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Immunoglobulin G (IgG)

This reagent is used to determine the content of IgG in human serum and plasma.

REF: BS.1/IGG02.025.0050

CLINICAL SIGNIFICANCE

IgG is one of the most abundant immunoglobulins produced by plasma cells, accounting for 75% of total immunoglobulins. Its main function is to bind to antigens and further trigger their breakdown. decreases in IgG concentrations occur in primary and secondary immunodeficiency syndromes. Decreases may also be caused by loss of protein from the intestine or through scalded skin. Severe infections and autoimmune diseases can cause increased IgG concentrations, such as lupus erythematosus, infectious diseases and cholecystic fibrosis.

METHOD PRINCIPLE

IgG and its corresponding antibody meet in the liquid phase to form insoluble immune complexes, resulting in turbidity in the reaction solution, and the turbidity level reflects the IgG content of the serum sample.

REAGENT COMPOSITION

R1: Dipotassium hydrogen phosphate 20 g/L PEG6000 55 g/L Preservatives, surfactants Amount
R2: Tris(hydroxymethyl)aminomethane(Tris) 6.0 g/L Goat anti-human IgG serum, preservative the right amount

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to IgG reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien IgG reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C contamination is avoided. Do not freeze and protect from light.

Deterioration

The ***BioScien*** IgG reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum or Plasma

Plasma anticoagulated with serum or heparin or EDTA should be separated within 2 hours after blood collection and stored at room temperature (15-25°C) for 4 months and 2-8°C or -20°C for 8 months.

SYSTEM PARAMETERS

Wavelength	600(580-620)nm
Optical path	1 cm
Assay type	Turbidimetric
Direction	Increase
Sample Reagent Ratio	4:1
Incubation Time	10 min. at 37 C
Temperature	37˚C
Zero adjustment	Reagent blank

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Specimen	*Calibrator*
R1	250 µl	250 µl
Specimen	2 µl	-
Calibrator	-	2 µl
Mix well and incubate for 5 min at 37 ,read initial absorbance A1.		
R2	50 µl	50 µl

Mix well and incubate for 5 min at 37 ,read initial absorbance A1.

CALCULATION

IGg Concentration (g/L) =

(A2-A1) sample x Calibrator concentration

(A2-A1) calibrator

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Absorbance of reagent blank: wavelength 700 nm, optical diameter 1.0 cm, temperature 37°C, A0 ≤ 0. 15. Analytical sensitivity: the absorbance change value ΔA≥0.1 when the kit tests 20 g/L of the measured substance.
Linearity range: test serum samples, reagent linearity in the interval of 2~30 g/L, linear correlation coefficient|r| should not be less than 0.975; in the interval of 2~15 g/L, the absolute deviation of linearity should not exceed 1.5 g/L; in the interval of (15~30 g/L, the relative deviation of linearity should not exceed
±10%.
Precision: repeatability CV≤ 10.0%; relative extreme difference between batches≤ 15.0%. Accuracy: Relative deviation ≤ 10%

LIMITATIONS

1. The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

EXPECTED VALUES

7 to 16 g/L

INTERPRETATION OF TEST

Bilirubin

≤ 40 mg/dL,

Hemoglobin

≤ 500 mg/dL

Celiac

≤ 500 mg/dL did not interfere with the determination.

REFERENCES

1. Gitlin D, Edelhoch HJ. Immunol. (1991); 66: 76-78.
2.Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54 and 462-494.
3.Guder WG, Narayanan S, Wisser H, Zawta B. List of Analysis; Pre-analytical Variables. Brochure in: Samples: From the Patient to the Laboratory. Darmstadt: GIT Verlag. (1996).

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

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CE