MISPA-i_2 AGAPPE

ALPHA-1-ANTITRYPSIN

15 Tests, 30 Tests
12009013, 12009037

Intended Use
This reagent is intended for the *in vitro* quantitative determination of α1-Antitrypsin (AAT) inhuman serum by nephelometric immunoassay.
Nephelometry methodology
Linear up to 400 mg/dL
Ready to use reagents
No calibration required
Lower detection level 40 mg/dL

Clinical Significance
α1-Antitrypsin (AAT) is an acute phase protein showing anti protease activity. The main function of this protein consists in neutralizing lysosomal elastase released upon phagocytosis by polymorphonuclear leukocytes. Increased levels in serum are found in acute infection and inflammation, acute malaria, pregnancy, anabolic steroid therapy and advanced malignant tumors. Inherited deficiency of the protein is associated with lung and liver diseases. Decreased serum levels are seen in congenital deficiencies, juvenile cirrhosis, lung emphysema, COPD, testosterone administration and also encountered in neonatal respiratory syndrome and in severe protein losing disorders.

Principle
α1-Anti trypsin in the serum sample reacts with the specific antibody in the reagent and develop immune complexes. The turbidity is measured which is directly proportional to the concentration of AAT present in the serum.

Kit Components

Reagent/ Component	Product Code 12009013	Product Code 12009037	Description
α 1 Anti-trypsin R1	1 x 2.25 mL (15T)	1 x 4.4 mL (30T)	Glycine Buffer
α1 Anti-trypsin R2	1 x 2.25 mL (15T)	1 x 4.4 mL (30T)	Polyclonal goat anti-human α1 antitrypsin antibodies (stabilized)
Reagent 3	1 x 8 mL (15T)	1 x 8 mL (30T)	Normal Saline

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation
Alpha-1 antitrypsin R1, R2 & Reagent 3 are ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8°C.

Open Vial Stability
Once opened the reagents are stable for 60 days. .
The validity of the smart card will be up to 60 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Protein Control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
Bring the reagents to room temperature (RT) before use
To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum or plasma. Do not use lipemic or hemolysed sample.
Sample should be 1/10 diluted with R3

Interferences
No interference for

Bilirubin up to	20 mg/dL
Haemoglobin up to	500 mg/dL

Materials provided
Alpha 1-antitrypsin R1, R2 & Reagent 3
Smart Card, Cuvettes & Pipette Tips

Test Procedure
The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.
Step 1: Insert card to card reader slot & display will prompt to add R1+Sample-(Dilute the sample 1/10 with R3)
Step 2: Pipette 120 µL R1 & 10 µL sample to cuvette & place the cuvette into cuvette holder.
Step 3: After incubation display will prompt to add R2
Step 4: Pipette 120 µL R2 using attached sensor pipette to the cuvette
Step 5: The result will show in the display and print out

Calibration
The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control
It is recommended to use Agappe Protein Control (Bi Level) (Product Code: 11614007) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.
Normal range for adult: 89-205 mg/dL
Normal range for newborn: 145mg/dL– 270mg/dL
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 400 mg/dL. If the concentration is greater than linearity, dilute the 1/10 diluted sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9364 and a regression equation of y = 1.0179x.
3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (mg/dL)	96.73	198.25	95.25	192.41
SD	1.34	4.12	1.4	3.8
CV(%)	1.39	2.08	1.46	1.98

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	98.8 ± 19.7	96.73
Control Level 3	202 ± 40	198.2
Protein Control	100.5 ± 15	101

4. Sensitivity
Lower detection Limit is 40 mg/dL

Bibliography

1. Bergstrom, K. &Lefvert, A. K Scand. J. Clin. Lab. Invest. 40 (1980), 637.
2. Tietz Textbook of Clinical Chemistry, W. B. Saunders, Philadelphia, (1994)
3. Raitt, I. Essential Immunology, Blackwell, Oxford, (1991).

SYMBOLS USED ON THE LABELS

REF PRODUCT NUMBER/ CATALOGE NUMBER — CONTAINS 'N' TEST
IVD IN VITRO DIAGNOSTIC USE — SEE PACKAGE INSERT FOR PROCEDURE — LOT LOT NUMBER — MANUFACTURER'S ADDRESS — MANUFACTURING DATE — EXPIRY DATE — TEMPERATURE LIMIT

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EN ISO 13485:2016