diatron

RF-LATEX

For use on Diatron Pictus® series analyzers
Method: Immunoturbidimetry
Product code: 1419-1032, 1419-1030
Package: 6 x 27 ml (R1) + 6 x 9 ml (R2), 6 x 9 ml (R1) + 6 x 3 ml (R2)
Store at: 2 – 8°C
For *in vitro* use only

INTENDED USE
Ready to use reagents for the quantitative determination of Rheumatoid Factor in human serum or plasma, specifically for use with Diatron Pictus® series analyzers. For in vitro diagnostic use only.

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
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".
The reagent is designed especially for use with the Diatron Pictus® series of chemistry analyzers. For chemistry protocols and further information please contact the customer support unit at Diatron.

REAGENT COMPOSITION
Reagent 1 (R1)
MOPS Buffer pH=7.4
PEG 8000 1% w/w
Preservative, stabilizers
Reagent 2 (R2)
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
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON HELLAS (manufacturer) upon request.

REAGENT 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 Pictus® series analyzers.

REAGENT DETERIORATION
Reagents should not be used:
- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- When they appear turbid.
- After prolonged exposure to sunlight or high temperature.

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 28 days when stored in the cooled reagent tray of the Pictus® series analyzers.

SAMPLE
Specimens of fresh serum or plasma with EDTA or citrate may only be used. Samples must be kept at 2°– 8°C and measured within 24 hours from sampling. If measurement can't take place within 24 hours, freeze serum samples at –20°C. Do not refreeze after thawing. Plasma samples must be tested within 24 hours from sampling. Do not use frozen plasma samples.

CALIBRATION
Diatron provides the RF Calibrator (1478-1030). Calibration is performed with a 6-point curve. For the first calibration point use NaCl 0.9% as sample. Calibrate the assay every 14 days on Pictus® series 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 provides the 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 SUPPLIED WITH THE KIT
- RF calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- 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® series 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.

	Pictus® P400	Pictus® P700/P500
Linearity	Up to120 IU/mL	Up to 120 IU/mL
Hook effect	> 1000 IU/ml	> 600 IU/ml
Detection limit	0.37 IU/mL	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 consecutive days, 2 runs per day, 2 repeats per run).

	Pictus® P400			Pictus® P700/P500		
	Level (IU/mL)	Within Run CV%	Total CV%	Level (IU/mL)	Within Run CV%	Total CV%
	51.68	6.77	5.95	26.4	2.93	3.63
	68.4	3.19	4.06	50.3	2.83	3.42

Interference Criterion: recovery within ±20% from target value

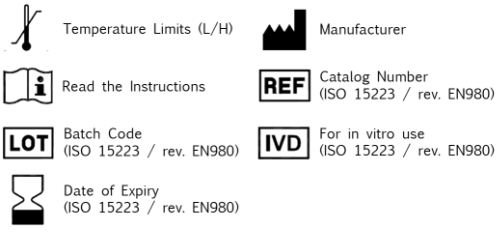
	Pictus® P400	Pictus® P700/P500
Lipemic	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to 3000 mg/dl Intralipid®
Hemoglobin	Insignificant up to 400 mg/dL	Insignificant up to 400 mg/dL
Non-Conj. Bilirubin	Insignificant up to 2 mg/dL	Insignificant up to 2 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3 mg/dL

Correlation: A comparison was performed between this reagent on a Pictus® series analyzer, and a BECKMAN COULTER AU-series system. The results were as follows:

Pictus® P400			
Y = 0.910X + 1.21	R=0.99	N=46	Sample range = 1.4 – 162.8 IU/mL
Pictus® P700/P500			
Y = 1.0569X + 0.2366	R= 0.9717	N=39	Sample range = 7.39 – 26.42 IU/mL

BIBLIOGRAPHY

1. Moore TL, Dorner RW. Rheumatoid factors. Clin Biochem. 1993;26(2):75-84
2. Nowak UM, Newkirk MM. Rheumatoid factors: good or bad for you? Int Arch Allergy Immunol. 2005; 138(2):180-8
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.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests, AACC, 5th ed. AACC Press, 2000.

SYMBOLS


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MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com
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