Bioway Chemistry Reagent Series
Carbon Dioxide Reagent Kit

Detection of Carbon Dioxide in Human Serum on Chemistry Analyzers

Cat. No. R021K11 ***Carbon Dioxide Reagent Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

Table 1: Instrument Parameters*

Calibration method	2-point linear	Slope of reaction	decrease
Wavelength	405nm	Sample volume	3 µl
Test method	2 point rate	R1 volume	300 µl
Reaction temperature	37℃		

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Carbon Dioxide Reagent Kit** (the Kit) is an enzymatic assay intended for *in vitro* quantitative detection of carbon dioxide in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Carbon Dioxide in serum exists primarily in the form of bicarbonate. The measurement of bicarbonate is useful in the assessment of acid-base balance. Elevated CO_2 can be a result of metabolic alkalosis and compensated respiratory acidosis. Low CO_2 is observed in compensated respiratory alkalosis and metabolic acidosis.

TEST PRINCIPLES

This kit is an enzymatic assay utilizing Phosphoenolpyruvate Carboxylase (PEPC) and a NADH analog method introduced by Wilson, Menson and Norris.

$$PEP + HCO^-_3 \xrightarrow{PEPC} Oxaloacetate + H_2PO^-_4$$

$$Oxaloacetate + NADH \xrightarrow{MDH} Malate + NAD$$

Bicarbonate ions reacts with phosphoenolpyruvate (PEP) to form oxaloacetate in the presence of phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) then catalyses the reduction of oxaloacetate to malate and the oxidation of NADH to NAD. The decrease in absorbance monitored at 405 nm is proportional to the amount of CO_2 in the sample.

MATERIALS PROVIDED

Reagent: PEP 6mM, Magnesium Ions 10mM analong, MDH 1200 U/L, PEPC 200 U/L, Buffer, pH 7.4 non-reactive stabilizers with surfactants and preservative.

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. Appropriate serum CO_2 calibrator and controls.

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. Reagent is stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

SPECIMEN COLLECTION AND HANDLING

It is recommended to use fresh, unhemolyzed serum collected under anaerobic conditions. The sample may be stored in ice water under anaerobic conditions for up to one hour.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: Use liquid CO_2 standard (30 mmol/L) pr an appropriate serum calibrator for 2 point linear calibration.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 3 µl of sample and 300 µl of R1; mix well and incubate at 37℃ for 180 seconds.
2. Take optical density measurement OD at 405 nm.

RESULT

$$\frac{\text{Abs. sample}}{\text{Abs. standard}} \times \text{Standard Conc. (mmol/L)} = CO_2 \text{ Conc. (mmol/L)}$$

EXPECTED VALUES

22 – 29 mmol/L

It is recommended for each laboratory to establish its own reference range.

QUALITY CONTROL

Using commercially available 2-level controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Carbon Dioxide contamination can cause inaccurate results and should be avoided. Keep reagent tightly capped when not in use.
3. Samples exceeding 50 mmol/L should be diluted with saline and retested.

4. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0 – 50 mmol/L (R≥0.990)

Precision: Within Run: CV≤8%;
Run-to-Run: CV≤15%

Interference: no interference detected for: Bilirubin (20 mg/dL), lipemia (1000 mg/dL), and hemoglobin (400 mg/dL). CO_2 from air and the breath o the analyst is a major interference in this assay. Reagent handling, specimen collection and storage instructions should be followed to minimize this interference.

Reagent Blank Absorbance: at 405nm wavelength and 10 mm optical diameter, O.D. ≤ 0.90

REFERENCES

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Not Intended for Sale in the United States.

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