

Immunoglobulin A(IgA) Diagnostic Reagent Kit (Immunoturbidimetry Method) Product Instruction

Product name

Generic Name: Immunoglobulin A (IgA)
Diagnostic Reagent Kit (Immunoturbidimetry Method)
Abbreviation: IgA

Package Specifications

R1	R2
30ml × 1	10ml × 1
750ml × 1	250ml × 1
7500ml × 1	2500ml × 1

Calibrator (lyophilized):

Specification 1 (0.5mL × 4; 4 levels);

Quality Control (lyophilized):

Specification 1 (0.5mL × 1; 1 level).

Intended use

Immunoglobulin A(IgA) diagnostic reagent is used for the quantitative in vitro determination of IgA in human serum on photometric systems.

Clinical significance

The main function of IgA is to bind to antigens and further trigger the breakdown of antigens. Clinically, the decrease of IgA concentration occurs in primary and secondary immunodeficiency syndromes; while the increase of IgA concentration occurs in severe infection and autoimmune diseases, especially the liver inflammation process will increase the IgA level in serum. Commonly used detection methods are immunoturbidimetry and chemiluminescence.

Principle

When Immunoglobulin A in human serum and its corresponding antibody (goat anti-human immunoglobulin A antibody) meet in the liquid phase, immediately an antigen-antibody complex forms and a certain turbidity also forms. Compared with the calibrators treated in the same way, the content of immunoglobulin A in the sample can be calculated.

Main ingredient

Composition	Main ingredients
R1	Phosphate buffer 20mmol/L
	Lipid elimination agent 5g/L
	Sodium chloride 9g/L
R2	Goat anti-human IgA specific antiserum 20%
Calibrator	Tris 50mM
	Trehalose 5%

Quality Control	BSA 5%
	human immunoglobulin A
	Tris 50mM
	Trehalose 5%
	BSA 5%
	human immunoglobulin A

Storage and stability

This kit stays stable for 18 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation

Fresh serum;

-20°C, stable for 7 days.

Assay procedure

1. Reagent preparation

This reagent is liquid and can be used directly.

Main wavelength	340nm	Sample(S)	3 μl
Subwavelength	700nm	Reagent 1	225 μl
Reaction temperature	37°C	Reagent 2	75 μl
Cuvette light path	1cm	Reaction type	Two Point End

2. Operation steps

Add to the cuvette:	
Sample (S)	3 μl
R1	225 μl
Mix well, incubate at 37°C for 5 minutes, 340nm, set zero with a blank tube, and measure the absorbance A1, then add	
R2	75 μl
Mix well, incubate at 37°C for 5 minutes, 340nm, set zero with a blank tube, and measure the absorbance A2, absorbance A2 ΔA= A2- A1	

Calculations

Calculate and plot $\Delta A = (A2 - A1)$ of the calibrators versus assigned concentration values on a linear-linear graph paper. Calculate ΔA optical densities of samples and read values in mg/dl on the reference curve. Samples yielding absorbances above highest calibrator should be retested after further dilution.

Reference interval

0.70 g/L-3.30g/L

It is recommended that each laboratory should establish its own reference interval.

Quality control

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics

1. Measuring range

0.1g/L-6.2g/L

Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

2. Sensitivity

When a control serum (2.5 g/L) is used as a sample, the range of absorbance change should not be smaller than 0.3000.

Interference

When Hemoglobin ≤ 5 g/L, ascorbic acid (vitamin C) ≤ 1000 mg/L, triglyceride ≤ 10 mmol/L, heparin lithium ≤ 200 U/mL, heparin sodium ≤ 200 U/mL, rheumatoid factor ≤ 800 IU/mL, no effects on the experimental results are to be found. In order not to affect the test results, please pay special attention to the operation.

Automation

Special adaptations for automatic analyzers can be made on request.

Precautions and warnings

General precautions

For in vitro diagnostic use only.

Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement

Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

Reagents with different lot numbers should not be

interchanged or mixed.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Material safety data sheet available for professional user on request.

Parameters on analyzers

HITACHI	
Model	7180
Assay Code	2 Point End
Reaction Time	10
Assay Point	16-34
Wave Length Sec	700
Wave Length Prim	340
ABS. Limit	32000
Sample Volume (uL)	3
R1 Volume (uL)	225
R2 Volume (uL)	0
R3 Volume (uL)	75
Calibration Type	SPLINE
Calibration Point	5
Span Point	3
SD Limit	999
Duplicate Limit	1000 or (0%-1000Abs)
Sensitivity Limit	0
Prozone Limit	32000

OLYMPUS 400	
Sample Volume (uL)	3
Sample DIL. VOL.	/
R1 Volume (uL)	225
R2 Volume (uL)	75
Reagent DIL. VOL.	/
Measure Wave 1	340
Measure Wave 2	700
METHOD	END
SLOPE	-
Method Point	9-27
Linear Limit	-
NO LAG TIME	Yes
OD L	-
OD H	-
Reagent OD Limit	
FIRST	-2.0-+2.5
LAST	-2.0-+2.5
Dynamic Range L	0
Dynamic Range H	6.2
Correlation Factor A	1.0
Correlation Factor B	0.0
Calibration Type	5AB

Formula	spline
STD(1) Conc.#	*
Unit	g/L

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