LiquiMAX Carbondioxide

PEP-PEPC Method

ORDER INFORMATION:

Ref. No.	Pack Size	Presentation
$AVCO_2$ - 10	10 ml	Mono Reagents with Calibrator
$AVCO_2$ - 20	2 x 10 ml	
$AVCO_2$ - 40	4 x 10 ml	

INTENDED USE:

LiquiMAX Carbondioxide is an in-vitro diagnostic kit for the quantitative determination of total carbon dioxide in human serum on both automated and manual systems.

PRODUCT FEATURES

Liquid Stable Mono Reagent

Incorporates 5 th Generation NADH Analogue

Measuring wavelength 405 nm.

Two Point Kinetic (Fixed Time) Assay : (20 Sec Delay + 240 Sec Measuring)

Linearity : 50 mMol/L

CLINICAL SIGNIFICANCE:

Elevated blood CO_2 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 CO_2 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 + HCO_3- ----------> Oxaloacetate + H_2PO4-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.

STORAGE AND STABILITY

All the reagents are stable up to the expiry date mentioned on the labels when the proper storage conditions are maintained.

KIT COMPONENTS

1. Carbon dioxide Reagent
2. Carbon dioxide Standard : Concentration as stated on the label

COMPOSITION

Ingredients	Concentration
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

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 1.8 at 405 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN COLLECTION AND STORAGE

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 CO_2 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
Linearity	:	50 mMol/L
High Normal	:	28 mMol/L

TEST PROCEDURE:

Reagent	Calibrator	Test
Reagent	1000 µL	1000 µL
Calibrator	10 µL	-
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

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

EXPECTED VALUES:

Adults: Arterial: (21-28)mMol/L;
Venous: (22-29)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 & CALIBRATION:

Co_2 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.

PERFORMANCE CHARACTERISTICS:

1. Linearity

Linearity : 50 mMol/L

2. Sensitivity/ Limit of Detection (LOD)

Detection limit: 0.2 mMol/L.

3. Interferences

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)

4. Precision:

Intra-Assay

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

Inter-Assay

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

5. Method Comparison:

Acomparison of the carbondioxide determination using the LiquiMAX 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.

LIMITATIONS

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.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

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.

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

Manufactured in India by :
AVECON Healthcare Pvt. Ltd.
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