BICARBONATE CO2

REF 1500520 5x20ml+1x2ml CAL

CE IVD For in vitro medical device

Use

Kit for the quantitative determination of bicarbonate (CO2) in serum and plasma. For in vitro diagnostics use only.

Summary

Serum CO2 is 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.
Historic procedures to measure HCO3– in the laboratory usually involve addition of acid to liberate CO2, followed by measurement by volumetric, manometric, thermal conductivity or GC/MS, or ISE methods. These procedures are both time consuming and cumbersome.Carbon Dioxide Enzymatic Assay is a quick, easy to use enzymatic procedure applicable to routine laboratory instrumentation.
The CO2 levels in the blood are influenced by kidney and respiratory (lung) function. Lower-than-normal levels of HCO3– 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).

Principle

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.

Phosphoenolpyruvate + HCO3– PEPC + Mg++ Oxaloacetate + H2PO4–
Oxaloacetate + Reduced Cofactor 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 Carbon Dioxide Enzymatic Assay on automated clinical chemistry analyzers are available upon request.

Reagents

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

Reagent Preparation

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

Reagent Stability and Storage

The assay reagent is stable up to the expiration date on the label when stored at 2-8°C.
The final concentration of the components is below the limits imposed by Regulation (EC) No. 1272/2008 - CLP (and subsequent amendments) and Directive 88/379/CEE and subsequent amendments to the classification-packaging and labeling of dangerous substances.

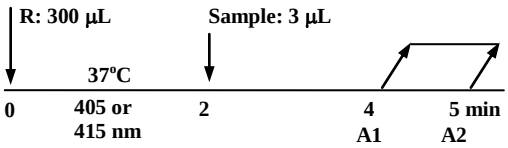
Specimen Collection and Preparation

Serum or heparinized plasma may be assayed. Ideally, venous blood should be collected and handled anaerobically. Do not use citrate or oxalate as anticoagulant. Plasma and serum, after prompt separation from cells or clot, should be kept tightly stoppered. CO2 content of blood is stable for 1 hour when stored at 2–4°C under anaerobic conditions.

Precaution in Use

1. Specimens containing human sourced materials should be handled as if potentially infectious using safe laboratory procedures, such as those outlined in Biosafety in Microbiological and Biomedical Laboratories (HHS Publication Number [CDC] 93-8395).
2. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
3. Avoid ingestion and contact with skin and eyes. See Material Safety Data Sheet.
4. The reagent contains <0.1% sodium azide, NaN3, 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.
5. Avoid contamination of the reagent with CO2. Do not blow into pipette, since breath contains a high content of CO2. Do not let bottles remain open unnecessarily, since CO2 from air can contaminate the reagent. Keep container tightly stoppered.
6. Do not use the reagents after the expiration date labeled on the outer box.
7. The reagent solution should be clear. If turbid, the reagent may have deteriorated.
8. Additional safety information concerning storage and handling of this product is provided within the Material Safety Data Sheet for this product.

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..

Results

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

Reference Range

Normal values of CO2 in serum or plasma are 22–29 mmol/L for adults and 20–28 mmol/L for infants and children.4 It is strongly recommended that each laboratory establish an expected range characteristic for the local population.

Limitations

The Assay is designed for use with human serum or plasma samples only.
The measuring range of the assay is from 1.12 to 50 mmol/L. Samples with carbon dioxide levels higher than 50 mmol/L 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 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

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Precision

The precision of the 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 40mM CO2 were tested 2 runs per day with duplicates over 20 working days.

	Within Run Precision		**Run to Run Precision**	
	25mM CO_2	40mM CO_2	25mM CO_2	40mM 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
CV%	2.3%	2.3%	2.8%	3.3%

Additionally, the precision of the 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, an 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 Carbon Dioxide Enzymatic Assay was evaluated on a Cobas Mira analyzer. The following substances normally present in serum produced less than 10% deviation at the listed concentrations: Triglycerides at 1000 mg/mL, Ascorbic acid at 5 mg/mL, Bilirubin at 40 mg/mL, Bilirubin Conjugated at 40 mg/mL, and Hemoglobin at 200 mg/mL.

References

Tietz, N. W. (Ed): Fundamentals of Clinical Chemistry, W. B. Saunders Co., Philadelphia, 865 (1982)

Contarow and Trumper, Clinical Biochemistry, 7th ed., Al Latner, Editor, Saunders, Philadelphia, p. 399 (1975)

Clinical Chemistry, LA Kaplan, AJ Pesce, Editors, CV Mosby Company, St. Louis (MO), p. 1056 (1984)

Burtis CA, Ashwood ER, eds. Tietz Textbook of Clinical Chemistry, 2nd ed. Philadelphia, PA: WB Saunders, p. 2181 (1994)

Simbols

CE	CE Mark (requirement of 98/79 regulation)
IVD	in vitro medical device
LOT	Batch Code
	Use by
	Storage temperature limits
	Read instruction for use
	Gesan Production srl