

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

A. 510(k) Number:

k083462

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for lactate dehydrogenase

D. Type of Test:

Not applicable.

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Dimension Vista® System Enzyme 5 Calibrator (ENZ 5 CAL)

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1150 Calibrator
2. Classification:
Class II
3. Product code:
JIT, Calibrator, Secondary
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
The ENZ 5 CAL is an *in vitro* diagnostic product for the calibration of the lactate dehydrogenase (LDI) method on the Dimension Vista® System.
2. Indication(s) for use:
See Intended Use section above.
3. Special conditions for use statement(s):
For prescription use only
4. Special instrument requirements:
Dimension Vista® System

I. Device Description:

ENZ 5 CAL is a liquid, bovine serum albumin-based product containing lactate dehydrogenase from chicken heart. The calibrator consists of one level (Calibrator A), and comes packaged with three vials at 1.5 mL per vial. System water (the zero level calibrator) does not come packaged with the calibrator. The calibrator contains preservatives and stabilizers.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension® clinical system Enzyme I Calibrator

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

k081789

Comparison with predicate:

Similarities		
Item	Proposed Device	Predicate Device
Analyte	Lactate dehydrogenase.	same
Intended use	For the calibration of the lactate dehydrogenase (LDI) method on the Dimension Vista® System.	For the calibration of the lactate dehydrogenase (LDI) method on the Dimension® clinical chemistry system.
Matrix	Liquid bovine serum albumin base with lactate dehydrogenase of chicken liver origin.	same
Form	Liquid	same
Traceability	IFCC LD at 37 ° C primary reference method.	same

Differences		
Item	Proposed Device	Predicate Device
Packaging	One Level – Calibrator A	Two Levels – Level 2 and Level 3
Calibration Levels	Two Levels: System water is Level 1 Calibrator A is Level 2	Three Levels: Purified Water Diluent or reagent grade water is Level 1 Level 2 Calibrator Level 3 Calibrator

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

Guidance:

- Guidance for Industry – Abbreviated 510 (k) Submissions for In Vitro Diagnostic Calibrators; February 22, 1999

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 calibrator is traceable to the IFCC lactate dehydrogenase (LD) Reference Measurement Procedure

Value Assignment: The expected value of the commercial calibrator, Calibrator A, is assigned by measuring the recovery of the calibrator using three instruments (Dimension Vista® System) and three lactate dehydrogenase method (LDI) reagent lots. A previously assigned commercial lot is used as the control for the assignment for the new commercial lot.

Stability: Target shelf life for the Dimension Vista® ENZ 5 CAL is 12 months at 2-8°C. Shelf life is determined by comparing results of the product stored at 2-8°C with the control material stored at -20°C and -70°C. Shelf life is also tested following three freeze-thaw cycles and three different stress testing routines. Real time and freeze-thaw stability testing is on-going.

The open vial stability for the Dimension Vista® ENZ 5 CAL is 30 days at 2-8°C. The punctured vial stability of the Dimension Vista® ENZ 5 CAL is 7 days at 2-8°C.

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.