LIQUID CO_2-2 (LCO_2-2)

RX SERIES

INTENDED USE

For the quantitative *in vitro* determination of Carbon Dioxide in serum and plasma. This product is suitable for use on RX **series** instruments, which includes the RX **daytona** and the RX **imola**.

Cat. No.

CD 4006	R1.	Liquid CO_2 -2 Reagent	4 x 21.7 ml
	CAL	Liquid CO_2 -2 Calibrator	1 x 10 ml

GTIN: 05055273208375

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]

$$\text{Phosphoenolpyruvate} + HCO_3^- \xrightarrow{PEPC+Mg^{++}} \text{oxaloacetate} + H_2PO_4^-$$

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

The reduction in absorbance at 415 nm caused by the oxidation of NADH analogue is proportional to the bicarbonate concentration in the sample.

SPECIMEN COLLECTION AND PREPARATION[4]

Serum or heparinised plasma.

REAGENT COMPOSITION

Contents		Concentration in the Test
R1.	**Liquid CO_2-2 Reagent**	
	Phosphoenolpyruvate (PEP)	12.5 mmol/l
	NADH analogue	0.6 mmol/l
	Microbial Phosphoenolpyruvate Carboxylase (PEPC)	>400 U/l
	Mammalian Malate Dehydrogenase (MDH)	>4100 U/l
	Buffer	pH 7.6
	Sodium Azide	0.08%
CAL.	**Liquid CO_2-2 Calibrator**	See Lot Specific Insert

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solution R1 and calibrator contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water for 10 minutes. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Safety data sheets are available on request.

Please dispose of all biological and chemical materials according to local guidelines.

The reagent must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

R1 Liquid CO_2-2 Reagent

The reagent is stable to expiry date at +2°C to +8°C in its original sealed vial or for 14 days on board the analyser at approximately +10°C.

CAL Liquid CO_2 -2 Calibrator

Contents ready for use. Stable up to expiry date when stored at +2°C to +8°C.

MATERIALS PROVIDED

Liquid CO_2-2 Reagent.
Liquid CO_2-2 Calibrator

MATERIALS REQUIRED BUT NOT PROVIDED

0.9% NaCl solution for sample dilutions (if required).
Randox Assayed Multi-sera, Level 2, Cat. No. HN1530 and Level 3, Cat. No. HE1532.

PROCEDURE NOTES

1. Do not expose reagent to the air longer than necessary and store tightly capped.
2. Do not pipette by mouth.
3. Do not shake reagent vigorously as this may cause excessive CO_2 absorption.

Do not load reagents in positions 1 and 40 for RX **daytona**, or 1, 29 and 60 for RX **imola**.

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the bar code. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue contact Randox Laboratories Technical services, Northern Ireland +44 (0) 28 94451070.

CALIBRATION

We recommend Randox Liquid CO_2-2 Calibrator. A 2-point calibration is recommended every day, or with change of reagent lot/bottle or as indicated by quality control procedures.

The Randox Liquid CO_2-2 Calibrator is traceable to Sodium Carbonate NIST reference material 351.

QUALITY CONTROL

Randox Assayed Multi-sera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants, i.e. bacterial growth, may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

INTERFERING SUBSTANCES[4]

The main interference in this assay is CO_2 from the air or from the breath of the analyst. Some drugs and other substances are also known to influence blood CO_2 levels.
Haemoglobin up to a concentration of 1000 mg/dl does not affect the assay.
No conjugated bilirubin interference up to a concentration of 30 mg/dl.
No free bilirubin interference up to a concentration of 60 mg/dl.
No lipid interference (trigs and Intralipid) up to a concentration of 1200 mg/dl.
Values are based on two medical decision pools of concentrations 18 mmol/l and 30 mmol/l.

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [5]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES IN SERUM[6]

Adults:	Arterial	21 - 28 mmol/l
	Venous	22 - 29 mmol/l
Arterial:	New-born	17.2 - 23.6 mmol/l
	Infants	19.0 - 23.9 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

The following performance data was obtained using a RX **series** analyser at +37°C.

LINEARITY

The method is linear up to a concentration of 45 mmol/l. In the event of a rerun the linearity is extended to 420 mmol/l.

SENSITIVITY

The minimum detectable concentration of Total CO_2 with an acceptable level of precision was determined as 5 mmol/l.

PRECISION

Within run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	9.15	18.6	30.6
SD	0.53	0.56	0.67
CV(%)	5.8	3.0	2.2
n	44	44	44

Between run precision

	Level 1	Level 2	Level 3
Mean (mmol/l)	9.15	18.6	30.6
SD	0.68	0.93	1.45
CV(%)	7.4	5.0	4.7
n	44	44	44

CORRELATION

This method (Y) was compared with another commercially available CO_2 reagent on the Advia 1650 (X) and the following linear regression equation obtained:

Y = 1.06 x + 0.68
and a correlation coefficient of r = 0.98

45 patient samples were analysed spanning the range 9.30 to 42.57 mmol/l.

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. Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Washington, DC: AACC Press; 2000.
6. Norris, K.A., Atkinson, A.R., Smith, W.G., Clin. Chem. 1975; **21/8**: 1093 - 1101.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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