

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

**A. 510(k) Number:**

k033060

**B. Analyte:**

pH, PCO<sub>2</sub>, PO<sub>2</sub>, TCO<sub>2</sub>, Sodium, Potassium, Calcium, Chloride, Lithium, Glucose, Lactate, Creatinine, Urea, Hematocrit

**C. Type of Test:**

Calibrators

**D. Applicant:**

Diamond Diagnostics, Inc., Mission Diagnostics Division

**E. Proprietary and Established Names:**

See table below under Indications for Use (G,2) for proprietary names

**F. Regulatory Information:**

1. Regulation section:  
862.1150, Calibrator, secondary
2. Classification:  
Class II
3. Product Code:  
JIT
4. Panel:  
Chemistry (75)

**G. Intended Use:**

1. Intended use(s):  
These calibrators are intended to replace the original equipment manufacturer's calibrators. Refer to Indications for Use for details.
2. Indication(s) for use:  
The fifteen Mission Diagnostic calibrator solutions appear in the table below, along with their intended use.

PN	Product Name	Intended Use
AV-BP1579D	BG Calibrator	Provide a second calibration point for the pH and pCO <sub>2</sub> electrodes on the AVL Compact 1 pH/Blood Gas Analyzer.
CD-105670D	Hct Slope	Provide a second calibration point for the Hct sensor on the 348 Analyzer.
CD-471818D	634 Ca/pH Slope Standard	To provide a second calibration point for the Ca & pH electrodes on the 634 Ca/pH Analyzer.
CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	To provide a second calibration point for the Lithium electrode on the 654 Na/K/Li Analyzer.
CD-473692D	pH Blood Gas Slope	To provide a second calibration point for pH, pCO <sub>2</sub> , and pO <sub>2</sub> on 238 pH/Blood Gas Analyzer.
RD-944015D	Calibrating Solution 1, Btl# 9	To provide a calibration point for the Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944030D	Calibrating Solution 1, Btl# 3	To provide a calibration point for the Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , pH and glucose, lactate electrodes on Radiometer 605, 615, 625, EML 100 & 105 Analyzers.
RD-944031D	Calibrating Solution 2, Btl# 4	To provide a second calibration point for the Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , and pH electrodes on Radiometer 555 Analyzer.
BK-465908D	Calibrator 1	Used in conjunction with Calibrator 2 and 3 to calibrate Na, K, Cl, Ca, TCO <sub>2</sub> , Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465909D	Calibrator 2	Used in conjunction with Calibrator 1 and 3 to calibrate Na, K, Cl, Ca, TCO <sub>2</sub> , Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-465910D	Calibrator 3	Used in conjunction with Calibrator 1 and 2 to calibrate Na, K, Cl, Ca, TCO <sub>2</sub> , Glucose, BUN, & Creatinine on Beckman Synchron CX Delta, CX®CE, and CX9 ALX Systems.
BK-443360D	Calibration Standard 1	Used in conjunction with Calibration Standard 2 to calibrate Na, K, Cl, Ca, TCO <sub>2</sub> , Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BK-443365D	Calibration Standard 2	Used in conjunction with Calibration Standard 1 to calibrate Na, K, Cl, Ca, TCO <sub>2</sub> , Glucose, BUN, & Creatinine on Beckman Synchron CX3 and CX5 Systems.
BM-620427D	ISE Standard High	To provide a calibration point for Na <sup>+</sup> , K <sup>+</sup> and Cl <sup>-</sup> electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.
BM-620428D	ISE Standard Low	To provide a calibration point for Na <sup>+</sup> , K <sup>+</sup> and Cl <sup>-</sup> electrodes on the ISE module of Hitachi 7xx, 911, 912 and 917 Analyzers.

3. Special condition for use statement(s):  
The devices are for in vitro diagnostic use.  
The devices are for prescription use.

4. Special instrument Requirements:  
Not applicable.

#### H. Device Description:

The products are liquid, ready to use. They consist of salts added to deionized water and, as needed, tonometered gas.

#### I. Substantial Equivalence Information:

1. Predicate device name(s):

### Substantial Equivalence Table of Product PN's & Trade Names – Mission vs OEM

	Mission Diagnostics		OEM* Equivalent			
#			Predicate Device			Cleared Date
1	AV-BP1579D	BG Calibrator	BP1579	BG Calibrator	K943570	08-24-1994
2	CD-105670D	Hct Slope	105670	Hct Slope	K962021	06-24-1996
3	CD-471818D	634 Ca/pH Slope Standard	471818	634 Slope Standard 2.50 <sup>Ca</sup> /6.84 <sup>pH</sup>	K844188	11-23-1988
4	CD-473606D	654 Lithium Slope Solution 2.50 mmol/L	473606	654 Lithium Slope Solution 2.50 mmol/L	K884769	01-17-1989
5	CD-473692D	pH Blood Gas Slope	473692	pH Blood Gas Slope	K904188	09-27-1990
6	RD-944015D	Calibrating Solution 1, Btl# 9	944015	Calibrating Solution 1, Btl# 9	K954612	11-09-1995
7	RD-944030D	Calibrating Solution 1, Btl# 3	944030	Calibrating Solution 1, Btl# 3	K973367	10-06-1997
8	RD-944031D	Calibrating Solution 2, Btl# 4	944031	Calibrating Solution 2, Btl# 4		
9	BK-465908D	Calibrator 1	465908	Calibrator 1	K942676	11-02-1994
10	BK-465909D	Calibrator 2	465909	Calibrator 2		
11	BK-465910D	Calibrator 3	465910	Calibrator 3		
12	BK-443360D	Calibration Standard 1	443360	Calibration Standard 1	K864236	12-31-1986
13	BK-443365D	Calibration Standard 2	443365	Calibration Standard 2		
14	BM-620427D	ISE Standard High	620427	ISE Standard High	K811194	05-27-1981
15	BM-620428D	ISE Standard Low	624028	ISE Standard Low		

\* OEM = Original Equipment Manufacturer

2. Predicate K number(s):

See the table in section I, 1, above.

3. Comparison with predicate:

In all cases the sponsor states that the products are manufactured to the same specifications of the original equipment manufactured products, including the type of vial that holds the material. The devices are made by different manufacturers.

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

The sponsor did not reference any standard in this submission.

**K. Test Principle:**

Not applicable.

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

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

The appropriate salts (chemical constituents) are gravimetrically weighed and added to Type 1 deionized water to yield the desired calibration values. The calibrators are tonometered with the appropriate gas to yield the desired pH, pCO<sub>2</sub>, and pO<sub>2</sub> levels for each control.

**VALUE ASSIGNMENT:**

In general, manufactured calibrators are tested on 1-2 instruments within their facility to evaluate their recovery against the OEM calibrator material, or a previous Mission lot. A bias between the manufactured product and the calibrator is established and values are adjusted. Alternately, if NIST material is used, then values are normalized to that standard. Details of the calibrating materials and methods used are summarized below.

Na	NIST 919a NaCl, using the flame photometer
K	NIST 918a KCl, using the flame photometer
pH	BG Calibrator BP1579, pH/Blood Gas Slope 473692 calibrator, Radiometer Calibrating Sol. 1 Btl #3, Radiometer Calibrating Sol. 2 Btl #4, or previous Mission Lot BG Calibrator, using the Corning 278 and 288 analyzers (or equivalent)
pCO <sub>2</sub>	BG Calibrator BP1579, pH/Blood Gas Slope 473692 calibrator, or previous Mission Lot BG Calibrator, using the Corning 278 and 288 analyzers (or equivalent)
TCO <sub>2</sub>	Beckman Calibrator 3 465910, Beckman Calibration Standard 2 443365, or previous Mission calibrator, run on the CX3 or Delta system.
pO <sub>2</sub>	BG Calibrator BP1579, pH/Blood Gas Slope 473692 calibrator, or previous Mission Lot BG Calibrator, using the Corning 278 and 288 analyzers (or equivalent)
Ca	NIST 915a Ca <sub>2</sub> CO <sub>3</sub> , Corning 288 ISE Ca or 634 ISE Ca (or equivalent) or, depending on the calibrator the Beckman Calibrator 1 465908 or previous Mission calibrator on the CX3 or CX Delta System, or the Beckman Calibrator 2 465909 or previous Mission calibrator run on the CX3 or CX Delta analyzer
Cl	NIST 919a NaCl, run on Corning 664 ISE Cl or 925 Chloridometer or equivalent
Hct	Commercially available standards such as Thermo Orion 011007 1413 µS/cm & 011006 12.9 mS/cm, Hct Slope 105670, or previous Mission calibrator, or conductivity standards (that are not specified), testing performed on a

	conductivity meter and Corning 348 Analyzer (or equivalent)
Li	IL Standard 02221350, using a flame photometer
Lactate	Commercially available kit such as SIGMA 115A or Radiometer Calibrating Sol 1 Btl #9 (or #3, depending on the calibrator), or previous Mission calibrator, run by a manual assay.
Glucose	Commercially available kit such as SIGMA 826A, Radiometer Calibrating Sol. 1 Btl #9, or previous Mission calibrator, run by a manual assay, or, depending on the calibrator the Beckman Calibrator 1 465908, Beckman Calibration Standard 1 443360, or previous Mission calibrator on the CX3 or CX Delta System, or the Beckman Calibrator 2 465909 or previous Mission calibrator run on the CX3 or CX Delta analyzer
Creat	Beckman Calibrator 1 465908 or previous Mission calibrator on the CX3 or CX Delta System, or, depending on the calibrator the Beckman Calibrator 2 465909 or previous Mission calibrator run on the CX3 or CX Delta analyzer
BUN	Beckman Calibrator 1 465908 or previous Mission calibrator on the CX3 or CX Delta System, or, depending on the calibrator the Beckman Calibrator 2 465909, Beckman Calibration Standard 1 443360, or previous Mission calibrator run on the CX3 or CX Delta analyzer

Summaries of the value assignment procedures are as follows:

For Na, K, Cl, Ca, Li (and pH for some of the calibrators) representative samples from the lot (the number of samples is not specified) are run along with NIST standards in a single run. Three replicates of each sample are run on one instrument. Values are normalized to match the standard.

For Glucose, Lactate, BUN, Creatinine, TCO<sub>2</sub> (and Ca, depending on the calibrator) representative samples (the number is not specified) of the lot are tested in 1 run along with the calibrator. Samples are run in duplicate (or triplicate, depending on the calibrator) according to the assay's instructions. The means and SDs are calculated and normalized to the calibrator.

For pH, PCO<sub>2</sub>, and pO<sub>2</sub> the testing is done on 2 instruments. During the tonometry process, ampules are monitored every 5-7 minutes (or every 10-15 minutes depending on the calibrator) to ensure they remain within established limits; the pCO<sub>2</sub> mean value

of the replicate measurements is within 1 (or 1.5 depending on the calibrator) and the pO<sub>2</sub> is within 8 (or 7 depending on the calibrator) mm/Hg of the calibrating material. No limit is identified for pH.

For Hct, conductivity of the calibrator is measured in duplicate on a single conductivity meter. The mean of the duplicates is compared to specifications (which are not provided by the sponsor). If they pass, they are tested on the Corning 348 Analyzer. If the samples do not pass specifications (not provided) then the lot is adjusted and retested.

#### **STABILITY:**

Accelerated and real time stability studies are summarized for the calibrators. The sponsor specifies the concentrations of materials evaluated in the studies, the frequency of testing, the method for testing the materials, environmental conditions of storage, and acceptance criteria for the study. One lot of each product is evaluated in accelerated studies and 3 lots are evaluated in real time studies, then stability studies are not done again. Acceptance criteria when compared to time zero are:

Na	within 2.0 (or 1.0 depending on calibrator) mmol/L
K	within 0.05 (0.2 or 3.0, depending on the calibrator) mmol/L
Li	within 0.05 mmol/L
pH	within 0.005 (or 0.01 or 0.02 or 0.008 depending on the calibrator)
pCO <sub>2</sub>	within 3 (or 5 depending on the calibrator) mm/Hg
pO <sub>2</sub>	within 10 mm/Hg
TCO <sub>2</sub>	within 2 mmol/L
Hct	within 15 mS/cm
Ca	within 0.05 (or 0.03, 0.2 or 0.12 depending on the calibrator) mmol/L, or 0.8 mg/dL
Cl	within 3 (or 2 depending on the calibrator) mmol/L
Glucose	within 0.4 mmol/L (or within 3, 3.5 or 5 mg/dL depending on the calibrator)
Lactate	within 0.2 mmol/L
Creat	within 0.2 (1.0 or 2.0 depending on the calibrator) mg/dL
BUN	within 1.0 (2.0 or 3.0 depending on the calibrator) mg/dL

*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:*

Not applicable. The sponsor did, however, run a series of spiked serum samples and analyzed them using their calibrator and several of the OEM calibrators. The data appears in their 510k Summary.

*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:

Representative target concentrations for the calibrators have been provided.

**M. Conclusion:**

I recommend that this device be found substantially equivalent to the predicate device.