IGG

IMMUNOGLOBULIN G

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

REF 1419-0790 **Packaging:** 4 x 8.8 mL (R1) + 4 x 8.8 mL (R2)

2°C – 8°C

Σ 160

INTENDED USE
Reagents for In Vitro quantitative automated determination of Immunoglobulin G – IgG in samples of human serum or plasma from the general patient population. Measurements of IgG are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for the assessment of immune status.

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
Immunoglobulin G (IgG) represents 75% of all immunoglobulins in the human serum. Increased levels of IgG are observed in chronic infection, hyperimmunization, severe malnutrition, sarcoidosis, rheumatoid fever, liver disease, multiple IgG myeloma, rheumatoid arthritis. Decreased IgG levels are observed in agammaglobulinemia, lymphoid hyperplasia, amyloidosis, familial IgG dysplasia, preeclampsia, leukemia.

METHOD PRINCIPLE
The immunoturbidimetric method is applied. When sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), IgG reacts selectively with human anti-IgG antibodies, leading to formation of insoluble aggregates. The absorbance of the test solution at 590/750 nm is proportional to the concentration of IgG 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)
Polyethylene glycol in Tris buffer (pH 8.0) Non-reactive ingredients, preservatives.	Goat anti-human IgG 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 (NaN_3). 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**
Reagents R1 and R2 are liquid, ready to use and can be placed on the analyzer. 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.

⚠ **SHELF LIFE**
Unopened reagents are stable at 2 – 8°C up to the expiry date stated on the label. Once opened, reagents R1 and R2 remain stable for 2 months when stored in the reagent sampler of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum, or Li-heparin plasma 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. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible and store properly if analysis cannot take place right after sample separation. IgG remains stable in serum or plasma for 3 days at 2 - 8°C and up to 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON Protein Standard Set (1578-1190) traceable to ERM-DA470k for calibration. Calibrate the assay every 1 month 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.

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
- IgG calibrator
- Quality control materials
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum/Plasma: 700 – 1600 mg/dl
Reference values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

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 2800 mg/dL
Hook effect > 14000 mg/dL

Lowest detection limit 5.8 mg/dL
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 EP5-T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (mg/dL)	**%CV**
637	1.10
1207	1.25
1778	1.80
Level (mg/dL)	**TOTAL %CV**
637	2.27
1207	2.89

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

	(Insignificant up to)
Triglycerides	1500 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 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 = 1.197 X - 550 R=0.987 N=50 Sample Range: 381 – 3349 mg/dL

BIBLIOGRAPHY

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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.
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