TA160 5 x 25 mL	TA160 5x 10 mL	TA160 5 x 5 mL
STORE AT 2-8ºC		
Reagents for measurement of IgG concentration Only for *in vitro* use in the clinical laboratory		

IMMUNOGLOBULIN G (IgG)

CE

archem

IMMUNOGLOBULIN G (IgG)
Turbidimetry

PRINCIPLE OF THE METHOD

Immunoglobulin G in the sample precipitates in the presence of anti-human immunoglobulin G antibodies. The light scattering of the antigen-antibody complexes is proportional to the immunoglobulin G concentration and can be measured by turbidimetry[1,2].

CONTENTS

	TA160	TA161	TA162
A. Reagent	5 x 25 mL	5 x 10 mL	5 x 5 mL

COMPOSITION

A. Reagent: Imidazole buffer 0.1 mol/L, goat anti-human IgG antibodies, sodium azide 0.95 g/L, pH 7.5.

STORAGE

Store at 2-8ºC.

The Reagent is stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during its use.

Indications of deterioration: Presence of particulate material, turbidity, absorbance of the blank over 0.300 at 540 nm.

ADDITIONAL REAGENTS

- Protein Calibrators (ARCHEM). The set contains 5 different levels of IgG concentration and it should be used to prepare the calibration curve. The calibrators are supplied ready to use.

REAGENT PREPARATION

Reagent is provided ready to use.

ADDITIONAL EQUIPMENT

- Thermostatic water bath at 37ºC.
- Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37ºC and able to read at 540 ± 20 nm.

SAMPLES

Serum or plasma collected by standard procedures. Use heparin or EDTA as anticoagulants. Lipemic samples are not suitable for testing.

Serum or plasma IgG is stable for 7 days at 2-8°C.

PROCEDURE

1. Bring the Reagent and the instrument to 37ºC.
2. Pipette into a cuvette (Note 1):

Reagent (A)	1.5 mL
Distilled water (Blank), Calibrator or Sample	10 µL

3. Mix and insert cuvette into the instrument. Start stopwatch.
4. Read the absorbance of the Blank, Calibrators and Sample at 540 nm after exactly 5 minutes of sample addition.

CALCULATIONS

Calibration curve: Plot the absorbance values of each calibrator against its IgG concentration. Use the Blank as the calibrator of 0 concentration. IgG concentration in the sample is calculated by interpolation of its absorbance on the calibration curve.

REFERENCE VALUES

Serum, adults[3]: 700 - 1600 mg/dL

This range is given for orientation only; each laboratory should establish its own reference range.

QUALITY CONTROL

It is recommended to use the Protein Control Serum level I () and II () to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

METROLOGICAL CHARACTERISTICS

- Detection limit: 0.2 mg/dL IgG
- Measurement interval (approximate value dependent on the highest standard concentration): 0.2-3500 mg/dL.For higher values dilute sample 1/5 with distilled water and repeat measurement.
- Repeatibility (within run):

Mean concentration	CV	n
713 mg/dL	4.1 %	20
1712 mg/dL	4.8 %	20

- Reproducibility (run to run):

Mean concentration	CV	n
713 mg/dL	4.8 %	25
1712 mg/dL	4.1 %	25

- Sensitivity: 0.580 mA dL/mg at 1600 mg/dL.
- Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.
- Zone effect: falsely low values are obtained when IgG is present in the sample at a concentration higher than 6000 mg/dL.
- Interferences: Bilirubin (20 mg/dL), hemoglobin (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides > 15 g/L) may affect the results. Other drugs and substances may interfere[4].

These metrological characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure are used.

DIAGNOSTIC CHARACTERISTICS

The major immunoglobulin produced by plasma cells is IgG, which makes up to 75% of the total immunoglobulins.

Plasma IgG concentration is decreased in inherited or acquired deficiencies of immunoglobulin production[3,5].

Diffuse (polyclonal) hyperimmunoglobulinemia is the normal response to infections. IgG tends to predominate in autoimmune responses as well as in chronic active hepatitis. Increases in serum monoclonal IgG (paraprotein) are found in multiple myeloma and other proliferative disorders of plasma cells[3,5].

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

NOTES

1. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

1. Narayanan S. Method-comparison studies on immunoglobulins. *Clin Chem* 1982; 28: 1528-1531.
2. Price CP, Spencer K and Whicher J. Light-scattering immunoassay of specific proteins: a review. *Ann Clin Biochem* 1983; 20: 1-14.
3. Dati F et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference range for 14 proteins in serum based on the standarization against the IFCC/CAP reference material (CRM 470). *Eur J Clin Chem Clin Biochem* 1996; 34: 517-520.
4. Young DS. Effects of drugs on clinical laboratory tests, 3th ed. AACC Press, 1997.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 3th ed. AACC Press, 1997.

IVD