

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

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

k061923

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Calibrator materials for Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE)

**D. Type of Test:**

Not Applicable

**E. Applicant:**

Dade Behring, Inc.

**F. Proprietary and Established Names:**

Dimension Vista Enzyme 1 Calibrator, (KC310)

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
<u>Calibrator, Multi-Analyte Mixture (JIX)</u>	<u>Class II</u>	<u>21 CFR 862.1150, Calibrator.</u>	<u>75 Clinical Chemistry (CH)</u>

**H. Intended Use:**

1. Intended use(s):

See below indications(s) for use.

2. Indication(s) for use:

The ENZ 1 CAL is an *in vitro* diagnostic product for the calibration of Amylase (AMY), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LDH), Lipase (LIP), and Pseudocholinesterase (PCHE) methods on the Dimension Vista™ System

3. Special conditions for use statement(s):

For Prescription Use

4. Special instrument requirements:

Dimension Vista™ System

**I. Device Description:**

ENZ 1 CAL is a liquid, multi-analyte, bovine serum albumin based product containing amylase (human saliva), gamma-glutamyl transferase (bovine kidney), lactate dehydrogenase (chicken heart), lipase (porcine pancreas), and pseudocholinesterase (horse serum). 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:**

Item	Device	Predicate Devices				
		Chem I Calibrator K860021 (URCA-k862359)	Chemistry II Calibrator k861700	Cholesterol Calibrator k861700	Troxine Calibrator k862359	Thyroxine Uptake Calibrator k862359
Intended Use	The CHEM I CAL is an <i>in vitro</i> diagnostic product for the calibration of Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Tyronine Uptake (TU), Blood Urea Nitrogen (BUN) <sup>2</sup> and Uric Acid (URCA) methods on the Dimension Vista Systems.	The Dimension® Chemistry I Calibrator is an <i>in vitro</i> diagnostic product used to calibrate the Dimension® clinical chemistry system for the Calcium (CA), Creatinine (CREA), Glucose (GLU/GLUC), Lactic Acid (LA), Urea Nitrogen (BUN) and Uric Acid (URCA) methods.	Chem II Calibrator is an <i>in vitro</i> diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Magnesium (MG), phosphorus (PHOS) and Triglycerides (TRIG) methods.	The Dimension® Cholesterol Calibrator is an <i>in vitro</i> diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Cholesterol (CHOL) method.	The Dimension® Troxine Calibrator is an <i>in vitro</i> diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Thyroxine (T4) method.	The Dimension® Thyroxine Uptake Calibrator is an <i>in vitro</i> diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the Thyroxine Uptake method.

	Device	Predicate Devices				
Item	Dimension Vista™ System Chemistry 1 Calibrator	Chem I Calibrator K860021 (URCA-k862359)	Chemistry II Calibrator k861700	Cholesterol Calibrator k861700	Troxine Calibrator k862359	Thyroxine Uptake Calibrator k862359
Analytes	Calcium (CA), Cholesterol (CHOL), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Magnesium (MG), Thyroxine (T4), Thyronine Uptake (TU), Blood Urea Nitrogen (BUN) and Uric Acid (URCA)	Calcium (CA), Creatinine (CREA), Glucose (GLU), Lactic Acid (LA), Blood Urea Nitrogen (BUN) and Uric Acid (URCA)	Magnesium (MG)	Cholesterol (CHOL)	Thyroxin (T4)	Thyronine Uptake (TU)
Form	Liquid	Lyophilized	Liquid	Lyophilized	Lyophilized	Lyophilized
Trace-ability	Bun – NIST SRM 912 <sup>2</sup> , CA – Abell Kendall (CDC-NCEP), CREA-NIST SRM 914, GLU-NIST SRM 917, LA-Lactic Acid-lithium salt A-Grade, MG-NIST SRM 929A, T4-USP, TU-Calculated value, URCA-NIST SRM 913	BUN- NIST SRM 912, CA-NIST SRM 915, CREA-NIST SRM 915, CREA-NIST SRM 914, GLU-NIST SRM 917, LA- Lactic Acid- lithium salt A-Grade, URCA-NIST SRM 913	MG- NIST SRM 924A	CHOL-NIST SRM 911	T4-Thyroxine Master Pool	TU- Thyronine Uptake Master Pool
Matrix	Bovine serum albumin based product.	Bovine serum albumin based product.	Pure magnesium dissolved in a dilute solution of HCL, reagent grade potassium dihydrogen phosphate and reagent grade glycerol	Bovine serum albumin based product	Human serum base product	Human serum base product
Number of Levels	Two levels	Three levels	Three levels	Three levels	Five levels	Five levels

**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)

GUIDANCE			
Document Title	Office	Division	Web Page
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	OIVD		<a href="http://www.fda.gov/cdrh/ode/calibrator.html">http://www.fda.gov/cdrh/ode/calibrator.html</a>
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			<a href="http://www.fda.gov/cdrh/ocd/guidance/4444.html">http://www.fda.gov/cdrh/ocd/guidance/4444.html</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 assigned values of the Enzyme 1 Calibrator were verified on a Dimension® Vista™ System calibrated with an approved Master Pool. Master Pool values were assigned on multiple Dimension® clinical chemistry instruments. According to the sponsor the traceability of the assigned values of the Enzyme 1 Calibrator was standardized to the below table of assigned values.

Analyte	Reference System	Master Pool Levels
Amylase (AMY)	Dimension® clinical chemistry system	3
γ-Glutamyl Transferase (GGT)	Dimension® clinical chemistry system	3
Lactic Dehydrogenase (LDH)	Dimension® clinical chemistry system	3

Lipase (LIP)	Dimension® clinical chemistry system	4
Pseudocholesterase (PCHE)	Dimension® clinical chemistry system	3

Stability: The target shelf life for the Dimension Vista™ Chemistry I Calibrator is 12 months. The sponsor's shelf life was determined by comparing results of the product stored at 4°C with control stored at -20°C. 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 has a stability claim of one day.

An open vial not on instrument, but recapped and stored in a refrigerator has a stability claim of 30 days.

- 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):
- 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 equivalent decision.