October 18, 2018

Laboratory Corporation of America Holdings
Suzette Warner
Director, Quality Assurance and Regulatory Affairs
500 Perimeter Park Drive
Morrisville, NC 27560

Re: K181373
Trade/Device Name: Extended Lipid Panel Assay
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class I, meets the limitation to the exemption 21 CFR 862.9 (c)(4)
Product Code: CHH, CDT, LBS, MSJ
Dated: September 12, 2018
Received: September 13, 2018

Dear Suzette Warner:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181373

Device Name
Extended Lipid Panel Assay

Indications for Use *(Describe)*
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 calculated 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary per 21CFR §807.92

1) 510(k) Number: k181373

2) Submitted By

Laboratory Corporation of America Holdings
500 Perimeter Park Drive
Morrisville, NC 27560
VTAC@labcorp.com

Contact Person:
Suzette Warner
Director, Quality Assurance and Regulatory Affairs
LabCorp
Ph: (919) 388-5539
warnes1@labcorp.com

3) Date Summary was Prepared:
October 1, 2018

4) Device Name(s)

Trade Name: Extended Lipid Panel Assay
Common Name: Cholesterol
Classification Names:

Triglyceride test system, 21 CFR 862.1705, Product Code CDT
Cholesterol test system 21 CFR 862.1175, Product Code CHH
Lipoprotein test system, 21 CFR 862.1475, Product Code LBS
Lipoprotein test system, 21 CFR 862.1475, Product Code MSJ

Panel: Clinical Chemistry (75)

5) Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

Roche Diagnostics HDL-Cholesterol plus 2nd Generation - k012286
Roche Diagnostics COBAS Integra Cholesterol Gen.2 - k031824
Roche Diagnostics Triglycerides GPO Without Free Glycerol - k873049
Dimension Vista Apolipoprotein B Flex reagent cartridge - k063608

6) Device Description

The Extended Lipid Panel Assay involves the acquisition of a 400 MHz proton NMR spectrum of serum or plasma, passing the spectral information through a Partial Least Squares (PLS) regression model, and deriving analyte concentrations from the spectrum based on the trained PLS model. The proton NMR spectrum of serum and plasma is replete with information from the lipids packaged in lipoproteins. The spectrum consists of multiple proton signals emanating from the TG, cholesteryl esters and free cholesterol present in chylomicrons, VLDL, LDL and HDL, out of which the methylene and methyl proton signals are the most abundant. NMR spectra were recorded for several hundred to several thousand representative serum specimens for which the TG, TC, HDL-C and ApoB were chemically measured. Using a PLS regression routine, the spectral information in the combined methylene and methyl region (0.56 – 1.40 ppm) was trained against the chemical measurements where the information is connected through latent variables. Cross-validation was performed with PRESS statistics to optimize the regression model with an appropriate number of latent variables. Once trained with sufficient number of specimens, for any test specimen spectrum, the spectral information is then converted into lipid or ApoB concentrations through the optimum number of 24 to 27 latent variables for which the regression coefficients were known from the predictor matrix.

7) 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 calculated 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.

8) Comparison to the Predicate

The proposed device, Extended Lipid Panel Assay, is substantially equivalent to the predicates (k012286, k031824, k873049, k013206). The substantial equivalence is supported by its similarity in its intended use, sample type, patient population and testing environment. The key features are summarized in the following tables:

	Total Cholesterol Assay (Predicate)	**Extended Lipid Panel Assay (Proposed Device)**
510(k) Number	K031824	K181373
Intended Use / Indications for Use	The cassette COBAS Integra Cholesterol Gen.2 (CHOL2) contains an in vitro diagnostic reagent system intended use for use on COBAS Integra systems for the quantitative determination of total cholesterol in serum and plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in blood and lipid and lipoprotein metabolism disorders.	The Extended Lipid Panel Assay is an in vitro diagnostic test for quantitative determination of Total Cholesterol, in human serum and plasma. Values are calculated 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.
Technology	Enzymatic colorimetric assay	Nuclear magnetic resonance
Sample Type	Human Serum and Plasma	Human Serum and Plasma
Population	General	General
Testing Environment	Professional Use	Professional Use
Medical Decision Limits	<200 and >240 mg/dL	<200 and >240 mg/dL
Sample size	2µL	150µL

	HDL Cholesterol (Predicate)	Extended Lipid Panel Assay (Proposed Device)
510(k) Number	K012286	K181373
Intended Use / Indications for Use	The cassette COBAS Integra HDL-Cholesterol plus 2nd Generation (HDL-C) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of HDL-cholesterol concentration in serum and plasma. A lipoprotein test system is a device intended to measure lipoprotein in serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases.	The Extended Lipid Panel Assay is an in vitro diagnostic test for quantitative determination of High Density Lipoprotein Cholesterol (HDL-C), in human serum and plasma. Values are calculated by the Vantera® Clinical Analyzer. 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.
Technology	Enzymatic colorimetric assay	Nuclear magnetic resonance
Sample Type	Human Serum and Plasma	Human Serum and Plasma
Population	General	General
Testing Environment	Professional Use	Professional Use
Medical Decision Limits	<40 and ≥60 mg/dL	<40 and ≥60 mg/dL
Sample size	2.5µL	150µL

	Triglyceride (Predicate)	**Extended Lipid Panel Assay (Proposed Device)**
510(k) Number	K873049	K181373
Intended Use / Indications for Use	In vitro test for the quantitative determination of triglycerides in human serum and plasma. The determination of triglycerides is utilized in the diagnosis and treatment of patients having diabetes mellitus, nephrosis, liver obstruction, lipid metabolism disorders and numerous other endocrine diseases.	The Extended Lipid Panel Assay is an in vitro diagnostic test for quantitative determination of Triglycerides in human serum and plasma. Values are calculated by the Vantera® Clinical Analyzer. 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.
Technology	Enzymatic colorimetric assay	Nuclear magnetic resonance
Sample Type	Human Serum and Plasma	Human Serum and Plasma
Population	General	General
Testing Environment	Professional Use	Professional Use
Medical Decision Limits	<150 and >200 mg/dL	<150 and >200 mg/dL
Sample size	2µL	150µL

	Apo B (Predicate)	**Extended Lipid Panel Assay (Proposed Device)**
510(k) Number	K063608	K181373
Intended Use / Indications for Use	An in vitro diagnostic test for the quantitative determination of apolipoprotein B. Measurements of apolipoprotein B aid in the diagnosis and treatment of lipid disorders, various liver and renal diseases, and in the assessment of risk for atherosclerosis and cardiovascular disease.	The Extended Lipid Panel Assay is an in vitro diagnostic test for quantitative determination of ApoB in human serum. Values are calculated by the Vantera® Clinical Analyzer. Apolipoprotein B measurements are used in the diagnosis and treatment of lipid disorders and atherosclerosis
Technology	Nephelometric immunoassay	Nuclear magnetic resonance
Sample Type	Human Serum and Plasma	Human Serum
Population	General	General
Testing Environment	Professional Use	Professional Use
Medical Decision Limits	<90 and >130 mg/dL	<90 and >130 mg/dL
Sample size	19.6µL	150µL

9) Performance Data – Non-Clinical:

Analytical Sensitivity

The analytical sensitivity of the Extended Lipid Panel Assay was determined as the lowest concentration measurable with acceptable precision and accuracy. Limits of quantification (LoQ) are 24 mg/dL for TC, 15 mg/dL for TG, 13 mg/dL for HDL-C, and 18 mg/dL for ApoB.

Assay Precision

Within-run precision and within-laboratory precision were determined by testing 20 replicates of three patient serum pools in the same run and in 40 total different runs over 20 days on 1 instrument. The pools were analyzed according to EP-5A. The results of this testing are summarized below:

Within-run Precision (n=20)

	Low Pool			**Medium Pool**			**High Pool**		
	Mean	**SD**	**%CV**	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
TC, mg/dL	159.3	2.6	1.6	196.3	2.6	1.3	275.8	2.6	0.9
TG, mg/dL	128.4	1.0	1.0	157.7	1.6	1.0	317.4	3.1	1.0
HDL-C, mg/dL	36.6	0.9	2.4	49.9	0.8	1.6	91.2	1.2	1.3
ApoB, mg/dL	76.7	0.9	1.2	105.5	1.1	1.1	133.8	1.4	1.1

Within-Laboratory Precision (n=80)

	Low Pool			**Medium Pool**			**High Pool**		
	Mean	**SD**	**%CV**	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
TC, mg/dL	166.6	2.7	1.6	197.1	2.8	1.4	279.6	3.2	1.1
TG, mg/dL	130.6	1.8	1.4	160.9	1.9	1.2	320.3	3.1	1.0
HDL-C, mg/dL	36.7	1.0	2.8	49.3	1.2	2.3	91.7	1.3	1.4
ApoB, mg/dL	78.9	1.9	2.4	109.4	2.4	2.2	137.9	2.6	1.9

Reproducibility

A reproducibility study was conducted in accordance to EP5-A2 at 3 sites each having 1 instrument incorporating five levels of serum panels at or around the medical decision limits. The panels were tested for 5 days, 6 runs per day, 2 replicates per run. The overall precision estimates are described below.

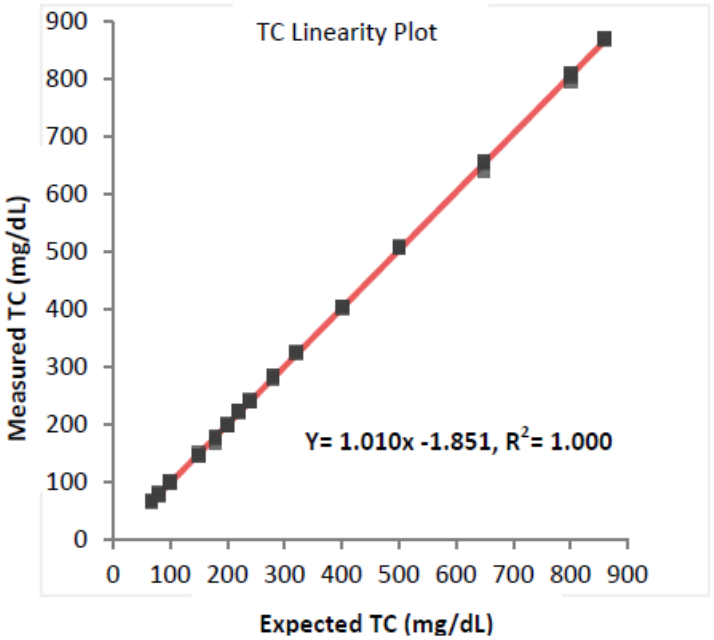
Precision from Reproducibility Study

	Low Pool			Medium Pool			High Pool		
	Mean	**SD**	**%CV**	**Mean**	**SD**	**%CV**	**Mean**	**SD**	**%CV**
TC, mg/dL	142	5.2	3.6	214	4.8	2.1	316	6.6	2.1
TG, mg/dL	107	3.7	3.4	170	5.1	3.0	296	6.2	2.1
HDL-C, mg/dL	36	1.7	4.6	52	2.2	4.2	80	2.4	2.1
ApoB, mg/dL	85	5.7	6.7	115	4.9	4.2	164	6.2	3.7

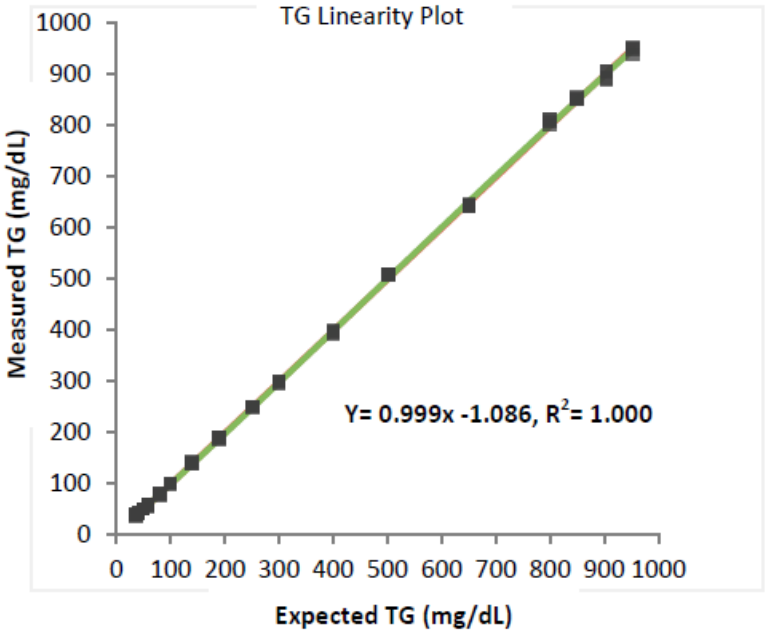
Linearity

Reference serum pools were prepared from patient specimens with low to high values of TC, TG, HDL-C and ApoB as determined by the Extended Lipid Panel Assay. Each were mixed and diluted in different proportions to produce a range of different samples with widely varying target concentrations. Mean values from analysis of four replicates of each pool were compared to the expected target values to determine the percent bias for each sample. The serum pools were analyzed according to EP6-A. Regression plots of the linearity data for TC, TG, HDL-C and ApoB are given below:

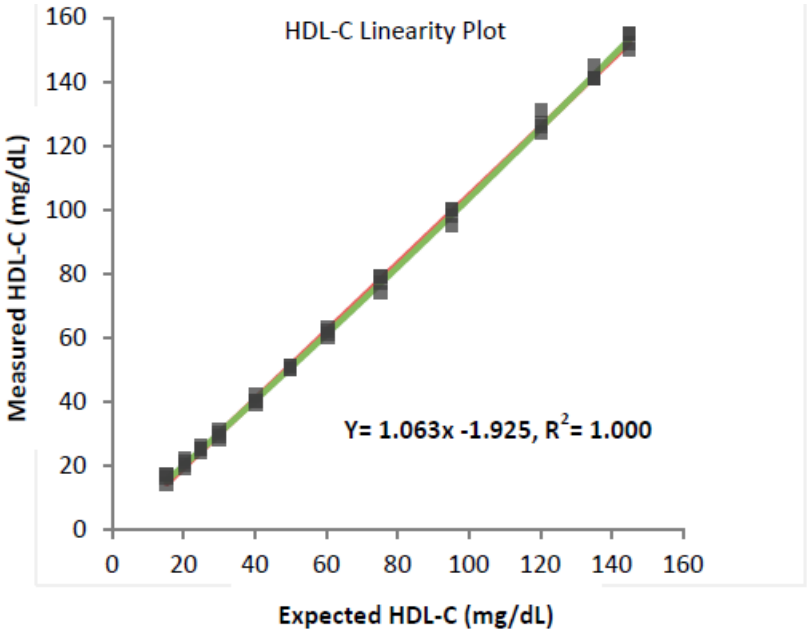
TC Measuring Range: 66-868 mg/dL



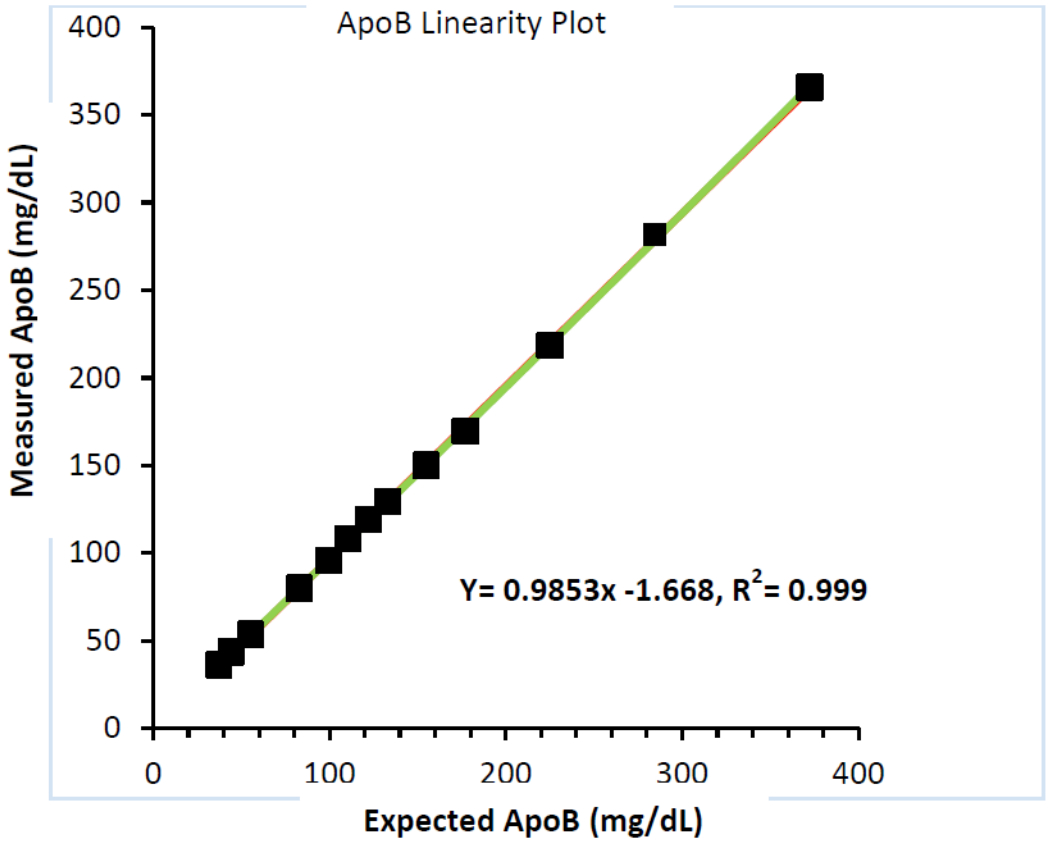
TG Measuring Range: 35-950 mg/dL



HDL-C Measuring Range: 14-152 mg/dL



ApoB Measuring Range: 35-366 mg/dL



Interfering Substances

Endogenous substances normally found in blood and exogenous substances (common and prescription drugs) were evaluated for potential interference with the Extended Lipid Panel Assay test results. Eight endogenous agents and thirty drugs were screened for potential interfering effects to Extended Lipid Panel Assay test using samples with spiked concentrations of interferent in accordance to CLSI EP7-A2 guidelines.

Substances tested in vitro that did not exhibit interference with ApoB test results.

Endogenous			***Exogenous (OTC drugs, etc.)***		
Potential Interferent	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**
Bilirubin, unconj.	20.	Atorvastatin	4.9	Ampicillin	6.1
Bilirubin, conj.	34	Fenofibrate	4.5	Ascorbic Acid	6.2
Creatinine	5.5	Acetylsalicylic acid	66	Calcium Dobesilate	30
Hemoglobin	219	Acetaminophen	20	Cyclosporine	6.1
Urea	263	Naproxen	28	Cefoxitin	70
Uric acid	24	Ibuprofen	44	Levodopa (L─DOPA)	1.6
Protein (albumin)	5986	Hydrochlorothiazide	0.65	Methyldopa	1.6
Triglycerides (lipemic)	633	Metoprolol	1.5	Metronidazole	12
		Nifedipine	0.04	Doxycycline	3.1
		Enalaprilat	0.04	Rifampin (Rifampicin)	34
		Hydralazine	19		
		Metformin	65		
		Salicylic acid	61		
		Clopidogrel	9.5		
		Furosemide	6.3		
		Glipizide	0.23		
		Heparin	303533 mU/dL		
		Isosorbide dinitrate	0.02		
		Menhaden Oil	241		
		Acetylcysteine	125		

Substances tested in vitro that did not exhibit interference with TC test results.

Endogenous			***Exogenous (OTC drugs, etc.)***		
Potential Interferent	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**
Bilirubin, unconj.	20	Atorvastatin	4.9	Hydralazine	19
Bilirubin, conj.	34	Fenofibrate	4.5	Metformin	65
Creatinine	5.5	Acetylsalicylic acid	66	Salicylic acid	61
Hemoglobin	219	Acetaminophen	20	Clopidogrel	18
Urea	263	Naproxen	42	Furosemide	6.3
Uric acid	24	Ibuprofen	59	Glipizide	0.23
Protein (albumin)	5987	Hydrochlorothiazide	0.65	Heparin	303533 mU/dL
Triglycerides (lipemic)	500	Metoprolol	1.5	Isosorbide dinitrate	0.02
		Nifedipine	0.04	Menhaden Oil	241
		Enalaprilat	0.04		

Substances tested in vitro that did not exhibit interference with HDL-C test results.

Endogenous			***Exogenous (OTC drugs, etc.)***		
Potential Interferent	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**
Bilirubin, unconj.	20	Atorvastatin	4.9	Hydralazine	19
Bilirubin, conj.	34	Fenofibrate	4.6	Metformin	65
Creatinine	5.5	Acetylsalicylic acid	66	Salicylic acid	61
Hemoglobin	219	Acetaminophen	20	Clopidogrel	18
Urea	263	Naproxen	28	Furosemide	6.3
Uric acid	24	Ibuprofen	44	Glipizide	0.23
Protein (albumin)	7493	Hydrochlorothiazide	0.65	Heparin	303533 mU/dL
Triglycerides (lipemic)	1135	Metoprolol	1.5	Isosorbide dinitrate	0.02
		Nifedipine	0.04	Menhaden Oil	242
		Enalaprilat	0.04		

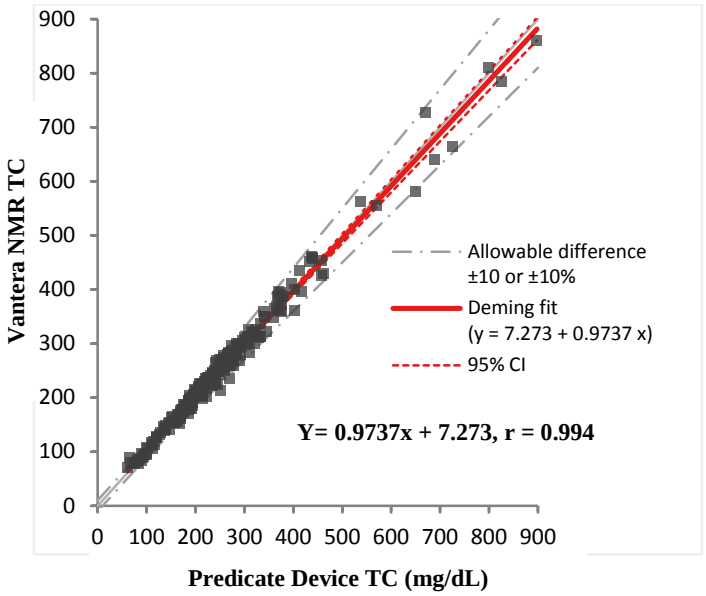
Substances tested in vitro that did not exhibit interference with TG test results.

Endogenous			***Exogenous (OTC drugs, etc.)***		
Potential Interferent	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**	**Potential Interferent**	**Highest Concentration Tested (mg/dL)**
Bilirubin, unconj.	20	Atorvastatin	4.9	Hydralazine	19
Bilirubin, conj.	34	Fenofibrate	4.5	Metformin	65
Creatinine	5.5	Acetylsalicylic acid	66	Salicylic acid	61
Hemoglobin	219	Acetaminophen	20	Clopidogrel	18
Urea	263	Naproxen	56	Furosemide	6.3
Uric acid	24	Ibuprofen	29	Glipizide	0.23
Protein (albumin)	5987	Hydrochlorothiazide	0.65	Heparin	303533 mU/dL
		Metoprolol	1.5	Isosorbide dinitrate	0.02
		Nifedipine	0.04	Menhaden Oil	241
		Enalaprilat	0.04		

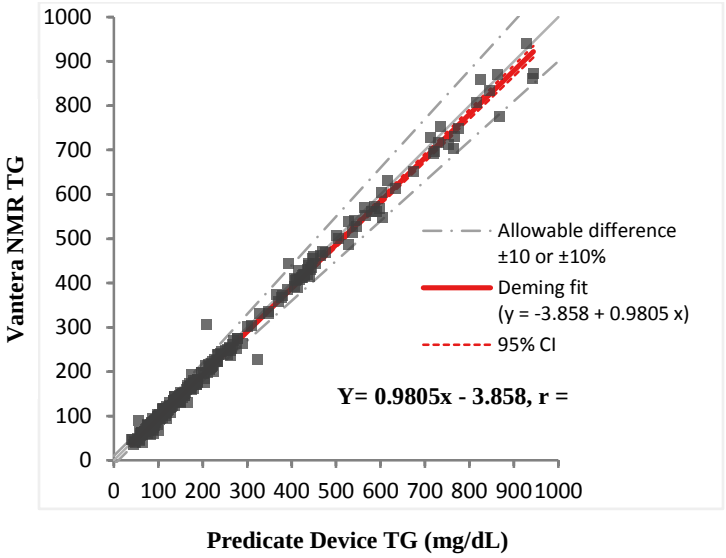
H. Method Comparison – Non-Clinical:

Method comparison was evaluated by using pooled serum samples across the reportable range of the Extended Lipid Panel Assay test for TC, TG, HDL-C and ApoB on the Vantera Clinical Analyzer. TC concentrations ranged from 71-859 mg/dL, TG concentrations ranged from 36 to 939.0 mg/dL, HDL-C concentrations ranged from 15 to 151.0 mg/dL and ApoB concentrations ranged from 36 to 344.0 mg/dL.

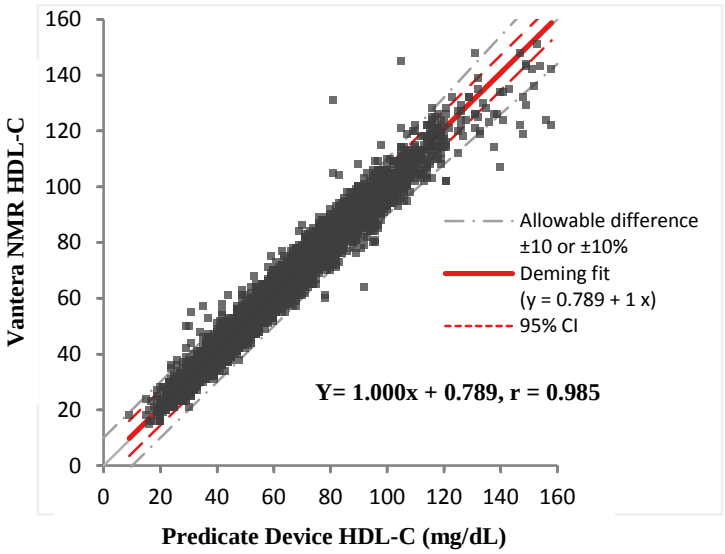
Vantera NMR (candidate device) vs. Predicate Device TC Regression Plot (n=281)



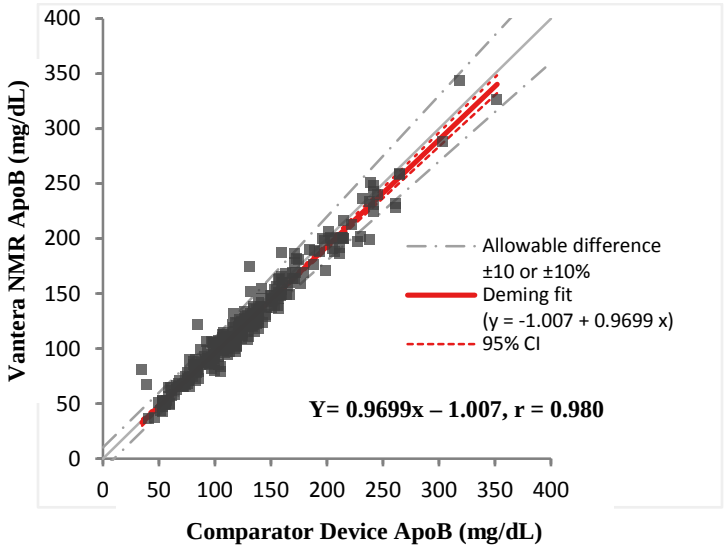
Vantera NMR (candidate device) vs. Predicate device TG Regression Plot (n=270)



Vantera NMR (candidate device) vs. Predicate Device HDL-C Regression Plot (n=15575)



Vantera NMR (candidate device) vs. Comparator Device ApoB Regression Plot (n=266)



10) Conclusion:

The submitted information in this premarket notification provides the data necessary to demonstrate substantial equivalence based on analytical validations and predicate comparisons.

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1991 and the implementing regulation 21 CFR 807.92.