

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k071980

B. Purpose for Submission:

Add additional analytes to existing multi-analyte calibrator and controls

C. Measurand:

New analytes added: Hemopexin (HPX), immunoglobulin IgG subclasses (IgG1, IgG2, IgG3 and IgG4), and retinol binding protein

D. Type of Test:

Calibrator and controls for an automated turbidimetric immunoassay

E. Applicant:

Dade Behring

F. Proprietary and Established Names:

Dade Behring Dimension Vista® Protein 1 Calibrator (Prot1 Cal) and Dimension Vista® Protein 1 Control L, M, and H (Prot1 control L, M, or H)

G. Regulatory Information:

1. Regulation section:

CFR 862.1150 Calibrator

CFR 862.1660 Quality control materials (assayed and unassayed)

2. Classification:

Calibrator: Class II

Controls: Class I

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):

PROT1 Cal is an in vitro diagnostic product for the calibration of the Dimension Vista® System for: α_1 -acid glycoprotein, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, **hemopexin**, homocysteine, IgA, IgE, IgG, **IgG subclasses (IgG1, IgG2, IgG3, and IgG4)**, IgM, prealbumin, **retinol binding protein**, soluble transferrin receptor, and transferrin.

PROT1 CON L is an assayed, low level, intra-laboratory quality control for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: α_1 -acid glycoprotein, α_1 -antitrypsin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, **hemopexin**, homocysteine, IgA, IgE, IgG, **IgG subclasses (IgG1, IgG2, IgG3, and IgG4)**, IgM, prealbumin, **retinol binding protein**, soluble transferrin receptor, and transferrin.

PROT1 CON M and H are assayed, mid- and high level, intra-laboratory quality

- controls for assessment of precision and analytical bias on the Dimension Vista® System in the quantitative determination of: α_1 -acid glycoprotein, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, **hemopexin**, homocysteine, IgA, IgE, IgG, **IgG subclasses (IgG1, IgG2, IgG3, and IgG4)**, IgM, prealbumin, **retinol binding protein**, soluble transferrin receptor, and transferrin.
2. Indication(s) for use:
Same as the Intended Uses
 3. Special conditions for use statement(s):
For prescription use only
 4. Special instrument requirements:
Dade Behring Dimension Vista System

I. Device Description:

PROT1 CAL is a multi-analyte, liquid, human serum based product containing: α_1 -acid glycoprotein, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, **hemopexin**, homocysteine, IgA, IgE, IgG, **IgG subclasses (IgG1, IgG2, IgG3, and IgG4)**, IgM, prealbumin, **retinol binding protein**, soluble transferrin receptor, and transferrin. It is ready to use and contains sodium azide (<0.1%) as a preservative.

PROT1 CON L, M, or H are multi-analyte, liquid, human serum based product containing: α_1 -acid glycoprotein, α_1 -antitrypsin, β_2 -microglobulin (PROT1 CON M and H only), C3 complement, C4 complement, ceruloplasmin, haptoglobin, **hemopexin**, homocysteine, IgA, IgE, IgG, **IgG subclasses (IgG1, IgG2, IgG3, and IgG4)**, IgM, prealbumin, **retinol binding protein**, soluble transferrin receptor, and transferrin. These reagents are ready to use and contain sodium azide (<0.1%) as a preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Dimension Vista® Protein 1 Calibrator and Protein 1 Control L, M, and H
2. Predicate K number(s):
k063663
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	1) Calibration of the Dimension Vista System 2) Assessment of precision and analytical bias	Same
Matrix	Liquid, human serum	Same
Levels	1 calibrator level 3 control levels	Same
Preservative	Sodium azide	Same
Source material	Homocysteine – purified S-adenosylhomocysteine; All other analytes – human	Same

Differences		
Item	Device	Predicate
Constituents	Addition of hemopexin, IgG subclasses (IgG1, IgG2, IgG3, and IgG4), IgM, retinol binding protein to predicate list of analytes.	α_1 -acid glycoprotein, α_1 -antitrypsin, β_2 -microglobulin, C3 complement, C4 complement, ceruloplasmin, haptoglobin, homocysteine, IgA, IgE, IgG, IgM, prealbumin, soluble transferrin receptor, and transferrin

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

None referenced

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 of Added Constituents:

Analyte	Traceability to:
IgG subclasses (IgG1, IgG2, IgG3, and IgG4)	ERM-DA470 (CRM 470)
Hemopexin, retinol binding protein	Highly purified protein

Stability:

The calibrators and controls follow the same stability protocol. Products are stored at 2-8° 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 the product at 37° C for 2 weeks then testing at 1 and 2 weeks. Open/punctured vial testing is performed at the mid-point of the shelf life study period. Vials are stored on board the instrument and contents are tested in duplicate on days 0, 4, 7, 9, 11 and 14. Acceptance criteria must be met.

Value assignment:

The calibrator master lot values for IgG 1-4 are assigned versus ERM-DA 470 (CR 470) using independently determined values for subclasses compared to

total IgG value of the reference material. The master calibrator lot values for hemopexin and retinol binding protein are assigned versus highly purified protein preparations. Commercial lot values are then assigned versus Master Calibrators with 3 reference curves, 4 runs, 3 vials, 4 replicates per vial tested on two nephelometric systems for a total of 144 values. The sum of IgG 1-4 must be $\pm 20\%$ of the total IgG.

- 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.