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

A. 510(k) Number:

k110169

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and Quality control material for Carbohydrate-Deficient Transferrin (CDT)

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics

F. Proprietary and Established Names:

Dimension Vista® CDT CAL

Dimension Vista® CDT CON L

Dimension Vista® CDT CON H

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIS	Class II	21 CFR 862.1150	Clinical Chemistry (75)
JJX	Class I, reserved	21 CFR 862.1660	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

Dimension Vista® CDT CAL

CDT CAL is an *in vitro* diagnostic product for the calibration of the carbohydrate-deficient transferring (CDT) method on the Dimension Vista® System.

Dimension Vista® CDT CON L

CDT CON L is an assayed, low level, intra-laboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferrin (CDT)

Dimension Vista® CDT CON H

CDT CON H is an assayed, high level, intra-laboratory quality control for the assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of carbohydrate-deficient transferring (CDT).

3. Special conditions for use statement(s):

For Prescription Use only

4. Special instrument requirements:

Dimension Vista® 1500 System

I. Device Description:

Dimension Vista® CDT CAL

CDT CAL is a liquid human serum based product containing carbohydrate-deficient transferring. CDT CAL is packed in 4 vials containing 2.0 ml calibrator material per vial.

Dimension Vista® CDT CON L and CON H

CDT CON L and CON H are liquid human serum based products containing human carbohydrate-deficient transferrin. CDT CON L and CDT CON H are packaged in 4 vials containing 2.0 ml quality control material per vial.
All human source materials were tested and found to be negative for HIV ½, HBsAg, and HCV by FDA- approved methods.

J. Substantial Equivalence Information:

1. Predicate device name(s)

N Latex CDT Kit with calibrator and control materials

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

   k060677

3. Comparison with predicate:

Similarities and Differences		
Item	Dimension Vista ®CDT CAL Candidate Device	N Latex CDT Calibrator Predicate Device (k060677)
Intended Use	For the calibration of the carbohydrate-deficient (CDT) method	Same
Composition	Liquid human serum based product containing carbohydrate-deficient transferring.	Same
Shelf-Life	24 months	Same
Storage Temperature	2-8˚C	Same
Form	Liquid, ready to use	Same
Instrumentation	Dimension Vista® 1500 System	Dimension BN™II and BN ProSpec System

Similarities and Differences		
Item	Dimension Vista ®CDT CON Candidate Device	N Latex CDT Control Predicate Device (k060677)
Intended Use	For *in vitro* diagnostic use as an assayed quality control material to monitor the precision of laboratory testing procedures for the CDT method	Same
Composition	Liquid human serum based product containing human carbohydrate-deficient transferring.	Same
Shelf-life	24 months	Same
Storage Temperature	2-8˚C	Same
Form	Liquid, ready to use	Same
Instrumentation	Dimension Vista® 1500 System	Dimension BN™II and BN ProSpec System

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

EP-5A2 Evaluation of Precision Performance of Quantitative Measurement Methods

Guidance for Industry and FDA Staff-Assayed and Unassayed Quality Control Material

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 Dimension Vista CDT controls and calibrator are traceable to an internally produced master calibrator which is calibrated against a highly purified in-house protein preparation.

Stability

Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Stability characteristics of the Dimension CDT controls and calibrators were determined using real-time stability studies. The Dimension CDT controls and calibrators are stable until the expiration date printed on the vial when stored unopened at 2-8˚C. Open vial stability is 14 days when stored on the Dimension Vista system. Storage recommendations are provided in the labeling.

Value Assignment

Three vials of each single level calibrator and control are analyzed in quadruplicate. The target value of the Dimension Vista CDT controls and calibrator is the median of the observed values which are obtained during multiple runs on the Dimension Vista 1500 analyzer. The expected ranges for the controls are ±20% of the target value. The expected values are provided in the labeling for each specific lot.

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 labeling for the control materials states that the values provided are intended only as a guideline. Each laboratory should determine its own individual values. A typical control value for the Vista CDT L control is 64 mg/L. A typical control value for the Vista CDT H control is 167 mg/L.

The lot specific value for the calibrator material is stated in the labeling. The target range is 299 mg/L – 365 mg/L.

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.