SyRe

TBA-120FR

AGAPPE

ADENOSINE DEAMINASE

1 x 45/1 x 23 mL
12011060

Intended Use
Adenosine deaminase (ADA) assay kit is for determination of ADA activity in human serum or plasma samples.
- Enzymatic Method

Clinical Significance
ADA is an enzyme catalyzing the deamination reaction from adenosine to inosine. The enzyme is widely distributed in human tissues, especially high in T lymphocytes. Elevated serum ADA activity has been observed in patients with acute hepatitis, alcoholic hepatic fibrosis, chronic active hepatitis, liver cirrhosis, viral hepatitis and hepatoma. Increased ADA activity was also observed in patients with tuberculous effusions. Determination of ADA activity in patient serum may add unique values to the diagnosis of liver diseases in combination with ALT or ?-GT (GGT) tests. ADA assay may also be useful in the diagnostics of tuberculous pleuritis.

Principle
The ADA assay is based on the enzymatic deamination of adenosine to inosine which is converted to hypoxanthine by purine nucleoside phosphorylase (PNP). Hypoxanthine is then converted to uric acid and hydrogen peroxide(H_2O_2) by xanthine oxidase (XOD). H_2O_2 is further reacted with TOOS and 4-aminoantipyrine (4-AA) in the presence of peroxidase (POD) to generate quinone dye which is monitored in a kinetic manner. The entire enzymatic reaction scheme is shown below.

$$\text{Adenosine} + H_2O \xrightarrow{\text{ADA}} \text{Inosine} + NH_3$$

$$\text{Inosine} + \text{Pi} \xrightarrow{\text{PNP}} \text{Hypoxanthine} + \text{Ribose 1-phosphate}$$

$$\text{Hypoxanthine} + 2H_2O + 2O_2 \xrightarrow{\text{XOD}} \text{Uric acid} + 2H_2O_2$$

$$2H_2O_2 + \text{4-AA} + \text{EHSPT} \xrightarrow{\text{POD}} 4H_2O + \text{Quinone dye (max 556nm)}$$

One unit of ADA is defined as the amount of ADA that generates one µmole of inosine from adenosine per min at 37°C

Kit Components

Reagent/ Component	Product Code 12011060	Description
ADA R1	1 x 45 mL	Tris-HCl, 4-AA, PNP, XO, Peroxidase
ADA R2	1 x 23 mL	Tris-HCl, Adenosine, EHSPT

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

Reagent Preparation
Adenosine deaminase R1 & R2 Reagents 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 up to 30 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 20 days.

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 control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. 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 and non-hemolysed serum/plasma

Interferences
No interference for

Hemoglobin	up to 800 mg/dL
Intra lipid:	up to 1000 mg/dL
Ascorbic acid:	up to 50 mg/dL

Materials provided
Adenosine Deaminase R1 & R2 Reagent

Reagents required but not provided
Adenosine Deaminase Calibrator (Product Code: 11636001)
Adenosine Deaminase Control (Product Code: 11636002)

Calibration
ADA Calibrator (Product Code:11636001) is recommended for calibration of the assay.

Quality Control
It is recommended to use Agappe Adenosine Deaminase Contol - Bi Level (Product Code: 11636002) to verify the performance of the measurement procedure.
Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values to reflect the age, sex, diet and geographical location of the population.
The following value may be used as guide line.

4-20 U/L, or 66-398 nkat/L.

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 176 U/L. If the concentration is greater than linearity (176 U/L), dilute the 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= 0.99891 and a regression equation of y =-0.9766x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (U/L)	29	140.4	33.1	137.1
SD	0.17	0.286	0.36	1.26
CV(%)	0.59	0.20	1.10	0.90

Accuracy (U/L)		
Control	Expected Value	Measured Value
Control Level 1	30 ± 4.5	32.6
Control Level 2	140± 21	139.3

4. Sensitivity
Lower detection limit is 4 U/L

Bibliography

1. Kobayashi F, Ikeda T, Marumo F, Sato C: Adenosine deaminase isoenzymes in liver disease. Am. J. Gastroenterol. 88: 266-271 (1993)
2. Kallkan A., Bult V., Erel O., Avci S., and Bingol N. K. : Adenosine deaminase and guanosine deaminase activities in sera of patients with viral hepatitis. Mem Inst. Oswaldo Cruz 94(3) 383-386 (1999)
3. Burgess LJ, Maritz FJ, Le Roux I, et al. Use of adenosine deaminase as a diagnositic tool for tuberculous pleurisy. Thorax 50: 672674 (1995)

SYMBOLS USED ON THE LABELS

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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CE ISO 9001:2015
EN ISO 13485:2016