Glenbio
Diagnostics & Research Laboratory Solutions

IgA Multi-Purpose (MPR) Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL606GA	1 x 50 ml 1 x 10 ml	IgA - 1 IgA - 2	2 - 8°C
GL616GA	5 x 50 ml 5 x 10 ml	IgA - 1 IgA - 2	2 - 8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the determination of Immunoglobulin A (IgA) in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION:

IgA accounts for 10 to 15% of the total immunoglobulins and serum. In its' monomeric form the structure of IgA is similar to that of IgG but 10% of IgA in serum is polymeric particularly IgA 2 which is more resistant to destruction by some pathogenic bacteria than IgA 1. Possibly the most important form of IgA is called secretory IgA found in tears, sweat, saliva, milk, colostrum and G.I. and bronchial secretions. Increased polyclonal IgA levels may occur in chronic liver diseases, chronic infections autoimmune disorders and sarcoidosis. Monoclonal IgA increases in IgA myeloma. Decreased levels of IgA are observed in acquired congenital immunodeficiency disease. Reduced levels can also be caused by protein losing gastro enteropathies and loss through the skin from burns.

PRINCIPLE OF THE TEST:

This assay is based on the reaction between IgA antigen and anti-IgA antibody. This reaction forms an insoluble complex producing a turbidity, which is measured spectrophotometrically. The amount of complex formed is directly proportional to the amount of IgA in the sample.

IgA antigen + Anti-IgA antibody ⟶ Antigen/antibody complex

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Components Colour and Appearance:
Reagent 1: Clear colourless liquid.
Reagent 2: Pale beige liquid.
Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

Safety Precautions:
Product is not hazardous under EU specification. Contain minute quantity of Sodium Azide. Material Safety Data Sheet is available upon request.

Handling precautions:
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

INSTRUMENTS:

Instrument application procedures are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	*Concentration in Tests*
Reagent 1	TRIS Buffer pH 7.6 with PEG	18.16 mmol/l
	Sodium Chloride	123.20 mmol/l
	DETERGENT & PRESERVATIVE	---
Reagent 2	TRIS Buffer pH 7.6	18.16 mmol/l
	Anti IgA antibody	---
	PRESERVATIVES	---

REAGENT PREPARATION AND STABILITY:

Reagent 1 and 2 are ready for use.
Before use, mix reagent by gently inverting each bottle.

If stored and handled properly, components are stable until expiry date stated on the label.

Prepare a range of 6 standards by serially diluting Calibrator (AD9605) in saline as follows:

Dilution	Neat	1/2	1/4	1/8	1/16	1/32
Factor	1	0.5	0.25	0.125	0.063	0.032

TYPE OF SPECIMEN:

Use serum or heparin/EDTA plasma as specimen.

It is recommended to follow CLSI procedures (or similar standardised conditions) regarding specimen handling. Specimen should be collected in an appropriate sampling container, with proper specimen identification. Plasma/serum should be separated from cells within 2 hours after collection.

Stability: up to 3 months at 2-8°C.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalog. No.*	*Description*	*Catalog. No.*
Specific Protein Calibrator	GL9605	Photometer	N/A
Specific Protein Control Level 1	GL9006	General Laboratory Equipment	N/A
Specific Protein Control Level 2	GL9016	Saline solution 0.9 g/l NaCl	N/A

Assay procedure:
Wavelength: λ: 340 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	Calibrator	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Calibrator	----	10 µl	----
Gently mix and Incubate at 37°C. Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C. Measure the Optical Density (OD2) after 10 minutes.			

Calibration:
Using recommended Calibrator, calibrate the assay:
- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part of the photometer used.
- When Quality Controls are out of range.

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the laboratory QC Programme.

CALCULATION:

- Calculate the Δ Abs for each standard and construct a calibration curve. Δ Abs = OD2 – OD1
- Calculate Δ Abs for the samples. Determine the corresponding concentration from the calibration curve.

(Conversion Factor: mg/dl x 0.01 = g/l)

EXPECTED VALUES: [4]

0.7 to 4.0g/l * (70 to 400mg/dl)
*Reference values according to CRM 470 Protein Standardisation.

Each laboratory should establish its own reference range. IgA results should always be reviewed with the patient's medical examination and history.

PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

Linearity:
This assay is linear across the calibration range.
For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

Prozone:
The system did not show prozone phenomena at least up to 50 g/l. (5000 mg/dl).

Interfering substances:
Bilirubin (mixed isomers): Less than 10% interference up to 600µmol/l Bilirubin.
Haemolysis: Less than 10% interference up to 5 g/l Haemoglobin.
Lipemia: Less than 10% interference up to 5 g/l Intralipid.

Sensitivity:
The Lowest Detectable Level was estimated at 0.08 g/l (8 mg/dl).

Precision:

Within Run N = 20	Mean *(g/l)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(g/l)*	*SD*	*% CV*
Level 1	1.47	0.02	1.09	Level 1	1.53	0.02	1.56
Level 2	2.26	0.02	0.97	Level 2	2.29	0.03	1.36

Method Comparison:
Using 50 samples, a comparison, between this IgA test (y) and another commercially available test (x), gave the following results:

y = 0.924X + 0.103	r = 0.990	Sample range: 0.47 to 7.50 g/l

BIBLIOGRAPHY:

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SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
BUF	Buffer	Ab	Antibody
CAL	Calibrator		
CE	CE Mark - Device comply with the Directives 98/79/EC		
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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Revision: 08 Issued on: 28 July 2021