

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: k040975

B. Purpose For Submission:

Premarket Notification 510(k) for GenChem, Inc. intentions to manufacture and market the GenChem CO₂ Acid Reagent Kit.

C. Analyte: CO₂, Carbon Dioxide

D. Type of Test:

Quantitative, ISE

E. Applicant: GenChem, Inc.

F. Proprietary and Established Names:

GenChem, Inc., CO₂ Acid Reagent Kit

G. Regulatory Information:

Regulation section:

1. Regulation section:

21 CFR §862.1160 - Bicarbonate/carbon dioxide test system.

2. Classification:

Class II

3. Product Code:

JFL

4. Panel:

75 (Chemistry)

H. Intended use(s):

1. Intended use(s)

The GenChem CO₂ Acid Reagent when used in conjunction with the GenChem ISE Electrolyte Reference, GenChem Electrolyte Buffer, GenChem CO₂ Alkaline Buffer, GenChem Wash Concentrate, and appropriate Calibrators or Calibration Standards is intended for the quantitative determination of Carbon Dioxide in serum and plasma. Carbon Dioxide results are used in the diagnosis and treatment of numerous and potentially serious disorders associated with changes in the body's acid-base balance.

2. Indication(s) for use:

The GenChem CO₂ Acid Reagent when used in conjunction with the GenChem ISE Electrolyte Reference, GenChem Electrolyte Buffer, GenChem CO₂ Alkaline Buffer, GenChem Wash Concentrate, and appropriate Calibrators or Calibration Standards is intended for the quantitative determination of Carbon Dioxide in serum and plasma. Carbon Dioxide results are used in the diagnosis and treatment of numerous and potentially serious disorders associated with changes in the body's acid-base balance.

3. Special condition for use statement(s): For Prescription Use.

4. Special instrument Requirements: Beckman CX3 System.

I. Device Description:

The device is a solution containing 0.6 mol/L sulfuric acid, nonreactive surfactants and other ingredients necessary for optimum system operation on the Beckman SYNCHRON CX3 System.

J. Substantial Equivalence Information:

GenChem claims substantial equivalence to the Beckman CO₂ Reagent for the CX3.

1. Predicate device name(s): Beckman CO₂ Reagent for the CX3

2. Predicate K number(s): (k014034)

3. Comparison with Predicate:

| | | |
|--------------------|--|--|
| Device Name | GenChem CO ₂ Acid Reagent Kit | Predicate Device Beckman Carbon Dioxide |
| 510(k) Number | (k040975) | (k897183) (k014034) |
| Chemical Principle | Rate of pH change as CO ₂ ions diffuse across a membrane | Rate of pH change as CO ₂ ions diffuse across a membrane |
| Intended Use | For the quantitative determination of CO ₂ in serum or plasma | For the quantitative determination of CO ₂ in serum or plasma |
| Format | Liquid, ready to use | Liquid, ready to use |
| Composition | Sulfuric Acid and detergent | Sulfuric Acid and detergent |
| Linearity | 5.0-50.0 mmol/L | 5.0-50.0 mmol/L |
| Storage | 2-30 °C | 2-30 °C |

K. Standard/Guidance Document Referenced (if applicable):

Within-Day and Day-to-Day precision was determined according to NCCLS EP5-A.
 Linearity was performed according to NCCLS EP6-A Guideline.
 Analytical specificity Determined according to NCCLS EP7-A.

L. Test Principle:

Stow and Randall first reported the direct measurement of the partial pressure of carbon dioxide with the PCO₂ electrode in 1954. The electrode has since been made more sensitive.

Principles of Procedure

The sample is mixed with high ionic strength Electrolyte Buffer. This dilution minimizes variation of the activity coefficients of the analytes to be measured. Before the diluted sample exits the flow cell, it is mixed with acid causing the dissolved carbon dioxide to out gas. Some of this CO₂ gas transverses the silicon rubber membrane of the CO₂ electrode and lowers the ph of the Alkaline Buffer. The rate of this pH change is directly proportional to the original CO₂ concentration in the sample.

M. Performance Characteristics (if/when applicable):1. Analytical performance:

a. Precision/Reproducibility:

Three control sera were each assayed for total CO₂ twice per day in triplicate using flow cell reagents, wash solutions and calibrators on a SYNCHRON CX3 System. Data were collected on ten different days over a thirty day period

Precision of Total CO₂ Recoveries (mmol/L)

| Sample | Within Run | | Total Imprecision | | | |
|---------|------------|------|-------------------|-----|------|-----|
| | n | mean | SD | %CV | SD | %CV |
| Serum 1 | 60 | 12.6 | 0.40 | 3.2 | 0.38 | 3.0 |
| Serum 2 | 60 | 22.2 | 0.32 | 1.4 | 0.36 | 1.6 |
| Serum 3 | 60 | 30.9 | 0.53 | 1.7 | 0.66 | 2.1 |

b. Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards ranging from 0 to 40 mmol/L were analyzed in triplicate on the Beckman CX3 and the results analyzed by the Least Squares method. The results gave a slope of 1.000 with an intercept of 0.15, a standard error of estimate of 0.41 and $r^2 = 1.000$. Samples exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

| Instrument | Usable Ranges | |
|------------|--------------------|----------|
| | Conventional Units | SI Units |
| CX3 | 0.0 to 40.0 mmol/L | same |

c. Traceability (controls, calibrators, or method):

Beckman Calibration Standards 1 and 2 for the CX3 System

d. Detection limit:

The sensitivity of this method was investigated by assaying serum first with a known concentration and then diluting the sample until the minimum result was obtained and then run in replicates of 10 on the SYNCHRON CX3 System. Under the conditions described the limit of detection for this method was found to be 5 mmol/L.

| Analyte | Limit of Detection |
|-----------------|--------------------|
| CO ₂ | 5.0 mmol/L |

e. Analytical specificity:

Determined according to NCCLS EP7-A. Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with a glucose level of 19 mmol/L. Stock solutions of the substance to be tested were prepared at 20x concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Sodium

Heparin, Lithium Heparin, Ammonium Heparin, sodium fluoride and potassium oxalate are acceptable anticoagulants

f. Assay cut-off:

Not applicable for this type of device.

2. Comparison studies:

a. Method comparison with predicate device:

Serum and plasma specimens, collected from adult patients, were assayed for total CO₂ on a SYNCHRON CX3 System using GenChem (Y) and Beckman(X) flow cell reagents, wash solutions and calibrators. Results were compared by least squares linear regression and the following statistics were obtained.

| VALUE | SERUM | PLASMA |
|----------------------|------------|------------|
| Intercept | 1.2 | 1.0 |
| Slope | 0.949 | 0.979 |
| R ² Value | 0.953 | 0.987 |
| N | 80 | 80 |
| Range (mmol/L) | 9.5 – 29.1 | 9.6 – 30.0 |

b. Matrix Comparison

See above method comparison studies.

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The expected values for total CO₂ are listed below. Use these ranges only as guides. Each laboratory should establish its own normal ranges.

| <u>Specimens</u> | <u>Normal Ranges¹</u> | |
|------------------|----------------------------------|-----------------|
| | <u>Conventional Units</u> | <u>SI Units</u> |
| Serum/Plasma | 22 - 29 mmol/L | same |

¹. Burtis, C.A., Ashwood, E.R. (eds.). Tietz Textbook of Clinical Chemistry. W.B. Saunders Company. Philadelphia, PA. (1994).

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.