

# IgA Estimation Kit

## High-Q Immunoglobulin IgA

### Turbidimetric Immuno Assay (TIA)

#### Intended Use:

Diagnostic reagent for quantitative in vitro determination of immunoglobulin A (IgA) in serum on photometric systems

#### Summary

The human immunoglobulin classes (IgG, IgA, IgM, IgE and IgD) are a group of functionally and structurally closely related glycoproteins. Human IgA has a molecular weight of about 160 000 daltons and consists of two identical heavy chains and two identical light chains which are bound together by disulfide bonds in a characteristic Y-shaped form. Serum IgA is produced by plasma cells (B-cells) and represents about 15% of all soluble immunoglobulin classes. About 90% of the serum IgA is monomeric the rest is dimeric and polymeric. Most of IgA is not present in serum but on the surface of mucous membranes. In the mucosal tissues of the lung and the gastrointestinal tract IgA is released by plasma cells in a dimeric form. The two Y-shaped pieces are bound together not only by a joining chain but also by a special peptide called secretory component. This IgA type is called secretory-IgA. It is normally not present in human serum but in other body fluids like sweat, tears, gastrointestinal and bronchial secretions. The main function of serum-IgA is to bind to antigens and trigger further catabolism of the antigen. Decreased serum-IgA concentrations occur in primary as well as in secondary immunodeficiency syndromes. A high increase of one immunoglobulin class due to multiple myeloma may result in a decrease in other immunoglobulin classes like IgA. Increased loss of IgA due to severe enteritis may result in a decreased concentration. Increased IgA concentrations can be observed in severe infections and autoimmune diseases. Especially inflammatory processes of the liver may result in increased serum IgA levels. Like for other Ig-classes many forms of myeloma produce high amounts of monoclonal or polyclonal IgA. Quantitative serum-IgA determination is necessary for differential diagnostics of these diseases. All methods for IgA quantitation are calibrated for polyclonal serum-IgA. The quantitation of monoclonal IgA is not standardized and values may differ for different reagents and methods. Values should only be used for follow up studies. Monoclonal immunoglobulinemia requires detailed differential diagnostic investigation in addition to the quantitative determination.

#### Principle

Determination of IgA concentration by photometric measurement of antigen-antibody-reaction of antibodies to human IgA with IgA present in the sample.

#### Reagents

##### Components and Concentrations

R1: TRIS	pH 7.5	100 mmol/L
NaCl		150 mmol/L
R2: TRIS	pH 8.0	100 mmol/L
NaCl		1150 mmol/L
Anti-human IgA antibody (goat)		< 1%

##### Storage Instructions and Reagent Stability

All the reagents are liquids and are stable till the expiry date mentioned on the labels when stored properly at 2-8°C

IgA Calibrator: Concentration lot specific and available as Liquid Calibrator. Calibrators are stable till the expiry date mentioned on the labels when stored properly at 2-8°C

IgA Controls: Concentration lot specific and available as Lyophilized Controls and are available optionally. Controls are stable till the expiry date mentioned on the labels when stored properly at 2-8°C

#### Specimen:

Serum is the specimen

Stability: 7 Days at 2-8°C and 1 month at -20°C when frozen as aliquots

Avoid Freeze Thaw cycles

#### TEST PROCEDURE:

##### System Parameters:

Calibration Method	Endpoint-Bichromatic
Reaction Direction	Increasing
Primary Wave Length	340
Secondary Wave Length	700 (600-700)
Flow Cell Temp.	37°C
Blank	Reagent Blank
Reagent Volume	500 µl (R1+R2)
Sample Volume)	5 µl
Calibrators Conc	Lot Specific (Check the labels))
Units	mg/dL
Linearity	800

##### PROCEDURE:

Reagent	Reagent Blank	Cal	Sample
IgA R1 Reagent	400 µL	400 µL	400 µL
Calibrator	-----	5 µL	-----
Sample	-----	-----	5 µL
<b>Incubate for 5 Minutes at 37°C</b>			
IgM R2 Reagent	100 µL	100 µL	100 µL

Mix well and incubate for 5 minutes at 37°C Read the absorbance of Calibrator (C) Sample (S) against Reagent Blank (B) Bichromatically at 340 nms (Primary Wavelength) and 700 nms (Secondary Wavelength- (600-700 nms)

#### Calculations:

$$\text{IgA (in mg/dl)} = \frac{\text{Abs. of Sample}}{\text{Abs. of Calibrator}} \times \text{Calibrator Concentration}$$

#### Performance Characteristics

##### Measuring Range (Linearity)

The test has been developed to determine concentrations of IgA within a measuring range from 30 - 900 mg/dL, at least up to the concentration of the highest calibrator. When values exceed the upper range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

##### Specificity/Interferences

Due to its antibodies, High-Q Immunoglobulin A is a specific immunoassay for human IgA. No interference was observed by conjugated and unconjugated bilirubin up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 2000 mg/dL triglycerides and RF up to 1700 IU/mL.

No cross reaction with IgG or IgM was observed under test conditions.

##### Sensitivity/Limit of Detection

The lower limit of detection is (the minimum concentration which can be measured and distinguished from zero) is 3 mg/dL.

##### Imprecision

According to protocol EP-5 of the NCCLS (National Committee of Clinical Laboratory Standards)

Within-run precision	Mean	SD	CV
n = 40	[mg/dL]	[mg/dL]	[%]
Sample 1	87.3	2.05	2.35
Sample 2	275	6.06	2.21
Sample 3	420	8.92	2.12
Between day precision	Mean	SD	CV
n = 40	[mg/dL]	[mg/dL]	[%]
Sample 1	87.3	1.78	2.04
Sample 2	275	3.43	1.25
Sample 3	420	7.12	1.69

### Method Comparison:

A comparison of High-Q Immunoglobulin A (y) with a nephelometric test (x) using 77 samples gave following results:  $y = 0.93x + 4.23$  mg/dL;  $r = 0.992$ .

### Reference Range:

Adults :	70 – 400mg/dL
Children :	Newborns 7 – 94 mg/dL
	1 – 12 month(s) 10 – 131 mg/dL
	1 – 3 Years 19 – 220 mg/dL
	4 – 5 Years 48 – 345 mg/dL
	6 – 7 Years 41 – 297 mg/dL
	8 – 10 Years 51 – 297 mg/dL
	11 – 13 years 44 – 395 mg/dL

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

### Literature:

1. Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 667-78.
2. Johnson AM, Rohlfis EM, Silverman LM. Proteins. In: Burtis CA, Ashwood ER. editors. Tietz textbook of clinical chemistry. 3<sup>rd</sup> ed. Philadelphia: W. B. Saunders Company; 1999. p. 507-12.
3. Bartl R, Hoechtlen-Vollmar W, Thomas L. Monoclonal immunoglobulins. In: Thomas L. Clinical Laboratory Diagnostics. 1<sup>st</sup> ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 742-58.
4. Guder WG, Narayanan S et al. List of Analytes; Preanalytical Variables. 1st ed. Darmstadt: Git Verlag, 1996: 16-7.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Dati F, Schumann G, Thomas L, Aguzzi F, Baudner S, Bienvu J et al. Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/BCR/CAP reference material (CRM 470). Eur J Clin Chem Clin Biochem 1996; 34: 517-20.
7. Heil R, Koberstein R, Zawta B. Referenzbereiche für Kinder und Erwachsene. Roche Diagnostics 2004. p. 48-49.
8. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanism, detection and prevention. Clin Chem Lab Med 2007; 45(9): 1240-1243.



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### Ordering Information

















Ref./Cat. No. Pack Size Presentation

P-IgA-25 25 ml Liquid Stable two Reagents and Liquid Calibrator

### Product Features

- Liquid Stable, Ready to use two reagents
- 10 Minutes Endpoint-Bichromatic Assay
- Liquid Stable Calibrator Provided
- Linearity: 30-900 mg/dL
- Measuring Wavelength - Primary 340 nm, Secondary 700 nms (600-700 nms)
- Serum is the Specimen
- Available as multipurpose reagents and dedicated system packs :

### Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry
	Catalog Number		Keep away from rain



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+91 7075706709

info@parikshabio.com

www.parikshabio.com

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