CARBON DIOXIDE

(LIQUID)

6 x 30 ml

RE – ORDER CAR1090

INTENDED USE

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

CLINICAL SIGNIFICANCE

Serum CO_2 is really is a blood test that measures the amount of carbon dioxide (CO_2) in serum. Serum CO_2 is really a measure of serum HCO_3^-, also call bicarbonate. In te body, 95% of the CO_2 is present as HCO_3^-, so most of what is measured in the laboratory represents HCO_3^-. Higher-than-normal levels of HCO_3^- may indicate excessive vomiting, respiratory dysfunction (breathing disorders), hyperaldosteronism, or Cushing syndrome. Historic procedures to measure HCO_3^- in the laboratory usually involve addition of acid to liberate CO_2, followed by measurement by volumetric, nanometric, thermal conductivity or GC/MS, or ISE methods. These procedures are both time consuming and cumbersome. Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay is a quick easy to use enzymatic procedure applicable to routine laboratory instrumentation. The CO_2 levels in the blood are influenced by kidney and respiratory (lung) function. Lower-than-normal levels of HCO_3^- may indicate ketoacidosis, lactic acidosis, kidney disease, diarrhea, methanol poisoning, salicylate toxicity (such as aspirin overdose), ethylene glycol poisoning, or Addison disease (adrenal gland insufficiency).

ASSAY PRINCIPLE

Resolution Biomedical, Inc. Carbon dioxide Enzymatic Assay is based on two coupled enzyme reactions including phosphoenolpruvate 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 CO_2 concentration in the sample.

Phosphoenolpyruvate + HCO_3^- $\xrightarrow{PEPC +Mg^{++}}$ Oxaloacetate + $H_2PO_4^-$

Oxaloacetate + Reduced Cofactor $\xrightarrow{MDH}$ Malate + Cofactor

MATERIALS REQUIRED BUT NOT PROVIDED

Any instrument with temperature control of 37± 0.5°C that is capable of reading absorbance accurately at 405 or 415 nm may be used. Application sheets for use of Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay on automated clinical chemistry analyzers are available upon request. Please call 949-309-2500.

REAGENT COMPOSITION

Reagent R1:	PEP, PEPC, NADH and MDH in buffer
Calibrator:	30mM Sodium Bicarbonate in 0.9% Saline

REAGENT PREPARATION

Resolution Biomedical, Inc. Carbon Dioxide Enzymatic Assay Reagent (R1) is a ready to use, single liquid reagent.

REAGENT STABILITY AND STORAGE

Unopened reagents are stable until the expiration date printed on the outer box.

SPECIMEN COLLECTION AND HANDLING

Serum or heparinized plasma may be assayed. Ideally, venous blood should be collected and handled anaerobically. Do not use citrate of oxalate as an anticoagulant. Plasma and serum, after prompt separation from cells or clot, should be kept tightly sealed, CO_2 content of blood is stable for 1 hour when stored at 2-4°C under anaerobic conditions.

PRECAUTIONS

For *in vitro* diagnostic use only.

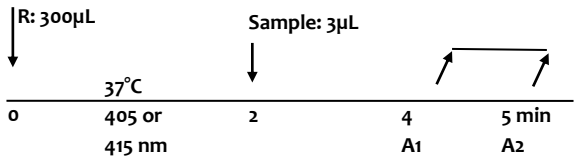
Specimens containing human sourced materials should be handled as if potentially infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiologial and Biomedial Laboratories (HHS Publication Number [CDC] 93-8395). As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient. Avoid ingestion and contact with skin and eyes. See Material Safety Data Sheet. The reagent contains <0.1% sodium azide, NaN_3, as preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide buildup. Avoid contamination of the reagent with CO_2. Do not blow into pipette, since breath contains a high content of CO_2. Do not let bottles remain open unnecessarily, since CO_2 exposure to fresh air can contaminate the reagent. Keep container tightly sealed. Do not use the reagents after the expiration date labeled on the outer box.The reagent solution should be clear. If turbid, the reagent may have deteriorated. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product. To obtain an MSDS, please contact our customer service department at 949-309-2500.

ASSAY PROCEDURES

CONDITIONS

Please contact ClearChem Diagnostics for instrument specific parameters.

TEST SCHEME FOR CHEMISTRY ANALYZERS



CALIBRATION

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.

RESULTS

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

REFERENCE RANGE

23-34 mmol/L

It is strongly recommended that each laboratory determine its own reference

Range.

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 1.2mmol/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 9reference method) + 0.1486 mmol/L.

PRECISION

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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 CO_2 were tested with 2 runs per day with duplicates over 20 working days.

	Within run precision		**Run to run Precision**	
	25mM CO_2	25mM CO_2	25mM CO_2	25mM CO_2
No. of Data Points	80	80	80	80
Mean (mM)	24.1	40.1	24.1	40.1
SD (mM)	0.56	0.91	0.68	1.32
C_V%	2.3%	2.3%	2.8%	3.3%

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 – 16.96mM CO_2 were tested in 3 runs on 2 working days, resulting in a Mean of 16.1mM, and SD of 0.275mM and a C_V% 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 40mg/mL, Bilirubin Conjugated at 40 mg/mL, and Hemoglobin at 200 mg/mL.

REFERENCE

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Manufactured for
ClearChem Diagnostics