

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

A. 510(k) Number:

k082680

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for N-terminal-pro-brain natriuretic peptide

D. Type of Test:

Calibrator material

E. Applicant:

Siemens Healthcare Diagnostics Inc.

F. Proprietary and Established Names:

LOCI NTP 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 LOCI NTP CAL is an in vitro diagnostic product for the calibration of the N-terminal pro-brain natriuretic peptide methods on the Dimension® EXL integrated chemistry system with LOCI® Module.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dimension ® EXL integrated chemistry system with LOCI® Module

I. Device Description:

The LOCI NTP CAL is a frozen liquid product containing synthetic human N-terminal peptide in bovine albumin matrix with stabilizers and preservative. The kit consists of ten vials, two vials per level (1, 2, 3, 4 and 5), 1.0 mL per vial.

The calibrator contains human source material. Each donor unit used in the preparation of this product was tested by FDA-approved methods for the presence of antibodies to Human immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2), and found to be negative (not repeatedly reactive).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista® PBNP Calibrator

2. Predicate K number(s):

k080578

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analyte	Synthetic PBNP	Synthetic PBNP
Matrix	Bovine albumin	Bovine albumin
Form	Liquid, frozen	Liquid, frozen

Differences		
Item	Device	Predicate
Instrument	Dimension ® EXL integrated chemistry system with LOCI® Module	Dimension Vista®

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):

The LOCI NTP CAL is a liquid product packaged as ten vials, two vials at each of five levels, to be stored at -20 ° C. The artificial matrix is BSA based spiked with synthetic NT-proBNP peptide. The master pool is a multi-level

liquid BSA-based artificial matrix spiked with synthetic NT-proBNP peptide stored at -70 °C. Values are assigned to each lot of calibrator from the master pool using the Dimension® EXL NTP method. Values are assigned to the master pool from the patient sample anchor pool which has been assigned on the Elecsys PBNP assay to which the Dimension® EXL NTP method is traceable.

The LOCI NTP CAL is stored at -20 to -10 °C and is stable until the expiration date. Thawed unopened product is stable for 30 days at 2-8 °C. Once the vial is opened, assigned values are stable for 30 days when recapped immediately after use and 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 -20 °C with the control material stored at -70 °C. Open vial stability is determined by comparing results of vials thawed, opened and recapped stored at 4 °C up to 31 days with the control material and test material stored at -70 °C and -20 °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:

Values for the calibrator materials are provided on the labels.

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.