

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

A. 510(k) Number:

k081319

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator material for lipase

D. Type of Test:

Calibrator material for lipase

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

LIPL Calibrators

G. Regulatory Information:

1. Regulation section:
21 CFR § 862. 1150, Calibrator
2. Classification:
Class II
3. Product Code:
JIT
4. Panel:
Chemistry (75

H. Intended Use:

1. Intended use(s):

The LIPL Calibrator is an in vitro diagnostic product to be used to calibrate the Lipase (LIPL) method for the Dimension® clinical chemistry systems.

2. Indication(s) for use:

See intended use(s) above.

3. Special conditions for use statement(s):

Prescription Use Only

4. Special instrument requirements:

Dimension® clinical chemistry systems

I. Device Description:

The LIPL calibrator is a liquid bovine serum albumin-based product. The level 1 calibrator contains no detectable lipase. Levels 2 and 3 contain porcine pancreas lipase. The kit consists of six vials, two vials of Calibrator Level 1, two vials of Calibrator Level 2, and two vials of Calibrator Level 3 which are ready for use (no preparation is required). The volume per vial is 1.0 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista® System Enzyme 1 Calibrator

2. Predicate K number(s):

k061923

3. Comparison with predicate:

The Dimension® Clinical Chemistry System Lipase Calibrator (DC56) and the predicate device, the Dimension Vista® Enzyme 1 Calibrator were compared. The following table provides a comparison of the important similarities and differences between the device and the predicate:

	Device	Predicate Device
Item	Dimension® clinical chemistry system Liquid Lipase calibrator	Dimension Vista® System Enzyme 1 Calibrator
Intended Use	The LIPL Calibrator is an in vitro diagnostic product to be used to calibrate the Lipase (LIPL) method for the Dimension® clinical chemistry systems.	The Vista® System Enzyme 1 Calibrator is an <i>in vitro</i> 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.
Analytes	Lipase	Amylase, Gamma-Glutamyl Transferase, Lactate Dehydrogenase, Lipase, and Pseudocholinesterase
Form	Liquid	Liquid
Traceability	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.
Matrix	Bovine serum base with Lipase (porcine pancreas).	Bovine serum base with amylase (human saliva), GGT (bovine kidney), LDH (chicken heart), lipase (porcine pancreas), and PCHE (horse serum).
Number of Levels	Three (3) levels.	Two (2) levels.

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

ISO 14971:2007 Medical Device – Application of risk management to medical devices (General)

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 Dimension® LIPL Calibrators are traceable to Master Pool values, assigned on the Dimension® clinical chemistry system.

Master Pool level 1 of BSA base is assigned a value of 0 U/L. LIPL Master Pool bottle values levels 2 and 3 are assigned on multiple instruments calibrated with LIPL Anchor Pool. The LIPL Anchor Pool values are assigned using an external reference system (PBS/Precical®). A previous Master Pool lot is used as a control. Calibrators are prepared gravimetrically from porcine lipase. The concentration of each level is verified against Master Pool values.

Stability was assessed by comparing vials opened, quantities removed and stored at 2-8°C for designated time periods to freshly opened vials. The sponsor's acceptance criteria were change in value must be $\leq 5\%$ over the shelf life of the product and $\leq 5\%$ over the open vial period.

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:

The assigned values for each calibrator are provided on the vial.

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.