diatron

IGM

For use on Diatron Pictus® series analyzers
Method: Immunoturbidimetry
Product code: 1419-0772, 1419-0770
Package: 4x22.5 ml (R1) + 4x4.5 ml (R2), 4x10 ml (R1) + 4x2 ml (R2)
Store at: 2°– 8°C
For *in vitro* use only

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

CLINICAL SIGNIFICANCE
Immunoglobulin M (IgM) is mainly responsible for the ABO categorization of blood and Rheumatoid factor. Increased levels of IgM are observed in macroglobulinemia, rheumatoid arthritis, brucellosis, lymphosarcoma, other autoimmune diseases, viruses, malaria, fungal infections.
Reduced IgM levels are observed in agammaglobulinemia, lymphoid hyperplasia, leukemia, amyloidosis.

METHOD PRINCIPLE
When sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), IgM reacts selectively with anti-IgM antibodies, leading to formation of insoluble aggregates. The absorbance of the test solution at 505/750 nm is proportional to the concentration of IgM in the sample.

METHOD LIMITATION
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)
Polyethylene glycol in Tris buffer (pH 8.0)
Non reactive ingredients, preservative
Reagent 2 (R2)
Goat anti-human IgM antibodies
Non reactive ingredients, preservative

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 and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- 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
Reagents R1 and R2 are ready to use when placed in the corresponding positions of the analyzer. The vials bear barcodes for automatic recognition by Pictus® series 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.

SHELF LIFE
Unopened, the reagent is stable at 2°– 8°C up to the expiry date stated on the label. Once opened, R1 and R2 remain stable for 56 days when stored in the cooled reagent tray of the Pictus® series analyzers

SAMPLE
Specimens of fresh serum or plasma with heparin or EDTA must be used. No fasting or special preparation of the patient is needed. IgM in the sample remains stable for 4 months at 2°– 8°C.

CALIBRATION
Diatron provides Protein Standard Set (code 1578-1190). Calibrate the assay every 28 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.

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
- IgM calibrator
- Quality control materials
- Diatron Pictus® P400/P700/P500
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 40 – 230 mg/dl
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 to 400 mg/dl	Up to 400 mg/dl
Hook effect	> 1500 mg/dl	> 1500 mg/dl
Lowest detection limit:	5.5 mg/dL	1.2 mg/dL

The lowest detection limit (LDL) is defined as the lowest concentration of IgM 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.
Ακρίβεια (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 (mg/dL)	Within Run CV%	Total CV%	Level (mg/dL)	Within Run CV%	Total CV%
	78.0	3.84	4.17	74.3	2.60	3.39
	164	3.29	3.77	141	2.22	3.29
	264	3.01	3.54	209	1.93	3.10

Interference Criterion: recovery within ±20% from target value

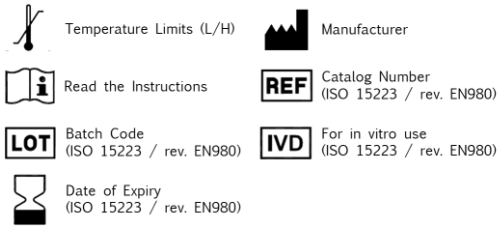
	Pictus® P400	Pictus® P700/P500
Lipemia	Insignificant up to Intralipid® 590 mg/dl	Insignificant up to 700 mg/dl Intralipid®
Haemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 13 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 8 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 mg/dL	Insignificant up to 3.0 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 = 1.15X – 7.66	R=0.978	N=40	Sample range = 26 – 197 mg/dL
Pictus® P700/P500			
Y = 1.091X – 8.075	R=0.98	N=28	Sample range = 26.3 – 198mg/dL

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. The American Association for Clinical Chemistry, Inc. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Ohio, Hudson: Lexi-Comp Inc., 1997.

SYMBOLS


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