


Bicarbonate FS*

Order Information

Cat. No.

1 0950 99 10 961

Kit size 960 (6 x 160)

Intended Use

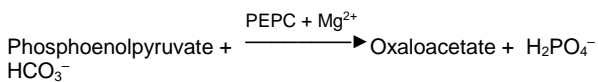
Diagnostic reagent for quantitative in vitro determination of bicarbonate/total CO₂ in human serum or heparin plasma on automated BioMajesty® JCA-BM6010/C.

Summary

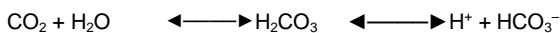
The pH values of human extra- and intracellular fluid are influenced by various factors and are expressed within the context of acid-base balance. Maintaining pH equilibrium is of major importance. Buffer systems serve as essential mechanisms to prevent alterations, with the HCO₃⁻/CO₂ system being the primary one [1]. Acidosis and alkalosis represent two types of acid-base balance disorders that can manifest in both metabolic and respiratory systems. Measurement of bicarbonate is used to aid in diagnosing acid-base balance and associated disorders and disturbances, as well as to monitor the efficacy of treatments targeting conditions impacting the body's pH levels [2].

Method

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



This reaction disturbs the following equilibrium:



This results in a conversion of CO₂ to bicarbonate (HCO₃⁻) which then is included in the reaction. Therefore, the total CO₂ 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.

Reagent

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	

Storage and Stability

Reagent is stable up to the date of expiry indicated on the kit, if stored at 2 - 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 15 months until expiry date.

Warnings and Precautions

- The reagent contains sodium azide (0.8 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagent contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
- In very rare cases, samples of patients with gammopathy might give falsified results [3].
- In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
- Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
- Please refer to the safety data sheets (SDS) 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.

- For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Reagent Preparation

The reagent is ready to use. The bottles are placed directly into the reagent rotor.

Materials Required

General laboratory equipment

Specimen

Human serum or heparin plasma

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Separate serum or plasma from cells immediately and store at 2 - 8°C. Avoid exposure of samples to air. Store samples tightly sealed to prevent loss of carbon dioxide and assay as soon as possible after collection.

Stability [4]:

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

Only freeze once. Discard contaminated specimens.

Standard and Control

DiaSys Bicarbonate Standard FS is recommended for calibration. Standard value has been standardized against a primary standard on basis of sodium carbonate. Use DiaSys TruLab Bicarbonate for internal quality control. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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 up to 46 mmol/L, linearity is given within ± 5%. In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.	
Limit of detection**	1.1 mmol/L
Onboard stability	3 weeks
Calibration stability	3 weeks

Interference by	Interferences ≤ 10% up to	Analyte concentration [mmol/L]
Ascorbic acid	30 mg/dL	19.3
Bilirubin (conjugated)	60 mg/dL	20.0
Bilirubin (unconjugated)	42 mg/dL	19.9
Hemolysis	500 mg/dL	20.4
Lipemia (triglycerides)	1600 mg/dL	18.8

For further information on interfering substances, refer to the literature [5,6].

Precision			
Repeatability (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	12.9	21.6	25.1
CV [%]	1.61	1.74	1.36
Between day (n=20)	Sample 1	Sample 2	Sample 3
Mean [mmol/L]	13.8	20.6	26.2
CV [%]	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 [7]

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. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2023 [cited 2024 Feb 21]. <https://www.clinical-laboratory-diagnostics.com>
2. Jung, B., Martinez, M., Claessens, YE. et al. Diagnosis and management of metabolic acidosis: guidelines from a French expert panel. *Ann. Intensive Care.* 2019; 9(92)
3. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: mechanisms, detection and prevention. *ClinChemLabMed* 2007;45(9):1240-1243.
4. W.G. Guder, F. da Fonseca-Wollheim, W. Heil, et al. Quality of Diagnostic Samples. German Society for Clinical Chemistry and Laboratory Medicine. 3rd completely revised edition 2010.
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. Young DS. Effects on Clinical Laboratory Tests - Drugs Disease, Herbs & Natural Products, <https://clinfx.wiley.com/aaccweb/aacc/>, accessed in October 2021. Published by AACC Press and John Wiley and Sons, Inc.
7. 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.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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* Fluid Stable

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.l	0
M-DET.P.m	32
M-DET.P.n	33
S-DET.P.p	3
S-DET.P.r	4
Check D.P.l.	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