IgG

IMMUNOGLOBULIN G

For discrete analyzers
Method: GSCC

Product Code:	**1418-0790**	**4 x 2.5 mL (R1) + 4 x 3.5 mL (R2)**
	1418-0797	**4 x 10 mL (R1) + 4 x 14 mL (R2)**

Store at 2 – 8°C
For *in vitro* use

INTENDED USE
MEDICON IgG is a set of immunoturbidimetric reagents for the quantitative determination of IgG in human serum, with BECKMAN COULTER AU400/600/600-IVD/640/2700/5400 and other discrete analyzers. For *in vitro* diagnostic use only.

CLINICAL SIGNIFICANCE
Antibodies consist of γ-globulin proteins, and are called immunoglobulins. Immunoglobulin G (IgG) represents about 75% of immunoglobulins in serum. Increased IgG levels are observed in chronic infections, serius malnutrition, hyperimmunizations, sarcoidosis, rheumatoid fever, liver disease, multiple IgG myeloma, rheumatoid arthritis. Decreased IgG levels are observed in agamaglobulinemia, lymphoid hyperplasia, amyloidosis, hereditary IgG dysplasias, preeclampsia, leukemia.

METHOD PRINCIPLE
The immunoturbidimetric method is applied. When the sample is mixed with the appropriate buffer (R1) and antiserum solution (R2), IgG reacts selectively with anti- human IgG leading to formation of insoluble aggregates. The absorbance of these aggregates at 600 nm is proportional to IgG concentration 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 for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.

REAGENT COMPOSITION
Reagent 1 (R1)
Polyethylenic glycol in Tris buffer (pH 8.0)
Non reactant components and preservatives
Reagent 2 (R2)
Goat anti -human IgG antibodies
Non reactant components and 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 according to the universal precautions and good laboratory practices.
- Antisera are raised in clinically healthy animals in monitored facilities under constant surveillance.
- The reagent contains sodium azide (NaN_3 < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

PREPARATION
Reagents 1 and 2 are ready to use. Vials bear barcodes for recognition by BECKMAN COULTER AU Series analyzers.

REAGENT DETERIORATION
The reagent should not be used:
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after recalibration.
- After prolonged exposure to high temperature.

SHELF LIFE
Unopened, reagents are stable up to the stated expiry date when stored at 2 – 8°C. Once opened, they can be stored refrigerated on the instrument for 2 months.

SAMPLE
Use serum as specimen. Strong lipemic samples should be avoided. IgG is stable in serum for 8 months when stored at 2 – 8°C.

CALIBRATION
MEDICON Protein Standard Set (1578-1190) traceable to CRM 470 from IRMM or BECKMAN COULTER ODR 3021 (MEDICON code: 4478-0754) can be used for calibration. Calibrate the assay every 1 month. Recalibrate following preventive maintenance or replacement of a critical part of the analyser, when using a new reagent kit or a new reagent lot number, or when Quality Control results are out of range.

QUALITY CONTROL
MEDICON provides the following products for quality control: Immunology Control levels 1,2,3 (1578-1195-04, 1578-1196-04, 1578-1197-04) or BECKMAN COULTER ODC0014 ITA Control Serum 1, ODC0015 ITA Control Serum 2, ODC0016 ITA Control Serum 3 (MEDICON code: 4478-1190, 4478-1191, 4478-1192).
Control target values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for IgG should be verified with the corresponding working protocol. Results outside the specified values 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 material
Automated biochemistry analyzer
Common laboratory equipment

REFERENCE INTERVALS
Serum: 700 – 1600 mg/dL
Each laboratory should determine its own expected values as dictated by good laboratory practice.

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
Linearity
The assay is linear within measuring range 22 – 2500 mg/dL. When values exceed this range samples should be diluted accordingly.
Prozone Tolerance
No hook effect is observed up to 20000 mg/dL.
Sensitivity
The lowest detectable level of IgG is estimated at 7 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

MEAN (mg/dL)	Within run CV%	Total CV%
580	1.94	2.10
909	1.17	1.70

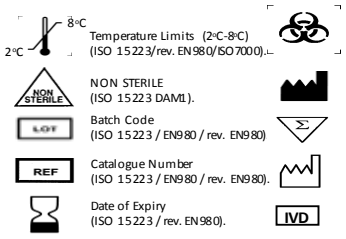
Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-5T (20 consecutive days, 2 runs per day, 2 repeats per run).
Interference

Lipemic:	insignificant up to 1000 mg/dL intralipid®
Hemoglobin:	insignificant up to 500 mg/dL
Non Conj. Bilirubin:	insignificant up to 20 mg/dL
Conj. Bilirubin:	insignificant up to 20 mg/dL
Ascorbic acid:	insignificant up to 3 mg/dL

Refer to Young[5] for further information on interfering substances.
Method Comparison
A comparison was performed between this reagent and another commercially available product. The results were as follows:
Y = 0.9621X + 28.123 R=0.9895 N=50 Sample range: 381 – 3349 mg/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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