

# DADE BEHRING

*Every minute of every day™*

OCT 17 2007

**510(k) Summary for  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L  
Dimension Vista® Protein 1 Control M  
Dimension Vista® Protein 1 Control H**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K072435

**1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:**

Manufacturer: Dade Behring Inc. Marburg GmbH  
Emil-von-Behring Str. 76  
35041 Marburg, Germany

Contact Information: Dade Behring Inc.  
P.O. Box 6101  
Newark, Delaware 19714-6101  
Attn: A. Kathleen Ennis  
Tel: 302-631-9352  
Fax: 302-631-6299

Preparation date: August 27, 2007

**2. Device Name:** Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L  
Dimension Vista® Protein 1 Control M  
Dimension Vista® Protein 1 Control H

**Classification:** Class II; Class I  
**Product Code:** JIX; JJY  
**Panel:** Clinical Chemistry (75)

**3. Identification of the Legally Marketed Device:**

Dimension Vista® Protein 3 Calibrator	K063508
Dimension Vista® Protein 3 Control	K063508
Dimension Vista® Protein 1 Control L	K063663

Dimension Vista® Protein 1 Control M                    K063663  
Dimension Vista® Protein 1 Control H                    K063663

#### 4. Device Descriptions:

##### **Dimension Vista® Protein 3 Calibrator**

PROT3 CAL is a multi-analyte, lyophilized, polygeline based product containing urinary  $\alpha_1$ -microglobulin, cystatin C and serum albumin of human origin.

##### **Dimension Vista® Protein 3 Control**

PROT3 CON is a multi-analyte, low level lyophilized, polygeline and rabbit albumin based product containing urinary  $\alpha_1$  -microglobulin and serum albumin of human origin.

##### **Dimension Vista® Protein 1 Control L**

Protein 1 Control L is a multi-analyte, low level liquid human serum based product containing:

$\alpha_1$ -acid glycoprotein	immunoglobulin E
$\alpha_1$ -antitrypsin	immunoglobulin G
C3 complement	immunoglobulin M
C4 complement	prealbumin
ceruloplasmin	soluble transferrin receptor
haptoglobin	albumin
homocysteine	transferrin
immunoglobulin A	

##### **Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H**

Protein 1 Control M and H are multi-analyte, mid and high level respectively, liquid human serum based products containing:

$\alpha_1$ -acid glycoprotein	immunoglobulin A
$\alpha_1$ -antitrypsin	immunoglobulin E
$\beta_2$ -microglobulin	immunoglobulin G
C3 complement	immunoglobulin M
C4 complement	prealbumin
ceruloplasmin	soluble transferrin receptor
haptoglobin	albumin
homocysteine	transferrin

## 5. Device Intended Uses:

### Dimension Vista® Protein 3 Calibrator

PROT3 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for the  $\alpha_1$ -Microglobulin (A1MIC), Cystatin C(CYSC), Microalbumin (MALB) and specialty Albumin (sALB)\* methods.

\* For serum, plasma and cerebrospinal fluid

### Dimension Vista® Protein 3 Control

PROT3 CON is an assayed intralaboratory quality control, for assessment of precision and analytical bias in the determination of  $\alpha_1$ -Microglobulin (A1MIC), specialty Albumin (sAlb)\*\* and Microalbumin (MALB) on the Dimension Vista® System.

\*\* For cerebrospinal fluid (CSF)

### Dimension Vista® Protein 1 Control L

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:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin E (IGE)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	soluble Transferrin Receptor (sTFR)
Haptoglobin (HAPT)	specialty Albumin (sALB)***
Homocysteine (HCYS)	Transferrin (TRF)
Immunoglobulin A (IGA)	

## **Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H**

PROT1 CON M and PROT1 CON H are assayed, mid-level and high level respectively, intralaboratory quality controls for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin E (IGE)
$\beta_2$ -Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin (sALB)***
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

\*\*\* For serum and plasma

### **6. Medical device to which equivalence is claimed and comparison information:**

Dimension Vista® Protein 3 Calibrator and Dimension Vista® Protein 3 Control modified to include specialty Albumin (sALB), are substantially equivalent in intended use to the current Dimension Vista® Protein 3 Calibrator and Dimension Vista® Protein 3 Control (K063508). The modified Protein 3 Calibrator and Protein 3 Control, like the current products, are intended to be used for the calibration of human protein assays and for use as assayed intralaboratory quality controls respectively, on the Dimension® Vista System.

Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H modified to include specialty Albumin (sALB), are substantially equivalent in intended use to the current Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H (K063663). Modified Protein 1 Control L, M, and H, like the current products, are intended to be used as assayed intralaboratory quality controls on the Dimension® Vista System.

### **7. Conclusion**

The modified Dimension Vista® Protein 3 Calibrator, Dimension Vista® Protein 3 Control and Dimension Vista® Protein 1 Control L, Dimension Vista® Protein 1 Control M and Dimension Vista® Protein 1 Control H, are substantially equivalent to the legally marketed devices based on the information described above.



Dade Behring Inc.  
c/o Ms. A. Kathleen Ennis  
Sr. Regulatory Affairs & Compliance Spec.  
500 GBC Drive, MS 514, P.O. Box 6101  
Newark, DE 19714-6101

OCT 17 2007

Re: k072435  
Trade Name: Dimension Vista® Protein 3 Calibrator,  
Dimension Vista® Protein 3 Control, Dimension Vista® Protein 3 Control L,  
Dimension Vista® Protein 3 Control M, Dimension Vista® Protein 3 Control H  
Regulation Number: 21 CFR 862.1150  
Regulation Name: Calibrator  
Regulatory Class: Class II  
Product Code: JIX, JJY  
Dated: August 28, 2007  
Received: August 30, 2007

Dear Ms. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

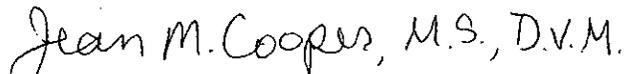
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Dade Behring Inc.  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L, M, H  
510(k) Notification

### Indications Statement

**Device Name: Dimension Vista® Protein 3 Calibrator**

**Indications for Use:**

**Dimension Vista® Protein 3 Calibrator**

PROT3 CAL is an *in vitro* diagnostic product for the calibration of the Dimension Vista® System for the  $\alpha_1$ -Microglobulin (A1MIC), Cystatin C (CYSC), Microalbumin (MALB) and specialty Albumin (sALB)\* methods.

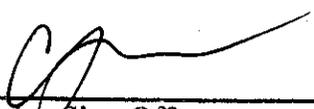
\* For serum, plasma and cerebrospinal fluid

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

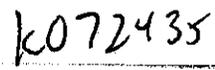
Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

  
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Evaluation and Safety

  
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Dade Behring Inc.  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L, M, H  
510(k) Notification

**Indications Statement**

**Device Name: Dimension Vista® Protein 3 Control**

**Indications for Use:**

**Dimension Vista® Protein 3 Control  
Intended Use**

PROT3 CON is an assayed intralaboratory quality control, for assessment of precision and analytical bias in the determination of  $\alpha_1$ -Microglobulin (A1MIC), specialty Albumin (sALB)<sup>1</sup> and Microalbumin (MALB) on the Dimension Vista® System.

<sup>1</sup> For cerebrospinal fluid (CSF)

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

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Dade Behring Inc.  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L, M, H  
510(k) Notification

### Indications Statement

**Device Name: Dimension Vista® Protein 1 Control L**

**Indications for Use:**

**Dimension Vista® Protein 1 Control L**

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:

$\alpha_1$ -Acid Glycoprotein (A1AG)	Immunoglobulin E (IGE)
$\alpha_1$ -Antitrypsin (A1AT)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin* (sALB)
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)
Immunoglobulin A (IGA)	

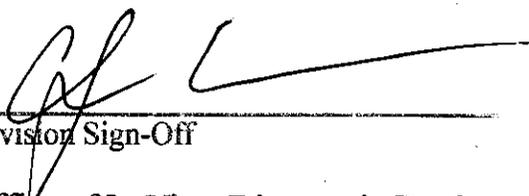
\*For serum and plasma

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

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Dade Behring Inc.  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L, M, H  
510(k) Notification

### Indications Statement

**Device Name: Dimension Vista® Protein 1 Control M**

**Indications for Use:**

**Dimension Vista® Protein 1 Control M**

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 <sub>1</sub> -Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
α <sub>1</sub> -Antitrypsin (A1AT)	Immunoglobulin E (IGE)
β <sub>2</sub> - Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin* (sALB)
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

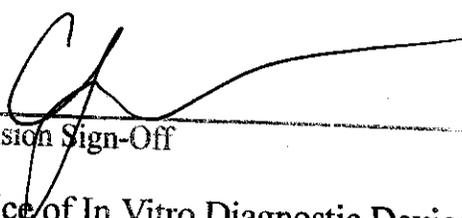
\*For serum and plasma

Prescription Use   X    
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

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Dade Behring Inc.  
Dimension Vista® Protein 3 Calibrator  
Dimension Vista® Protein 3 Control  
Dimension Vista® Protein 1 Control L, M, H  
510(k) Notification

### Indications Statement

**Device Name: Dimension Vista® Protein 1 Control H**

#### Indications for Use:

#### Dimension Vista® Protein 1 Control H

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 <sub>1</sub> -Acid Glycoprotein (A1AG)	Immunoglobulin A (IGA)
α <sub>1</sub> -Antitrypsin (A1AT)	Immunoglobulin E (IGE)
β <sub>2</sub> - Microglobulin (B2MIC)	Immunoglobulin G (IGG)
C3 Complement (C3)	Immunoglobulin M (IGM)
C4 Complement (C4)	Prealbumin (PREALB)
Ceruloplasmin (CER)	specialty Albumin* (sALB)
Haptoglobin (HAPT)	soluble Transferrin Receptor (STFR)
Homocysteine (HCYS)	Transferrin (TRF)

\*For serum and plasma

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

Over-The-Counter-Use \_\_\_\_\_  
(21 CFR 801)

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