INTENDED USE
For the in vitro quantitative determination of Carbon Dioxide content in human serum or plasma.

CLINICAL SIGNIFICANCE
Serum CO₂ is really a blood test that measures the amount of carbon dioxide (CO₂) in serum. Serum CO₂ is really a measure of serum HCO₃⁻ also called bicarbonate. In the body, 95% of the CO₂ is present as HCO₃⁻, so most of what is measured in the laboratory represents HCO₃⁻. Higher-than-normal levels of HCO₃⁻ may indicate excessive vomiting, respiratory dysfunction (breathing disorders), hyperaldosteronism, or Cushing syndrome.

Assay on automated clinical chemistry analyze sheets for use of Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay is based on two coupled enzyme reactions including phosphoenolpyruvate carboxylase (PEPC) and malate dehydrogenase (MDH). PEPC catalyzes the first reaction which produces oxaloacetate. In the presence of MDH, the reduced cofactor is oxidized by oxaloacetate. This results in a decrease of absorbance at 405 or 415 nm that is directly proportional to CO₂ concentration in the sample.

Carbonate concentration is expressed as mmol/L (mEq/L).

RESULTS

For the in vitro quantitative determination of Carbon Dioxide content in human serum or plasma.

CLARIFICATION
A carbon dioxide calibrator is included with the reagent and, along with 0.9% saline as a zero reference, should be used as directed to calibrate the procedure.

QUALITY CONTROL
We recommend that each laboratory use carbon dioxide controls to validate the performance of carbon dioxide reagents. A set of normal and abnormal range carbon dioxide controls is available from Resolution Biomedical, Inc. (Cat. # DZ112A-Con). If the results from the controls fall outside the acceptable limits, as determined by the manufacturer, the test should not be performed. We recommend that your quality control testing follows federal, state and local guidelines or accreditation requirements.

REFERENCE RANGE
Carbon dioxide concentration is expressed as mmol/L (mEq/L).

LIMITATIONS
A sample with a carbon dioxide level exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

PERFORMANCE CHARACTERISTICS
These performance characteristics were determined at Resolution Biomedical, Inc. using automated procedures on Olympus AU400.

LIMIT OF DETECTION
The limit of detection is 1.2 mmol/L. Sensitivity was calculated on 12 replicates of normal saline and reported as the “mean zero value +3 SD”.

ACCURACY
The performance of this assay was compared with the performance of a similar carbon dioxide assay on a Cobas Mira analyzer using serum and plasma samples. Sixty serum samples ranging from 5.9 – 44.5 mmol/L gave a correlation coefficient of 0.9859. Linear regression analysis gave the following equation:

This method = 1.0447 (reference method) – 0.9742 mmol/L. Sixty plasma samples ranging from 3.73 – 40.46 mmol/L gave a correlation coefficient of 0.9731. Linear regression analysis gave the following equation:

This method = 0.9863 (reference method) + 0.1486 mmol/L.

PRECISION

A sample with a carbon dioxide level exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

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This method = 0.9863 (reference method) + 0.1486 mmol/L.
The precision of the Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay was evaluated on the Cobas Mira instrument according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, two specimens containing 25mM and 40 mM CO₂ were tested with 2 runs per day with duplicates over 20 working days.

<table>
<thead>
<tr>
<th>Within run precision</th>
<th>Run to run Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>25mM CO₂</td>
<td>25mM CO₂</td>
</tr>
<tr>
<td>No. of Data Points</td>
<td>80</td>
</tr>
<tr>
<td>Mean (mM)</td>
<td>24.1</td>
</tr>
<tr>
<td>SD (mM)</td>
<td>0.56</td>
</tr>
<tr>
<td>CV (%)</td>
<td>2.3%</td>
</tr>
</tbody>
</table>

Additionally, the precision of the Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay was evaluated on the Cobas Mira instrument using samples in the abnormal low range. In the study, 20 specimens ranging from 15.39 – 16.96 mM CO₂ were tested in 3 runs on 2 working days, resulting in a Mean of 16.1 mM, and SD of 0.275 mM and a CV of 1.70%.

**LINEARITY**

The linearity of the procedure is from 1.12 to 50 mmol/L.

**INTERFERENCE**

Interference for the Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay was evaluated on the Cobas Mira analyzer. The following substances normally present in a serum produced less than 10% deviation at the listed concentrations: Triglycerides at 1000 mg/mL, Bilirubin at 40 mg/mL, Bilirubin Conjugated at 40 mg/mL, and Hemoglobin at 200 mg/mL.

**REFERENCE**


Manufactured for ClearChem Diagnostics