

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

A. 510(k) Number:

k072435

B. Purpose for Submission:

This submission is for the addition of albumin to the Dimension Vista® Protein Control 1 L, M, H; Dimension Vista® Protein 3 Control; and Dimension Vista® Protein 3 Calibrator

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 Control L (low)

Dimension Vista® Protein 1 Control M (medium)

Dimension Vista® Protein 1 Control H (high)

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 (control—assayed and unassayed)

3. Product code:

JIX – Calibrator, multi-analyte,

JJY – Control, 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:

PROT1 CON L is an assayed, low level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), Albumin (sALB)*, soluble Transferrin receptor (STFR), Transferrin (TRF).

*For serum and plasma

PROT1 CON M is an assayed, mid-level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), Albumin (sALB)*, soluble Transferrin receptor (STFR), Transferrin (TRF).

*For serum and plasma

PROT1 CON H is an assayed, high level, intralaboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS),

Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), Albumin (sALB)*, soluble Transferrin receptor (STFR), Transferrin (TRF).

*For serum and plasma

PROT3 CON is an assayed intralaboratory quality control, for assessment of precision and analytical bias in the determination of α_1 -Microglobulin (A1MIC), Albumin (sALB)¹ and Microalbumin (MALB) on the Dimension Vista[®] System.

¹For cerebrospinal fluid

PROT3 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista[®] System for the α_1 -Microglobulin (A1MIC), Cystatin C (CYSC), Microalbumin (MALB) and Albumin (sALB)* methods.

*For serum, plasma and cerebrospinal fluid

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 Control L (low): PROT1 CON L is a multi-analyte, low level liquid human serum based product containing human α_1 -acid glycoprotein , albumin, α_1 -antitrypsin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, immunoglobulin A , immunoglobulin E, immunoglobulin G, immunoglobulin M, prealbumin, soluble transferrin receptor, transferrin, and purified S-adenosylhomocysteine.

Dimension Vista[®] Protein 1 Control M (medium): PROT1 CON M is a multi-analyte, mid-level liquid human serum based product containing human α_1 -acid glycoprotein , albumin, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, homocysteine, immunoglobulin A , immunoglobulin E, immunoglobulin G, immunoglobulin M, prealbumin, soluble transferrin receptor, transferrin, and purified S-adenosylhomocysteine.

Dimension Vista[®] Protein 1 Control H (high): PROT1 CON H is a multi-analyte, high level liquid human serum based product containing human α_1 -acid glycoprotein , albumin, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, immunoglobulin A , immunoglobulin E, immunoglobulin G, immunoglobulin M, prealbumin, soluble transferrin receptor, transferrin, and purified S-adenosylhomocysteine.

Dimension Vista[®] Protein 3 Control: PROT3 CON is a multi-analyte, low level lyophilized, polygeline and rabbit albumin based product containing urinary α_1 -

microglobulin and serum albumin of human origin.

Dimension Vista® Protein 3 Calibrator: PROT3 CAL is a multi-analyte, lyophilized, polygelene based product containing urinary α_1 -microglobulin, cystatin C and serum albumin of human origin.

Each donor or donor unit was tested and found to be negative for human immunodeficiency virus (HIV) 1 and 2, Hepatitis B virus (HBV), and Hepatitis C virus (HCV) using either tests found to be in conformance with the In Vitro Diagnostic Directive in the EU or FDA approved tests. Because no known test can offer complete assurance of the absence of infectious agents, all human derived products should be handled with caution.

The previously cleared analytes for the calibrators and controls were cleared under k061990, k063351, k063508, k051087, k061338, k061845, k061852, k062055, k063206, k063222, k063425, k063508, k063610, k063655, k063663, k063272, and k071980.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dimension Vista® Protein 1 Control L (low)
Dimension Vista® Protein 1 Control M (medium)
Dimension Vista® Protein 1 Control H (high)
Dimension Vista® Protein 3 Calibrator
Dimension Vista® Protein 3 Control

2. Predicate K number(s):

k063508, k063663

3. Comparison with predicate:

Dimension Vista® Protein 3 Calibrator

Similarities		
Item	Device	Predicate
Form	Lyophilized polygelene human based albumin	Lyophilized polygelene human based albumin
Traceability to	ERM®-DA470(C470)	ERM®-DA470(C470)

Differences		
Item	Device	Predicate
Constituents	Albumin,, α_1 -Microglobulin, Microalbumin, Cystatin C	α_1 -Microglobulin, Microalbumin, Cystatin C

Dimension Vista® Protein 3 Control

Similarities		
Item	Device	Predicate
Form	Lyophilized polygelene human based albumin	Lyophilized polygelene human based albumin
Traceability to	ERM®-DA470(C470)	ERM®-DA470(C470)

Differences		
Item	Device	Predicate
Constituents	Albumin, α_1 -Microglobulin, Microalbumin, Cystatin C	α_1 -Microglobulin, Microalbumin, Cystatin C

Dimension Vista® Protein 1 Control L

Similarities		
Item	Device	Predicate
Form	Human source material	Human source material
Constituents	A ₁ -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).	α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).

Differences		
Item	Device	Predicate
Constituents	Albumin, α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).	α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).

Dimension Vista[®] Protein 1 Control M, H

Similarities		
Item	Device	Predicate
Form	Human source material	Human source material
Constituents	α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).	α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).

Differences		
Item	Device	Predicate
Constituents	Albumin, α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).	α_1 -Acid Glycoprotein (A1AG), α_1 -Antitrypsin (A1AT), β_2 -Microglobulin (B2MIC), C3 Complement (C3), C4 Complement (C4), Ceruloplasmin (CER), Haptoglobin (HAPT), Homocysteine (HCYS), Immunoglobulins A (IGA), E (IGE), G (IGG), M (IGM), Prealbumin (PREALB), soluble Transferrin receptor (STFR), Transferrin (TRF).

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

Control or Calibrator	Standard for Traceability
Protein Control 1 (L, M, H), Protein Control 3, Protein Calibrator 3	Protein reference preparation ERM® - DA470 (CRM 470)

Stability

The calibrators and controls are tested per the same stability protocol. The stability protocols and acceptance criteria were reviewed and found to be acceptable.

Value Assignment

The calibrator master lot value is assigned vs. ERM®-DA470 (CRM470). Values assigned to the controls are calibrated by reference to protein standard preparations and are lot-dependent.

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.