BICARBONATE

(PEPC Enzymatic Method)

Intended Use

Bicarbonate FS is a reagent kit used for the determination of bicarbonate/Total CO2 in serum or plasma based on Phosphoenolpuruvate Carboxylase(PEPC) method. The reagents are for *in-vitro* diagnostic use.

Principle

The assay consists of two reaction steps:

$$PEP + HCO_3^- \xrightarrow{PEPC} Oxaloacetate + H_2PO_4^-$$

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

Bicarbonate in the sample reacts with phosphoenol pyruvate in the presence of PEP-C to produce oxaloacetate and phosphate. Then MDH catalyzes the reduction of oxaloacetate to malate and the oxidation of NADH to NAD+. The decrease in absorbance can then be measured at 405nm. The decrease in absorbance is directly proportional to the amount of bicarbonate in the sample.

Reagent provided

1. R1-Bicarbonate Reagent
2. R2- Bicarbonate Calibrator

Reagent storage and stability

The reagent and calibrator are stable at 2-8°C till the expiry date stated on the container label.

Specimen collection and preservation

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

Assay guidelines for Analyzers

Reaction type	End Point
Reaction slope	Increasing
Wavelength	405 nm
Delay	5 Secs
Temperature	37°C
Sample volume	10 µl (0.01 ml)
Reagent volume	1000 µl (1.0 ml)
Linearity	50 mmol/L
Sensitivity	3 mmol/L

Assay guidelines for Manual procedure

Bring the reagent and standard to room temperature before performing the assay.

Reagents	Blank	Standard	Sample
Bicarbonate Reagent	1000 µl (1.0 ml)	1000 µl (1.0 ml)	1000 µl (1.0 ml)
Sample	-	-	10 µl (0.01ml)
Mix well , incubate at 37°C for 5 min, Read the absorbance at 405 nm			

Calculation

$$\text{Bicarbonate (mmol/L)} = \frac{\Delta A \text{ Sample} - \Delta A \text{ Blank}}{\Delta A \text{ Standard} - \Delta A \text{ Blank}} \times \text{Conc. Std.[mmol/L]}$$

KEE DIAGNOSTICS

Normal Range

Guidance value : 20 – 29 mmol/L

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

- The reagent contains sodium azide (0.8g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- The reagent contains animal material. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practices.
- In very rare cases, samples of patients with gammopathy might give falsified results.
- Please refer to the safety data sheet 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!

Quality Control

To ensure adequate quality control, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware and accuracy of pipetting.

References

1. Muller-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.
2. Norris KA, Atkinson AR, Amith WG. Colorimetric enzymatic determination of serum total carbon dioxide as applied to the Vickers multichannel 300 discrete analyzer. Clin Chem 1975; 21: 1093-1101.
3. US patent # 5,801,006
4. Guder WG, Zawta B et al. The quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 18-9.
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, Mucke M. Gammopathy interference in clinical chemistry assays; mechanisms, detection and prevention. ClinChemLabMed 2007; 45(9): 1240-1243.

Symbols

IVD	In Vitro Diagnostics.		Caution.		Keep away from sun light.		Date of Manufacture.
LOT	Batch No.		Read Instructions.		Fragile.		Product Expiry Date.
CONT	Content.		Storage Temperature.		Keep Dry.		Manufactured By.
REF	Catalogue No.						

KEE DIAGNOSTICS PVT LTD
CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.
NEW DELHI-110028.
W. www.keediagnostics.com.
E. info@keediagnostics.com, T. 011 43136000.

Kee Diagnostics
because life matters

CE **ISO 9001: 2015 & ISO 13485: 2016 Certified Company**

KEE DIAGNOSTICS