

Intended Use

Adenosine deaminase (ADA) assay kit is for determination of ADA activity in human serum or plasma samples.

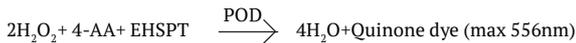
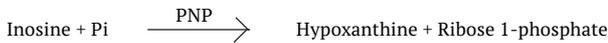
- Enzymatic Method

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 (H₂O₂) by xanthine oxidase (XOD). H₂O₂ 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.



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 Control - 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 r²= 0.99891 and a regression equation of y = -0.9766x.

3. Precision

Control	Intra Run		Inter Run	
	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

- Kobayashi F, Ikeda T, Marumo F, Sato C: Adenosine deaminase isoenzymes in liver disease. Am. J. Gastroenterol. 88: 266-271 (1993)
- Kall kan 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)
- Burgess LJ, Maritz FJ, Le Roux I, et al. Use of adenosine deaminase as a diagnostic 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