

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

A. 510(k) Number:

k093645

B. Purpose for Submission:

New device

C. Measurand:

Calibrator materials for vitamin B12, folate, and ferritin

D. Type of Test:

Not applicable

E. Applicant:

Siemens Healthcare Diagnostics, Inc

F. Proprietary and Established Names:

Dimension EXL Anemia Calibrator

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX	Class II	21CFR§862.1150	Chemistry 75

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The ANEMIA CAL is an *in vitro* diagnostic product for the calibration of the LOCI Vitamin B12 (B12) and LOCI Folate (FOL) methods on the Dimension® EXL™

integrated chemistry system and the Ferritin (FERR) method on the Dimension® clinical chemistry system.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Dimension® EXL™

I. Device Description:

Dimension EXL™ Anemia Calibrator is a multi-analyte, liquid, frozen bovine serum albumin based product containing ferritin from human liver, Vitamin B12 and Folate. The kit consists of ten vials, two each of five levels containing 2.0 mL per vial for Level A, B, C, D, & E.

All human source materials used to produce this product have been tested for HbsAg, anti-HCV, HIV-1 and HIV-2 and found to be non-reactive by FDA licensed tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista® LOCI 4 Calibrator

2. Predicate 510(k) number(s)

k071224

3. Comparison with predicate:

Similarities		
	Candidate Device	Predicate Device (k071224)
Item	Dimension Anemia Calibrator	Dimension Vista® LOCI 4 calibrator k071224
Intended Use	EXL ANEM CAL is an <i>in vitro</i> diagnostic product for the calibration of the Ferritin (FERR), LOCI Vitamin B12 (B12), and LOCI Folate (FOL) methods on the Dimension EXL™ integrated chemistry system.	LOCI 4 CAL is an <i>in vitro</i> diagnostic product for calibration of the Ferritin (FERR), Vitamin B12 (B12) and Folate (FOL) methods on the Dimension Vista® System.
Form	frozen liquid, bovine serum	frozen liquid, bovine serum

	albumin	albumin
Levels	5	5
Stability and storage	ANEMIA CAL is stored at -25 to -15° C. ANEMIA CAL is stable, thawed and unopened for 30 days @ 2-8°C	LOCI 4 CAL is stored at -20 to -10°C. LOCI 4 CAL is stable, thawed and unopened for 30 days @ 2-8°C

Differences		
	Candidate Device	Predicate Device (k071224)
Name of the device	Dimension Anemia Calibrator	Dimension Vista® LOCI 4 calibrator
Instrumentation	ANEMIA CAL is for use on the Dimension® EXL™ integrated chemistry system.	LOCI 4 Cal is for use on the Dimension Vista® System.

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):

United States Pharmacopoeia (USP) grade B12 and Folate in a B12/Folate depleted human serum matrix are used to make anchor pools. The Ferritin Master Pool bottle values are traceable to an anchor pool prepared from WHO IS 94/572. The concentrations are verified by testing patient samples with values across the method's

assay range.

Standard values are assigned to a master calibrator lot using USP grade B12 and Folate into a bovine serum albumin matrix. Values are then assigned to the commercial calibrator (bovine serum albumin matrix at target concentration) versus master calibrator using chemistry analyzers calibrated with the master pool. Each level is tested on multiple analyzers multiple times. Acceptance criteria and protocol for assigning the value were provided and found to be acceptable.

The sponsor provided protocols and acceptance criteria to establish the stability of the product, closed and open vial. Un-open calibrators stored frozen at -25 to -15°C are stable for 12 months. Un-open thawed calibrators stored at 2-8°C are stable for 30 days. Open vial stability is 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:

An example of the lot specific target values are as follows:

Level	Target
B12	pg/mL
1	0
2	200
3	500
4	1000
5	2100
Folate	ng/mL
1	0
2	2.5
3	5.0
4	10.0
5	21.0
Ferritin	ng/mL
1	0
2	27
3	156
4	510
5	1080

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.