interfering substances.

PERFORMANCE CHARACTERISTICS

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Data contained within this section is representative of performance on Beckman Coulter systems. Data obtained in your laboratory may differ from these values.

LINEARITY

The test is linear within a concentration range of 10 – 120 IU/mL.

SENSITIVITY

The lowest detectable level was estimated as follows:

Analyzer	Lowest Detectable Level (IU/mL)
AU2700	1.38

The lowest detectable level represents the lowest measurable level of RF that can be distinguished from zero. It is calculated as the absolute mean plus three standard deviations of 20 replicates of an analyte free sample.

METHODS COMPARISON

Patient serum samples were used to compare this RF Latex OSR61105 assay on the AU640 against other commercially available RF Latex assay (Method 2). Results of linear regression analysis were as follows:

y = 0.996x - 1.217	r = 0.996	n = 55	Sample range = 6.30 – 103.20 IU/mL

PRECISION

The following data was obtained for the RF (Latex) assay on an AU2700 using 4 serum pools analysed over 20 days.

AU2700:

n = 80	Within-run		Total	
Mean (IU/mL)	SD	CV%	SD	CV%
9.99	0.46	4.63	0.79	7.89
19.74	0.47	2.39	0.64	3.25
75.37	0.47	0.62	0.88	1.16
112.93	0.98	0.87	1.24	1.10

ADDITIONAL INFORMATION

DxC 700 AU requires that each reagent application has a standard format of abbreviated Closed Test Name. This Closed Test Name is required to allow automated loading of the calibrator information for each application as part of the DxC 700 AU Closed System. Refer to the table below for the Closed Test Name assigned to each application for this assay.

Test Name	Description
RF-1G	RF Latex (Serum)

Setting Sheet Footnotes

User defined

† RF Latex Calibrator Cat. No.: ODC0028

§ Saline should be used for the Level 1 calibrator.

* Values set for working in IU/mL

* Values set for working in SI IU/mL

REVISION HISTORY

Added new languages

Preceding version revision history

Revised GHS section

REFERENCES

1. Ismail AA, Snowden N. Autoantibodies and specific serum proteins in the diagnosis of rheumatological disorders. Ann Clin Biochem 1999;36:565-578.

2. Mierau R, Genth E. Autoantibodies in rheumatoid arthritis. In: Thomas L, ed. Clinical laboratory diagnostics. Use and assessment of clinical laboratory results. Frankfurt/Main: TH-Books Verlagsgesellschaft, 1998:810-813.

3. Ehret W, Heil W, Schmitt Y, Töpfer G, Wisser H, Zawta B, et al. Use of Anticoagulants in Diagnostic Laboratory Investigations and Stability of Blood, Plasma and Serum Samples. WHO/DIL/LAB/99.1 Rev.2:41pp.

4. Anderson SG, Bentzon MW, Houba V, Krag P. International reference preparation of rheumatoid arthritis serum. Bull Wld Hlth Org 1970;42: 311-318.

5. In-house data on file.

6. Young DS. Effects of drugs on clinical laboratory tests, 5thed. AACC Press, 2000.

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