

**INTENDED USE:**

This reagent is intended for the *in-vitro* quantitative determination of total CO<sub>2</sub> in human serum or plasma.

**ORDER INFORMATION**

REF	Cont.
BIM 50	10 X 5 ML
BIM 25	25 X 1 ML
BIM 10	10 X 1 ML
BIM 25	5 X 5 ML

**CLINICAL SIGNIFICANCE:**

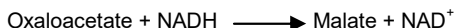
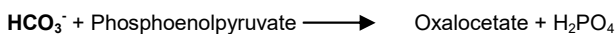
Approximately 90% of carbon dioxide present in serum or plasma is in the form of bicarbonate, the measurement of bicarbonate, usually in conjunction with tests such as glucose, urea, sodium, potassium and chloride is useful in the assessment of disturbances of acid base balance resulting from metabolic 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<sup>+</sup>. The resulting decrease in absorbance can be measured at 380nm and is proportional to the amount of bicarbonate present in the sample.



**PRESENTATION:**

Reagent 1 : Bicarbonate Reagent  
Bicarbonate Calibrator : 22.0 mmol/L (mEq/L)

**NOTE: All reagent to be stored at 2-8°C**

**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

**SPECIMEN COLLECTION AND HANDLING:**

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 - 28°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	405 nm
Cuvette	1 cm
Reaction Temperature	37°C
Reaction Type	Fixed Time
Reaction Direction	Decreasing
Blank	Reagent
Incubation	5 Min.
Sample Volume	10 µL
Delay Time	5 Sec.
Read Time	300 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 405 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:**

Abs T = Absorbance of Blank - Absorbance of Sample  
Abs C = Absorbance of Blank - Absorbance of Standard/Calibrator

$$\text{Bicarbonate (mmol/L)} = \frac{\text{Abs T}}{\text{Abs C}} \times \text{Calibrator Value (m/Lit)}$$

Example

Absorbance of reagent blank	1.3
Absorbance of standard/Calibrator	0.94
Absorbance of Sample	1.0
Standard Value	22 mmol/L

$$\text{Abs T} = 1.3 - 1.0 = 0.3$$

$$\text{Abs S} = 1.3 - 0.94 = 0.36$$

$$\text{Bicarbonate (mmol/L)} = (0.3 \times 22) / 0.36 = 18.33 \text{ mmol/L}$$

## 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.

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 %
Level 1	7.58	0.28	3.71%
Level 2	26.20	0.36	2.41%

### RUN TO RUN

Sample	Mean Concentration	SD	CV %
Level 1	7.37	0.21	2.83%
Level 2	26.94	0.35	1.29%

## LINEARITY

This method is linear upto a concentration of 45 mEq/L. Dilute samples above this concentration 1:1 with DI Water and Repeat assay. Multiply the result by 2

Limit of detection:

## SENSITIVITY:

The sensitivity of the assay is such that a change in absorbance of 0.001 AU equals 0.08 mmol/L (0.08 mEq/L).

## METHOD COMPARISON

A comparison of Bicarbonate with a commercially available assay (x) using 20 samples gave following results: R2 = 0.9769

## NORMAL VALUES:

23.0-29.0 mmol/L

## LIMITATIONS:

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.









## WARNING:

Do not ingest. Avoid contact with skin and eyes. If spilt thoroughly wash affected areas with water. Reagent contains sodium azide which may react with copper and lead plumbing. Flush with plenty of water when disposing.

## REFERENCES:

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. Philadelphia 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		Lot Number
	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer		For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight		Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.  
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