

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

A. 510(k) Number:

k062334

B. Purpose for Submission:

Notification of intent to manufacture and market a new device

C. Measurand:

Alcohol, Ammonia, Carbon Dioxide

D. Type of Test:

Calibrator

E. Applicant:

DADE BEHRING, INC.

F. Proprietary and Established Names:

Proprietary name – DADE Behring Dimension Vista™ Chemistry 3 Calibrator
Established Name - Calibrator

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX	Class II	21 CFR 862.1150	75, Chemistry

H. Intended Use:

1. Intended use(s):

The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC), ammonia (AMON), and carbon dioxide (CO2) methods on the Dimension Vista™ System.

2. Indication(s) for use:

The CHEM 3 CAL is an *in vitro* diagnostic product for the calibration of alcohol (ALC), ammonia (AMON) and carbon dioxide (CO2) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

None

4. Special instrument requirements:

None.

I. Device Description:

The DADE Behring Dimension Vista™ Chemistry 3 Calibrator is a multi-analyte, aqueous product containing ethyl alcohol, ammonium bicarbonate and sodium carbonate. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 2.5 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dade Behring Dimension Ammonia Calibrator, Dade Behring Dimension ECO2 Calibrator, and Dade Behring Dimension Alcohol Calibrator

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

K863840, k010208, and k904308 respectively

3. Comparison with predicate:

	New Device	Predicate	Predicate	Predicate
Item	DADE Behring Dimension Vista™ Chemistry 3 Calibrator	Dade Behring Dimension Ammonia Calibrator	Dade Behring Dimension Alcohol Calibrator	Dade Behring Dimension ECO2 Calibrator,

Intended Use	The CHEM 3 CAL is an <i>in vitro</i> diagnostic product for the calibration of alcohol (ALC), ammonia (AMON) and carbon dioxide (CO2) methods on the Dimension Vista™ System.	The Ammonia Calibrator is an <i>in vitro</i> diagnostic product for the calibration of ammonia (AMON) on the Dimension Clinical Chemistry System.	The Alcohol Calibrator is an <i>in vitro</i> diagnostic product for the calibration of Alcohol (ALC) on the Dimension Clinical Chemistry System.	The ECO2 Calibrator is an <i>in vitro</i> diagnostic product for the calibration of Enzymatic Carbonate (ECO2) on the Dimension Clinical Chemistry System.
Analytes	Alcohol (ALC), Ammonia (AMON) and Carbon Dioxide (CO2)	Ammonia	Alcohol	Carbon Dioxide
Form	Liquid	Liquid	Liquid	Liquid
Traceability	ALC - USP ¹ Grade Ethyl Alcohol ACS ² Grade AMON - Ammonium Sulfate CO2 - NIST SRM ³ 351	ACS ² - Ammonium Sulfate	ALC - USP ¹ Grade Ethyl Alcohol	CO2 -NIST SRM ³ 351
Matrix	Aqueous	Aqueous	Aqueous	Aqueous
Number of Levels	2	3	4	3

¹ United States Pharmacopeia

² American Chemical Society

³ National Institutes of Standards and Technology Standard Reference Material

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

STANDARDS
Title and Reference Number
Stability Testing of In Vitro Diagnostic Reagents (13640)
Medical devices - Application of risk management to medical devices (14971:2000)

Other Standards

GUIDANCE			
Document Title	Office	Division	Web Page
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD		http://www.fda.gov/cdrh/ode/calibrator.html
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			http://www.fda.gov/cdrh/ocd/guidance/4444.html

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):*

Assigned values are standardized to the materials in the table below:

Analyte	Reference Material
Alcohol	USP ¹ Grade Ethyl Alcohol
Ammonia	ACS ² Grade Ammonium Sulfate
Carbon Dioxide	NIST SRM ³ 351

¹ United States Pharmacopeia

² American Chemical Society

³ National Institutes of Standards and Technology Standard Reference Material

Reference materials are weighed into water and stored at appropriate

temperatures. Master Pool values are verified by comparing against previously approved Master Pool values. The stock solution is made by adding alcohol, ammonia and carbon dioxide reference materials gravimetrically to stock solution at target concentrations. The stock solution values are verified on an instrument calibrated with a previously approved Master Pool. The commercial lot is made by adding calculated quantities of stock solution to purified water in appropriate concentrations for each of the calibrator levels. The concentration of each level is verified by using an instrument calibrated with Master Pools. The final bottle values for each level of the commercial lot is assigned using multiple instruments by testing N = 45 replicates per level.

Stability:

Target shelf life for the Dimension Vista™ System Chemistry 3 Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change should be less than or equal to 5%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc. A vial punctured by the instrument and stored on board is stable for 24 hours. An open vial not on instrument, but recapped and stored in a refrigerator is stable for 30 days.

For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 1, 3, and 32 versus freshly opened vials.

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.

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