RF-LATEX

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

REF 1419-1030 **Packaging:** 6 x 9 mL (R1) + 6 x 3 mL (R2)

300

2°C 8°C

INTENDED USE

Reagents for In Vitro quantitative automated measurement of the concentration of Rheumatoid Factor -RF in samples of human serum from the general patient population. Measurements of RF are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid in the differential diagnosis, prognosis and management of rheumatoid arthritis in adult and juvenile patients.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE

Rheumatoid factors (RF) are a heterogeneous group of auto-antigens directed against the F_C area of the IgG molecules. RF and IgG form immunocomplexes which appear in several rheumatoid diseases. The determination of RF in patients with possible rheumatoid arthritis does not have absolute clinical significance, because increased values may also result from other causes, while negative results don't preclude the disease. The higher the RF levels, the higher the possibility of a more severe arthritic disease. False positive results may occur because of conditions such as chronic hepatitis, chronic viral infection, leukemia, dermatomyositis, infectious mononucleosis, scleroderma, and systemic lupus erythematosus.

METHOD PRINCIPLE

The Immunoturbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and a solution (R2) of polystyrene particles covered with human γ--globulins, rheumatoid factor reacts selectively with the antibodies on covered particles (Latex), leading to formation of insoluble aggregates. The absorbance of the test solution at 750 nm is proportional to the concentration of rheumatoid factor in the sample.

METHOD LIMITATIONS

Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests". This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
MOPS Buffer pH=7.4 PEG 8000 1% w/w Preservative, stabilizers	Latex particles covered with human globulins Preservative, stabilizers

⚠ **WARNINGS – PRECAUTIONS**

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes, skin or mucus membranes.
- Materials of human origin used for manufacturing of this reagent have been tested and found negative for HBsAg, anti-HCV, anti-HIV1/2 and HIV-1 Antigen with methods approved by the US FDA. Since there is no method yet that can provide absolute guarantee that those materials do not carry infectious factors, you are to handle this product as potentially infectious. Avoid inhalation and contact with eyes, skin or mucus membranes.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**

R1 is ready to use when placed in the appropriate position of the analyzer. R2 should be mixed by gentle swirling 5 – 10 times before being placed on the analyzer and this mixing must be repeated on a weekly basis to avoid precipitation of Latex particles. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**

The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.
- When the solution is turbid.

⚠ **SHELF LIFE**

Unopened reagents are stable at 2°– 8°C up to the expiry date stated on the label. After opening, they remain stable for 1 month when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. RF remains stable in serum for 1 days at 2 - 8°C, and up to 3 months at -20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON RF Calibrator (1478-1030) traceable to NIBSC W1066 for calibration. Calibration is performed with a 6-point curve. For the first calibration point use NaCl 0.9% as sample. Calibrate the assay every 2 weeks on Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. Calibrator values are traceable in the RF 1st British Standard NIBSC 64/002 reference material.

QUALITY CONTROL Diatron offers MEDICON Immunology Control Levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04 respectively) for quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- RF Calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS

Serum: < 12 IU/ml

Reference values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.

Linearity Up to 120 IU/mL
Hook effect > 600 IU/ml
Lowest Detection Limit 5.7 IU/mL

The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP 5-A (20 consecut 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (IU/mL)	**%CV**
26.4	0.93
50.3	1.83
Level (IU/mL)	**TOTAL %CV**
26.4	2.03
50.3	2.52

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	400 mg/dL
Bilirubin	2 mg/dL
Ascorbate	3 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 1.0569X + 0.2366 R=0.9717 N=39 Sample range = 7.39 – 26.42 IU/mL

BIBLIOGRAPHY

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3. Bartifield H. Distribution of rheumatoid factor activity in non-rheumatoid states. Ann NY Acad Sci 1969; 168:30-40.
4. Tietz NW. Clinical guide to laboratory tests. 2nd ed.
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SYMBOLS

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Biological Risks

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