β-Hydroxybutyrate FS*

Diagnostic reagent for quantitative in vitro determination of β-hydroxybutyrate in serum or plasma on DiaSys respons® 910

Order Information
Cat. No. 1 3701 99 10 921
4 twin containers for 120 tests each

Method
Enzymatic endpoint determination

Principle
β-Hydroxybutyrate + NAD → β-Hydroxybutyrate-dehydrogenase → Acetoacetate + NADH + H⁺

The absorbance of the blue dye at 546 nm is proportional to the β-hydroxybutyrate concentration in the sample.

Reagents
Components and Concentrations
R1: Buffer pH 8.4 115 mmol/L
β-Hydroxybutyrate dehydrogenase ≥ 3 KU/L
Diaphorase 2.1 KU/L
R2: NAD 21 mmol/L
Oxalac acid 66 mmol/L
Nitroblue-tetrazolium (NBT) 1.7 mmol/L
β-Hydroxybutyrate Standard FS: 1 mmol/L

Storage Instructions and Reagent Stability
The reagents and the standards 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. DiaSys respons containers provide protection from light. Do not freeze the reagents.

Warnings and Precautions
1. The reagents contain sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Reagent 1 contains biological material. Handle the product as potentially infectious according to universal precautions and good laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [5].
4. 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.
5. For professional use only!

Waste Management
Please refer to local legal requirements.

Reagent Preparation
The reagents and the standard are ready to use. The reagent bottles are placed directly into the reagent trays.

Note: After a long cool storage, a slightly violet sediment in reagent R2 can accrue which does not influence the measurement, however, it should be re-dissolved into solution by shaking the bottle gently before further measurement.

Specimen
Serum and plasma
Stability in serum/plasma [4]:
- 1 month at 20 – 25°C
- 1 month at 2 – 8°C
- 1 month at -20°C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
For calibration DiaSys β-Hydroxybutyrate standard FS is recommended. β-Hydroxybutyrate Standard FS values have been made traceable to the weighing of purest β-hydroxybutyrate. For internal quality control DiaSys TruLab N and P controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Kit size</th>
</tr>
</thead>
<tbody>
<tr>
<td>β-Hydroxybutyrate Standard FS</td>
<td>3 x 3 mL</td>
</tr>
<tr>
<td>TruLab N</td>
<td>5 9000 99 10 062 20 x 5 mL</td>
</tr>
<tr>
<td>TruLab P</td>
<td>5 9050 99 10 062 20 x 5 mL</td>
</tr>
</tbody>
</table>

Performance Characteristics
Measuring range up to 6.9 mmol/L β-hydroxybutyrate (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function).

Limit of detection**: 0.04 mmol/L β-hydroxybutyrate
On-board stability: 6 weeks
Calibration stability: 1 weeks

Interfering substance Interferences % HΒUT [mmol/L]

| Ascorbate | 0.04 | 0.64 |
| Segemoglobin | 0.12 | 0.36 |
| Bilirubin, conjugated | 0.45 | 1.26 |
| Bilirubin, unconjugated | 0.65 | 1.43 |
| Lipemia (triglycerides) | >6000 | 0.91 |

For further information on interfering substances refer to Young DS [1].

Precision
Within run (n=20)
- Sample 1: 0.06 | 0.69 | 1.14
- Sample 2: 0.00 | 0.67 | 1.61
- Sample 3: 0.03 | 0.45 | 1.26

Between run (n=139)
- Mean [mmol/L]: 0.30 | 0.67 | 1.15
- Coefficient of variation [%]: 2.50 | 3.68 | 2.78

Conversion factor
β-Hydroxybutyrate [mg/dL] x 0.0962 = β-Hydroxybutyrate [mmol/L]

Reference Range [2]

<table>
<thead>
<tr>
<th>Fasting</th>
<th>[mmol/L]</th>
<th>[mg/dL]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.02 – 0.27</td>
<td>0.21 – 2.81</td>
<td></td>
</tr>
</tbody>
</table>

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature
4. Data on file at DiaSys Diagnostic Systems GmbH.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65550 Holzheim Germany
β-Hydroxybutyrate FS

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.

**Identification**
- This method is usable for analysis: Yes
- Twin reaction: No
- Name: HBUT
- Shortcut: 041
- Reagent barcode reference: 041
- Host reference:

**Technic**
- Type: End point
- First reagent [µL]: 160
- Blank reagent: Yes
- Sensitive to light: 546
- Second reagent [µL]: 40
- Blank reagent: Yes
- Main wavelength [nm]: 546
- Secondary wavelength [nm]:
- Polychromatic factor:
- 1st reading time (min:sec): (04:24)
- Last reading time (min:sec): 10:00
- Reaction way: Increasing
- Linear Kinetics
- Linearly: Maximum deviation [%]
- Fixed Time Kinetics
- Endpoint
- Prozone Limit [%]

**Reagents**
- Decimals
- Units

**Sample**
- Diluent: DIL A (NaCl)
- Hemolysis:
  - Agent [µL]: 0 (no hemolysis)
  - Cleaner
  - Sample [µL]: 0
- Technical limits
  - Concentration technical limits-Lower: 0.00
  - Concentration technical limits-Upper: 6.90
- SERUM
  - Normal volume [µL]: 4
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 20
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 2
  - Above normal dilution (factor): 1
- URINE
  - Normal volume [µL]: 4
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 20
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 2
  - Above normal dilution (factor): 1
- PLASMA
  - Normal volume [µL]: 4
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 20
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 2
  - Above normal dilution (factor): 1
- CSF
  - Normal volume [µL]: 4
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 20
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 2
  - Above normal dilution (factor): 1
- Whole blood
  - Normal volume [µL]: 4
  - Normal dilution (factor): 1
  - Below normal volume [µL]: 20
  - Below normal dilution (factor): 1
  - Above normal volume [µL]: 2
  - Above normal dilution (factor): 1

**Results**
- Decimals: 2
- Units: mmol/L
- Correlation factor-Offset: 0.000
- Correlation factor-Slope: 1.000

**Range**
- Gender: All
- Age
- SERUM: >=0.02 <=0.27
- URINE: >=0.02 <=0.27
- CSF: Whole blood
- Gender: All
- Age
  - SERUM
  - URINE: Whole blood
  - PLASMA
  - CSF: Whole blood

**Contaminants**
- Please refer to r910 Carryover Pair Table

**Calibrators details**

<table>
<thead>
<tr>
<th>Calibrator list</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cal. 1/Blank</td>
<td>0</td>
</tr>
<tr>
<td>Cal. 2</td>
<td>*</td>
</tr>
<tr>
<td>Cal. 3</td>
<td></td>
</tr>
<tr>
<td>Cal. 4</td>
<td></td>
</tr>
<tr>
<td>Cal. 5</td>
<td></td>
</tr>
<tr>
<td>Cal. 6</td>
<td></td>
</tr>
</tbody>
</table>

**Max delta abs.**
- Cal. 1: 0.003
- Cal. 2: 0.020
- Cal. 3
- Cal. 4
- Cal. 5
- Cal. 6: 0.8

**Calculations**
- Model: X
- Degree: 1

* Enter calibrator value

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Application respons®910

November 2018/7