**ADA Adenosine Deaminase**

**For discrete analyzers**

**Method: Enzymatic**

| Product code: | 1418-0000 |
| Packaging: | 4 x 9 ml (R1) + 4 x 4.5 ml (R2) |
| Store at: | 2 – 8°C |
| For in vitro use |

**INTENDED USE**

MEDICON ADA is a set of reagents for the enzymatic determination of ADA in human serum or plasma fluid, with BECKMAN COULTER AU400/400i/680/680-i/4700/5400 and other types of automated analysers. For in vitro diagnostic use only.

**CLINICAL SIGNIFICANCE**

Adenosine Deaminase (ADA) is an enzyme that catalyzes the conversion of adenosine into inosine. The concentration of enzyme in serum is increased in several conditions, and the measurement of enzyme levels can be used as a diagnostic tool in several cases. ADA activity is increased in cases of hepatitis, cirrhosis, hemolytic anemia, rheumatoid and thyroid fever, Mediterranean anemia, myelogenous leukemia, tuberculosis, and autoimmune diseases. Especially in children, enzyme activity is significantly increased in cases of tuberculosis, when compared to any other respiratory system disease. When combined with γ-GT, it can contribute greatly to the diagnosis of hepatic conditions. It should be noted that enzyme levels are significantly low in conditions of the biliary tract, while it is systematically increased in chronic liver conditions.

ADA enzymatic activity is due to two isoenzymes, ADA1 and ADA2. The ADA1 isoenzyme is found in monomer and dimer in all cell types, exhibiting the greatest activity in lymph cells and monocytes. The ADA2, on the contrary, only appears in monocytes. In tuberculosis pleural effusions, ADA is mainly increased because of the ADA2 isoenzyme, suggesting increased production of the monocyte enzyme. In effusions caused by other reasons, increased ADA activity comes from lymphocytes, or neutrophils, and mainly because of the ADA1 isoenzyme.

**METHOD PRINCIPLE**

The kinetic determination of adenosine deaminase is based on the following reaction:

- Adenosine → Inosine + Ammonia
- Inosine + Phosphate → Hypoxanthine + Phosphoric ribose
- Hypoxanthine + O2 + H2O → Xanthine + H2O
- Xanthine + O2 + H2O → Xanthine Oxidase
- Xanthine Oxidase
- H2O2 + TOOS + 4-Aminopyrine → Peroxidase → Quinonimine + 2 H2O + H2

**METHOD LIMITATIONS**

Refer to the book “Effects of Preanalytical Variables on Clinical Laboratory Tests” for possible interference of Xanthine Oxidase, Enzyme activity is significant in the presence of monocytes. The X2 activity is found only in monocytes. Enzyme activity is significant in the presence of monocytes. Enzyme inhibition may occur in other cell types, with the greatest activity found in lymphocytes and monocytes. The ADA1 inhibition may occur in other cell types, with the greatest activity found in lymphocytes and monocytes. The ADA2 inhibition may occur in other cell types, with the greatest activity found in lymphocytes and monocytes. The ADA2 inhibition may occur in other cell types, with the greatest activity found in lymphocytes and monocytes.

**REAGENT COMPOSITION**

**Reagent 1 (R1):**
- Buffer (pH 8.0): 50 mmol/L
- 4-AAA: 1 mmol/L
- PNp: > 500 U/L
- XO: > 1000 U/L
- Peroxidase: > 1000 U/L
- Non-reactant components and preservatives.

**Reagent 2 (R2):**
- Buffer (pH 3.5): 50 mmol/L
- Adenosine: 10 mmol/L
- TOOS: 1.5 mmol/L
- Non-reactant components and preservatives.

**WARNINGS - PRECAUTIONS**

- Samples should be considered as potentially infectious. Handle according to usual precautions and good laboratory practices.
- This reagent is designed for in vitro diagnostic use only. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory practices and techniques. Avoid inhalation and contact with eyes and skin.
- The reagent contains sodium azide (NaN3). Avoid swallowing and contact of the reagent with skin and mucous membrane.
- Dispose all waste according to national laws.
- MSDS is available by MEDICON upon request.

**PREPARATION**

Reagents R1 and R2 are liquid, ready to use, and placed in the corresponding spots of the analyzer. Vials bear a barcode for recognition by BECKMAN COULTER AU analyzers.

**REAGENT DESTRUCTION**

The reagent should not be used:
- When it is cloudy.
- When it does not exhibit the specified linearity or recovery of control values lies outside the acceptable range after reacalibration.
- After prolonged exposure to high temperature.

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**SHELF LIFE**

Unopened, the reagent is stable up to the stated expiry date when stored at 2 – 8°C. Once opened, the reagent can be stored refrigerated for the instrument on 1 month.

**SAMPLE**

Serum, plasma fluid.

**CALIBRATION**

MEDICON provides the MEDICON ADA Calibrator (1473-0900) for calibration. Calibrate the assay every 15 days. Recalibration should also be repeated when a major maintenance is performed on the analyzer or a critical part is replaced or a significant shift in control values occurs.

**QUALITY CONTROL**

MEDICON provides the MEDICON Clinical Chemistry Control Level 1 & 2 (1578-0901 & 1578-0922 respectively) for quality control.

Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unstable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**

- ADA Calibrator
- Quality control material
- Automated biochemistry analyzer
- Common laboratory equipment

**REFERENCE INTERVENS**

Serum: 4 – 20 U/L
Pneumonic fluid: 0 – 24 U/L
Each laboratory should determine its own expected values as dictated by good laboratory practice.

**WASTE DISPOSAL**

This product contains sodium azide (NaN3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

**Linearity:**

- **Sensitivity:**

  The lowest detectable level of Aldolase is estimated at 0.6 U/L.
  The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.

  **Precision:** Precision is estimated on two concentration levels of analyte according to NCCLS protocol EP-20 (20 consecutive days, 2 runs per day, 2 repeats per run).

<table>
<thead>
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<th>Within-Run</th>
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<tr>
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  **Interferences:**
  - Bilirubin: insignificant up to 20 mg/dL
  - Triglycerides: insignificant up to 1000 mg/dL
  - Hemoglobin: insignificant up to 500 mg/dL

  **Method Comparison:**

  A comparison was performed between this reagent and another commercially available product for serum and plasma. The results were as follows, on a BECKMAN COULTER AU series analyzer:

  Y = 0.93X + 2.49
  R=0.993
  N=47
  Sample range = 6 – 47 U/L

**BIBLIOGRAPHY**


**SYMBOLS**

- Temperature Limits: (2°C-30°C)
- Batch Code
- Catalogue Number
- Date of Expiry
- Production Date
- Biohazard
- Manufacturer
- Content enough for...
- For in vitro use

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