

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

A. 510(k) Number:

k103612

B. Purpose for Submission:

To include **ALTI** method of traceability and value assignment based on the IFCC method to the previously cleared Calibrator for Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST), k061390.

C. Measurand:

Calibrator for Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST).

D. Type of Test:

Not applicable.

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

Dimension Vista™ Enzyme 2 Calibrator (ENZ 2 CAL-KC321)

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX (Calibrator, Multi-Analyte Mixture)

4. Panel:

75 Clinical Chemistry (CH)

H. Intended Use:

1. Intended use(s):

See below indication(s) for use.

2. Indication(s) for use:

The ENZ 2CAL-KC321 is an in vitro diagnostic product for the calibration of the alanine aminotransferase (ALT and **ALTI**) and aspartate aminotransferase (AST) 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 2CAL-KC321 is a liquid, multi-analyte, bovine serum albumin based product containing alanine aminotransferase (ALT) and aspartate aminotransferase (AST) from porcine heart. It includes **ALTI** method of traceability and value assignment based on the IFCC method.

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 1.5 mL.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista® ENZ 2 CAL (KC320)

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

k061390

3. Comparison with predicate:

Similarities

Item	Device	Predicate
Indication for Use	Same	For calibration of Aspartate Aminotransferase and Alanine Aminotransferase methods on the Dimension Vista [®] System.
Form	Same	liquid, bovine serum albumin based
Constituents	Same	aspartate aminotransferase and alanine aminotransferase from porcine heart
Traceability of Constituents	Same	ALT and AST traceable to Master pool, Dimension [®] clinical chemistry system values
Packaging	Same	ENZ 2 CAL is packaged in glass vials containing 1.5 mL/vial. Each carton contains 3 vials of each level.
Levels	Same	2
Stability and Storage	Same	ENZ 2 CAL is stored at 2 to 8° C

Differences		
Item	Device	Predicate
Traceability of Constituents	ALTI is traceable to the IFCC ALT@ 37°C primary reference method.	ALTI is not available

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: **ALTI** is traceable to the IFCC ALT@ 37°C primary reference method. The ALT and AST methods uses the older traceability and value assignment methods cleared under k061390 as ENZ 2CAL-KC320.

Value Assignment: For use with the Vista[®] Alanine Aminotransferase (**ALTI**) method, the bottle value assignment for **ALTI** in the Vista[®] ENZ 2 Calibrator (KC321) is accomplished using an anchor pool, traceable to the IFCC reference method, and then, a master pool assigned based on the anchor pool using the Dimension Vista[®] System. The bottle value assignment for ALT and AST methods uses the older traceability and value assignment methods cleared under k061390 as ENZ 2CAL-KC320.

Stability: Calibrator shelf life for the Dimension Vista[™] Enzyme 2 Calibrator was determined to be 12 months using the Dimension Vista System in a real time study. A vial that has been punctured (opened) by the instrument and stored on board has a seven day stability claim. Once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2 - 8°C. Stability study protocols and acceptance criteria were described and found to be acceptable.

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.