Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO₂ in serum or plasma on DiaSys respons®920

Order Information
Cat. No. 1 0950 99 10 923
4 containers for 200 tests each

Method
Enzymatic test using phosphoenolpyruvate carboxylase (PEPC) and a stable NADH analog

Principle
Phosphoenolpyruvate + HCO₃⁻ ➔ PEPC + Mg²⁺ Oxaloacetate + H₂PO₄⁻ Oxaloacetate + Cofactor red. ➔ Malate + Cofactor

The reaction disturbs the following equilibrium:

CO₂ + H₂O ➔ H₂CO₃ ➔ H⁺ + HCO₃⁻

This results in a conversion of CO₂ to bicarbonate (HCO₃⁻) which then is included in the reaction. Therefore, the total CO₂ concentration is measured. The decrease of reduced cofactor concentration is measured at 405 nm and is proportional to the concentration of total carbon dioxide in the sample.

Reagents
Components and Concentrations
Buffer pH 7.5
Phosphoenolpyruvate (PEP) 12.5 mmol/L
Phosphoenolpyruvate carboxylase (PEPC) > 400 U/L
Malate dehydrogenase (MDH) > 4100 U/L
NADH analog 0.6 mmol/L
Standard: 30 mmol/L

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

The standard is stable up to the end of the indicated month of expiry, if stored at 2 – 6°C and protected from light. Once opened, the standard is stable for 12 months, if recapped immediately after use.

Warnings and Precautions
1. The reagent contains sodium azide (0.8 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. The reagent contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
3. To avoid carryover interference, please take care of efficient washing especially after use of interfering reagents. Please refer to the DiaSys respons®920 Carryover Pair Table. Carryover pairs and automated washing steps with the recommended cleaning solution can be specified in the system software. Please refer to the user manual.
4. In very rare cases, samples of patients with gammopathy might give falsified results [8].
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!

Waste Management
Please refer to local legal requirements.

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

Specimen
Serum or heparin plasma
Serum or plasma should be separated from cells immediately and stored at 2 – 8°C. Exposure of samples to air should be avoided. Samples should be stored tightly sealed to prevent loss of carbon dioxide and assayed as soon as possible after collection.

Stability [1]:
1 day at 20 – 25°C
7 days at 4 – 8°C
2 weeks at 20°C
Discard contaminated specimens. Freeze only once.

Calibrators and Controls
DiaSys Bicarbonate Standard FS is recommended for calibration. This method has been standardized against a primary standard on basis of sodium carbonate. DiaSys TruLab Bicarbonate control should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

Performance Characteristics
Measuring range up to 50 mmol/L bicarbonate (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L or use rerun function).

Limit of detection** 2 mmol/L bicarbonate
On-board stability 3 weeks
Calibration stability 3 weeks

Interfering substance Interferences < 10% Bicarbonate [mmol/L]
Ascorbate up to 30 mg/dL 18.3
Hemoglobin up to 1000 mg/dL 23.2
Bilirubin, conjugated up to 60 mg/dL 15.0
Bilirubin, unconjugated up to 60 mg/dL 34.5
Lipemia (triglycerides) up to 2000 mg/dL 16.4
up to 1900 mg/dL 41.5

For further information on interfering substances refer to Young DS [2].

Precision
Within run (n=20)

<table>
<thead>
<tr>
<th>Mean [mmol/L]</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20.0</td>
<td>34.3</td>
<td>46.2</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>1.05</td>
<td>1.19</td>
<td>1.17</td>
</tr>
</tbody>
</table>

Between run (n=20)

<table>
<thead>
<tr>
<th>Mean [mmol/L]</th>
<th>Sample 1</th>
<th>Sample 2</th>
<th>Sample 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>17.4</td>
<td>26.7</td>
<td>44.3</td>
</tr>
<tr>
<td>Coefficient of variation [%]</td>
<td>3.48</td>
<td>2.86</td>
<td>1.57</td>
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</tbody>
</table>

Method comparison (n=114)

<table>
<thead>
<tr>
<th>Test y</th>
<th>Test x</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>DiaSys Bicarbonate FS (Hitachi 917)</td>
<td>DiaSys Diagnostic Systems GmbH</td>
<td>Correlation Coefficient of correlation 0.998</td>
</tr>
</tbody>
</table>

** according to NCCLS document EP17-A, vol. 24, no. 34

Conversion factor
Bicarbonate [mmol/L] = Bicarbonate [mEq/L] × 3.86

Reference Range [3]
Adults: 22 – 29 mmol/L (mEq/L)

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

Literature
5. US patent #5,601,006.

Manufacturer
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

* fluid stable

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# Bicarbonate FS

## Application for serum and plasma

<table>
<thead>
<tr>
<th>Test Details</th>
<th>Test Volumes</th>
<th>Reference Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test</td>
<td>HCO3</td>
<td>Auto Rerun</td>
</tr>
<tr>
<td>Report Name</td>
<td>BICARB</td>
<td>Online Calibration</td>
</tr>
<tr>
<td>Unit</td>
<td>mmol/L</td>
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</tr>
<tr>
<td>Wavelength-Primary</td>
<td>405</td>
<td>505</td>
</tr>
<tr>
<td>Assay Type</td>
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<td></td>
</tr>
<tr>
<td>M1 Start</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>M2 Start</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Sample Replicates</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Control Replicates</td>
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<td>0</td>
</tr>
<tr>
<td>Reaction Direction</td>
<td>Decreasing</td>
<td>React. Abs. Limit</td>
</tr>
<tr>
<td>Prozone Limit %</td>
<td>0</td>
<td>Prozone Check</td>
</tr>
<tr>
<td>Linearity Limit %</td>
<td>0</td>
<td>Delta Abs / Min.</td>
</tr>
<tr>
<td>Technical Minimum</td>
<td>0.0000</td>
<td>Technical Maximum</td>
</tr>
<tr>
<td>Y = aX + b</td>
<td>1.0000</td>
<td></td>
</tr>
</tbody>
</table>

* Please enter standard value.

## Test Details

<table>
<thead>
<tr>
<th>Test</th>
<th>Serum</th>
</tr>
</thead>
</table>

**Sample Volumes**

| Normal     | 2.00 µL | Dilution Ratio | 1 X |
| Increase   | 10.00 µL| Dilution Ratio | 1 X |
| Decrease   | 2.00 µL | Dilution Ratio | 6 X |

**Reagent Volumes and Stirrer Speed**

| RGT-1 Volume | 200 µL | R1 Stirrer Speed | Medium |
| RGT-2 Volume |        | R2 Stirrer Speed |       |

## Reference Ranges

**Reference Range**

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>22.0</td>
</tr>
<tr>
<td>Panic</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Sample Types**

- Serum
- Urine
- CSF
- Plasma
- Whole Blood
- Other