ADENOSINE DEAMINASE (ADA) FL

AD F080 CH 4 x 20 ml

INTENDED USE

Reagent for quantitative in vitro determination of adenosine deaminase in biological fluids (serum) and intended as aid to diagnosis of tuberculous pleurisy and ADA severe immunodeficiency disease.
The IVD devie can be used both in manual or on automatic analyzers. The product is intended for professional use in clinical laboratories.

TEST PRINCIPLE

ADA enzyme converts adenosine to inosine, which starts a sequence of enzymatic reactions mediated by PNP (Purine Nucleoside Phosphorylase) and XOD (Xanthine Oxidase), leading to hydrogen peroxide (H_2O_2). This compound reacts with TOOS (N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline) in the presence of peroxidase, to form a chinone compound. Absorbance increase per unit time, measured at 546, is proportional to the concentration of ADA in the sample[1-3].

MATERIALS PROVIDED AND COMPOSITION

ADA R1 **F080: 4 x 16 ml (liquid) blue cap**

Composition: Phosphate buffer, PNP > 1 KU/l, XOD > 1 KU/l, POD > 1 KU/l, 4-AAP (4-Aminoantipyrine) > 1 mM, stabilizer and preservative.

ADA R2 **F080: 1 x 16 ml (liquid) red cap**

Composition: Phosphate buffer, adenosine > 5 mM, TOOS > 1 mM, stabilizers and preservative.

NOT SUPPLIED REQUIRED MATERIALS

Appropriate laboratory instrumentation. Spectrophotometer UV/VIS fitted with thermostatic cuvette holder. Automatic micropipettes. Glass or high quality polystyrene cuvettes. Saline solution.

REAGENT PREPARATION

Use ready-to-use reagents.

STORAGE AND STABILITY

Store all kit components at 2-8°C, away from direct light sources.
Stability of reagents: up to expiration date claimed on label storing at 2-8°C;
Stability after first opening of reagent bottle: preferably within 60 days storing at 2-8°C.

PRECAUTIONS

ADA R1: It is not classified as hazardous.

ADA R2: It is not classified as hazardous.

Follow required safety procedures when handling all laboratory reagents.

SPECIMEN

Serum.
Samples are stable for one week when stored at 2-8°C[4].

PROCEDURE

Wavelenght:	546 nm	
Lightpath:	1 cm	
Temperature:	37°C	
dispense:	standard	sample
reagent R1	1 ml	1 ml
standard	25 µl	-
sample	-	25 µl
Mix, incubate at 37°C for 5 minutes.		
dispense:	standard	sample
reagent R2	250 µl	250 µl
Mix, after 3 minutes read the absorbance against water, by incubating at 37°C. Perform other two readings at 60 seconds intervals. Calculate the ΔA/min.		

RESULTS CALCULATION

Serum:

$$\text{ADA U/l} = \frac{\Delta A/\text{min}_{(\text{sample})}}{\Delta A/\text{min}_{(\text{standard})}} \times \text{Standard value}$$

REFERENCE INTERVALS

Adults[5]: ≤ 14.0 U/l

Each laboratory should establish appropriate reference intervals related to its population.

QUALITY CONTROL AND CALIBRATION

Calibration is required with each change in reagent lot number. It is suggested to verify calibration with at least one level of an internal quality control. If control results fall outside acceptable ranges, recalibration may be necessary. For this purpose the following human based control sera are available:
QUANTINORM CHEMA - MULTINORM CHEMA
with normal or close to normal control values
QUANTIPATH CHEMA - MULTIPATH CHEMA
with pathological control values.
If required, a calibrator is available:
ADA CALIBRATOR

Please contact Customer Care for further information.

TEST PERFORMANCE

Sensitivity / Limit of Detection (LOD)[6]
The method is able to detect up to 0.50 U/l.

Analytical specificity:
Interferences[7]
interference does not occurr in the presence of:

hemoglobin	≤ 500 mg/dl
bilirubin	≤ 36 mg/dl
Intralipid	≤ 1600 mg/dl
ascorbic acid	≤ 5 mg/dl

Veridicity[8]
BIAS% < 10.54

Accuracy:
Trueness[8]
Total observed error% < 16.7 (allowable total error)

Precision[9]
Repeatability

intra-assay (n=10)	mean (U/l)	SD (U/l)	CV%
sample 1	13.1	0.22	1.65
sample 2	34.9	0.32	0.92

Reproducibility

inter-assay (n=20)	mean (U/l)	SD (U/l)	CV%
sample 1	13.2	0.41	3.08
sample 2	34.9	0.53	1.53

Measurement range[10]
2.01 - 200.0 mg/dl

Linearity[10]
the method is linear up to 200 U/l.
If the limit value is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Methods comparison[9]
a comparison between Chema and a commercially available product gave the following results:
Serum:
Adenosine Deaminase (ADA) FL Chema = x
Adenosine Deaminase competitor = y
n = 112

Linear regression
y = 1.006x - 1.045 U/l r = 0.9992

Passing-Bablok[11-12]
y = 0.947x - 0.284 U/l

WASTE DISPOSAL

P501: Dispose of product according to national/international regulations.

NOTICE TO THE USER

Any serious accident involving the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is located.

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SYMBOLS

Chema Diagnostica uses symbols listed in the ISO 15223-1 (see www.chema.com - Section “Products" for definition of symbols used).

Addition, deletions or changes are indicated with a vertical line on the side of the affected paragraph.

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