

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

A. 510(k) Number:

K033061

B. Analyte:

Sodium, potassium, chloride, calcium, carbon dioxide (CO₂)

C. Type of Test:

Instrument calibrator

D. Applicant:

Diamond Diagnostics / Mission Diagnostics

E. Proprietary and Established Names:

CO₂ Alkaline Buffer for Beckman Synchron CX[®] & CX[®] Delta Systems

CO₂ Acid Reagent for Beckman Synchron CX[®] & CX[®] Delta Systems

ISE Electrolyte Reference for Beckman Synchron CX[®] & CX[®] Delta Systems

F. Regulatory Information:

1. Regulation section:
21 CFR § 862.1150, Calibrator
2. Classification:
Class II
3. Product Code:
JIX, Calibrator, multi-analyte mixture
4. Panel:
Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

Mission CO₂ Acid Reagent is used to release CO₂ from samples on the Beckman Synchron CX[®] & CX[®] Delta.

Mission CO₂ Alkaline Buffer provides a constant CO₂ concentration as reference for the CO₂ electrode on the Beckman Synchron CX[®] & CX[®] Delta.

Mission Electrolyte Reference Reagent provides reference points for Na, K, Cl, Ca (on Delta's only) and TCO₂ for Beckman Synchron CX[®] & CX[®] Delta.

2. Special condition for use statement(s):

These reagents are intended to serve as direct replacements to like-named products of the original equipment manufacturer (OEM).

For use with the Synchron CX[®] & CX[®] Delta Systems.

For in vitro diagnostic use.

3. Special instrument Requirements:
The Synchron CX[®] & CX[®] Delta analyzers.

H. Device Description:

Three reagents make up the calibrating material: the CO₂ Alkaline buffer, the CO₂ Acid reagent, and the ISE Electrolyte Reference. These reagents are used to provide reference points for the listed analytes using the Beckman Synchron CX[®] & CX[®] Delta Systems.

The CO₂ Alkaline buffer (pH 8.8) contains 6 mmol/L potassium bicarbonate, 10 mmol/L potassium chloride, buffer, dye, surfactant, and preservative.

The CO₂ Acid reagent contains 6 mmol/L sulfuric acid and preservative.

The ISE Electrolyte Reference contains 140 mmol/L sodium, 4 mmol/L potassium, 100 mmol/L chloride, 10 mmol/L total CO₂, 2 mmol/L calcium, buffer, surfactant, and preservative.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Beckman PN 443320, 443330, 450214
2. Predicate K number(s):
K942676, K864236
3. Comparison with predicate:

These reagents are intended to be able to be used in place of the OEM reagents. The device and its predicate have the same intended use, composition, packaging quantities and dimensions, storage conditions, and shelf life.

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

K. Test Principle:

These reagents are for use in the calibration of the Synchron CX[®] & CX[®] Delta Systems. Please refer to the predicate submission for test principles.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. Precision/Reproducibility:

Total precision was measured on the CX® Delta analyzer. Samples were measured in triplicate 4 to 5 days in 2 to 5 runs per day. Results are summarized below (units = mmol/L):

Analyte	Level	N	Mean	SD	% CV
Sodium (Na⁺)	DControl 1	43	142.0	6.4	4.5
	DControl 2	38	155.7	6.9	4.4
	CSF 1	13	127.4	6	3.8
	CSF 2	12	159.9	5	4.9
	Urine 1	48	65.6	4.9	7.5
	Urine 2	44	208.2	7.9	3.8
Potassium (K⁺)	DControl 1	43	4.22	0.22	5.10
	DControl 2	45	8.10	0.37	4.59
	Urine 1	48	33.7	2.2	6.4
	Urine 2	45	108.4	6.1	5.6
Chloride (Cl⁻)	DControl 1	43	107	5	4
	DControl 2	38	118	5	4
	CSF 1	13	89	4	4
	CSF 2	12	105	3	3
	Urine 1	47	100	6	6
	Urine 2	47	256	10	4
Calcium (Ca⁺⁺)	DControl 1	31	2.51	0.08	3.06
	DControl 2	27	3.35	0.18	5.23
	Urine 1	29	1.57	0.14	8.97
	Urine 2	32	3.50	0.14	3.99
CO₂	DControl 1	40	14.8	0.7	4.4
	DControl 2	43	25.4	1.1	4.2

Within run precision was tested by running serum controls (or samples for calcium) in triplicate six times. Sodium, potassium, chloride, and CO₂ were tested on the CX®3 analyzer while calcium was tested on the CX® Delta analyzer. Results are summarized below (units = mmol/L):

Analyte	Level	N	Mean	SD	% CV
Sodium (Na⁺)	DControl 1	18	139.7	0.08	0.6
	DControl 2	18	154.1	1.03	0.7
Potassium (K⁺)	DControl 1	14	4.07	0.01	0.29
	DControl 2	12	7.36	0.03	0.42
Chloride (Cl⁻)	DControl 1	18	104	0.5	0.5
	DControl 2	18	118	0.8	0.7
CO₂	DControl 1	18	14.8	0.2	1.4
	DControl 2	18	26.5	0.3	1.3
Calcium (Ca⁺⁺)	Normal	18	2.42	0.06	2.5
	Low	18	1.96	0.06	3.1

	High	18	3.65	0.13	3.6
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b. Linearity/assay reportable range:

Not applicable.

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

Calibrators and reagents are prepared gravimetrically and traceable to the following standards (using the following methods):

Analyte	Standard Used for Determination of Analyte Value	Instrument Used
sodium & potassium	NIST	Flame Photometer
Calcium	NIST	Ion selective electrode (ISE)
chloride	OEM Calibrator	Ion selective electrode (ISE)
Total CO ₂	OEM Calibrator	TCO ₂ module

Reagents are tested prior to bottling, adjusted if necessary to meet specifications, tested during bottling process, and prior to release to stock for distribution.

Stability studies are summarized for the calibrators. Accelerated studies are being used by the sponsor to estimate the expiration date; however, on-going real time studies are being performed.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

The analyzer was calibrated using the Mission reagents and the predicate reagents, and samples were measured and compared to yield the following correlations:

CO₂:

- Range = 8 – 30.7 mmol/L, $y = 0.93x - 1.58$, $R^2 = 0.991$

Chloride:

- Range = 54 – 203 mmol/L, $y = 0.97x - 1.49$, $R^2 = 0.998$

Potassium:

- Range = 1.81 – 8.79 mmol/L, $y = 0.99x - 0.03$, $R^2 = 0.998$

Sodium:

- Range = 95.4 – 203.4 mmol/L, $y = 0.95x - 3.59$, $R^2 = 0.992$

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

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

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

M. Conclusion:

I recommend that the Mission Diagnostic CO₂ Alkaline Buffer for Beckman Synchron CX[®] & CX[®] Delta Systems, CO₂ Acid Reagent for Beckman Synchron CX[®] & CX[®] Delta Systems, ISE Electrolyte Reference for Beckman Synchron CX[®] & CX[®] Delta Systems are substantially equivalent to the legally marketed predicate device.