selectra MACH

RHEUMATOID FACTOR

RHFA
RHFA-M130
R1 : 1 x 26 mL
R2 : 1 x 7 mL
Cal : 1 X 2 mL

CE

PIMAC-RHFA-EN-V2 (02/2022)

INTENDED USE

This *in vitro* diagnostic reagent is intended for the quantitative determination of rheumatoid factor in human serum samples on Selectra Mach Series analyzers.

The calibrator is intended for the calibration of the reagent.

These *in vitro* diagnostic devices are for professional use only.

CLINICAL SIGNIFICANCE [1-2]

Rheumatoid factors (RF) are autoantibodies directed against the Fc fragment of immunoglobulin G. RF are present in about 80% of patients with rheumatoid arthritis, for which a diagnosis must also involve other parameters (such as joints pain, CRP, ESR, anti-citrullinated peptide antibody). RF also increase in other rheumatoid diseases such as Sjögren's syndrome and systemic lupus erythematosus as well as in infections and chronic inflammatory conditions.
Rheumatoid factor measurement is used to help diagnose rheumatoid arthritis or to distinguish it from other forms of arthritis and conditions with similar joint pain, inflammation and stiffness.

LIMITATION OF USE

The quantitative assay of rheumatoid factor alone cannot be used to diagnose a disease or a specific pathology.
The results must be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

METHOD & PRINCIPLE

Immuno-turbidimetry - End Point.

The formation of RF / anti-RF antibody complexes is started by the addition of the antiserum to the sample. These complexes agglutinate leading to an increase of turbidity measured at 340 nm.

COMPOSITION

Reagent 1: R1
Good's Buffer
Sodium azide < 0.1 % (w/w)
Reagent 2: R2
Heat-aggregated human IgG
Sodium azide < 0.1 % (w/w)
Calibrator : Cal
Liquid product prepared from human plasma.
The RF concentration of this calibrator is lot-specific.

MATERIALS REQUIRED BUT NOT PROVIDED

- IRCT-0046 RHEUMATOLOGY CONTROL I
- IRCT-0047 RHEUMATOLOGY CONTROL II
- Normal saline solution (NaCl 9 g/L)
- General Laboratory equipment (e.g. pipette).
- Selectra Mach analyzer and accessories.
- Do not use materials that are not required as indicated above.

PRECAUTIONS OF USE AND WARNINGS

- Consult Safety Data Sheet (SDS) for a proper handling.
- The reagents R1 and R2 contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these reagents always flush with copious amounts of water to prevent azide buildup.
- Each unit of human blood used in the manufacture of calibrator and reagent R2 was tested and found to be negative/non-reactive for the presence of HbsAg, HCV and HIV1/2. The methods used were FDA-approved or CE compliant. Nevertheless, since the risk of infection cannot be fully excluded these products must be handled as potentially infectious. In case of exposure, follow the guidelines of the competent health authorities.
- Take precautions when handling broken glass vials as sharp edges can injure the user.
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.
- Do not interchange reagent vials from different kits.

STABILITY

Reagent / Calibrator:
Store at 2-8 °C and protect from light. Do not freeze.
Do not use after expiration date indicated on the vial labels.
Reagent:
On board stability : 4 weeks.
For optimal performance, it is recommended to homogenize the reagent bottles by successive inversions before each day of utilization.
Calibrator:
The calibrator should be immediately and tightly capped to prevent contamination and evaporation.
Open vial stability :
Calibrator is stable for 6 weeks when stored at 2-8 °C.

PREPARATION

Reagent:
The device is ready to use.
Calibrator:
Prepare a dilution range as following:

Dilution	1	2	3	4	5	6
RHEUMATOID FACTOR CALIBRATOR (µL)	--	20	40	80	150	300
NaCl 9 g/L (µL)	300	300	280	240	150	-
Dilution factor	0	1/16	1/8	1/4	1/2	1

PRODUCT DETERIORATION

- The product should be clear. Cloudiness would indicate product deterioration.
- Do not use the product if there is visible evidence of contamination or damage (e.g. particle matter).
- Damage to the product container may impact on product performance. Do not use the product if there is physical evidence of deterioration (e.g. leakages or punctured container).

SAMPLES

Specimens required [3]
- Serum.
- Using any other specimen type should be validated by the laboratory.
Warnings and precautions [4]
- Avoid multiple freeze/thaw cycles.
- Samples should be collected in accordance with Good Laboratory Practice and appropriate guidelines that may be in place.
Storage and stability [2]
- 1 day at room temperature
- 3 days at 2-8°C
- 1 month at -20°C

REFERENCE VALUES [2]

Serum	IU/mL	KIU/L
Adults	< 30	< 30

RF levels can be increased in some people over 60 years old.

Note : *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

INSTALLATION AND USE

Consult Selectra Mach operator manual.
Special Programming instructions: Programming special instructions is mandatory when some combinations of tests are performed together on the analyzer. Refer to Instructions For Use for WASH SOLUTION A & WASH SOLUTION B for adequate programming (See PIMAC-WASH).

PROCEDURE

The application is included in the 2D barcode on this insert.

CALCULATION

Calculations and/or unit conversions are performed by the analyzer.

CALIBRATION

RHEUMATOID FACTOR CALIBRATOR is traceable to the "Rheumatoid Arthritis Serum, 1st British Standard, NIBSC Code 64/002".

Calibration frequency : 4 weeks.
Recalibrate when reagent lots change, when quality control results fall outside the established range and after a maintenance operation.

ELITechGroup
EMPOWERING IVD

QUALITY CONTROL

It is recommended that quality control sera such as RHEUMATOLOGY CONTROL I and RHEUMATOLOGY CONTROL II be used to monitor the performance of the assay.
Controls have to be performed :
- prior to assaying patient samples,
- at least once per day,
- after every calibration,
- and/or in accordance with laboratory and regulatory requirements.

Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take necessary corrective measures.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and federal regulatory requirements (please refer to the Safety Data Sheet (SDS)).

PERFORMANCES

Performances were obtained on Selectra Mach5, following CLSI technical recommendations, under controlled environmental conditions.

- Measuring range

10-200 IU/mL (10-200 KIU/L)

Samples having greater concentrations will automatically be diluted 1:5 with NaCl 9 g/L solution and re-assayed. Results take the dilution into account. This procedure extends the measuring range up to 1000 IU/mL (1000 KIU/L).
The exact range depends on the calibrator used.
Do not report results outside this extended range.

- Hook effect

No hook effect up to 1 400 IU/mL (1 400 KIU/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

LoD : 2 IU/mL (2 KIU/L)
LoQ : 10 IU/mL (10 KIU/L)

- Precision

Imprecision data has been obtained on 2 Selectra Mach5 analyzers over 20 days (2 runs per day, tests performed in duplicate).

Representative results are presented below.

		Mean		Within-run	Total
	n	IU/mL	KIU/L	CV (%)	
Level 1	80	19	19	5.8	10.3
Level 2	80	51	51	3.2	7.1
Level 3	80	119	119	2.3	4.7

- Correlation

A comparative study has been performed between RHEUMATOID FACTOR reagent on a Selectra Mach5 analyzer and a similar commercially available system on 50 human serum samples.
The sample concentrations ranged from 11 to 216 IU/mL. (11 - 216 KIU/L).
The results are as follows :
Correlation coefficient : (r) = 0.993
Linear regression: y = 0.992 x + 1 IU/mL (1 KIU/L).

- Limitations/Analytical interferences

- Studies have been performed to determine the level of interference from different compounds.
The following rheumatoid factor levels were tested: 20 IU/mL and 60 IU/mL.
No significant interference is defined by a recovery ≤±5 IU/mL of initial value at rheumatoid factor concentration of 20 IU/mL and ≤±15 % of initial value at rheumatoid factor concentration of 60 IU/mL

Hemoglobin: No significant interference up to 500 mg/dL
Triglycerides: No significant interference up to 2 000 mg/dL (22.60 mmol/L)
Unconjugated bilirubin: No significant interference up to 30.0 mg/dL (513 µmol/L)
Conjugated bilirubin: No significant interference up to 29.5 mg/dL (505 µmol/L)

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[5]

- Many other substances and drugs may interfere. Some of them are listed in reviews plublished by Young.[6-7]

DECLARATION OF SERIOUS INCIDENT

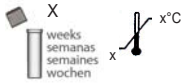
Please notify the manufacturer (through your distributor) and competent authority of the Member state of the European union in which the user and/or the patient is established, of any serious incident that has occurred in relation to the device. For other jurisdictions, the declaration of serious incident should be in accordance with local, state and federal regulatory requirements.
By reporting a serious incident, you provide information that can contribute to the safety of *in vitro* medical devices.

BIBLIOGRAPHY

1. Aletaha, D. *et al*., Ann Rheum Dis, (2010), **69**, 1580.
2. Pry, T., *Rheumatoid Factor*. Clinical Chemistry: Theory, Analysis, Correlation, 5th Ed., Kaplan, L.A, Pesce, A.J., (Mosby Inc. eds), (2010), appendix.
3. Guder, W.G., et al., *Use of anticoagulants in diagnostic laboratory investigations and stability of blood, plasma and serum samples.* (2002). WHO/DIL/LAB/99.1 Rev.2.
4. BIOMNIS. Précis de biopathologie – Analyses médicales spécialisées. 2016
5. Berth, M. & Delanghe, J., *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.
6. Young, D.S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
7. Young, D.S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

☛SYMBOLS

Symbols used are defined in ISO 15223-1 standard, except those presented bellow :

CONT	Content
R1	Reagent 1
R2	Reagent 2
CAL	Calibrator
	These products are stable X weeks at X°C
	These products should be immediately and tightly capped to prevent contamination and evaporation
☛	Modification from previous version
CE	European Conformity

TECHNICAL ASSISTANCE

Contact your local distributor or ELITech Clinical Systems SAS (ccsupport@elitechgroup.com).

RHFA

Place for 2D barcode

ELITech Clinical Systems SAS
Zone Industrielle - 61500 SEES FRANCE
www.elitechgroup.com