

Interferences from icterus, lipemia, hemolysis, and ascorbic acid were evaluated for this carbon dioxide method on a Hitachi® 717 analyzer using a significance criterion of >10% variance from control. Data for plasma is similar to that present for serum.

Concentration of Analyte		Substance Tested	Concentration of Interferent Where Interference is Insignificant	
Conventional Units	SI Units			
30.8 mmol/L	30.8 mEq/L	Hemoglobin	1000 mg/dL	155 µmol/L
32.8 mmol/L	32.8 mEq/L	Ascorbic Acid	3000 µg/dL	170 µmol/L
32.9 mmol/L	32.9 mEq/L	Bilirubin	40 mg/dL	684 µmol/L
30.4 mmol/L	30.4 mEq/L	Intralipid	1000 mg/dL	3000 mg/dL (33.9 mmol/L) Simulated Triglycerides

The information presented above is based on results from Genzyme Diagnostics studies and is current at the date of publication.

A summary of the influence of drugs on clinical laboratory tests may be found by consulting Young, D.S.⁽⁴⁾

ANALYTICAL PROCEDURE

MATERIALS PROVIDED

Genzyme Diagnostics' Carbon Dioxide L3K®-C Reagent.

MATERIALS REQUIRED (BUT NOT PROVIDED)

- 1) Automated analyzer capable of adding a system diluent and capable of accurately measuring absorbance at appropriate wavelengths as per instrument application.
- 2) Calibration material.
- 3) Quality Control materials.

TEST CONDITION

For the data presented in this insert, studies using this reagent were performed on an automated analyzer using an endpoint test mode, with a sample to reagent ratio of 1:100, and a wavelength reading of 405 nm or 415 nm. For assistance with applications on automated analyzers within Canada and the U.S., please contact Genzyme Diagnostics Technical Services at (800)565-0265. Outside Canada and the U.S., please contact your local distributor.

CALIBRATION

Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used.

QUALITY CONTROL

A normal and abnormal concentration control should be analyzed as required in accordance with local, state and federal guidelines. The results should fall within the acceptable range as established by the laboratory.

CALCULATIONS

The analyzer automatically calculates the carbon dioxide concentration of each sample.

TEST LIMITATIONS

A sample with a carbon dioxide concentration exceeding the linearity limit should be diluted with 0.9% saline and reassayed incorporating the dilution factor in the calculation of the value.

REFERENCE INTERVALS

22-29 mmol/L (22-29 mEq/L)⁽⁵⁾

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

PERFORMANCE CHARACTERISTICS

Data presented was collected on Hitachi® 717 analyzer unless otherwise stated.

RESULTS

Carbon Dioxide concentration is reported as mmol/L (mEq/L).

REPORTABLE RANGE (CLSI EP6)⁽⁶⁾

The linearity of the procedure described is 50.0 mmol/L (mEq/L). The lower limit of detection of the procedure described is 1.0 mmol/L (mEq/L). This data results in a reportable range of 1.0-50.0 mmol/L (1.0-50.0 mEq/L).

PRECISION STUDIES (CLSI EP5)⁽⁶⁾

Precision estimates for serum were obtained using two concentrations of control sera. Plasma based precision materials were prepared in-house and spiked to appropriate levels.

Total precision was collected on two concentrations of control samples in 40 runs conducted over 20 days.

Carbon Dioxide	Concentration mmol/L (mEq/L)	Total SD	Total CV%
Serum 1	13.3	0.6	4.4
Serum 2	24.9	1.2	4.6

Within run precision data was collected on two concentrations of control samples, each run 20 times in a single assay.

Carbon Dioxide	Concentration mmol/L (mEq/L)	Within Run SD	Within Run CV%
Serum 1	13.3	0.2	1.2
Serum 2	24.9	0.3	1.3
Plasma 1	14.1	0.2	1.3
Plasma 2	22.5	0.4	1.9

ACCURACY (CLSI EP9)⁽⁶⁾

The performance of this method (y) was compared with the performance of another carbon dioxide method (x) on a Hitachi® 717 analyzer.

Forty-five serum samples ranging from 9.4 to 48.3 mmol/L (mEq/L) were tested and gave a correlation coefficient of 0.9944. Linear regression analysis gave the following equation:










$$\text{This method} = 1.014(\text{reference method}) + 0.50 \text{ mmol/L (mEq/L)}.$$

Fifty plasma samples ranging from 9.6 to 46.8 mmol/L (mEq/L) gave correlation coefficient of 0.9907. Linear regression analysis gave the following equation:

$$\text{This method} = 0.973(\text{reference method}) + 0.89 \text{ mmol/L (mEq/L)}.$$

REFERENCES

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3. US Patent #5,801,006
4. Young, D.S., *Effects of Drugs on Clinical Laboratory Tests*, AACC Press, Third Edition, Washington (1990).
5. Burtis, C.A., Ashwood, E.R.T. (Editors), *Tietz Textbook of Clinical Chemistry*, 3rd Edition, W.B. Saunders Company, Philadelphia (1999).
6. *CLSI Guidelines and Standards*, Clinical and Laboratory Standards Institute, Wayne, PA.

Definitions for Symbols	
	This product fulfills the requirements of the European Directive for In Vitro Diagnostic Medical Devices.
 LOT	Batch code
 Use by	YYYY-MM-DD or YYYY-MM
	Manufacturer
 REF	Catalog number
	Consult instructions for use
 EC REP	Authorized representative in the European Community
 IVD	In vitro diagnostic medical device
	Temperature limitation

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