TURBICHEM IMMUNOGLOBULIN-A

IgA (Turbidimetry Method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - IgA	1 x 40 ml	TIGA00040M

INTRODUCTION

Immunoglobulin A (IgA) is intended for Invitro quantitative determination of IgA in human serum. Immunoglobulin A (IgA) accounts for 10 to 15% of serum immunoglobulin. IgA plays a critical role in muscosal immunity and is found to be at high levels in the gastrointestinal system, genitourinary system and respiratory system. IgA measurement is used to diagnose diseases of the respiratory tract, monitor IgA myeloma and evaluate IgA immunity. Increase in IgA levels can be due to recurrent infections, anaphylactic transfusion reactions, chronic liver disease, chronic infections, neoplasia of the lower GI tract, and inflammatory bowel disease. Decreased levels of IgA may be found in isolated genetic deficiency, combined immunodeficiency disorders, non-IqA multiple myeloma or macroglobulinemia.

METHOD PRINCIPLE

The Kit utilizes latex-enhanced immunoturbidimetry to measure the IgA level in human serum or plasma. During the test, IgA in the sample binds with the specific anti IgA antibody to cause agglutination. The turbidity caused by agglutination is detected optically by chemistry, analyzer. The change in absorbance is proportional to the level of IgA in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

KIT CONTENTS

R1 - IgA Buffer	1 x 30 ml
R2 - IgA Antibody	1 x 10 ml
R3 - IgA Calibrator	1 vial

The reagents when stored at $2\text{-}8^\circ\text{C}$ are stable up to expiry date printed on the package. The reagents are stable for 7-10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-IgA and R2-IgA reagents of 3 parts of R1-IgA with 1 part of R2-IgA. Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Phosphate buffer, Polyethylene glycol, Sodium azide < 0.1% R2 - anti-IgA antibodies, Tris buffer, sodium azide < 0.1%

WARNINGS AND NOTES

- 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.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

ADDITIONAL EQUIPMEN

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

Follow standard laboratory procedures to collect serum samples. It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at $2-4^{\circ}$ C for up to 3 days or at -20° C for up to 1 months. Avoid repeated freezing and thawing.



PLOTTING OF MULTIPOINT CURVE

The Turbichem IgA is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 μl from 1st Tube	50 μl from 2nd Tube	50 μl from 3rd Tube	50 μl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay and in several automatic analyzers. Applications for them are available on request.

Wavelength	630 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)	
R1 IgA Buffer	750 μl	750 µl	
Caibrator	10 µl	-	
Sample	-	10 µl	
Mix well and incubate for 5 mins at 37° C			
R2 IgA Antibody	250 μl	250 µl	

Mix well & incubate for 5 min. at 37°C. Measure the absorbance of calibrator & sample.

CALCULATION

IgA concentration = <u>Abs.Test</u> X Calibrator Concentration Abs.Calibrator

REFERENCE VALUES

72-429 mg/dL

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls

PERFORMANCE CHARACTERISTICS

- Linearity: 0 to 670 mg/dL
- Precision: within Run CV \leq 6 %
- Specificity / Interferences

No interference detected for bilirubin upto 60 mg/dL and hemoglobin 10 g/L

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

- Burtis C, Ashwood, ER (ed). Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia, P; WB Saunders Co; 509; 1999.
- Junqueira, Luiz C.; Jose Carneiro (2003). Basic Histology. McGraw-Hill.
- S Fagarasan and T Honjo (2003). "Intestinal IgA Synthesis Regulation of Front-line Body Defenses". Nat. Rev. Immunology 3(1): 63–72.
- Tietz NW, Pruden E, McPherson RA, Fuhrman, SA (eds). Clinical Guide to Laboratory Tests. 3rd ed. Philadelphia, PA: WB Saunders Co; 355–357; 1995.

SYSTEM PARAMETERS

Method	End Point
Wavelength	630 nm
Zero Setting	Reagent Blank
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	5 mins + 5 mins
Delay Time	
Read Time	
No. of Reading	2
Interval Time	
Sample Volume	0.010 ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Calibrator vial
Units	mg/dl
Factor	
Reaction Slope	Increasing
Linearity	670 mg/dl





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