Carbondioxide Estimation Kit

High-Q Carbondioxide

PEP-PEPC Method

Command on Quality

Intended Use:

This reagent is intended for the in vitro quantitative determination of total carbon dioxide in human serum on both automated and manual systems.

Clinical significance:

Elevated blood CO2 is almost synonymous with respiratory acidosis. The latter is restricted to clinical conditions with a primary increase in carbon dioxide in the inspired air or increased metabolic production of carbon dioxide.

Decreased blood CO2 is almost synonymous with respiratory alkalosis. The latter is restricted to clinical conditions with a primary decrease in carbon dioxide which can result from increased pulmonary ventilation dueto mechanical ventilation or stimulation of the respiratory center.

Approximately ninety percent of Carbon Dioxide present in serum 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 acid-base balance resulting from metabolic or respiratory causes.

Principle:

The assay consists of two reaction steps:

PEP-C

1. PEP + HCO3- ----------> Oxaloacetate + H2PO4-MDH
2. Oxaloacetate + NADHAnalogue ----------> Malate + NAD+

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

Kit components:

Composition Concentration of solutions:

Tris/HCL buffer	25 mMol/L,	pH=7.60
Phosphoenolpyruvate (PEP)	6.3 mMol/L	
NADH Analogue	0.45 mMolL	
PEP-C	200 U/L	
Mg2+	8.0 mMol/L	
Malate Dehydrogenase (MDH)	600U/L	

Storage and stability :

Co2 reagent is Mono Reagent and is stable till the expiry date mentioned on the labels when the air contamination is avoided and strictly stored at 2-8°C . Reagent should be kept tightly closed and should not be exposed to air for much longer time.

Specimen preparation:

1) Serum or heparinized blood plasma. (Caution: No EDTA, citrate or oxalate can be used as anticoagulants)

2) The sample should be exposed to air as little as possible. Samples should be drawn on ice and analyzed within 1 hour. Samples should be kept tightly closed, as Co2 will diffuse from the sample causing erroneous values (up to 6 mMol/L/hr).

System Parameters:

Reaction Type (Mode) :	Fixed Time
Reaction Direction :	Decreasing
Wave Length :	405 nm
Flow Cell Temp. :	37°C
Zero Setting with :	Distilled Water
Delay Time :	20 Seconds (A1)
Measuring Time :	240 Seconds (A2)
Reagent Volume :	1000 µl
Calibrator / Sample Volume :	10 µl
Calibrator Concentration :	25 mMol/L (Lot Specific)
Linearity :	50 mMol/L
Low Normal :	20 mMol/L
High Normal :	29 mMol/L

Test Procedure:

Reagent	Calibrator	Serum
Co2 Reagent	1000 µL	1000 µL
Calibrator	10 µL (Derive the factor)	——
Serum/Plasma	——	10 µL

Mix well and immediately aspirate in to the analyzer. Record the first absorbance (A1) at 20 seconds after adding the Calibrator /Sample. Exactly 240 Seconds after the first reading record the absorbance (A2) at 37 °C.

Calculate the change in absorbance for the Calibrator and Samples.

Calculations with calibrator:

$$\text{Carbondioxide (mMol/L)} = \frac{\text{A1-A2 Sample}}{\text{A1-A2 Calibrator}} \times 25 \text{ (Conc. Calibrator mMol/L)}$$

Reference Values:

Adults:	Arterial: (19-28)mMol/L;
	Venous: (20-29)mMol/L.
Newborn:	(17.2-23.6) mMol/L;
Infants:	(19.0-23.9) mMol/L.

It is recommended that each laboratory should establish its own reference interval.

Quality control:

High-Q CO2 Control is recommended for daily quality control.The control intervals and limits should be adapted to each laboratory individual requirement. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Carbondioxide Estimation Kit

High-Q Carbondioxide

PEP-PEPC Method

Command on Quality

Performance characteristics:

Linearity:

The method is linear up to 50 mMol/L. Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.

Analytical sensitivity (Low detection limit. Detection limit: 0.2 mMol/L.

Precision :

Within-Run

n= 20

	Level 1	Level 2	Level 3
Mean (mmol/L)	21.87	30.71	40.12
SD (mmol/L)	0.43	0.39	0.44
CV (%)	1.97	1.27	1.10

Between -Run

n= 20

	Level 1	Level 2	Level 3
Mean (mmol/L)	22.04	31.20	41.50
SD (mmol/L)	0.76	0.65	0.98
CV (%)	3.47	2.07	2.37

Interference:

The effect of the following substances can be neglected if the concentrations of the following substances are at or below the given values. Substances Concentrations

Bilirubin 30 mg/dl

Haemoglobin 4 g/L

Intralipid 0.1 %

VC 0.5 g/L(50 mg/dL)

Correlation:

Acomparison of the carbondioxide determination using the High-Q method (y) versus with another commercially available method (x) gave the following correlation (mMol/L):

y = 1.00x -0.70

r = 0.9937

Number of samples measured: 60

The concentrations of the samples were between 9.7 and 55.2 mMol/L.

Automation:

Special adaptations for automatic analyzers can be made on request. Precautions and warnings

References:

1. Tietz, N.n., et al “Textbook of clinical Chemistry” W. B. Saunders Co., 1986; 1172-1253.

2. Jacobs, N., et al “Laboratory test hand book” 2nd ed., Williams an Wilkins 1990.

3. Forrester, R.L., Wataji, L.J. Silverman, D.A., Pierre K.J, Clin Chem. 1976; 22/2: 243-245.

Order Information:

Ref./Cat. No.	Pack Size	Presentation
P-CDO - 10	10 ml	Two Liquid Reagents with Calibrator
P-CDO - 20	2 x 10 ml	
P-CDO - 40	4 x 10 ml	

Product Features

- Liquid Stable Mono Reagent
- Incorporates 5 th Generation NADHAnalogue
- Measuring wavelength 405 nm.
- Two Point Kinetic (Fixed Time) Assay : (20 Sec Delay+ 240 Sec Measuring)
- Linearity : 50 mMol/L

Symbols used with IVD devices

	Date of manufacture		Manufactured by
IVD	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)	R	Reagent
CAL	Calibrator Material	LOT	Batch code
2°C 8°C	Temperature limitation (store at)	CONTROL	Control
	Consult instructions for use		Keep dry Keep away from rain
REF	Catalog Number		

eIFU Indicator

Pariksha's world inside

SCAN TO EXPLORE MORE

Manufactured in India by :
Pariksha Biotech Pvt Ltd,
Plot no.1/B-14, SVICE,
Balanagar,
Hyderabad-500037
Telangana State

+91 7075706709

info@parikshabio.com

www.parikshabio.com

AN ISO 13485 Certified Company

Rev # 2