

REFERENCES

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2. Norris, K.A., Atkinson, A.R., Smith, W.G., Clin. Chem. 21 (1975).
3. US Patent #5,801,006
4. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Third Edition, Washington (1990).
5. Tietz, N.W. (Editor), Textbook of Clinical Chemistry, W.B. Saunders Co., Philadelphia (1986)

ORDERING/PRICING/TECHNICAL INFORMATION:

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CO₂ ULTRA

CATALOG NUMBER: E598100
E598140

SIZE: 1 x 500 mL
1 x 1000 mL

INTENDED USE

For the quantitative determination of carbon dioxide in serum. For IN VITRO diagnostic use.

PRECAUTIONS

Avoid ingestion and contact with skin and eyes. See Material Safety Data Sheet.

REAGENTS

CO₂ Ultra Reagent: a solution containing buffer (pH 7.5 at 25°C), 12.5 mmol/L PEP, > 400 U/L PEPC (microbial), > 4100 U/L malate dehydrogenase (mammalian), 0.6 mmol/L NADH analog, activators, stabilizers, a surfactant, and a preservative.

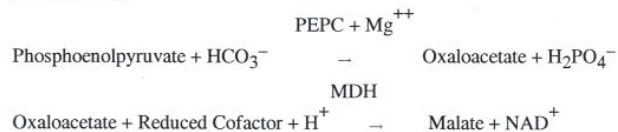
HISTORY

Elevated blood CO₂ is almost synonymous with respiratory acidosis. The latter is restricted to clinical conditions with a primary increase in carbon dioxide in the inspired air or increased metabolic production of carbon dioxide.

Decreased blood CO₂ is almost synonymous with respiratory alkalosis. The latter is restricted to clinical conditions with a primary decrease in carbon dioxide which can result from increased pulmonary ventilation due to mechanical ventilation or stimulation of the respiratory center (1).

Classic techniques for the measurement of carbon dioxide (CO₂) involve the addition of acid to liberate the carbon dioxide and the measurement of carbon dioxide thus released by either manometric, volumetric, or titrimetric techniques. These procedures are both time consuming and cumbersome. CO₂ Ultra Reagent uses an enzymatic procedure, employing phosphoenolpyruvate carboxylase (PEPC) (2) and a stabilized NADH analog (3), which is easy to use and applicable to routine laboratory instrumentation.

PRINCIPLE



PEPC catalyses the first reaction which produces oxaloacetate. In the presence of MDH, the reduced cofactor is oxidized by oxaloacetate. The decrease in concentration of the reduced cofactor is monitored between 405 and 415 nm and is proportional to the total carbon dioxide concentration in the sample.

PEPC is specific for the bicarbonate ion (HCO₃⁻) and its action disturbs the following equilibrium which results in conversion of the CO₂ to HCO₃⁻.



REAGENT PREPARATION

The reagent is provided in a ready to use format.

REAGENT STABILITY AND STORAGE

The reagent included is stable at 2-8°C until the expiration date printed on the label.

REAGENT DETERIORATION

The reagent solution should be clear. Turbidity would indicate deterioration.

INSTRUMENTS

Any instrument with temperature control of ± 0.5°C that is capable of reading absorbance accurately with a sensitivity of 0.001 absorbance at 405 or 415 nm may be used. The band width should be 10 nm or less, stray light 0.5% or less, and the wavelength accuracy within 2 nm.

SPECIMEN COLLECTION AND PREPARATION

Fresh, clear, unhemolysed serum is the specimen of choice. The specimen should be promptly separated from the clot and stored tightly sealed to prevent the loss of carbon dioxide.

INTERFERING SUBSTANCES

Interferences from icterus, lipemia, and hemolysis were evaluated for this carbon dioxide method on a Hitachi 717 analyzer using a significance criterion of > 10% variance from control.

No significant lipemic interference was found at Intralipid levels from 0-1000 mg/dL (0-3000 mg/dL triglycerides) in a 24.6 mmol/L (mEq/L) sample.

No significant icteric interference was found at Bilirubin levels from 0-40 mg/dL (0-684 µmol/L) in a 27.1 mmol/L (mEq/L) carbon dioxide sample.

Hemoglobin levels of 0-155 µmol/L (0-1000 mg/dL) were studied with acceptable results to a level of 93 µmol/L (600 mg/dL). At a hemoglobin level of 93 µmol/L (600 mg/dL), a 10.3% positive interference was displayed in a 26.3 mmol/L (mEq/L) carbon dioxide sample.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S. (4).

PROCEDURE

Materials Provided

The reagent necessary for the determination of carbon dioxide is provided.

Conditions

Follow the guidelines provided for adaptation to specific automated analyzers or contact Equal Diagnostics Technical Services for instrument specific parameters.

	Automated Analyzer
Wavelength	405 nm or 415 nm
Temperature	37°C
Pathlength	Instrument dependent
Mode	Fixed Rate
Reaction Time	8 minutes
Sample Volume	3 µL
Reagent Volume	300 µL
Total Volume	303 µL
Sample to Reagent Ratio	1:100

CALIBRATION

A carbon dioxide standard is not included with the reagents, however one should be used as directed to calibrate the procedure.

QUALITY CONTROL

A normal and abnormal level control serum should be analyzed with each run of samples and the results should fall within plus or minus two standard deviations of the established values.

CALCULATION AND RESULTS

Results

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.

EXPECTED VALUES (5)

22-29 mmol/L (mEq/L)

These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

PERFORMANCE CHARACTERISTICS

These performance characteristics were generated in laboratories using automated procedures unless otherwise stated.

Recovery Study

Carbon dioxide was added to pooled human sera to increase the carbon dioxide concentration by 2.6 mmol/L (mEq/L) and 4.3 mmol/L (mEq/L). Recovery of the added carbon dioxide averaged 105.0%.

Reportable Range (NCCLS EP6-P)

The linearity of the procedure described is 50 mmol/L (mEq/L). The lower limit of detection of the procedure described is 2.9 mmol/L (mEq/L). This data results in a reportable range of 2.9-50 mmol/L (2.9-50 mEq/L).

Precision Studies

Within run precision was established by assaying two control sera twenty times each.

Carbon Dioxide	Mean mmol/L (mEq/L)	Standard Deviation mmol/L (mEq/L)	Coefficient of Variation %
Serum 1	13.5	0.18	1.3
Serum 2	24.0	0.40	1.7

Run to run precision was established by assaying two control sera in triplicate in each of 5 runs.

Carbon Dioxide	Mean mmol/L (mEq/L)	Standard Deviation mmol/L (mEq/L)	Coefficient of Variation %
Serum 1	14.1	0.24	1.7
Serum 2	24.8	0.27	1.1

Accuracy (NCCLS EP9-P)

The performance of this method (y) on a Hitachi 717 was compared with the performance of a similar carbon dioxide method (x) on a Cobas Mira. Forty-five patient serum samples ranging from 15.4-43.7 mmol/L (mEq/L) gave a correlation coefficient of 0.9861. Linear regression analysis gave the following equation:

This method = 1.00 (reference method) - 0.42 mmol/L (mEq/L).