### INTENDED USE

MEDICON Aldolase is a set of reagents for the enzymatic determination of Aldolase in human serum and plasma, with BECKMAN COULTER AU400/480/600/6000/VD/BS/400/600/2700/5400 automated analyzers or any other type of biochemical analyzers. For in vitro diagnostic use only.

### CLINICAL SIGNIFICANCE

Aldolase is an enzyme that catalyses the aldol reaction: the substrate, fructose 1,6-bisphosphate (F-1,6-BP) is broken down by aldolase into glyceraldehyde 3-phosphate and dihydroxyacetone phosphate (DHAP). This reaction is a part of glycolysis. Increased levels of the enzyme are observed during acute hepatitis (viral or toxic) and other liver diseases, muscular dystrophy, myocardial infarction, gangrene, carcinomas (lung, breast, genitalurinary system), melanoma, CNS tumors, granulocytic leukemia, megablastic anemia, delirium tremens, 60 – 80% of patients with acute psychosis and schizophrenia, tetanus, hematopoietic malignancies, hemolytic anemias, tissue infection, and acute pancreatitis. The enzyme is detected at reduced levels at hereditary fructose intolerance.

### METHOD PRINCIPLE

The kinetic determination of Aldolase is based on the following reactions:

\[
\text{Fructose-1,6-5P} \rightarrow \text{GA-3P} + \text{DHAP} \\
\text{GA-3P} + \text{TPH} \rightarrow \text{DHAP} \\
\text{DHAP} \rightarrow \text{P-Dihydroxyacetone} \\
\text{GA-3P} + \text{3P-Glyceraldehyde} \\
\text{The rate of the observed decrease of absorbance at 340 nm due to NADH consumption is proportional to the aldolase activity.} \\
\]

### METHOD LIMITATIONS

The 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.

### REAGENT COMPOSITION

For in vitro diagnostic use only.

- Hepes buffer (pH 7.4): 5 mM
- G6PDH: < 10.5 KU/L
- TIM: < 15 KU/L
- LDH: < 210 KU/L
- Hepes buffer (pH 7.4): 50 mM
- Fructose-1,6-bisphosphat: 3 mM
- Non reactive particles and preservatives.

### WARNINGS – PRECAUTIONS

- Samples should be considered as potentially infectious. Handle according to universal precautions and good laboratory practices.
- The reagent contains sodium azide (NaN₃ < 0.1%). Avoid swallowing and contact of the reagent with skin and mucous membranes.
- Dispose of waste according to national laws.
- MSDS is available by MEDICON upon request.

### PREPARATION

Reconstitute the freeze dried lyophil reagent with all of R1. Shake gently until it is completely dissolved. Avoid foaming. The reconstituted reagent is ready to use when placed in the corresponding position of the analyzer.

### 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 on the instrument for 1 week.

### REAGENT DETERIORATION

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 recalibration.
- After prolonged exposure to high temperature.

### SAMPLE

Use serum as specimen. Separate red cells immediately. Sample is stable for 8 hours at room temperature, for 5 days at 2 – 8°C, and for 15 days at –20°C.

### CALIBRATION

Calibration is not required. The protocol of the analyzer contains the appropriate Calibration Factor. Blank measurement is suggested when the lot of the reagent is changed.

### QUALITY CONTROL

MEDICON provides the following products for quality control: MEDICON Aldolase Control (1578-0512). Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls should be tested each date patient samples are tested and each time calibration is performed. Control values and limits should fall within acceptable intervals adjusted to the requirements of each laboratory. Target values for aldolase should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, unacceptable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

### MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

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

### REFERENCE INTERVALS

<table>
<thead>
<tr>
<th>Serum, plasma: Children (10 – 24 months)</th>
<th>Adults (&gt; 7 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children (25 months – 16 years)</td>
<td>Adults (&gt; 7 years)</td>
</tr>
<tr>
<td>3.4 – 11.8 U/L</td>
<td>&lt; 7.4 U/L</td>
</tr>
</tbody>
</table>

Each laboratory should determine its own expected values as dictated by good laboratory practice.

### WASTE DISPOSAL

NaNO₃ may form explosive compounds with copper or lead. To avoid possible build up of azide compounds flush waste pipes with water after the disposal of undiluted reagent.

### SPECIFIC PERFORMANCE CHARACTERISTICS

#### Linearity

- The assay is linear in measuring range 0.017 – 75 U/L. When values exceed this range samples should be diluted accordingly.

#### Sensitivity

- The lowest detectable level of Aldolase is estimated at 0.17 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 05

#### Interference

- Lipemic: Insignificant up to 600 mg/dL
- Bilirubin: Insignificant up to 20 mg/dL
- Non-Conj. Bilirubin: Insignificant up to 20 mg/dL
- Ascorbic acid: Insignificant up to 3 mg/dL
- Pyruvate: Insignificant up to 12 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:

<table>
<thead>
<tr>
<th>Serum</th>
<th>Plasma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y = 0.9069X + 0.3557</td>
<td>R = 0.9903</td>
</tr>
<tr>
<td>Y = 0.9576X – 0.111</td>
<td>R = 0.9742</td>
</tr>
</tbody>
</table>

### BIBLIOGRAPHY


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