

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

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

k123321

**B. Purpose for Submission:**

New calibrator material

**C. Measurand:**

Ammonia, Carbon Dioxide (CO<sub>2</sub>), Ethyl Alcohol

**D. Type of Test:**

Not applicable.

**E. Applicant:**

Siemens Healthcare Diagnostics

**F. Proprietary and Established Names:**

Dimension Chemistry III Calibrator (CHEM III CAL)

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1150

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

75 (Clinical Chemistry)

## **H. Intended Use:**

1. Intended use(s):

Refer to Indications for Use.

2. Indication(s) for use:

The CHEM III CAL is an in vitro diagnostic product for the calibration of Ammonia (AMM), Carbon Dioxide (EC02) and Ethyl Alcohol (ETOH) assays on the Dimension® clinical chemistry system.

3. Special conditions for use statement(s):

None

4. Special instrument requirements:

Siemens Dimension RxL Max

## **I. Device Description:**

The Dimension® Chemistry III Calibrator (CHEM III CAL) is a multi-analyte, aqueous product containing ammonium bicarbonate, ethyl alcohol and sodium carbonate. It is packaged as a kit of six vials with two vials each of Levels 1, 2 and 3, containing 2.5 mL per vial. Level 1 is made by adding preservatives to purified water and is also the base for Levels 2 and 3. Levels 2 and 3 are prepared by adding the targeted quantities of ammonia, carbon dioxide, and ethyl alcohol to levels 2 and 3.

## **J. Substantial Equivalence Information:**

1. Predicate device name(s):

Dimension Vista® Chemistry 3 Calibrator (CHEM 3 CAL)

2. Predicate 510(k) number(s):

k062334

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended Use	Same	Calibration of ammonia, carbon dioxide, and ethyl alcohol assays
Preparation	Same	Liquid, ready to use
Storage	Same	2 – 8° C
Matrix	Same	Aqueous, containing ethyl alcohol, ammonium bicarbonate, and sodium bicarbonate
Traceability	Same	Ammonia - ASC Grade ammonium sulfate Carbon Dioxide – NIST SRM 351 Ethyl alcohol – USP grade ethyl alcohol

<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Number of calibrator levels	3	2
Levels for specific analytes	<p>Ammonia level 1: 0 µg/dL level 2: 707 µg/dL level 3: 1405 µg/dL</p> <p>CO2 level 1: 0 mmol/L level 2: 25 mmol/L level 3: 50 mmol/L</p> <p>Ethyl Alcohol level 1: 0 mg/dL level 2: 100 mg/dL level 3: 315 mg/dL</p>	<p>Ammonia Level 1: 17 µg/dL Level 2: 1804 µg/dL</p> <p>CO2 level 1: 0 mmol/L level 2: 47 mmol/L</p> <p>Ethyl Alcohol level 1: 0 mg/dL level 2: 308 mg/dL</p>

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

CLSI EP25-A

**L. Test Principle:**

Not applicable

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

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability:

The traceability of the three analytes in the Dimension Chemistry III Calibrator (CHEM III CAL) is as follows:

Ammonia – traceable to ACS Grade Ammonium Sulfate  
Carbon Dioxide (CO<sub>2</sub>) – traceable to NIST SRM 351  
Ethyl Alcohol – traceable to USP Grade Ethyl Alcohol

Value assignment:

Ammonia – the assigned values for ammonia are based on results from 3 instruments, 3 reagent lots, and 9 test runs. Each run generates 10 replicates per calibrator level resulting in 90 total replicates per level.

Carbon Dioxide - the assigned values for CO<sub>2</sub> are based on results from 3 instruments, 3 reagent lots, and 9 test runs. Each run generates 5 replicates per calibrator level resulting in 45 total replicates per level.

Ethyl Alcohol - the assigned values for alcohol are based on results from 3 instruments, 3 reagent lots, and 9 test runs. Each run generates 5 replicates per calibrator level resulting in 45 total replicates per level.

The labeling states that obtained values should fall within the specified range provided in the labeling and that laboratories should establish appropriate acceptance criteria when using this product for its intended use.

Stability:

Calibrator shelf life is determined in real-time. Protocols and acceptance

criteria were reviewed and determined to be acceptable. The testing supports the sponsor's claimed shelf life stability of 12 months when stored at 2-8°C.

Calibrator opened vial stability is determined in real-time. Protocols and acceptance criteria were reviewed and determined to be acceptable. The testing supports the sponsor's claimed opened vial stability of 30 days when stored at 2-8°C.

Storage recommendations are provided in the labeling.

*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

*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):*

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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