Bicarbonate Assay Kit (CO_2)

Method: PEPC Enzymatic

Cat .No.	Size	Instrument
GB460E	5×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GB460E/B	6×80 ml	
GS461E	5×20 ml	For Hitachi 917 & OlympusAU640/400/600
GS461E/B	8×60 ml	
GH461E	5×20 ml	Hitachi 902
GT461E	5×20 ml	For TOSHIBA 40
GX461E	1×100 ml	For SYNCHRON CX4-5-7-9/ LX20/DXC600-800

INTENDED USE

For the *in vitro* quantitative determination of CO_2 in serum or plasma.

CLINICAL SIGNIFICANCE[1]

Increased blood CO_2, (hypercapnia) causes respiratory acidosis. CO_2 rises with decreased alveolar ventilation due to diseases of the lungs or bronchial tree, or breathing CO_2 enriched air. Depression of the overall lung capacity by certain drugs may lead to retention of CO_2.

PRINCIPLE[2, 3]

$$\text{Phosphoenolpyruvate} + HCO_3^- \xrightarrow{\text{PEP-C+Mg}^{2+}} \text{oxaloacetate} + H_2PO_4^-$$

$$\text{oxaloacetate} + \text{NADH} + H^+ \xrightarrow{\text{MDH}} \text{malate} + NAD^+$$

The reduction in absorbance at 340 nm caused by the oxidation of NADH is proportional to the bicarbonate concentration in the sample.

SPECIMEN COLLECTION AND PREPARATION[4]

Serum or heparinized plasma may be used.

EDTA, citrate and oxalate should not be used as anticoagulants, as they will affect results. 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/hr).

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1 (R1)	
Tris Buffer	PH 7.5
PEP	12.5 mmol/L
NADH analog	0.6 mmol/L
MDH	>4100 U/L
PEPC	>400 U/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

Stable up to the expiry date when stored at 2-8℃. The reagent is stable for 28 days On-board the analyzer after opening and kept at 2-8℃.

ASSAY PROCEDURE

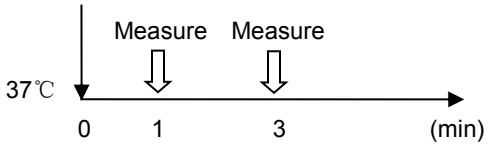
Test Procedure for Analyzers (HITACHI7170/917)

Assay Mode: 2 Point Rate, 4 - 10

Wave Length (main/sub): 405 nm/546 nm

Sample: 2 µl

R1: 200 µl



1. Mix 2 µl sample with 200 µl R1 and incubate at 37 ℃ for 1 minute.
2. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multi-sera Level 2 (Cat .No.HN 1530) and Level 3 (Cat .No. HE 1532).

CALCULATION

$$\text{Concentration} = \frac{\Delta A_{sample}/\text{min}}{\Delta A_{calibrator}/\text{min}} \times \text{Calibrator value}$$

CALIBRATION

Recommend that this assay should be calibrated using Gcell Calibrator (Cat .No. GC-CO_2).

QUALITY CONTROL

Use Gcell multi-control serum or Randox control serum. Values obtained should fall within a specified range. If these values fall outside the range and, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE[5]

Serum or plasma: Venous 22 - 29 mmol/L.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 50 mmol/L. Sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by

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CE version 10 APR 2017

dilution factor.

PRECISION

The CV of this test should be less than 10%.

Intra assay precision		
N=20	Level1	Level2
Mean	13.1	19.6
SD	0.24	0.19
CV	1.82%	0.96%
Inter assay precision		
N=5	Level1	Level2
Mean	16.2	19.0
SD	0.48	0.49
CV	2.98%	2.62%

SENSITIVITY

The minimum detectable level that can be distinguished from zero has been determined as 2 mmol/L.

INTERFERENCE

The main interference in this assay is CO_2 from the air or from the breath of the analyst. The assay is not affected by the following interfering substances at the indicated concentration:

Hemoglobin: 400 mg/dl
Direct bilirubin: 40 mg/dl
Intralipid: 1000 mg/dl
Ascorbic acid: 50 mg/dl

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 Handbook" 2nd. ed., Williams and Wilkins 1990.
3. Forrester, R.L., Wataji, L.J., Silverman, D.A., Pierre K.J., Clin, Chem. 1976; 22/2: 243-245.
4. Young D.S., Effects of Drugs on Chemical Laboratory Tests, 3rd ed., AACC Press 1990.
5. Norris, K.A., Atkinson, A.R., Smith, W.G., Clin. Chem. 1975; 21/8: 1093 - 1101.

INDEX OF SYMBOLS


Manufacture

Catalogue Number

Lot number

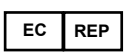

Date of manufacture


Use by(Expiration date)

For In-Vitro Diagnostic use only

Stored at 2-8℃


Attention:See instruction for use



Authorized Representative in the European Company

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