

ADA (ADENOSINE DEAMINASE)

Diagnostic reagent for determination of Adenosine Deaminase (ADA) concentration.

Liquid. Dual reagents. Store at +2/+8°C. For in Vitro Diagnostic Use (IVD). Do not freeze.

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
T1010	375 mL	TB1010	300 mL	ZA52	75 mL		
T1011	225 mL	TB1011	180 mL				

Changes made in the instructions for use are marked as grey.

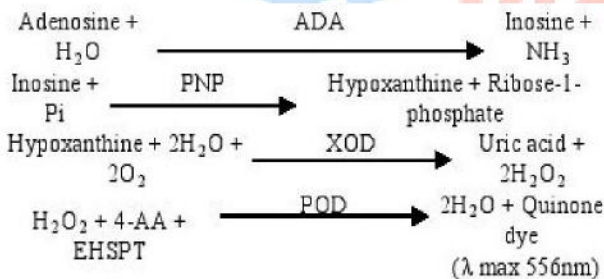
INTENDED USE

This test is applied for the quantitative determination of ADA (Adenosine Deaminase) in human serum and heparinate plasma.

TEST SUMMARY AND PROCEDURE ^{1, 2, 3, 4, 5}

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 N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline (EHSPT) 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.



TEST PARAMETERS

Method	: Colorimetric, Kinetic, Increasing Reaction
Wavelength	: Main: 546 nm Sub: 800 nm
Linearity	: 200 U/L

REAGENT COMPONENTS

Reagent 1:

Tris-HCl pH 8.0	: ≤60 mM
4-AA	: ≤3 mM
PNP	: ≤0.3 U/mL
XO	: ≤0.5 U/mL
Peroxidase	: ≤0.8 U/mL

Reagent 2:

Tris-HCl pH 4.0	: ≤50mM
Adenosine	: ≤15 mM
TOOS	: ≤3 mM

REAGENT PREPARATION

Reagents are ready for use.

REAGENT STABILITY AND STORAGE ⁶

Reagents are stable at +2/+8°C till the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at +2/+8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage data have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SAMPLE

Serum and heparinate plasma are collected by standard procedures.

ADA is stable for one week at 4°C.

Unit Conversion

U/L = 10 x U/dL

REFERENCE INTERVAL (NORMAL VALUES) ⁷

Adult: 4 - 20 U/L

It is recommended that each laboratory establish its own normal range.

Reference interval has been verified by using CLSI EP28-A3c protocol.

QUALITY CONTROL AND CALIBRATION

Commercially available control material with established values determined by this method may be used. We recommend:

ADA-Adenosine Deaminase-Control Level 1-2

Ref.No: ZA67

The assay requires the use of an ADA (Adenosine Deaminase) Calibrator Set. We recommend:

ADA (Adenosine Deaminase) Calibrator Set
Ref.No: ZA66

Calibration Stability: It strongly depends on the application characteristics of in-use auto analyser and capacity of cooling. Calibration stability is 10 days.

Each laboratory should establish its own internal Quality Control scheme and procedures for corrective and preventive action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Limit of Detection (LoD): Limit of detection of the test is 0.25 U/L.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) % ≤ 20]:⁸ 0.5 U/L

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

High Linearity: The method is linear up to 200 U/L.

For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.

Linearity may considerably vary depending on the instrument used.

Precision Studies:⁹

Intra assay CV% < 4.5%, Inter assay CV% < 6.0%

Reference interval has been verified by using CLSI EP05-A3 protocol.

Method Comparison:^{10, 11}

A comparison between Archem and a commercially available product gave the following results:

ADA Archem = x
 ADA competitor = y
 $r^2 = 0.995$

Interference:^{2, 3, 4, 12}

No significant interference was observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given.

Hemoglobin : ≤ 200 mg/dL
 Bilirubin : ≤ 20 mg/dL
 Lipemia : ≤ 750 mg/dL

The acceptable interference limit is set 10% below the highest interference concentration within ± 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

WARNINGS AND PRECAUTIONS

IVD: For in Vitro Diagnostic use only.

Do not use expired reagents.

Reagents with two different lot numbers should not be interchanged.

For professional use.

Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

EUH032 :Releases a very toxic gas if contacts with acid.

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.

P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

REFERENCES
















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SYMBOLS	
	In Vitro Diagnostic Medical Device
	Lot Number
	Reagent 1
	Reagent 2
	Global Trade Item Number
	Reference Number
	Good Laboratory Practices
	Identifies Products to Be Used Together
	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests