

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

A. 510(k) Number: K032798

B. Analyte: Automated HDL Cholesterol

C. Type of Test: Quantitative Colorimetric Lipoprotein

D. Applicant: Dade Behring Inc.

E. Proprietary and Established Names: Dade Behring Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48A)

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1475
2. Classification: Class I
3. Product Code: JHM
4. Panel: 75

G. Intended Use:

1. Intended use(s): For the quantitative determination of HDL Cholesterol in human serum or plasma on the Dimension® clinical chemistry system.
2. Indication(s) for use: The AHDL method for the Dimension clinical chemistry system is an in vitro diagnostic test intended to quantitatively measure high density lipoprotein cholesterol (HDL-C) in human serum or plasma. HDL-C measurements are used as an aid in the diagnosis of lipid disorders.
3. Special condition for use statement(s): none stated
4. Special instrument Requirements: Dade Behring Dimension clinical chemistry system

H. Device Description: The Dimension Automated HDL Cholesterol Flex Reagent module is an in vitro diagnostic device used for the determination of HDL-Cholesterol in plasma and serum.

I. Substantial Equivalence Information:

1. Predicate device name(s): Dade Behring “current” Dimension Automated HDL Cholesterol (ADHL) Flex reagent cartridge

2. Predicate K number(s): K983849

3. Comparison with predicate:

Item	Device	Predicate
Intended Use	For the measurement of high density lipoproteins	For the measurement of high density lipoproteins
Sample type	Human Serum or Plasma	Human Serum or Plasma
Sample Volume	3ul	3ul
Detection	Enzymatic Colorimetric Bichromatic Endpoint	Enzymatic Colorimetric Bichromatic Endpoint
Wavelengths	600 and 700 nm	600 and 700 nm
Reagent volume	Reagent 1 300 ul Reagent 2 100 ul	Reagent 1 300 ul Reagent 2 100 ul
Methodology	Accelerator Selective Detergent Methodology	Polyanion Selective Detergent Methodology

J. Standard/Guidance Document Referenced (if applicable): NCCLS EP7-A, NCCLS EP5-A, National Cholesterol Education Program Adult Treatment Panel III

K. Test Principle: The Dade Behring Dimension Automated HDL Cholesterol assay contains an in vitro diagnostic reagent system indicated for the quantitative determination of High Density Lipoprotein Cholesterol in human plasma or serum. The calibrators and controls for this assay are sold separately.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility: Reproducibility testing was done in accordance with the NCCLS Approved guidelines of Precision Performance of Clinical Chemistry Devices (EP5-A). Specimens at each level were analyzed in duplicate, twice a day, for 20 days. The within run and total standard deviations were calculated by the analysis of variance method

Material	Mean Mg/dl	S.D. Within Run	%C.V. Total

Multiqual*			
Level 1	30	0.33 [0.01](1.10)	1.76 [0.06](5.87)
Level 2	47	0.52 [0.01](1.11)	1.84 [0.05](3.91)
Level 3	80	0.84 [0.02](1.05)	3.06 [0.08](3.83)
Serum Pool	46	0.72 [0.02](1.57)	0.92 [0.02](2.00)

* Multiqual Chemistry Control is a product of Bio-Rad Laboratories Inc.

b. Linearity/assay reportable range: The assay range is provided in the Assay Range section of the product labeling. Assay range was based on scientifically valid protocols, supported with dilutional linearity/parallelism data and/or spiked recovery as appropriate for the methodology. Supporting data for the 510K submission is documented in Dade Behring Inc files. The reportable (assay) range is challenged across the existing labeled range for the AHDL assay using comparative analysis after normal recommended systems and equipment quality control checks are performed. The linear/reportable range of the assay is 10 – 150mg/dl.

c. Traceability (controls, calibrators, or method): Traceability of calibration and controls were determined using split sample comparison to the predicate device in conjunction with Multiqual Bio-Rad's assayed quality control material and a human serum pool. The method has not been evaluated by the Cholesterol Reference Method Laboratory Network (CRMLN).

d. Detection limit: 10 mg/dL

e. Analytical specificity: Interference testing was done in accordance with NCCLS Approved Guideline for Interference Testing in Clinical Chemistry. (EP7-A). Interference from all compounds tested, when added to a 40 mg/dl HDL-C serum pool, was less than 10%

f. Assay cut-off: The reference intervals for the AHDL assay were provided by the National Cholesterol Education Program Adult Treatment Panel III for the following classifications of HDL-C concentrations.

HDL < 40mg/dl Low HDL Cholesterol
HDL ≥ 60mg/dl High HDL Cholesterol

2. Comparison studies:

a. *Method comparison with predicate device:* Split sample comparison between the “current” Automated HDL Cholesterol (ADHL) Flex reagent cartridge and the “revised” Dimension Automated HDL Cholesterol Flex reagent cartridge gave the following correlation studies when tested with clinical patient samples.

Revised AHDL vs. Current AHDL Slope 1.04, Intercept -3.38 mg/dl, Corr. Coeff 0.995, n=101

b. *Matrix comparison:* Serum, EDTA-treated or heparinized (lithium or sodium heparin) plasma are the recommended specimens for the “revised” Dimension Automated HDL Cholesterol assay, EDTA results should be multiplied by 1.03 to provide serum equivalent results. Regression studies are shown as:

Serum vs.	Slope	Intercept (mg/dl)	Corr Coeff	n
EDTA	1.03	-1.31	0.99	50
Lithium Heparin	1.01	-0.66	1.00	50
Sodium Heparin	1.00	- 0.48	1.00	50

3. Clinical studies:

a. *Clinical sensitivity:* none stated

b. *Clinical specificity:* none stated

c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off: The reference intervals for the AHDL assay were provided by the National Cholesterol Education Program Adult Treatment Panel III for the following classifications of HDL-C concentrations.

HDL < 40mg/dl Low HDL Cholesterol

HDL ≥ 60mg/dl High HDL Cholesterol

The assay range or “Analytical Measurement Range”

For the Dimension “revised” Automated HDL was determined to be 10mg/dl – 150mg/dl using the following rationale:

1) It was possible to demonstrate both visual and statistical linearity between 0 and 255 mg/dl of HDL-C.

2) The use of calibrator levels at 10, 40, and 165 mg/dl allowed for correlation between values obtained using the “revised” method AHDL assay and values obtained by the Cholesterol Reference Method Laboratory Network using the reference method.

3) A preference by customers to not claim an assay range either higher or lower than the highest or lowest calibrator used for purposes of compliance to laboratory accreditation agencies

M. Conclusion: Based upon the information provided, I recommend that the Dade Behring Dimension Automated HDL (AHDL) Flex reagent cartridge be found substantially equivalent to the respective predicate device.