ADA SYSTEM PACK

(PNP-XOD METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA201	ADA System Pack	1x30 + 1x15 ml
BA201A	ADA System Pack	1x20 + 1x10 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Adenosine Deaminase in human serum.

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 y-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-AAP) 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.

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

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

$$\text{Hypoxanthine} + 2H_2O + 2O \xrightarrow{\text{XOD}} \text{Uric Acid} + 2H_2O_2$$

$$2H_2O_2 + \text{4-AAP} + \text{TOOS} \xrightarrow{\text{POD}} 2H_2O_2 + \text{Quinone dye}\ (\text{max } 556\ \text{nm})$$

REAGENT COMPOSITION

Reagent 1 : ADA R1 Reagent

Buffer	>80 mmol/L
4-AAP	<2 mmol/L
PNP	<3 KU/L
Peroxidase	>0.6 KU/L

Reagent 2: ADA R2 Reagent

Buffer	>50 mmol/L
Adenosine	<10 mmol/L
TOOS	<2 mmol/L

REAGENT PREPARATION

Reagents are liquid, ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

On board stability: Min 30 days if refrigerated (+8-+14°C) and not contaminated.

WARNING & PRECAUTIONS

Solution R1 and CAL contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention. MSDS will be provided on request.

All specimens used in this test should be considered potentially infectious.

CALIBRATION

Recommend that this assay should be calibrated using the ADA Calibrator.
Reagents and calibrator are ready to use.

STORAGE AND STABILITY

All the components of the kit are stable until the expiration date on the label when stored tightly closed at +2-+8°C, protected from light and contaminations prevented during their use.
Do not use reagents over the expiration date.

REAGENT DETERIORATION:

Presence of particles and turbidity

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance.

SPECIMEN AND STABILITY

Fresh serum and non-hemolyzed serum or plasma, Pleural, Pericardial, Ascitic fluid and CSF can be used.
Ideally, venous blood should be collected and handled anaerobically. Do not use citrate or oxalate as anticoagulant.
Stability: 7 days at +2-+4°C

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QUALITY CONTROL:

Control sera are recommended to monitor the performance of assay procedures.

If control values are found outside the defined range, check the instrument, reagents and technique for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

REFERENCE VALUES

Serum/Plasma : 0-22U/L

CSF : Normal : < 10U/L

Positive : > 10 UL

Pleural, Pericardial & Ascitic Fluids:

Normal : < 40U/L

Suspect : > 40 U/L to <60 U/L

Positive : > 60 U/L

These values are for orientation purpose

Each laboratory should establish its own reference range.

WASTE MANAGEMENT

Please refer to local legal requirements.

REAGENT PERFORMANCE

1. Linearity limit: The assay is linear up to ADA concentration of 200 U/L. If the results obtained were greater than linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

2. Detection limit: The minimum detectable concentration of ADA with an acceptable level of precision was determined as 1 U/L.

3. PRECISION

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (gm/dl)	CV (%)
Sample 1	131	1.56	1.196
Sample 2	48.48	0.615	1.27

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	19.60	0.737	3.76

4. Accuracy: Results obtained using the above reagents (y) did not show systematic differences when compared with other commercial reagents (x).

The results obtained were the following:

Correlation coefficient (r) : 0.997

Regression equation: y = 0.988x + 1.836

The results of the performance characteristics depend on the analyzer used.

5.Interferences:

Hemoglobin (up to 800 mg/dL), Intralipid (up to 1000 mg/dL) and Ascorbic acid (up to 50 mg/dL) do not interfere.

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Test Name	ADA
Full Name	ADA
Pri Wave	546 nm
Sec Wave	-
Assay/point	Fixed Time
Start	21
End	34
Decimal	2
Unit	U/L
Linearity Range Low	1
Linearity Range High	200
Sample Volume	5 µl
Reagent 1 (R1) Volume	180 µl
Reagent 2 (R2) Volume	90 µl
Subsatrate Depleted	-
Linearity	200 U/L
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Reagent
Concentration Blank	0.00
Concentration Std	Refer calibrator value sheet

NOTE

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

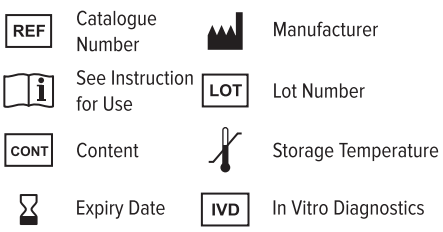
REFERENCES

1.KobayashiF, Ikeda T, Marumof, Sato C: Adenosine deaminase isoenzymes in liver disease. Am. J. Gastroenterol. 88: 266-271 (1993).

2.KallkanA., BultV., Erelo.,Avci S, And Bingol N.K.: Adenosine deaminase and guanosine deaminase activities in sera of patients with viral hepatitis.
Menm Inst. Oswaldo Cruz 94(3) 383-386 (1999)

3.Burgess L J, Maritz FJ, LeRouxl, etal. Use of adenosine deaminase as a diagnostic tool for adenosine deaminase as diagnostic tool for tuberculous. Pleurisy. Thorax 50: 672-674 (1995)

Symbols Used On Labels



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