

IGA

For use on Diatron Pictus® series analyzers

Method: Immunosorbent assay

Product code: 1419-0782, 1419-0780

Package: 4x21.6 ml (R1) + 4x10.8 ml (R2), 4x9.6 ml (R1) + 4x4.8 ml (R2)

Store at: 2°– 8°C

For *in vitro* use only

INTENDED USE

Ready to use reagents for the quantitative determination of Immunoglobulin A in human serum specifically for use with Diatron Pictus® series analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE

Immunoglobulin A (IgA) represents 15% of all immunoglobulins in the human body and is found mainly in the secretions of the gastrointestinal tract, in saliva, and in tears. Increased levels of IgA are observed in cirrhosis, rheumatoid fever, inflammatory diseases of the intestines, alcoholism, chronic infections, carcinoma especially of the gastrointestinal or hepatocellular tract.

METHOD PRINCIPLE

The immunoturbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), IgA reacts selectively with anti-IgA antibodies, leading to formation of insoluble aggregates. The absorbance of the test solution at 550/750 nm is proportional to the concentration of IgA 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
Non reactive ingredients, preservatives.

Reagent 2 (R2)

Goat anti-human IgA antibodies
Non reactive ingredients, preservatives.

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 (NaN₃) ≤ 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 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, it remains 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 necessary. IgA in the sample remains stable for 4 months at 2°– 8°C.

CALIBRATION

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

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

REFERENCE INTERVALS

Serum: 70 – 400 mg/dl

Expected values may vary with age, sex, sample type, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practices.

WASTE DISPOSAL

This product contains sodium azide (NaN₃), 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 600 mg/dl	Up to 600 mg/dl
Hook effect:	> 3750 mg/dl	> 4000 mg/dl
Lowest detection limit	7.9 mg/dL	5.9 mg/dL

The lowest detection limit (LDL) is defined as the lowest concentration of IgA 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 EP5-A (20 consecutive days, 2 runs per day, 2 repeats per run).

Level (mg/dL)	Pictus® P400			Pictus® P700/P500		
	Within Run CV%	Total CV%		Level (mg/dL)	Within Run CV%	Total CV%
131	1.78	2.49		113	1.91	2.89
277	1.51	2.18		215	1.38	2.52
389	1.85	2.38		321	1.35	2.00

Interference Criterion: recovery within ±20% from target value

	Pictus® P400	Pictus® P700/P500
Lipemic	Insignificant up to Intralipid® 1000 mg/dl	Insignificant up to Intralipid® 1000 mg/dl
Haemoglobin	Insignificant up to 500 mg/dL	Insignificant up to 500 mg/dL
Non conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Conj. Bilirubin	Insignificant up to 20 mg/dL	Insignificant up to 20 mg/dL
Ascorbate	Insignificant up to 3 g/dL	Insignificant up to 3 g/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 = 1.010X + 1.485	R=0.978	N=40	Sample range = 117 – 522 mg/dL
Pictus® P700/P500			
Y = 1.019X + 2.411	R=0.9796	N=25	Sample range = 118 – 522 mg/dL

BIBLIOGRAPHY

- Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
- Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
- 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.
- The American Association for Clinical Chemistry, Inc. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Ohio, Hudson: Lexi-Comp Inc., 1997.

SYMBOLS

 Temperature Limits (L/H)	 Manufacturer
 Read the Instructions	 Catalog Number (ISO 15223 / rev. EN980)
 Batch Code (ISO 15223 / rev. EN980)	 For <i>in vitro</i> use (ISO 15223 / rev. EN980)
 Date of Expiry (ISO 15223 / rev. EN980)	

