

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

A. 510(k) Number:

k060266

B. Purpose for Submission:

Clearance of a new calibrator

C. Measurand:

Total Iron

D. Type of Test:

Not applicable.

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension® IRON Calibrator (IRON Cal-DC85)

G. Regulatory Information:

1. Regulation section:
§862.1150, Calibrator, Primary
2. Classification:
Class II
3. Product code:
JIS
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See "Indication(s) for use" below.
2. Indication(s) for use:
The IRON Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the IRON method for 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 IRON calibrator is an aqueous solution of iron wire dissolved in a dilute solution of HCl. The kit consists of 6 ampules, two at each of three levels.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dimension® IRN/TIBC Calibrator (DC21)
2. Predicate 510(k) number(s):
k944093
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	<i>In vitro</i> diagnostic devices for calibrating iron assays	<i>In vitro</i> diagnostic devices for calibrating iron assays
Matrix	Aqueous solutions of iron wire dissolved in a dilute solution of HCl	Aqueous solutions of iron wire dissolved in a dilute solution of HCl
Detection	Bi-chromatic endpoint measurement (600 and 700 nm)	Bi-chromatic endpoint measurement (600 and 700 nm)
Assay Methodology	Chromatic	Chromatic
Levels	Multi-point with 3 levels	Multi-point with 3 levels
Traceability	NIST SRM 937	NIST SRM 937

Differences		
Item	Device	Predicate
Target Concentrations	0, 500 and 1075 ug/dL	50, 500 and 1000 ug/dL

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

- 1) Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (GP 22-A)
- 2) Stability Testing of In Vitro Diagnostic Reagents (13640)
- 3) Medical devices - Application of risk management to medical devices (14971:2000)
- 4) Medical Devices - Symbols to be used with medical device labels, labeling and information to be supplied (15223)
- 5) Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
- 6) Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final

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):

Calibrator set points are traceable to NIST SRM 937.

Calibrator shelf life was determined by comparing results of three different lots of the product stored at 2-8°C with product stored at -20°C over 13 months. Product was stored at 2-8 °C throughout testing cycle and tested at month 0, 1, 2, 4, 6, 7, 10, 12, 13, 18, 24, 25 (using 5 replicates per calibrator level). The control material was stored at -20 °C and tested at the same frequency. Stress testing was also performed using one lot of product stored at 2 -8 °C throughout testing cycle and tested at days 7, then months 6,7,12 and 13 (using 5 replicates per calibrator level) under hot (stressed shipping) conditions ((a) Store product at 30°C for 36 h, 35°C for 12h, then 45°C for 4 h then stored long term at 4°C. (b) Store product at 25°C for 48h, then 30°C for 6 h then store long term at 4°C. (c) Store product at 15°C for 54h, then store long term at 4°C.) and cold (stressed shipping) conditions (three freeze/thaw cycles then stored long-term @ 4°C). Calibrator shelf life was determined by comparing results of the product stored at 4°C with product stored at -20°C to ensure that analytical system drift is dissociated with calibrator drift. The drift at each test level must meet the following sponsor-set criteria:

Less than or equal to 5µg/dL for Level 1 (0 µg/dL)

Less than or equal to 5% CV Level 2 (500 µg/dL) and

Less than or equal to 8% CV for level 3 (1075 µg/dL).

Using this criteria, the sponsor claims the time frame which the criteria are met and applies that time frame as the stability for unopened product stored at 2-8°C.

The Dimension® IRON Calibrator is in a single-use glass ampule product. According to the Dimension® IRON Calibrator Instructions for Use, opened ampules should be used immediately and any portion not used should be discarded. As such, no “Opened Product” stability studies were performed.

The target concentrations will be 0, 500 and 1075 µg/dL. This strategy supports a preference by the customer to have an assay range that is never lower than the lowest level of calibrator and never higher than the highest level of calibrator in order to be in compliance accrediting agencies and demonstrate linearity with each lot of reagent. The intermediate level was chosen based on a level to achieve the best linear curve fit.

Assay Range: 5 – 1000 µg/dL

Calibrator Target Levels: 0, 500, 1075 µg/dL

(These levels may vary based on lot to lot assignment.)

- 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.