QUANTON BIOLIFE SCIENCES

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Bicarbonate Test Kit

Enzymatic

QBL/PDS/BiC_016

Quantitative determination of Bicarbonate in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Pack Size
BICMONO 25	25 X 1 ml
BICMONO 50	50 X 1 ml
BIC 25	1 X 25 ml
BIC 50	1 X 50 ml
BIC 100	1X100 ml
BIC 1000	1X1000 ml
BIC 5000	1X5000 ml
BIC 10000	1X10000 ml

CLINICAL SIGNIFICANCE

Approximately 90% of carbon dioxide present in serum or plasma is in the form of bicarbonate, the measurement of bicarbonate, usually in conjunction with tests such as glucose, urea, sodium, potassium and chloride is useful in the assessment of disturbances of acid base balance resulting from metabolic or respiratory causes.

Method

Enzymatic Method.

PRINCIPLE

This reagent is based upon phosphoenolpyruvate carboxylase (PEPC) utilizing bicarbonate present in the sample to produce oxaloacetate and phosphate. Malate dehydrogenase (MDH) then catalyzes the reduction of oxaloacetate to malate and the oxidation of NADH to NAD^+. The resulting decrease in absorbance can be measured at 380nm and is proportional to the amount of bicarbonate present in the sample.

$$HCO_3^- + \text{Phosphoenolpyruvate} \xrightarrow{\text{PEPC}} \text{Oxalocetate} + H_2PO_4$$

$$\text{Oxaloacetate} + \text{NADH} \xrightarrow{\text{MDH}} \text{Malate} + NAD^+$$

REAGENT

Reagent I : Bicarbonate reagent
Bicarbonate Calibrator : 24.5 mEq/L

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

Reagent is stable till expiry when stored at 2-8°C.
Store protected from light.

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.
- Proceed carefully with this product because due to its nature it can get contaminated easily.
- Most of the detergents and water softening products used in the laboratories contain chelating agents. A defective rinsing will invalidate the procedure.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or heparinized plasma free of hemolysis is suitable specimens for use with this reagent. The whole blood should be collected and handled anaerobically to minimize exposure to air. Serum bicarbonate is stable for one hour when stored under anaerobic conditions in an ice bath.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, Calibrator and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm
Reaction Temperature	37ºC
Reaction Type	Fixed Time
Reaction Direction	Decreasing
Incubation	5 Min.
Sample Volume	10 µL
Delay Time	5 Sec.
Read Time	30 Sec.
Reagent Volume	1000 µL
Linearity	40 mEq/L
Blank Absorbance Limit	< 0.30
Units	mEq/L

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STD	SAMPLE
Sample	-	-	10µl
Calibrator	-	10µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 05 min. at RT. Measure absorbance of Sample (AT) and Calibrator (AC) against Reagent Blank at 505 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 40 mEq/L.
- Dilute samples above this concentration 1:1 with DI Water
- Repeat assay. Multiply the result by 2.

CALCULATION

A1 = Absorbance of Blank - Absorbance of Sample
A2 = Absorbance of Blank - Absorbance of Calibrator

$$\text{Bicarbonate (mmol/L)} = \frac{A1}{A2} \times \text{Calibrator Value (mmol/L)}$$

CLIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of Bicarbonate calibrator have been made traceable to the NIST Standard Reference Material SRM 956.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS
WITHIN RUN

Sample	Mean Concentration	SD	CV %
Randox 2	14.79	0.36	2.43%
Randox 3	15.26	0.35	2.29%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	14.52	0.30	2.07%
Randox 3	14.55	0.04	0.26%

LINEARITY
This method is linear upto a concentration of 40 mEq/L.
Dilute samples above this concentration 1:1 with DI Water and
Repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Bicarbonate is 0.08 mEq/L.

METHOD COMPARISON
A comparison of Bicarbonate with a commercially available assay (x) using 20 samples gave following results: R2 = 0.9590

REFERENCE VALUES
23.0-29.0 mEq/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE
1. Bicarbonate levels are elevated or depressed due to a variety of diseases and conditions. Other tests may be necessary for differential diagnosis.
2. Keep exposure of the reagent to air to a minimum and avoid extraneous carbonate contamination.

INTERFERENCE
Bilirubin: No interference found upto 50mg/dl.
Hemoglobin: : No interference found upto 450 mg/dL.
Lipemia: No interference found upto 450 mg/dl.
These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY
1. Zilva JF, Pannall PR. "Hydrogen ion Homeostasis: Blood Gas level" in Clinical Chemistry in Diagnosis and Treatment. LLoyd-Luke London 1979. Chapter iv:78-113.
2. Henry RJ. Clinical Chemistry: Principles and Technics. Harper and Row New York 1974.
3. Tietz NW. Fundamentals of Clinical Chemistry, WB Saunders Co. Philadelpha 1976; 15:885.
4. Young DS. Effects of Drugs on Clinical Laboratory Tests. Third edition 1990; 3:57-9

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,
Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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