510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

k063508

B. Purpose for Submission:

510(k) premarket notification to manufacture and market the Dimension Vista™ Protein 1 Calibrator and the Dimension Vista™ Protein 1 Control (Low, Medium, and High). The calibrator and controls have been modified to include α1-acid glycoprotein (A1AG) and haptoglobin (HAPT).

510(k) premarket notification to manufacture and market the Dimension Vista™ Protein 2 Calibrator and the Dimension Vista™ Protein 2 Control (Low and High). The calibrator and controls have been modified to include antistreptolysin O (ASL).

510(k) premarket notification to manufacture and market the Dimension Vista™ Protein 3 Calibrator and the Dimension Vista™ Protein 3 Control. The calibrator and controls have been modified to include α_1-microglobulin (A1MIC).

C. Measurand:

None - submission is for clearance of calibrator and control material

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

Dimension Vista™ Protein 2 Calibrator
Dimension Vista™ Protein 2 Control L
Dimension Vista™ Protein 2 Control H

Dimension Vista™ Protein 3 Calibrator
Dimension Vista™ Protein 3 Control

G. Regulatory Information:

1. Regulation section:

   21 CFR§ 862.1150 – Calibrator

   21 CFR§ 862.1660 – Quality control material (assayed and unassayed)

2. Classification:

   Class II (calibrator)

Class I, reserved (controls)

3. Product code:

   JIX - Calibrator, multi-analyte mixture

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

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 α1-acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin (PREALB) methods on the Dimension Vista® System.

   The Dimension Vista™ Protein 1 Control L, M, and H are for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of α1-acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin (PREALB) methods on the Dimension Vista® System.

   The Dimension Vista™ Protein 2 Calibrator is an in vitro diagnostic product for the calibration of the antistreptolysin O (ASL), C-reactive protein (CRP), CardioPhase® high sensitivity CRP (hsCRP) and Rheumatoid Factors (RF) methods on the Dimension Vista® System.

   The Dimension Vista™ Protein 2 Control L and H are for use as assayed intralaboratory quality controls for the assessment of precision and analytical bias in the determination of antistreptolysin O (ASL), C-reactive protein (CRP) and Rheumatoid Factor (RF) on the Dimension Vista® System.

   The Dimension Vista™ Protein 3 Calibrator is an in vitro diagnostic product for the calibration of the α_1-microglobulin (A1MIC) and microalbumin (MALB) methods on the Dimension Vista® System.

   The Dimension Vista™ Protein 3 Control is for use as assayed intralaboratory quality controls for assessment of precision and analytical bias in the determination of α_1-microglobulin (A1MIC) and microalbumin (MALB) on the Dimension Vista® System.

3. Special conditions for use statement(s):

   For prescription use.

4. Special instrument requirements:

For use with the Dade Behring Dimension Vista® System

I. Device Description:

Dimension Vista™ Protein 1 Calibrator: Protein 1 Calibrator is a liquid, human serum based product containing α1-acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin (PREALB).

Dimension Vista™ Protein 1 Controls L, M, and H: Protein 1 Control L, M, and H are liquid, multi-analyte, human serum based products containing α1-acid glycoprotein (A1AG), C3 complement (C3), C4 complement (C4), haptoglobin (HAPT), Immunoglobulin A (IGA), Immunoglobulin G (IGG), Immunoglobulin M (IGM), and Prealbumin (PREALB) in three concentration ranges: low, medium, and high.

Dimension Vista™ Protein 2 Calibrator: Protein 2 Calibrator is a liquid, human serum based product containing antistreptolysin O (ASL), C-reactive protein (CRP), CardioPhase® high sensitivity CRP (hsCRP) and Rheumatoid Factors (RF).

Dimension Vista™ Protein 2 Controls L and H: Protein 2 Control L and H are liquid, multi-analyte, human serum based products containing antistreptolysin O (ASL), C-reactive protein (CRP), high sensitivity CRP (hsCRP) and Rheumatoid Factors (RF) in two concentrations: low and high.

Dimension Vista™ Protein 3 Calibrator: Protein 3 Calibrator is a lyophilized, polygeline, based product of human urinary and serum proteins containing α_1-microglobulin (A1MIC) and microalbumin (MALB).

Dimension Vista™ Protein 3 Control: Protein 3 Control is a lyophilized, polygeline, and rabbit albumin based product containing urinary α_1-microglobulin (A1MIC) and serum albumin of human origin.

Refer to the product labeling for assigned values for each constituent. All human materials were tested by FDA approved methods and found to be negative for the presence of antibodies to HIV-1, HIV-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

Dimension Vista™ Protein 2 Calibrator

Dimension Vista™ Protein 2 Control L

Dimension Vista™ Protein 2 Control H

Dimension Vista™ Protein 3 Calibrator

Dimension Vista™ Protein 3 Control

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

k062055 – Dimension Vista™ Protein 1 Calibrator
k062055 – Dimension Vista™ Protein 1 Control L, M, H

k062035 – Dimension Vista™ Protein 2 Calibrator
k062035 – Dimension Vista™ Protein 2 Control L, H

k061990 – Dimension Vista™ Protein 3 Calibrator
k061990 – Dimension Vista™ Protein 3 Control

3. Comparison with predicates:

1. Dimension Vista™ Protein 1 Calibrator and Control (L, M, and H)

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

Differences		
Item	Device	Predicate
Constituents	C3 complement, C4 complement, IgA, IgG, IgM and prealbumin	C3 complement, C4 complement, IgA, IgG, IgM, prealbumin, α1-acid glycoprotein, and haptoglobin

2. Dimension Vista™ Protein 2 Calibrator and Control (L and H)

Similarities		
Item	Device	Predicate
Form	Liquid, human serum	Liquid, human serum

Differences		
Item	Device	Predicate
Traceability to	ERM®-DA470 (C470) and 1st British Standard 64/0023	1st International Standard, ERM®-DA470 (C470) and 1st British Standard 64/0023
Constituents	C-reactive protein (CRP), high sensitivity CRP (hsCRP) and Rheumatoid Factors (RF)	antistreptolysin O (ASL), C-reactive protein (CRP), high sensitivity CRP (hsCRP), and Rheumatoid Factors (RF)

3. Dimension Vista™ Protein 3 Calibrator and Control

Similarities		
Item	Device	Predicate
Traceability to	ERM®-DA470 (C470)	ERM®-DA470 (C470)

Differences		
Item	Device	Predicate
Form	Lyophilized, polygeline, human based albumin	Lyophilized, polygeline, and rabbit albumin based product containing urinary and serum proteins of human origin
Constituents	C-reactive protein (CRP), high sensitivity CRP (hsCRP) and Rheumatoid Factors (RF)	antistreptolysin O (ASL), C-reactive protein (CRP), high sensitivity CRP (hsCRP), and Rheumatoid Factors (RF)

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

Not Applicable

L. Test Principle:

Not Applicable

M. Performance Characteristics (if/when applicable): 3

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

Protein 1 Calibrator, Protein 1 Control (L, M, and H), Protein 3 Calibrator, and Protein 3 Control are traceable to ERM®-DA470 (CRM470). Protein 2 Calibrator and Protein 2 Control (L and H) are traceable to 1st International Standard, ERM®-DA470 (C470) and 1st British Standard 64/0023.

Value Assignment

The calibrator master lot value is assigned vs. ERM®-DA470 (CRM470) and 1st International Standard. 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. Values assigned to

controls are calibrated by reference to protein standard preparations and are lot-dependent.

Stability

The calibrators and the controls are tested per the same stability protocol. Products are stored at +2 to +8°C and the stability studies are conducted for 24 months using 3 vials and 3 replicates per vial. Testing cycles are 0, 12, 18 and 24 months. Additional stress testing is done at 6 months after storing at +37 °C for two weeks. Once the products reach 50% shelf life stability, opened/punctured vial testing is performed on days 0, 4, 7, 9, 11, and 14.

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.