Bicarbonate FS*

Order Information

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

Kits for use in conjunction with DiaSys CE applications.

Intended Use

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

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 HCO_3-/CO_2 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

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

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

This 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 405 or 415 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

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 material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. In very rare cases, samples of patients with gammopathy might give falsified results [3].
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. 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.
6. 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.
7. 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.

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.

Assay Procedure

Basic settings for BioMajesty® JCA-BM6010/C

Wavelength	410/505 nm
Temperature	37°C
Measurement	Endpoint
Sample/Standard	1.0 µL
Reagent	100 µL
Addition reagent	Cycle 19 (286 s)
Absorbance 1	Cycle 3/4 (25 s/39 s)
Absorbance 2	Cycle 32/33 (464 s/478 s)
Calibration	Linear

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]

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

Data evaluated on BioMajesty® JCA-BM6010/C

Measuring range up to 46 mmol/L, linearity is given within ± 5%. When values exceed this range, samples should be diluted 1 + 1 with NaCl solution (9 g/L) and the result multiplied by 2.

Limit of detection**	1.1 mmol/L

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.

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
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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.
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IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim
Germany
www.diasys-diagnostics.com

* Fluid Stable