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

A. 510(k) Number:

k181373

B. Purpose for Submission:

New device

C. Measurand:

Total cholesterol, high density lipoprotein (HDL) cholesterol, triglycerides and apolipoprotein B

D. Type of Test:

Quantitative, Nuclear Magnetic Resonance (NMR) spectroscopy assay

E. Applicant:

Laboratory Corporation of America Holdings

F. Proprietary and Established Names:

Extended Lipid Panel Assay

G. Regulatory Information:

Regulation	Classification	Product Code	Panel
21 CFR 862.1175 Cholesterol (total) Test System	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	CHH: Enzymatic esterase--oxidase, Cholesterol	Chemistry (75)
21 CFR 862.1475 Lipoprotein Test System	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	LBS: LDL & VLDL precipitation, cholesterol via esterase-oxidase, HDL	Chemistry (75)
21 CFR 862.1705 Triglyceride Test System	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	CDT: lipase hydrolysis/glycerol kinase enzyme, Triglycerides	Chemistry (75)

Regulation	Classification	Product Code	Panel
21 CFR 862.1475 Lipoprotein Test System	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	MSJ: Apolipoproteins	Chemistry (75)

H. Intended Use:

1. Intended uses:
   See indications for use below.

2. Indications for use:
   The Extended Lipid Panel Assay is an in vitro diagnostic test for quantitative determination of total cholesterol, high density lipoprotein cholesterol, and triglycerides in human serum and plasma, and apolipoprotein B in human serum. Values for total cholesterol, high density lipoprotein cholesterol, triglycerides and apolipoprotein B are quantified by the Vantera Clinical Analyzer.

   Total cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, lipid, and lipoprotein metabolism disorders.

   High density lipoprotein cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

   Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

   Apolipoprotein B measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis.

3. Special conditions for use statements:
   For in vitro diagnostic use only.
   For prescription use only.

4. Special instrument requirements:
   Vantera Clinical Analyzer

I. Device Description:

The test system includes the following consumables and instrument:

NMR Diluent 1 - A ready to use aqueous solution (Na_2EDTA, $CaCl_2$, KCl, $NaHPO_4 \cdot 7H_2O$) to dilute specimens.

Wash Solution - A ready to use aqueous solution (Triton X-100, LiquiNox, sodium bicarbonate, sodium carbonate).

NMR Reference Standard - A ready to use aqueous solution (trimethyl acetate sodium salt, NA_2EDTA, $CaCl_2$, KCl, and D_2O) for a daily calibration of the instrument.

Vantera Clinical Analyzer - The Vantera Clinical Analyzer is an automated laboratory analyzer which quantitates clinical samples using 400 MHz proton NMR. The Vantera Clinical Analyzer was cleared in k113830.

Liquichek Lipids Controls - Two levels of pooled human serum based control material.

J. Substantial Equivalence Information:

1. Predicate device names:

   Total Cholesterol: k031824
   Roche Diagnostics, COBAS Integra Cholesterol Gen.2

   HDL Cholesterol: k012286
   Roche Diagnostics, HDL-Cholesterol plus 2nd Generation

   Triglyceride: k873049
   Boehringer Mannheim, Triglycerides GPO Without Free Glycerol

   Apolipoprotein B: k063608
   Dade Behring, Dimension Vista APOB Flex reagent cartridge

2. Predicate 510(k) numbers:
   See predicate device names in section J.1 above.

3. Comparison with predicate:

Similarities and Differences		
Item	Candidate Device, Total cholesterol, Extended Lipid Panel Assay k181373	Predicate Device, Total Cholesterol k031824
Intended Use	For the quantitative determination of total cholesterol.	Same
Use type	Prescription use	Same
Specimens	Serum and plasma	Same
Analytical method	400 MHz proton NMR	Enzymatic colorimetric assay

Similarities and Differences		
Item	Candidate Device, HDL cholesterol, Extended Lipid Panel Assay k181373	Predicate Device, HDL-Cholesterol k012286
Intended Use	For the quantitative determination of HDL cholesterol.	Same
Use type	Prescription use	Same
Specimens	Serum and plasma	Same
Analytical method	400 MHz proton NMR	Enzymatic colorimetric assay

Similarities and Differences		
Item	Candidate Device, Triglycerides, Extended Lipid Panel Assay k181373	Predicate Device, Triglycerides k873049
Intended Use	For the quantitative determination of triglycerides.	Same
Use type	Prescription use	Same
Specimens	Serum and plasma	Same
Analytical method	400 MHz proton NMR	Enzymatic colorimetric assay

Similarities and Differences		
Item	Candidate Device Apolipoprotein B, Extended Lipid Panel Assay k181373	Predicate Device, Dimension Vista Apolipoprotein B Flex reagent cartridge k063608
Intended Use	For the quantitative determination of Apolipoprotein B.	Same
Use type	Prescription use	Same
Specimens	Serum	Serum and Plasma
Analytical method	400 MHz proton NMR	Nephelometric immunoassay

K. Standard/Guidance Document Referenced:

Clinical and Laboratory Standards Institute (CLSI) Guideline EP5-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline -Third Edition.

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition.

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition.

L. Test Principle:

The methodology of the test system involves measurement of a 400 MHz proton NMR spectrum on a plasma or serum sample. The NMR spectra generated by the Vantera Clinical Analyzer can be used to simultaneously quantify total cholesterol, triglycerides, HDL cholesterol, and apolipoprotein B. The sample is diluted 1:2 with NMR Diluent 1. The NMR spectrum consists of multiple proton signals from the triglycerides, cholesteryl esters and free cholesterol present in chylomicrons, VLDL, LDL and HDL in the combined methylene and methyl region (0.56 – 1.40 ppm). The NMR signals from these lipoproteins have distinctive frequencies and line shapes, and the amplitude of the NMR signal is proportional to the concentration. The quantitative results are generated based on a Partial Least Squares regression method using spectral information.

M. Performance Characteristics:

1. Analytical performance:

   a. Precision/Reproducibility:

   The precision performance of the Extended Lipid Panel Assay was evaluated following the recommendations in the CLSI EP5-A3 guideline.

   #1 Repeatability (Within-run precision)
   Repeatability was assessed using 3 levels of pooled serum samples, and tested in one run of 20 replicates on one instrument by one operator. The results are summarized below:

Analyte	Pool	Mean, (mg/dL)	SD	%CV
Total cholesterol	Low	159	2.6	1.6
	Medium	196	2.6	1.3
	High	276	2.6	0.9
Triglycerides	Low	128	1.0	1.0
	Medium	158	1.6	1.0
	High	317	3.1	1.0
HDL cholesterol	Low	37	0.9	2.4
	Medium	50	0.8	1.6
	High	91	1.2	1.3
Apolipoprotein B	Low	77	0.9	1.2
	Medium	106	1.1	1.1
	High	134	1.4	1.1

#2 Within-laboratory precision

Within-laboratory precision was assessed using 3 levels of pooled serum samples, and tested in 2 replicates per run, 2 runs per day for 20 days for a total of 80 measurements per level. One operator conducted the study using one lot of reagents using one instrument. The results are summarized below:

Analyte	Pool	Mean, (mg/dL)	SD	%CV
Total cholesterol	Low	167	2.7	1.6
	Medium	197	2.8	1.4
	High	280	3.2	1.1
Triglycerides	Low	131	1.8	1.4
	Medium	161	1.9	1.2
	High	320	3.1	1.0
HDL cholesterol	Low	37	1.0	2.8
	Medium	49	1.2	2.3
	High	92	1.3	1.4
Apolipoprotein B	Low	79	1.9	2.4
	Medium	109	2.4	2.2
	High	138	2.6	1.9

#3 Reproducibility

A reproducibility study was performed at three intended use sites using 3 levels of pooled serum samples. At each site with one instrument and one operator, the samples were tested in 2 replicates per run, 6 runs per day for 5 days for a total of 60 measurements per level. Each site performed testing using the same three lots of reagents. The precision analysis used a mixed effects model with reagent lot, site/instrument/operator, day, run, and within-run as random effects. The results are summarized below.

			Between lot		Between site		Reproducibility	
Analyte	Pool	Mean, mg/dL	SD	%CV	SD	%CV	SD	%CV
TC	Low	142	0	0	3.86	2.7%	5.16	3.6%
	Med	214	0	0	2.71	1.3%	4.78	2.1%
	High	316	0	0	4.03	1.3%	6.58	2.1%
TG	Low	107	0	0	1.33	1.2%	3.66	3.4%
	Med	170	0	0	1.82	1.1%	5.14	3.0%
	High	296	0.49	0.2%	0	0	6.16	2.1%
HDL	Low	36	0	0	0.80	2.2%	1.66	4.6%
	Med	52	0.11	0.2%	1.80	3.4%	2.21	4.2%
	High	80	0.23	0.3%	1.81	2.3%	1.67	2.1%
ApoB	Low	85	0.38	0.4%	4.96	5.8%	5.73	6.7%
	Med	115	0.25	0.2%	4.34	3.8%	4.85	4.2%
	High	164	0	0	4.83	2.9%	6.16	3.7%

In some instances when analyzing the variance by mixed effects model the result was a negative number, and therefore the contribution was considered negligible and the variance set to 0.

b. Linearity/assay reportable range:

A linearity study was conducted on the Extended Lipid Panel Assay following the recommendations in the CLSI EP06-A guideline. The linearity was assessed using pooled serum samples spanning the target analyte concentration range which were prepared by combining volumes from three pools; low pool, mid pool, and high pool. A total of 15 samples for total cholesterol, 13 samples for Apolipoprotein B, 17 samples for triglycerides, and 12 samples for HDL cholesterol were prepared for the linearity assessment. For each sample 4 replicates were tested by one operator using one instrument. The mean values of four replicates of each pool were compared to the expected target values to determine the deviation from linearity. For all samples the deviation from linearity was less than 10%. The linear regression results are given in the table below:

Analyte	Slope	Intercept	R^2
Total cholesterol	1.010	-1.851	1.000
Triglycerides	0.999	-1.086	1.000
HDL cholesterol	1.063	-1.925	1.000
Apolipoprotein B	0.985	-1.668	0.999

Based on these results, the sponsor concluded that the linearity data supported the claimed analytical measurement range for total cholesterol, triglycerides, HDL cholesterol, and apolipoprotein B:

- 66 to 868 mg/dL for total cholesterol
- 35 to 950 mg/dL for triglycerides
- 14 to 152 mg/dL for HDL cholesterol
- 35 to 366 mg/dL for apolipoprotein B

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:
The Extended Lipid Panel Assay for total cholesterol, HDL cholesterol, triglycerides, and apolipoproteins B is traceable to internal instrument standards.

The Extended Lipid Panel Assay is CRMLN certified for total cholesterol using serum samples. The total cholesterol assay is traceable to the National Reference System for Cholesterol.

d. Detection limit:

Determination of the Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) for the Extended Lipid Panel Assay were conducted following the recommendations in the CLSI EP17-A2 guideline.

Limit of Blank:
The LoB study followed a classical protocol and utilized 5 different pools of human serum albumin solution free of analyte. Each pool was tested in 4 replicates over a three day period using one instrument by one operator for a total 60 measurements. Using the parametric approach, LoB was derived from the 95th percentile of a normal distribution.

Limit of Detection:
The LoD study followed a classical protocol and utilized 5 different serum pools which were diluted 20-fold using human serum albumin solution. Each pool was tested in 4 replicates per day on one instrument by one operator for three days for a total of 60 measurements. The data was analyzed to calculate the LoD using a parametric analysis recommended in the CLSI guideline EP17-A2.

Limit of Quantification:
The LoQ study followed an approach similar to the LoD study. Five 5 serum pools with low concentrations were tested in replicates of 4 over 3 days on one instrument and one operator for a total of 12 measurements per pool. The sponsor defined the LoQ as the lowest analyte concentration where the %CV was ≤ 20%. The detection limit results are summarized as follows:

Analyte	LoB	LoD	LoQ
Total cholesterol, mg/dL	18.9	22.2	23.5
Triglycerides, mg/dL	11.9	13.8	15.2
HDL cholesterol, mg/dL	11.3	12.9	12.9
Apolipoprotein B, mg/dL	15.7	17.9	17.9

The LoQ values support the sponsors claimed measurement ranges of:

Analyte	Measurement range
Total cholesterol	66 - 868 mg/dL
Triglycerides	35 - 950 mg/dL
HDL cholesterol	14 - 152 mg/dL
Apolipoprotein B	35 - 366 mg/dL

e. Analytical specificity:

Interference testing on the Extended Lipid Panel Assay was evaluated following the recommendations in the CLSI EP7-A2 guideline. Serum samples at two analyte concentrations near the medical decision concentrations were evaluated for each substance. The samples were divided into two aliquots: control with no added interferent and test with added interferent. Each sample was measured in 2 replicates. The study tested for possible interference from common endogenous substances, and exogenous substances such as medications or supplements likely to be used by the target patient population. The interferent concentrations were selected using the criteria recommended in CLSI EP7-A2. The following tables list the concentration of each substance at which no significant interference was detected; defined as a difference of less than or equal ±10% between the test sample and control.

Total cholesterol - Substances tested	**Highest concentration tested at which no significant interference was observed.**
Exogenous Substances	
Atorvastatin	4.9 mg/dL
Fenofibrate	4.5 mg/dL
Acetylsalicylic Acid	66 mg/dL
Acetaminophen	20 mg/dL
Naproxen Sodium	42 mg/dL
Ibuprofen Sodium Salt	59 mg/dL
Hydrochlorothiazide	0.6 mg/dL
Metoprolol Tartrate	1.5 mg/dL
Nifedipine	0.041 mg/dL
Enalaprilat Dihydrate	0.037 mg/dL
Hydralazine	19 mg/dL
Metformin	65 mg/dL
Salicylic Acid	61 mg/dL
Clopidogrel	18 mg/dL
Furosemide	6.3 mg/dL
Glipizide	0.22 mg/dL
Heparin Sodium	3035 mU/mL
Isosorbide Dinitrate	0.016 mg/dL
Menhaden Oil	241 mg/dL
Endogenous Substances	
Bilirubin, unconjugated	20 mg/dL
Bilirubin, conjugated	34 mg/dL
Creatinine	5.5 mg/dL
Hemoglobin	219 mg/dL
Urea	263 mg/dL
Uric acid	24 mg/dL
Albumin	5987 mg/dL
Triglycerides	500 mg/dL

Triglycerides - Substances tested	**Highest concentration tested at which no significant interference was observed.**
Exogenous Substances	
Atorvastatin	4.9 mg/dL
Fenofibrate	4.5 mg/dL
Acetylsalicylic Acid	66 mg/dL
Acetaminophen	20 mg/dL
Naproxen Sodium	56 mg/dL
Ibuprofen Sodium Salt	29 mg/dL
Hydrochlorothiazide	0.65 mg/dL
Metoprolol Tartrate	1.5 mg/dL
Nifedipine	0.041 mg/dL
Enalaprilat Dihydrate	0.037 mg/dL
Hydralazine	19 mg/dL
Metformin	65 mg/dL
Salicylic Acid	61 mg/dL
Clopidogrel	18 mg/dL
Furosemide	6.3 mg/dL
Glipizide	0.22 mg/dL
Heparin Sodium	3035 mU/mL
Isosorbide Dinitrate	0.016 mg/dL
Menhaden Oil	241 mg/dL
Endogenous Substances	
Bilirubin, unconjugated	20 mg/dL
Bilirubin, conjugated	34 mg/dL
Creatinine	5.6 mg/dL
Hemoglobin	219 mg/dL
Urea	263 mg/dL
Uric acid	24 mg/dL
Albumin	5987 mg/dL

HDL cholesterol - Substances tested	**Highest concentration tested at which no significant interference was observed.**
Exogenous Substances	
Atorvastatin	4.9 mg/dL
Fenofibrate	4.6 mg/dL
Acetylsalicylic Acid	66 mg/dL
Acetaminophen	20.0 mg/dL
Naproxen Sodium	28 mg/dL
Ibuprofen Sodium Salt	44 mg/dL
Hydrochlorothiazide	0.65 mg/dL
Metoprolol Tartrate	1.5 mg/dL
Nifedipine	0.041 mg/dL
Enalaprilat Dihydrate	0.037 mg/dL
Hydralazine	19 mg/dL

HDL cholesterol - Substances tested	Highest concentration tested at which no significant interference was observed.
Metformin	65 mg/dL
Salicylic Acid	61 mg/dL
Clopidogrel	18 mg/dL
Furosemide	6.3 mg/dL
Glipizide	0.22 mg/dL
Heparin Sodium	3035 mU/mL
Isosorbide Dinitrate	0.016 mg/dL
Menhaden Oil	242 mg/dL
Endogenous Substances	
Bilirubin, unconjugated	20 mg/dL
Bilirubin, conjugated	34 mg/dL
Creatinine	5.6 mg/dL
Hemoglobin	219 mg/dL
Urea	263 mg/dL
Uric acid	24 mg/dL
Albumin	7493 mg/dL
Triglycerides	1135 mg/dL

Apolipoprotein B - Substances tested	Highest concentration tested at which no significant interference was observed.
Exogenous Substances	
Atorvastatin	4.9 mg/dL
Fenofibrate	4.5 mg/dL
Acetylsalicylic Acid	66 mg/dL
Acetaminophen	20.4 mg/dL
Naproxen Sodium	28 mg/dL
Ibuprofen Sodium Salt	44 mg/dL
Hydrochlorothiazide	0.65 mg/dL
Metoprolol Tartrate	1.5 mg/dL
Nifedipine	0.041 mg/dL
Enalaprilat Dihydrate	0.033 mg/dL
Hydralazine	19 mg/dL
Metformin	65 mg/dL
Salicylic Acid	61 mg/dL
Clopidogrel	9.5 mg/dL
Furosemide	6.3 mg/dL
Glipizide	0.23 mg/dL
Heparin Sodium	3035 mU/mL
Isosorbide Dinitrate	0.016 mg/dL
Menhaden Oil	241 mg/dL
Acetylcysteine	125 mg/dL
Ampicillin	6.1 mg/dL
Ascorbic Acid	6.2 mg/dL

Apolipoprotein B - Substances tested	Highest concentration tested at which no significant interference was observed.
Calcium Dobesilate	30 mg/dL
Cyclosporine	6.1 mg/dL
Cefoxitin	70 mg/dL
Levodopa	1.6 mg/dL
Methyldopa	1.6 mg/dL
Metronidazole	12 mg/dL
Doxycycline	3.1 mg/dL
Rifampin (Rifampicin)	34 mg/dL
Endogenous Substances	
Bilirubin, unconjugated	20 mg/dL
Bilirubin, conjugated	34 mg/dL
Creatinine	5.5 mg/dL
Hemoglobin	219 mg/dL
Urea	263 mg/dL
Uric acid	24 mg/dL
Albumin	5986 mg/dL
Triglycerides	633 mg/dL

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

To establish the accuracy of the Extended Lipid Panel Assay, a method comparison study was conducted to evaluate the analytical agreement to a comparator method for each of the 4 analytes. Serum samples were tested in singlicate on the Vantera Clinical Analyzer and the comparator methods. The results of the method comparison studies are summarized as follows.

Deming regression analysis

	N	Slope	Intercept	R	Range
Total Cholesterol	281	0.974	7.27	0.992	71 to 859 mg/dL
Triglycerides	270	0.980	-3.86	0.997	36 to 939 mg/dL
HDL Cholesterol	15575	1.000	0.789	0.985	15 to 151 mg/dL
Apolipoprotein B	266	0.970	-1.01	0.980	36 to 344 mg/dL

Predicted Bias at Medical Decision Points

An estimate of the predicated bias at the medical decision points was calculated as the percent difference between the regression line and the unity line at each medical decision point.

Predicated Bias at Medical Decision Points (95% CI)		
Total cholesterol	200 mg/dL	240 mg/dL
	1.0% (-0.7% to 2.7%)	0.4% (-1.0% to 1.8%)
Triglycerides	150 mg/dL	200 mg/dL
	-4.5% (-5.7% to -3.4%)	-3.9% (-4.7% to -3.0%)
HDL Cholesterol	40 mg/dL	60 mg/dL
	2.0% (1.7% to 2.3%)	1.3% (1.1% to 1.5%)
Apolipoprotein B	90 mg/dL	130 mg/dL
	-4.1% (-6.5% to -1.8%)	-3.8% (-5.4% to -2.2%)

b. Matrix comparison:

A matrix comparison study was conducted on matched specimens collected in 4 different blood collection tube types; see table below. The NMR LipoTube (cleared in k960858) was the comparator in the study and was used to collect specimens for all the above analytical studies.

Specimen Type	**Collection Tube**
Plasma	EDTA
Plasma	Sodium heparin
Serum	Plain
Serum	Gel barrier / NMR LipoTube

EDTA plasma, sodium heparin plasma, and serum samples (47 native and 5 contrived) were analyzed in singlicate on the Vantera Clinical Analyzer for total cholesterol, HDL cholesterol, triglycerides, and Apolipoprotein B. These were compared to the results from testing specimens collected using the NMR LipoTube measured in duplicate. The matrix comparison results were analyzed by Deming regression and are given in the table below:

Analyte	**Collection tube**	**Intercept (95% CI)**	**Slope (95% CI)**	**R^2**	**Concentration range, mg/dL**
Total cholesterol	Na Heparin	6.12 (3.37, 8.87)	0.985 (0.974, 0.996)	0.998	79-798
	Plain	10.29 (7.14, 13.44)	0.963 (0.951, 0.976)	0.998	

Analyte	Collection tube	Intercept (95% CI)	Slope (95% CI)	R^2	Concentration range, mg/dL
Triglycerides	EDTA	1.75 (-1.85, 5.36)	0.938 (0.925, 0.952)	0.997	42 - 934
	Na Heparin	4.28 (2.09, 6.47)	0.947 (0.938, 955)	0.999	
	Plain	2.19 (-0.21, 4.59)	0.985 (0.976, 994)	0.999	
HDL cholesterol	EDTA	0.68 (-0.44, 1.80)	0.956 (0.938, 0.974)	0.996	22 - 153
	Na Heparin	0.66 (-0.49, 1.82)	0.997 (0.978, 1.01)	0.996	
	Plain	1.51 (0.37, 2.66)	0.994 (0.975, 1.01)	0.996	
Apolipoprotein B	Plain	5.67 (3.71, 7.63)	0.967 (0.950, 983)	0.996	33 - 360

Based on the study data, serum collected from the NMR LipoTube or a plain tube is the acceptable specimen type when simultaneously quantifying all four analytes. Sodium heparin plasma is an acceptable specimen type for total cholesterol, HDL cholesterol, and triglycerides. EDTA plasma is an acceptable specimen type for HDL cholesterol and triglycerides. The product labeling states that serum and plasma specimens drawn in gel barrier collection tubes other than the NMR LipoTube are unsuitable for analysis and should not be used.

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:

The reference values for total cholesterol, HDL cholesterol, and triglycerides were identified in the labeling as:

Analyte	Concentration, mg/dL	Adult Treatment Panel III Classification
Total cholesterol	< 200	Desirable
	200 - 239	Borderline high
	≥ 240	High
HDL cholesterol	< 40	Low
	≥ 60	High
Triglycerides	< 150	Normal
	150 - 199	Borderline high
	200 - 499	High
	≥ 500	Very high

Source: Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA, Vol. 285, 2486-2497; 2001.

The reference values for Apolipoprotein B were identified in the labeling as:

	Concentration, mg/dL	Classification
Apolipoprotein B	< 90	Low
	90 - 130	Intermediate
	> 130	High

Source: Grundy SM. Low Density Lipoprotein, Non-High Density Lipoprotein, and Apolipoprotein B as Targets for Lipid-Lowering Therapy. Circ. 2002;106:2526–9

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.