BioMajesty

Ethanol FS*

Diagnostic reagent for quantitative in vitro determination of ethanol in serum or plasma on BioMajesty JCA-BM6010/C

Order Information
Cat. No. 1 0881 99 10 964
R1: 6 x 90 tests
R2: 6 x 90 tests

Method
Enzymatic UV test with alcohol dehydrogenase (ADH).
The values of Ethanol Standard FS have been determined using a NIST SRM 2893 qualified Headspace gas chromatography/flame ionization detector (GC/FID).

Principle
Ethanol + NAD⁺ → Acetaldehyde + NADH + H⁺

In the presence of NAD, ethanol is converted by alcohol dehydrogenase. The measured absorbance of the produced NADH is proportional to the ethanol concentration in the sample.

Reagents
Components and Concentrations
R1: Buffer  pH 9.0  300 mmol/L
R2: Buffer  pH 6.0  40 mmol/L
NAD  ≥ 10 mmol/L
Alcohol dehydrogenase (ADH)  ≥ 200 kU/L

Storage Instructions and Reagent Stability
The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8°C, protected from light and contamination is avoided. Do not freeze the reagents!

The standards are stable up to the end of the indicated month of expiry, if stored at 20°C. 

Warnings and Precautions

2. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes!

3. Reagent 2 contains animal material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.

4. In very rare cases, samples of patients with gangrenosis might give falsified results.

5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient’s medical history, clinical examinations and other findings.

6. For professional use only!

Prepare the reagents for use until the end of the indicated month of expiry. If stored at 20°C, protected from light and contamination is avoided. Do not freeze the reagents!

The standards are stable up to the end of the indicated month of expiry, if stored at 20°C.

Due to alcohol evaporation, the sample container has to be filled as complete as possible, tightly closed, and should not stand open for longer than 5 min. In tightly closed sample tubes the stability in serum and plasma is 2 weeks at 20 – 25°C, 6 months at 4 – 8°C and 6 months at –20°C. [1]

Prepare the reagents for use until the end of the indicated month of expiry. If stored at 20°C, protected from light and contamination is avoided. Do not freeze the reagents!

Do not use alcohol or volatile disinfectants during ethanol measurement. Only freeze once! Discard contaminated specimens!

Calibrators and Controls
For calibration, Diasys Ethanol Standard FS is recommended.

For internal quality control Diasys TruLab Ethanol should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 2.5 g/L (54.3 mmol/L) ethanol
(in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use reur function)

Limit of detection** 0.1 g/L (2.17 mmol/L) ethanol

On-board stability 7 days

Calibration stability 1 day

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 60 mg/dL
Hemoglobin up to 1000 mg/dL
Lipemia (triglycerides) up to 2000 mg/dL
Creatinine up to 250 mg/dL
Glucose up to 2000 mg/dL
Urea up to 2000 mg/dL
LDH up to 2000 U/L

For further information on interfering substances refer to Young DS [4].

Precision

<table>
<thead>
<tr>
<th>Method comparison (n=91)</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (g/L)</td>
<td>0.168</td>
<td>0.782</td>
<td>1.68</td>
</tr>
<tr>
<td>Mean (mmol/L)</td>
<td>3.55</td>
<td>16.8</td>
<td>35.7</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>4.97</td>
<td>1.83</td>
<td>1.42</td>
</tr>
<tr>
<td>Mean (mmol/L)</td>
<td>3.63</td>
<td>17.0</td>
<td>36.4</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>4.68</td>
<td>2.60</td>
<td>11.7</td>
</tr>
</tbody>
</table>

Sample 1: Ethanol [g/L] x 21.7 = Ethanol [mmol/L]
Sample 2: Ethanol [g/L] x 0.8 = Ethanol ‰

Conversion factor
Ethanol [g/L] x 21.7 = Ethanol [mmol/L]
Ethanol [g/L] (serum/plasma) x 0.8 = Ethanol ‰ (whole blood)

Reference Range [2]
Ethanol is present in serum and blood only after ingestion.

<table>
<thead>
<tr>
<th>Ethanol [g/L]</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 – 1.2 g/L</td>
<td>Slowly reflexes, diminution of attention, judgment and control</td>
</tr>
<tr>
<td>1.2 – 2.5 g/L</td>
<td>Reduced visual acuity and increased reaction time</td>
</tr>
<tr>
<td>2.5 – 3.5 g/L</td>
<td>Muscular incoordination, decreased response to stimuli</td>
</tr>
<tr>
<td>&gt; 3.5 g/L</td>
<td>Impairment of circulation and respiration, possible death</td>
</tr>
</tbody>
</table>

Literature

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9   65558 Holzheim   Germany

* fluid stable
Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

### Analytical Conditions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1 volume</td>
<td>160</td>
</tr>
<tr>
<td>R2e volume</td>
<td>0</td>
</tr>
<tr>
<td>R2 volume</td>
<td>40</td>
</tr>
<tr>
<td>R1 diluent vol</td>
<td>0</td>
</tr>
<tr>
<td>R2e diluent vol</td>
<td>0</td>
</tr>
<tr>
<td>R2 diluent vol</td>
<td>0</td>
</tr>
<tr>
<td>Sample vol (S)</td>
<td>1</td>
</tr>
<tr>
<td>Sample vol (U)</td>
<td>1</td>
</tr>
<tr>
<td>Reagent 1 mix</td>
<td>weak</td>
</tr>
<tr>
<td>Reagent 2e mix</td>
<td>weak</td>
</tr>
<tr>
<td>Reagent 2 mix</td>
<td>weak</td>
</tr>
<tr>
<td>Reaction time</td>
<td>10</td>
</tr>
</tbody>
</table>

### Endpoint Method

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re.absorb (u)</td>
<td>9.999</td>
</tr>
<tr>
<td>Re.absorb (d)</td>
<td>-9.999</td>
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</tbody>
</table>

### Calculation Method Setting

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>M-DET.P.I</td>
<td>0</td>
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<tr>
<td>M-DET.P.m</td>
<td>41</td>
</tr>
<tr>
<td>M-DET.P.n</td>
<td>42</td>
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<tr>
<td>S-DET.P.p</td>
<td>17</td>
</tr>
<tr>
<td>S-DET.P.r</td>
<td>18</td>
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<tr>
<td>Limit value</td>
<td>0.003</td>
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<tr>
<td>Variance</td>
<td>10</td>
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<tr>
<td>Reac.type</td>
<td>Inc</td>
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</table>

### Reaction Rate Method

<table>
<thead>
<tr>
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<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Cycle</td>
<td>2</td>
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<tr>
<td>Factor</td>
<td>2</td>
</tr>
<tr>
<td>E2 corre</td>
<td>Not do</td>
</tr>
<tr>
<td>Sample (u)</td>
<td>9.999</td>
</tr>
<tr>
<td>Sample (d)</td>
<td>-9.999</td>
</tr>
</tbody>
</table>

### Prozone

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prozone form</td>
<td>No</td>
</tr>
<tr>
<td>Prozone limit</td>
<td>9.999</td>
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<tr>
<td>Prozone judge</td>
<td>Upper limit</td>
</tr>
<tr>
<td>Judge limit</td>
<td>9.999</td>
</tr>
<tr>
<td>M-DET.P.m</td>
<td>0</td>
</tr>
<tr>
<td>M-DET.P.n</td>
<td>0</td>
</tr>
<tr>
<td>S-DET.P.p</td>
<td>0</td>
</tr>
<tr>
<td>S-DET.P.r</td>
<td>0</td>
</tr>
</tbody>
</table>

### Analysis Test Condition Setting (M)

#### Sample Type

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Serum</th>
<th>Urine</th>
</tr>
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<tbody>
<tr>
<td>Reac. sample vol.</td>
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<td>1</td>
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<tr>
<td>Undil. sample vol.</td>
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<td>0</td>
</tr>
<tr>
<td>Diluent volume</td>
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<td>0</td>
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<tr>
<td>Diluent position</td>
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### MULTI-STD Setting

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<td>Points</td>
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</thead>
<tbody>
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<td>BLK</td>
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<td>No dil</td>
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<td>0</td>
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<tr>
<td>1</td>
<td>0.500</td>
<td>1</td>
<td>No dil</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>9.999</td>
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<tr>
<td>2</td>
<td>1.000</td>
<td>1</td>
<td>No dil</td>
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<td>0</td>
<td>9.999</td>
</tr>
<tr>
<td>3</td>
<td>2.000</td>
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<td>No dil</td>
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<tr>
<td>4</td>
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<td>No dil</td>
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<td>5</td>
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<td>No dil</td>
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<td>0</td>
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</tbody>
</table>

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