

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

A. 510(k) Number:

k081789

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for lactate dehydrogenase

D. Type of Test:

Calibrator material

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

ENZ I CAL

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150 Calibrator, secondary

2. Classification:

Class II

3. Product code:

JIT

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The ENZ I CAL is an in vitro diagnostic product for the calibration of the LDI method on the Dimension® clinical chemistry system.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dimension ® clinical chemistry system

I. Device Description:

The ENZ I CAL is a liquid bovine serum albumin based product containing lactate dehydrogenase (chicken heart). The liquid calibrator is packaged with 4 vials per carton; 2 vials of Level 2 and 2 vials of Level 3. Purified Water Diluent or reagent grade water is used as the Level 1 calibrator. The ENZ I CAL is used for the calibration of the Dimension® clinical chemistry system Lactate Dehydrogenase Flex® reagent cartridge (LDI).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Calibrator for Automated Systems

2. Predicate K number(s):

k990460

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Traceability	IFCC	same

Differences		
Item	Device	Predicate
Form	Liquid, ready to use	lyophilized
Matrix	Bovine serum albumin containing lactate dehydrogenase (chicken heart)	Human based containing lactate dehydrogenase (porcine heart)

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

None 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 and value assignment involves preparation of anchor pools and master pools. The anchor pool is prepared from pooled normal and high human serum and is assigned by the IFCC Reference Method. LD enzyme is weighed into BSA based matrix to make (LDI)stock solution. Three levels of LDI master pools are manufactured by adding the appropriate volume of LDI stock, with a known concentration into an aqueous BSA base material. Level 1 of the LDI master pool, containing no analyte is assigned zero U/L. Levels 2 and 3 of the LDI master pool are assigned by the IFCC reference method and verified against the anchor pools using multiple Dimension instruments

Stability: ENZ I CAL is supplied as a ready to use liquid. Target shelf life for the ENZ I CAL is 12 months when stored at 2-8° C. The shelf life and open stability of the calibrator have been demonstrated using real time data. 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. Recovery vs. time is monitored and percent change over time is determined with allowable drift (control vs. test): Level 2 and 3: $\leq 5\%$. Once the cap is removed, the assigned values are stable for 30 days when recapped immediately 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:

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.