BioMajesty

Bicarbonate FS*

Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO_2 in serum or plasma on BioMajesty JCA-BM6010/C

Order Information

Cat. No. 1 0950 99 10 961
6 x 160 tests

Method

Enzymatic test using phosphoenolpyruvate carboxylase (PEPC) and a stable NADH analog.

Principle

$$\text{Phosphoenolpyruvate} + HCO_3^- \xrightarrow{PEPC+Mg^{2+}} \text{Oxaloacetate} + H_2PO_4^-$$

$$\text{Oxalacetate} + \text{Cofactor red.} \xrightarrow{MDH} \text{Malate} + \text{Cofactor}$$

The reaction disturbs the following equilibrium.

$$CO_2 + H_2O \longleftrightarrow H_2CO_3 \longleftrightarrow H^+ + HCO_3^-$$

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 410 nm and is proportional to the concentration of total carbon dioxide in the sample.

Reagents

Components and Concentrations

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
Standard:		30 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!
The standard is stable up to the end of the indicated month of expiry, if stored at 2 – 8°C. Once opened, the standard is stable at least 12 months, if recapped immediately after use. Protect reagent and standard 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 laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [6].
4. Please refer to the safety data sheets 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. The bottles are placed directly into the reagent trays.

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 minimized. Samples should be stored tightly sealed to prevent loss of carbon dioxide and assayed as soon as possible after collection.

Stability [1]:

1 day	at	20 - 25°C
7 days	at	4 - 8°C
2 weeks	at	-20°C

Freeze only once. Discard contaminated specimens.

Calibrators and Controls

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

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

Performance Characteristics

Measuring range up to 46 mmol/L CO_2 (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use the rerun function).	
Limit of detection**	1.1 mmol/L CO_2
On-board stability	3 weeks
Calibration stability	3 weeks

Interferences < 10% by
Ascorbate up to 30 mg/dL
Conjugated bilirubin up to 60 mg/dL
Unconjugated bilirubin up to 42 mg/dL
Hemoglobin up to 500 mg/dL
Lipemia (triglycerides) up to 1600 mg/dL
For further information on interfering substances refer to Young DS [5].

Precision			
Within run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	12.9	21.6	25.1
Coefficient of variation [%]	1.61	1.74	1.36
Between run (n=20)	**Sample 1**	**Sample 2**	**Sample 3**
Mean [mmol/L]	13.8	20.6	26.2
Coefficient of variation [%]	2.66	1.84	2.03

Method comparison (n=100)	
Test x	DiaSys Bicarbonate FS (Hitachi 917)
Test y	DiaSys Bicarbonate FS (BioMajesty JCA-BM6010/C)
Slope	0.994
Intercept	0.849 mmol/L
Coefficient of correlation	0.999

** lowest measurable concentration which can be distinguished from zero mean + 3 SD (n = 20) of an analyte free specimen

Conversion factor

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

Reference Range [2]

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.

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Literature

1. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
2. 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.
3. Norris KA, Atkinson AR, Smith WG. Colorimetric enzymatic determination of serum total carbon dioxide as applied to the Vickers multichannel 300 discrete analyser. Clin Chem 1975; 21: 1093-1101.
4. US patent #5,801,006
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. Clin Chem Lab Med 2007;45(9):1240-1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
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Bicarbonate FS

Chemistry code 10 095

Application for serum and plasma samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

Analytical Conditions	
R1 volume	100
R2e volume	0
R2 volume	0
R1 diluent vol	0
R2e diluent vol	0
R2 diluent vol	0
Sample vol (S)	1.0
Sample vol (U)	1.0
Reagent 1 mix	weak
Reagent 2e mix	weak
Reagent 2 mix	weak
Reaction time	10

Sub-analy. Conditions	
Name	HCO3
Digits	1
M-wave L.	410
S-wave.L	505
Analy.mthd.	EPA
Calc.mthd.	STD
Qualit. judge	No

Analysis Test Condition Setting (M)		
Sample Type	**Serum**	**Urine**
Reac. sample vol.	1	1
Diluent method	No dil	No dil
Undil. sample vol.	0	0
Diluent volume	0	0
Diluent position	0	0

entered by user

Endpoint method	
Re.absorb (u)	9.999
Re. Absorb (d)	-9.999

Calculation Method Setting	
M-DET.P.I	0
M-DET.P.m	32
M-DET.P.n	33
S-DET.P.p	3
S-DET.P.r	4
Check D.P.I.	0
Limit value	0.003
Variance	10
Reac.type	Dec.

Reaction Rate Method	
Cycle	2
Factor	2
E2 corre	Not do
Blank (u)	9.999
Blank (d)	-9.999
Sample (u)	9.999
Sample (d)	-9.999

Standards Setting	
FV	#
BLK H	9.999
BLK L	-9.999
STD H	9.999
STD L	-9.999