todylaboratories®

Clinical Chemistry

CE IVD REF C23CC1095

Bicarbonate (CO_2) · Liquid Stable Instructions For Use

For in-vitro diagnostic use only.
Store at 2-8°C.

KIT CONTENTS

R1 CO_2 Reagent	10x5ml
R4 Standard	1x1ml

INTENDED USE

For quantitative determination of CO_2 from Serum.

TEST PRINCIPLE

The reaction of Phosphoenolpyruvate with HCO_3-
In the presence of Phosphoenolpyruvate carboxylase yields oxaloacetate which is used in the following reaction.

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

The absorbance is measured at 405 or 415 nm. The oxidation of NADH causes reduction in absorbance and is proportional to the serum/plasma bicarbonate concentration.

CLINICAL SIGNIFICANCE

Measurement of total CO_2 as part of an electrolyte profile is useful mainly in evaluation of HCO_3 – concentration in assessment of acid-base disorders such as respiratory acidosis and metabolic alkalosis.

REAGENT CONCENTRATION

R1 CO_2 Reagent	Tris Buffer	25 mmol/l
	PEP	6.0 mmol/l
	NADH	0.42 mmol/l
R4 Standard		30 mmol/l

REAGENT HANDLING AND PREPARATION

R1: Ready to use.
R4: Ready to use.
Unopened kit components: up to the expiry date at +2°C to +8°C
Onboard stability:
R1: 7 days opened and refrigerated.
Store protected from light after opening.
Calibration stability: 10 Days

SAMPLE

Serum: Collect serum using standard sampling tubes.
Plasma: Heparin (Li-, Na-, NH_4-) plasma.
EDTA, citrate and oxalate should not be used as anticoagulants, as they will affect results. Samples should be drawn on ice and analysed within 1 hour. Samples should be kept tightly closed, as CO2 will diffuse from the sample causing erroneous values .
The preferred specimen is from venous blood collected anaerobically as instructed above. Bicarbonate content in uncapped tubes decreases approximately 4 mmol/l after one hour. It has been reported that alkalinized serum stored in open cups is stable for up to four hours.
Storage of serum at -20°C or -80°C for up to 6 months had no significant effect.
Centrifuge samples containing precipitate before performing the assay.

STABILITY

2-4°C about 1 hour

TESTING PROCEDURE

Materials Provided:
- Working Solutions as described above

Additional Materials Required:
- Calibrators and controls as indicated below
- 0.9% NaCl

MANUAL PROCEDURE

Wavelength	Temperature	Cuvette	Zero adjustment
405 nm 415 nm	+37°C	1 cm light path	One Reagent Blank Per Series Only

Pipette into test tubes as follows:			
	Blank	**Sample**	**Standard**
R1 CO_2 Reagent	1 ml	1 ml	1 ml
Sample/Standard	-	10 µl	10 µl
Mix and incubate exactly 10 minutes at +37°C and read absorbance against reagent blank.			

CALCULATION

$$\frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \times \text{Standard concentration} = \text{Bicarbonate concentration (mmol/L)}$$

Conversion Factor: Bicarbonate (mmol/L = Bicarbonate (mEq/L)

SENSITIVITY

Analytical sensitivity (lower detection limit):
Detection limit: 1.12 mmol/l (1.12 mEq/l)
The detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying three standard deviations above that of the lowest Standard (standard 1 + 3 SD, within-run precision, n = 21).
Measuring/reportable range:
1.12 - 50 mmol/l (1.12 - 50 mEq/l)
Each laboratory should investigate the transfer ability of the expected values to its own patient population and if necessary determine its own reference ranges.

PRECISION

Reproducibility was determined using controls in an internal protocol. The following results were obtained:

Intra Assay – Within run			
Sample	**Mean mmol/l**	**SD mmol/l**	**CV %**
Sample 1	20.5	0.18	0.9
Sample 2	34.4	0.19	0.6

Inter Assay – Between Run			
Sample	**Mean mmol/l**	**SD mmol/l**	**CV %**
Sample 1	17.8	0.4	2.5
Sample 2	29.8	0.5	1.8

NORMAL VALUES

22-29 mmol/l (22-29 mEq/l)
Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

METHOD COMPARISON

A comparison of the bicarbonate determination using the Bicarbonate liquid stable assay on a AU 600 analyzer (y) with the former HCO_3- assay on the same analyzer (x) with 50 samples gave the following correlation (mmol/l):
y=1.01x-0.1486 ; r = 0.9863

USE ON AUTOMATED ANALYSERS

This reagent is suitable for use on a range of automated analysers. Specific instructions for these applications are available on request from our technical department.
For automated use we recommend a serum based calibrator to eliminate any matrix bias which may be observed with the aqueous standard.
CO_2 (Bicarbonate) Calibrator

LIMITATIONS – INTERFERENCE

Criterion: Recovery within ±10% of initial value.
Icterus: No significant interference up to an approximate conjugated and unconjugated bilirubin concentration of 50 mg/dl..
Haemolysis: No significant interference up to an approximate hemoglobin concentration of 40 mg/dl.
Lipaemia: No significant interference up to an approximate Triglyceride concentration of 1400 mg/dl..
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

QUALITY CONTROL

CO_2 (Bicarbonate) Control Low/ High
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

HEALTH & SAFETY

This kit is designed for use by suitably qualified laboratory personnel only. Exercise the normal precautions required for the handling of laboratory reagents. Do not ingest the material. Dispose of material according to local guidelines.

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REFERENCES

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SYMBOL INDEX

IVD	For In Vitro Diagnostics Use Only		Expiry Date (Year/Month)
LOT	Lot Number		Warning, Read Enclosed Documents
REF	Catalogue Number		Instructions For Use
	Storage Temperature		Manufactured By

Revision No.13 SEPT/16; St. 18.08.20

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