COD 31082 1 x 20 mL	COD 31071 1 x 50 mL	COD 31077 1 x 250 mL
STORE AT 2-8ºC		
Reagents for measurement of IgA concentration Only for *in vitro* use in the clinical laboratory		

IMMUNOGLOBULIN A (IgA)

BioSystems
REAGENTS & INSTRUMENTS

CE

IMMUNOGLOBULIN A (IgA)

Turbidimetry

PRINCIPLE OF THE METHOD

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

CONTENTS

	COD 31082	COD 31071	COD 31077
A. Reagent	1 x 20 mL	1 x 50 mL	1 x 250 mL

COMPOSITION

A. Reagent: Imidazole buffer 0.1 mol/L, goat anti-human IgA 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 340 nm.

ADDITIONAL REAGENTS

– Protein Calibrators (BioSystems cod. 31075). The set contains 5 different levels of IgA 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 340 ± 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 IgA is stable for 7 days at 2-8ºC.

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 340 nm after exactly 8 minutes of sample addition.

CALIBRATION

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

A calibration is recommended at least every 2 months, after reagent lot change or as required by quality control procedures.

REFERENCE VALUES

Serum, adults[3]: 70 - 400 mg/dL = 0.70 - 4.00 g/L.

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 (Cod. 31211) and II (Cod. 31212) 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: 3.7 mg/dL = 0.037 g/L.

– Measurement interval (approximate value dependent on the highest standard concentration): 3.7 - 650 mg/dL = 0.037 - 6.50 g/L. For higher values dilute sample 1/5 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean concentration	CV	n
155 mg/dL = 1.55 g/L	2.7 %	20
372 mg/dL = 3.72 g/L	3.7 %	20

– Reproducibility (run to run):

Mean concentration	CV	n
155 mg/dL = 1.55 g/L	2.6 %	25
372 mg/dL = 3.72 g/L	3.8 %	25

– 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: > 2300 mg/dL = 23.00 g/L.

– Interferences: Bilirubin (20 mg/dL) and rheumatoid factors (300 IU/mL) do not interfere. Lipemia (triglycerides 7.1 g/L) and hemoglobin (7.0 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

Approximately 10 to 15% of serum immunoglobulin is IgA. In its monomeric form, its structure is similar to that of IgG, but 10 to 15% of IgA in serum is dimeric.

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

Diffuse (polyclonal) hyperimmunoglobulinemia is the normal response to infections. IgA is often increased in skin, lungs, gut and renal infections, as well as in cirrhosis. Increases in serum monoclonal IgA (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

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4. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.
5. Friedman and Young. Effects of disease on clinical laboratory tests, 4th ed. AACC Press, 2001.