DXC (CO2) CARBON DIOXIDE

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PURPOSE

To provide instructions for the quantitative determination of carbon dioxide on the DXC 600/800.

PRINCIPLE

ISE Electrolyte Buffer reagent, ISE Electrolyte Reference reagent, CO_2 Alkaline Buffer and CO_2 Acid Reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems AQUA CAL 1 and 3, are intended for the quantitative determination of Carbon Dioxide in human serum or plasma.

BACKGROUND

Clinical Significance

Carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.

Methodology

The SYNCHRON® System(s) determines total carbon dioxide using a pH rate of change method utilizing a glass carbon dioxide electrode in conjunction with a glass pH reference electrode.
The electrode measures the rate of change of the pH and compares it to the reference electrode.

Chemical Reaction

A CO_2 electrode is a glass pH electrode covered with a gas permeable silicone membrane, with a layer of bicarbonate solution in between. To measure CO_2 concentrations, a precise volume of sample (40 microliters) is mixed with a buffered solution. The ratio used is one part sample to 33 parts buffer. When this mixture is delivered into the flow cell, it is acidified with a fixed volume of CO_2 acid reagent which is delivered to the upper portion of the flow cell. All forms of carbon dioxide are converted to their gaseous form according to the following equation:

$$CO_2 + H_2CO_3 + HCO_3 + CO_3^{=} + RNHCOO + H^+ \longrightarrow CO_{2(g)} + H_2O$$

A portion of the liberated CO_2 gas diffuses through the silicone membrane and lowers the pH of the bicarbonate solution. The rate of pH change, measured by the glass pH electrode, is directly proportional to the carbon dioxide concentration in the solution.

For more accurate measurement, the reference reagent containing carbon dioxide is introduced into the flow cell after the sample cycle. The same reaction scheme and gas diffusion process take place. The ratio of the rate of pH change between sample and reference reagent cycles is used for the calculation.

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RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood or urine are not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

Sample Type	Volume	Sample Stability
Plasma (LiHeparin) Serum	0.5mL	• Separate serum from cells within 6 hours. • Room Temp 8 hours • Refrigerated 48 hours

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

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REAGENTS

Contents

Each kit contains the following items:
ISE ELECTROLYTE BUFFER REAGENT:
Two Electrolyte Buffer Reagent Bottles (2 x 2 L) Kit reorder #A28945
ISE ELECTROLYTE REFERENCE REAGENT:
Two Electrolyte Reference Reagent Bottles (2 x 2 L) Kit reorder #A28937
CO_2 ACID REAGENT:
Two Acid Reagent Bottles (2 x 2 L) Kit reorder #472481
CO_2 ALKALINE BUFFER REAGENT:
One CO_2 Alkaline Buffer Reagent Bottle (500 mL) Kit reorder #472515

Volume Per Test	
Sample	40uL
Reagents	
ISE Electrolyte Buffer	1.27mL
ISE Electrolyte Reference	3.23mL
CO2 Acid	2.53
CO2 Alkaline Buffer	---

Reactive Ingredients	
ISE Electrolyte Buffer Reagent	
Tris	230mmol/L
ISE Electrolyte Reference Reagent	
Sodium	7 mmol/L
Potassium	0.2 mmol/L
Chloride	5 mmol/L
Carbon Dioxide	1.5 mmol/L
Calcium	0.1 mmol/L
Acid Reagent	
Sulphuric Acid	0.17M
CO2 Alkaline Buffer Reagent	
Potassium Bicarbonate	6 mmol/L
Potassium Chloride	10 mmol/L
Also Non-Reactive Chemicals Necessary For Optimal System Performance	

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within acceptance criteria.

Reagent Storage and Stability

1. ISE Electrolyte Reference reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

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2. ISE Electrolyte Buffer reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

3. Acid Reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

4. CO_2 Alkaline Buffer reagent stored unopened at room temperature is stable until the expiration date printed on the bottle label. Once opened, the reagent is stable at room temperature for 30 days, unless the expiration date is exceeded.

5. For any electrolyte reagents frozen in transit, completely warm to room temperature and mix thoroughly by gently inverting bottle at least 20 times to redissolve salts into solution.

CALIBRATION

Calibrator Required

SYNCHRON® Systems AQUA CAL 1 and 3

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, SYNCHRON® Systems AQUA CAL 1 and 3 should be stored at +2°C to +8°C until the expiration date printed on the calibrator bottle. Once opened, calibrators stored at room temperature are stable for 30 days. Do not exceed the manufacturer's expiration date.

Calibration Information

1. The system must have a valid calibration in memory before controls or patient samples can be run.

2. Under typical operating conditions the CO_2 assay must be calibrated every 12 hours or with each new bottle of reagent and also with certain parts replacement or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

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QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

NOTICE: Do not use controls containing diethylamine HCl.

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested For In Vitro Interference	Average Plasma-Serum Bias (Mmol/L)
Ammonium Heparin	14 Units/mL	NSI
Lithium Heparin	14 Units/mL	NSI
Sodium Heparin	14 Units/mL	NSI
Potassium Oxalate/Sodium Fluoride	2.0 / 2.5 mg/mL	NSI

2. The following anticoagulant was found to be incompatible with this method:

Anticoagulant	Level Tested For In Vitro Interference	Average Plasma-Serum Bias (Mmol/L)
EDTA	1.8 mg/mL	- 4.19

PERFORMANCE CHARACTERISTICS

Age	Reference Range
0 Min - 11 days	13-22 mmol/L
11 days – 5 years	20-28 mmol/L
5 – 150 Years	22-31 mmol/L
Critical Low- all ages	<10 mmol/L
Critical High- all ages	>45 mmol/L

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For Critical Value reporting protocol, refer to FHS Critical Policy

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical ranges:

Sample Type	Conventional Units
Serum or Plasma	5.0 – 50.0 mmol/L

Reporting results outside of analytical range

Lower limit of detection	5 mmol/L	Results below 5, report as <5 mmol/L
Upper limit of detection	50 mmol/L	Results >50 should be diluted, a maximum of X2, using Nerl H20 and reanalyzed. Results greater than 100 are reported as >100 mmol/L.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for CO_2 determination is 5.0 mmol/L.

LIMITATIONS

None identified.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Interferences
Bilirubin (unconjugated)	Bovine	30 mg/dL INDEX of 20	NSI
Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	NSI
Lipemia	Intralipid	500 mg/dL INDEX of 9	NSI
Acetoacetic Acid	Lithium Acetoacetic Acid	125 mg/dL	+3 mmol/L
N-Acetyl Cysteine	NA	5 mmol/L	-3 mmol/L

2. Lipemic samples with visual turbidity >3+, or with a Lipemia Serum Index >10, should be ultracentrifuged and the analysis performed on the infranate.

3. Refer to References (9,10,11) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

REFERENCES

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