

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

A. 510(k) Number:

k062055

B. Purpose for Submission:

510(k) premarket notification to manufacture and market the Dimension Vista™ Protein 1 Calibrator and the Dimension Vista™ Protein 1 Controls (Low, Medium, and High). The calibrator and controls have been modified to include Prealbumin.

C. Measurand:

Calibrators and Controls for Immunoglobulin A (IGA), Immunoglobulin G (IGG), Prealbumin (PREALB)

D. Type of Test:

Calibrators and Controls

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Dimension Vista™ Protein 1 Calibrator

Dimension Vista™ Protein 1 Control L

Dimension Vista™ Protein 1 Control M

Dimension Vista™ Protein 1 Control H

G. Regulatory Information:

1. Regulation section:

862.1150 – Calibrator

862.1660 – Quality control material (assayed and unassayed)

2. Classification:

Class II (calibrator)

Class I, reserved (controls)

3. Product code:

calibrator, multi-analyte mixture (JIX)

multi-analyte controls, all kinds (assayed and unassayed) (JJY)

4. Panel:

Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The Dimension Vista™ Protein 1 Calibrator is an in vitro diagnostic product for the calibration of the Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin/Transthyretin (PREALB) methods on the Dimension Vista™ System.

The Dimension Vista™ Protein 1 Control L, M, and H are assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of Immunoglobulin A (IGA), Immunoglobulin G (IGG) and Prealbumin/Transthyretin (PREALB) methods on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use.

4. Special instrument requirements:

Dimension Vista™ Integrated System

I. Device Description:

Dimension Vista™ Protein 1 Calibrator: Protein 1 Calibrator is a multi-analyte, liquid human serum based product containing Immunoglobulin A, Immunoglobulin G, and Prealbumin.

Dimension Vista™ Protein 1 Control L, M, and H: Protein 1 Control L, M, and H are multi-analyte, liquid human based serum based products containing Immunoglobulin A, Immunoglobulin G, and Prealbumin.

All human source materials were tested by FDA approved methods and found to be negative for antibodies to HIV-1/2, HbsAg, and HCV.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista™ Protein 1 Calibrator

Dimension Vista™ Protein 1 Control L

Dimension Vista™ Protein 1 Control M

Dimension Vista™ Protein 1 Control H

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

k061338

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Form	Liquid, human serum	Liquid, human serum
Traceability to	ERM®-DA470 (CRM470)	ERM®-DA470 (CRM470)

Differences		
Item	Device	Predicate
Constituents	IgA, IgG, prealbumin	IgA, IgG

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

Not Applicable

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 calibrator is traceable to ERM®-DA470 (CRM470).

Value Assignment

The calibrator master lot value is assigned vs. ERM®-DA470 (CRM470). The commercial calibrator lot value is assigned with three reference curves, 4 runs, 3 vials, 4 replicates per vial tested on two nephelometric instruments for a total of 144 values. The control values are assigned using the procedure outlined for the calibrators.

Stability

The calibrator and the controls follow the same stability protocol. Protocols and acceptance criteria were described and found to be acceptable.

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.