

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

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

k103836

**B. Purpose for Submission:**

New device

**C. Measurand:**

Calibrator materials for Alanine Aminotransferase (ALT1)

**D. Type of Test:**

Not Applicable

**E. Applicant:**

Siemens Healthcare Diagnostics, Inc.

**F. Proprietary and Established Names:**

Dimension<sup>®</sup> ENZ II Calibrator

**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):

See Indications for Use below.

2. Indications(s) for use:

The Enzyme II Calibrator is an in vitro diagnostic product for the calibration of Alanine Aminotransferase (ALT1) on the Dimension<sup>®</sup> clinical chemistry system.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Value assignment was provided for the Dimension RxL.

**I. Device Description:**

The Enzyme II Calibrator is liquid, ready to use bovine serum based product which is provided in three levels. Each level is packaged 1.5 mL/vial in a 2.0 mL vial. Each carton contains 2 vials of each level.

**J. Substantial Equivalence Information:**1. Predicate device name(s):

Dimension Vista<sup>®</sup> ENZ 2 CAL

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

k061390

3. Comparison with predicate:

<b>Reagent Similarities and Differences</b>		
	Candidate Device Dimension <sup>®</sup> ENZ II Calibrator (k103836)	Predicate Device Dimension Vista <sup>®</sup> ENZ 2 Calibrator (k061390)
Intended Use	An <i>in vitro</i> diagnostic product for calibration of the Alanine Aminotransferase method	same
Specimen Matrix	Liquid bovine serum albumin based	same

<b>Reagent Similarities and Differences</b>		
	<b>Candidate Device Dimension<sup>®</sup> ENZ II Calibrator (k103836)</b>	<b>Predicate Device Dimension Vista<sup>®</sup> ENZ 2 Calibrator (k061390)</b>
Analytes	ALT	ALT and AST
Assigned Constituents	Alanine aminotransferase from porcine heart	Aspartate aminotransferase and alanine aminotransferase from porcine heart
Packaging	Plastic vials containing 1.5 mL/vial. Each carton contains 2 vials of each level.	same
Levels	Level 1- 0U/L Level 2- 550 U/L Level 3- 1100 U/L	Level 1- 0 U/L Level 2- 1047 U/L
Traceability	ALT I traceable to the IFCC	ALT and AST traceable to Master pool, Dimension clinical chemistry system values
Storage	2 to 8°C	Same

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

None were referenced.

**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 values for the commercial Dimension ENZ II CAL Levels 1, 2, and 3 are assigned by creating an anchor pool from native human serum and using Gas Chromatography Mass Spectrometry by an IFCC reference laboratory yielding certified results (the zero level pool has a bovine serum albumin matrix). The Master Pools are made by spiking commercially purified ALT into the BSA calibrator base and each Master Pool level is assigned from anchor pool curves run on the Dimension Vista system. An ALT stock solution is created by spiking commercially purified ALT into a BSA base. The concentration is determined from a Dimension<sup>®</sup> instrument calibrated with Master Pool calibrators. The calculated quantities of ALT stock solution are added to levels 2 and 3 of the commercial calibrator; the zero calibrator is made of bovine serum albumin only. The concentration of the commercial calibrator is verified by measuring recovery on an instrument calibrated with ENZ II Master Pools. Each commercial lot is verified to be within acceptable ranges with an instrument calibrated with Master Pools. The final bottle values are assigned against the master pool curves using multiple instruments and reagent lots. The bottle value for each level is the mean of the replicates.

*Stability:*

The calibrators are tested for shelf life projections for a period of at least 12 months, stored at 4°C. The calibrators are tested at structured intervals against a portion of the same lot stored at -70°C. Open vial stability was determined by opening a vial at day 0 and withdrawing an amount of the calibrator and recapping the vial and storing at 2 to 8°C. The material in the vials was tested on day 8, 15, 22, and 31 versus freshly opened material. Once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored 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:

The following are target values for the proposed calibrator materials.

ENZ II ALT Calibrator DC143 ALT Method Range 0 to 1000 U/L			
Level	Target	Range U/L	Level Precision
1	0	< 6 U/L	< 6 U/L
2	550	475 to 600	$\leq 2\%$
3	1100	1000 - 1200	$\leq 2\%$

**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.