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

A. 510(k) Number:

k061251

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for total iron binding capacity

D. Type of Test:

Not Applicable

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1150

2. Classification:

   Class II

3. Product code:

   JIS

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   The TIBC CAL is an *in vitro* diagnostic product for the calibration of Total Iron Binding Capacity (TIBC) method on the Dimension Vista™ System.

2. Indication(s) for use:

   The Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator is intended for use in the calibration of the TIBC method 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:

The Dimension Vista™ Total Iron Binding Capacity (TIBC) Calibrator is a liquid, bovine albumin based product containing human transferrin. The kit consists of three vials, each containing 1.0 mL. The zero level calibrator is system water provided on board the instrument.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® IBCT Calibrator

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

   k994114

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Indications for Use	Calibration of total iron binding capacity method	Same

Similarities		
Item	Device	Predicate
Analyte	Human transferrin	Same
Matrix	Bovine Albumin	Same

Differences		
Item	Device	Predicate
Levels	One	Three
Instrument	Dimension Vista™ System	Dimension® Clinical Chemistry System

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

National Institute of Standards and Technology (NIST) Iron Standard – SRM937

L. Test Principle:

Refer to the calibration procedure is in the Calibration section of the Operator's Guide for the Dimension Vista™ System.

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 Primary Standards are traceable to NIST reference material (SRM937).

TIBC calibrator is prepared in a bovine albumin base matrix. A calculated quantity of human transferrin is added to the base material using standard gravimetric procedures. The concentration is verified to be within acceptable ranges using an instrument calibrated with Primary Standards. The values are assigned to each lot using multiple reagent lots on multiple instruments.

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), as well as for Hepatitis B Surface Antigen (HBsAg) and antibody to Hepatitis C Virus (HCV), and found to be negative (not repeatedly reactive).

Several studies are conducted to support product stability:

For shelf life testing, product is stored at 4ºC throughout the testing cycle and tested on days 0, 3, 7, 35, 98, 189, 280, 325, 371, 462, 553, 664, and 735. Identical lot of calibrator product stored at -20ºC and tested at the same frequency.

For freeze – thaw testing, the product is frozen and thawed three times over three days and then stored at 4ºC. Testing occurs over a 13 month period.

For stress testing, the product is first stored at 30ºC for 36 hours, 35ºC for 12 hours, and then 45ºC for 4 hours. Next, the product is stored at 25ºC for 48 hours, then 30ºC for 6 hours. Lastly, the product is stored at 15ºC for 54 hours. After storage at these three conditions, the calibrators are stored at 4ºC and tested over a 24.5 month period.

For open vial stability testing, vials are opened/punctured on day zero. A portion for multiple calibrations is removed and the vials are recapped and stored at 2-8ºC. Opened/punctured vials are tested on days 1, 8, 15, 22, 32 vs. freshly opened vials.

The 4ºC material values are recovered vs. the calibrations. Recovery vs. time is monitored and percent change over time is determined.

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.