Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO_2 in serum or plasma on photometric systems

Order Information

Cat. No.	Kit size		
1 0950 99 10 021	R	6 x	25 mL
1 0950 99 10 026	R	6 x	100 mL
1 0950 99 10 917	R	10 x	60 mL
1 0950 99 10 930	R	6 x	20 mL

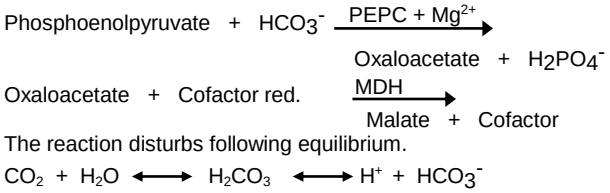
Summary [1]

Measurement of bicarbonate is used in the diagnosis of the acid-base-balance in the blood. Elevated and decreased values indicate disorders associated with disturbances of the metabolic and respiratory systems.

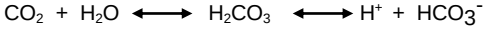
Method

Enzymatic test using phosphoenolpyruvate carboxylase (PEPC) and a stable NADH analog. This method has been standardized against a primary standard on basis of sodium carbonate.

Principle



The reaction disturbs following equilibrium.



This results in a conversion of CO_2 to bicarbonate (HCO_3^-) which then is included in the reaction. Therefore, the total CO_2 concentration is measured.

The decrease of reduced cofactor concentration is measured at 405 or 415 nm and is proportional to the concentration of total carbon dioxide in the sample.

Reagents

Components and Concentrations

Reagent:

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

Storage Instructions and Reagent Stability

The reagent is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C and contamination is avoided. Do not freeze the reagent! Protect reagent from light!

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. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheet 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.
5. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagent is ready to use.

Materials required but not provided

NaCl solution 9 g/L
General laboratory equipment

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 [4]:			
	1 day	at	20 – 25°C
	7 days	at	4 – 8°C
	2 weeks	at	–20°C

Freeze only once! Discard contaminated specimens!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	405 nm, 415 nm
Optical path	1 cm
Temperature	37°C
Measurement	Against reagent blank

	Sample/Standard
Sample/Standard	10 µL
Reagent	1000 µL
Mix, incubate and read absorbance A1 after exactly 2 min. and absorbance A2 after exactly 10 min. against reagent blank.	

$\Delta A = (A2 - A1)$ Sample/Standard

Calculation

With standard

$$\text{Bicarbonate [mmol/L]} = \frac{\Delta A\text{Sample}}{\Delta A\text{Std.}} \times \text{Conc. Std [mmol/L]}$$

Conversion factor

Bicarbonate [mmol/L] = Bicarbonate [mEq/L]

* fluid stable

Standard and Control

For calibration of automated photometric systems, DiaSys Bicarbonate Standard FS is recommended. The standard value has been standardized against a primary standard on basis of sodium carbonate. TruLab Bicarbonate control should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruLab Bicarbonate	5 9700 99 10 065	3 x 3 mL
Bicarbonate Standard FS	1 0950 99 10 030	6 x 3 mL

Performance Characteristics

Measuring Range

The test has been developed to determine CO_2 concentrations within a measuring range from 4 – 50 mmol/L. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Specificity/Interferences

No interference was observed by ascorbic acid up to 30 mg/dL, conjugated bilirubin up to 50 mg/dL, free bilirubin up to 40 mg/dL, hemoglobin up to 500 mg/dL and lipemia up to 1400 mg/dL triglycerides. For further information on interfering substances refer to Young DS [5].

Sensitivity/Limit of Detection

The lower limit of detection is 1 mmol/L.

Precision

Intra-assay precision n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	17.6	0.14	0.80
Sample 2	19.9	0.16	0.80
Sample 3	30.1	0.28	0.93

Inter-assay precision n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	16.8	0.53	3.16
Sample 2	20.3	0.49	2.40
Sample 3	30.0	0.68	2.26

Method Comparison

A comparison of DiaSys Bicarbonate FS (y) with a commercially available assay (x) using 107 samples gave following results:
y = 0.989 x + 0.354 mmol/L; r = 0.998

Reference Range [1]

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

1. Müller-Plathe O. Acid base balance and blood gases. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 318–329.
2. Norris KA, Atkinson AR, Smith WG. Colorimetric enzymatic determination of serum total carbon dioxide as applied to the Vickers multichannel 300 discrete analyzer. Clin Chem 1975; 21: 1093–1101.
3. US patent #5,801,006
4. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
5. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, DC: The American Association for Clinical Chemistry Press 2000.
6. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. ClinChemLabMed 2007;45(9):1240–1243.

Manufacturer

IVD CE
DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany