HƯỚNG DẪN SỬ DỤNG TIẾNG ANH

Tài liệu được xác nhận bằng chữ ký số

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Người đại diện hợp pháp của cơ sở

M.S.D.N: 0106162113 - C.T.T.N.H.H
CÔNG TY TRÁCH NHIỆM HỮU HẠN THIẾT BỊ NHẬT ANH
THÀNH PHỐ HÀ NỘI

GIÁM ĐỐC

Uông Tuấn Phương

ADENOSINE DEAMINASE (ADA)

COD 12754 4 x 10 mL

Only for *in vitro* use in the clinical laboratory

Automated Systems

BioSystems

ADENOSINE DEAMINASE (ADA)

Adenosine-Glutamate dehydrogenase

INTENDED USE

Reagent for the measurement of adenosine deaminase concentration in human serum or pleural liquid for the assessment of its variations in the general population.

This reagent is for use in the BioSystems A25 and A15 analyzers.

CLINICAL BENEFIT

The adenosine deaminase catalytic concentration in pleural fluid is elevated in patients with tuberculosis, therefore its measurement is useful for differentiating tuberculous and nontuberculous pleural effusions[4]. Elevated serum adenosine deaminase concentration has been described in patients with liver disease[6].

Based on clinical guidelines and textbooks, and when used in conjunction with other diagnostic technologies and options, this medical information is useful for the assessment of ADA variations. Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

PRINCIPLE OF THE METHOD

Adenosine deaminase (ADA) catalyzes the deamination of adenosine to inosine and ammonium. The catalytic concentration is determined from the rate of decrease of NADH, measured at 340 nm, by means of the glutamate dehydrogenase (GLDH) coupled reaction[1-3].

$$\text{Adenosine} + H_2O \xrightarrow{\text{ADA}} \text{Inosine} + NH_4^+$$

$$\text{2-Ketoglutarate} + NH_4^+ + H^+ + \text{NADH} \xrightarrow{\text{GLDH}} \text{Glutamate} + H_2O + \text{NAD}^+$$

CONTENTS AND COMPOSITION

A. Reagent. 4 x 8 mL. Tris 125 mmol/L, 2-Ketoglutarate 1.1 mmol/L, adenosine 6.5 mmol/L, glutamate dehydrogenase > 100 U/L, sodium azide 0.95 g/L, pH 6.8.

B. Reagent. 1 x 10 mL. NADH 1.5 mmol/L, sodium azide 9.5 g/L.

WARNING: H302: Harmful if swallowed. EUH031: Contact with acids liberates toxic gas. P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. P330: Rinse mouth.

STORAGE

Store at 2-8ºC.

Reagents are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Indications of deterioration:

– Reagents: Presence of particulate material, turbidity, absorbance of the blank lower the limit indicated in "Assay parameters".

WARNING AND PRECAUTIONS

Exercise the normal precautions required for handling all laboratory reagents. Safety data sheet available for professional user on request. Disposal of all waste material should be in accordance with local guidelines. Any serious incident that might occur in relation to the device shall be reported to BioSystems S.A.

AUXILIARY REAGENTS

S. ADA Standard 1 x 1 mL (BioSystems Cod. 18052). Bovine ADA, Tris 50 mmol/L. ADA concentration is given on the vial label. ADA value is traceable to the reference material BCR-647 (IRMM).

Reconstitute with 1.0 mL of distilled water.Stable for 7 days at 2-8ºC or for 2 months at –18ºC when frozen in aliquots.

REAGENT PREPARATION

Working Reagent: Add 2 mL of Reagent B into one bottle of Reagent A. Mix gently. Other volumes can be prepared in the proportion: 4 mL Reagent A + 1 mL Reagent B. Stable for 30 days at 2-8ºC.

Reagent open and kept in the refrigerated compartment of the analyzer is stable 12 days.

ADDITIONAL EQUIPMENT

– Analyzer, spectrophotometer or photometer with cell holder thermostatable at 37ºC and able to read at 340 nm.

SAMPLES

Pleural fluid or blood serum collected by standard procedures.

Adenosine deaminase in samples is stable for 7 days at 2-8ºC.

CALIBRATION

It is recommended to use an ADA Standard.

A calibration is recommended at least every 12 days, after reagent lot change or as required by quality control procedures.

PROCEDURE

Automated procedure (Note 1)

		A25	A15
GENERAL	Test name	ADA	ADA
	Analysis mode	kinetic mono	kinetic mono
	Sample type	LIQ/SER	LIQ/SER
	Units	U/L	U/L
	Reaction type	decreasing	decreasing
	Decimals	1	1
	No. of replicates	1	1
	Test name in patient report	-	-
PROCEDURE	Reading	monoch.	monoch.
Volumes	Sample	15	15
	Reagent 1	300	300
	Reagent 2	-	-
	Washing	1.2	1.2
	Predilution factor	-	-
	Postdilution reduced factor	2	2
Filters	Main	340	340
	Reference	-	-
Times	Reading 1	270 s	264 s
	Reading 2	420 s	408 s
	Reagent 2	-	-
CALIBRATION	Calibration type	specific	specific
	Calibrator replicates	-	-
	Blank replicates	3	3
	Calibration curve	-	-
OPTIONS	Blank absorbance limit	0.800	0.800
	Kinetic blank limit	-	-
	Linearity limit	150	150

Manual procedure

1. Bring the Working Reagent and the instrument to reaction temperature.
2. Pipette into a cuvette:

Working Reagent	1.0 mL
Sample / Standard (S)	50 µL

3. Mix and insert the cuvette into the photometer. Start the stopwatch.
4. After 4 minutes, record initial absorbance and at 1 minute intervals thereafter for 3 minutes.
5. Calculate the difference between consecutive absorbances, and the average absorbance difference per minute (ΔA/min).
6. Calculate the adenosine deaminase concentration in the sample using the following formulas:

$$\frac{\Delta A/\text{min}_{\text{Sample}}}{\Delta A/\text{min}_{\text{Standard}}} \times C_{\text{Standard}} = U/L$$

REFERENCE VALUES

Pleural fluid[3]: Up to 33 U/L = 0.55 µkat/L.

Serum[4]: Up to 18 U/L = 0.30 µkat/L.

These ranges are given for orientation only; each laboratory should establish its own reference ranges.

QUALITY CONTROL

It is recommended to use the ADA Controls levels I and II (cod. 18048) to verify the performance of the measurement procedure. Reconstitute the contents of the vials with 1.0 mL of distilled water. Swirl gently, avoiding the formation of foam, to ensure complete dissolution of contents. Treat the Controls in the analytical procedure as patient samples.

Stable for 7 days at 2-8ºC or for 2 months at –18ºC when frozen in aliquots.

ADA concentrations are given on the vial labels. ADA value is traceable to the reference material BCR-647 (IRMM). Traceability can be assured only if the BioSystems reagents and recommended measurement procedures are used.

The intervals of suggested acceptable values have been calculated from previous experience in interlaboratory variability and are given for orientation only; each laboratory should establish its own precision parameters.

PERFORMANCE CHARACTERISTICS

– Detection limit: 1.65 U/L = 0.028 µkat/L.

– Linearity limit: 150 U/L = 2.50 µkat/L. For higher values dilute sample 1/10 with distilled water and repeat measurement.

– Repeatibility (within run):

Mean Concentration	CV	n
26.7 U/L = 0.45 µkat/L	1.6 %	20
63.8 U/L = 1.06 µkat/L	1.2 %	20

– Reproducibility (run to run):

Mean Concentration	CV	n
26.7 U/L = 0.45 µkat/L	4.1 %	25
63.8 U/L = 1.06 µkat/L	4.4 %	25

– Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

– Interferences: Hemolysis or delayed serum separation may cause higher results due to elevated adenosine deaminase concentration in erythrocytes. Lipemia (triglycerides < 500 mg/dL) and bilirubin (< 20 mg/dL) do not interfere. Other drugs and substances may interfere[5].

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

DIAGNOSTIC CHARACTERISTICS

Adenosine deaminase is an ubicuous enzyme. The highest concentrations are found in the T lymphocytes, especially when stimulated. The adenosine deaminase concentration in pleural fluid is elevated in patients with tuberculosis, therefore its measurement is useful for differentiating tuberculous and nontuberculous pleural effusions, with a diagnostic sensitivity of 90% and a diagnostic specificity of 85%[4]. Elevated serum adenosine deaminase concentration has been described in patients with liver disease[6].

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

NOTES

1. These reagents may be used in several automatic analysers. Instructions for many of them are available on request.

BIBLIOGRAPHY

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