α-1-ANTITRYPSIN
Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL109AT	1 x 50 ml 1 x 10 ml	ANTITRYPSIN - 1 ANTITRYPSIN - 2	2 - 8°C
GL119AT	5 x 50 ml 5 x 10 ml	ANTITRYPSIN - 1 ANTITRYPSIN - 2	2 - 8°C

INTENDED USE:

In Vitro Diagnostic reagent pack for the quantitative determination of α-1-Antitrypsin in serum and plasma on automated and semi-automated analysers.

SUMMARY AND EXPLANATION: [2]

Alpha-foeto protein is one of the first alphaglobulins to appear in mamalian sera during the development of the embryo. Synthesis and catabolism occur in the hepatic parenchymal's cells. Elevated maternal serum or amniotic fluid AFP indicates the possibility of an open neural tube or an abdominal wall defect in the foetus. Increased levels are also associated with foetal demise and foetal maternal bleeds. In addition AFP is increased in many forms of hepatocellular and serum cell carcinomas. α 1-Antitrypsin is the highest concentration of Proteinase inhibitor in plasma on a molar basis. Decreased levels of Antitrypsin are due to primary or genetic deficiency and are associated with a very high risk for the development of Basalar Pulmonary Emphysema. Decreased levels of α 1-Antitrypsin are also associated with diseases of liver including neo-natal cholestasis, cirrhosis and hepatocellular carcinoma.

PRINCIPLE OF THE TEST: [1]

This assay is based on the reaction between antigen and 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 α 1-Antitrypsin in the sample.

α 1-Antitrypsin antigen + Anti-α 1-Antitrypsin 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. Contains 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 applications 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 & PRESERVATIVES	---
Reagent 2	TRIS Buffer pH 7.6	18.16 mmol/l
	Anti α 1-antitrypsin antibody	---
	PRESERVATIVE	---

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 (GL9605) 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 heparinised plasma as specimen.

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

Stability: up to 1 week 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		

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. OD1 = abs sample – abs blank			
Reagent 2	200µl	200µl	200µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 10 minutes. OD2 = abs sample – abs blank			

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

(Conversion Factor: mg/dl x 0.1 = g/l)

EXPECTED VALUES:

		mg/dl	*g/l*
Serum Values:	Newborn	145 to 270	1450 to 270
	Adult	78 to 200	780 to 2000
	> 60 Years	115 to 200	1150 to 2000

Each laboratory should establish its own reference range. α 1-Antitrypsin 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.

Interfering substances:
Results of study are as follows:

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 1.1 mg/dl (11 g/l).

Precision:

Within Run N = 20	Mean *(mg/dl)*	*SD*	*% CV*	*Between Run N = 20*	Mean *(mg/dl)*	*SD*	*% CV*
Level 1	90.1	1.47	1.63	Level 1	87.3	1.77	2.02
Level 2	132.4	1.21	0.92	Level 2	128.1	2.46	1.92

BIBLIOGRAPHY:

1. Lieverns M, Bienvenu J, Buitrago JMG et al. Evaluation of four Tina-Quant assays for the determination of α 1-Acid Glycoprotein, α 1-Antitrypsin, Haptoglobin and Prealbumin.
2. Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 325-351 and 965.

SYMBOLS:

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

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
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

GLENBIO LTD
10 Kilbegs Road, Antrim, Co. Antrim, BT41 4NN
Tel/Fax: +44(0)2879659842
Email: info@glenbio.com
Web: www.glenbio.com

EC REP
GLENBIO IRELAND LTD
17b Fota Business Park, Carrigtwohill, Co. Cork,
T45 PK77, Ireland

Revision: 04 Issued on: 27 July 2021