**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

k163406

**B. Purpose for Submission:**

New device

**C. Measurand:**

Total cholesterol, high density lipoprotein (HDL) cholesterol, and triglycerides in whole blood.

**D. Type of Test:**

Quantitative, enzymatic assays by reflectance measurement

**E. Applicant:**

ACON Laboratories Inc.

**F. Proprietary and Established Names:**

Mission Cholesterol Monitoring System
Mission Cholesterol Pro Monitoring System

**G. Regulatory Information:**

1. Regulation section:
   21 CFR 862.1175 Cholesterol (total) Test System
   21 CFR 862.1705 Triglyceride Test System
   21 CFR 862.1475 Lipoprotein Test System

2. Classification:
   Class I, meets the limitation of exemption 21 CFR 862.9(c)(4)

3. Product codes:
   CHH
   JGY
   LBR

4. Panel:
   Chemistry (75)

## H. Intended Use:

1. Intended use:
   See indications for use.

2. Indications for use:

   *Over-the-counter:*

   The Mission Cholesterol Monitoring system is intended for the quantitative determination of total cholesterol, high density lipoprotein cholesterol, and triglycerides in human capillary whole blood from the fingertip. The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

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

   HDL (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.

   Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism or various endocrine disorders. Use this product at the frequency your doctor recommends for testing total cholesterol, HDL cholesterol, and triglycerides.

   An estimated value for low density lipoprotein cholesterol is calculated by the Mission Cholesterol Meter and is reported only when triglycerides are ≤400 mg/dL.

   *Prescription use:*

   The Mission Cholesterol Pro Monitoring System is intended for the quantitative determination of total cholesterol, high density lipoprotein cholesterol, and triglycerides in human capillary whole blood from the fingertip and lithium heparin venous whole blood. The Mission Cholesterol Pro Monitoring System is a portable system consisting of the Mission Cholesterol Pro Meter, Mission Cholesterol Pro Test Cartridges, Mission Cholesterol Optical Verifier, and Mission Cholesterol Control Solution, and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

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

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

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

An estimated value for low density lipoprotein cholesterol is calculated by the Mission Cholesterol Meter and is reported only when triglycerides are ≤400 mg/dL.

3. Special conditions for use statement(s):

*Over-the-counter:*

- Do not test samples other than fresh capillary whole blood obtained from the fingertip.
- For single-patient use only.
- Do not use on neonates.
- Do not reuse; each test cartridge is for single use only.
- Users with low or high red blood cell counts (e.g. users with anemia or polycythemia) may have inaccurate results.
- Do not use when hematocrit is outside the acceptable hematocrit range for testing of 30% to 50%.
- Users with dehydration or peripheral vascular disease should avoid fingertip testing.
- Do not use when humidity is higher than 90% and lower than 20%, as extremes in humidity may affect results.
- Critically ill patients should not use this test.
- Do not use test cartridge after the expiration date shown on the pouch.
- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for total cholesterol and HDL cholesterol.
- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for total cholesterol and HDL cholesterol.

*Prescription use:*

- Do not use on neonates.
- Do not reuse; each test cartridge is for single use only.
- Users with low or high red blood cell counts (e.g. users with anemia or polycythemia) may have inaccurate results.
- Do not use when hematocrit is outside the acceptable hematocrit range for testing of 30% to 50%.
- Users with dehydration or peripheral vascular disease should avoid fingertip testing.

- Do not use when humidity is higher than 90% and lower than 20%, as extremes in humidity may affect results.
- Critically ill patients should not use this test.
- Do not use test cartridge after the expiration date shown on the pouch.
- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for total cholesterol and HDL cholesterol.
- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for total cholesterol and HDL cholesterol.
- Heparin is recommended anticoagulant for use with venous whole blood. Do not use other anticoagulants, e.g. iodoacetate, sodium citrate or those containing fluoride. Arterial blood is not recommended for use. Hemolyzed blood or thrombolytic therapy blood may lower the results. Venous occlusion might increase the results and is not recommended for blood draws.

4. Special instrument requirements:
   Mission Cholesterol Meter
   Mission Cholesterol Pro Meter

## I. Device Description:

The Mission Cholesterol Monitoring System
The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges (3-1), Mission Cholesterol Optical Verifier, Mission Cholesterol Control solution, code chip, safety lancet, carrying case, capillary transfer tube, User's Manual, Quick Reference Guide, package insert, and warranty card.

Mission Cholesterol Pro Monitoring System
The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges (3-1), Mission Cholesterol Optical Verifier, Mission Cholesterol Control solution, code chip, safety lancet, carrying case, capillary transfer tube, User's Manual, Quick Reference Guide, package insert, and warranty card.

## J. Substantial Equivalence Information:

1. Predicate device name(s):
   CardioChek Plus Test System
   CardioChek Home Test System

2. Predicate 510(k) number(s):
   k140068

3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| Item | Candidate Device, Mission Cholesterol Monitoring System k163406 | Predicate Device, CardioChek Home Test System k140068 |
| Intended use | For the quantitative determination of total cholesterol, HDL cholesterol and triglycerides | Same |
| Methodology | Enzymatic, reflectance photometry | Same |
| LDL cholesterol | Calculated | Same |
| Test cartridge storage temperature | 36-86°F (2-30°C) | Same |

| Differences | | |
|---|---|---|
| Item | Candidate Device, Mission Cholesterol Monitoring System k163406 | Predicate Device, CardioChek Home Test System k140068 |
| Hematocrit range | 30 to 50% | 30 to 45% |
| System operating conditions | 59-104ºF (15-40ºC), 20-90% RH | 50-104ºF (10-40 ºC), 20-80% RH |
| Specimen volume | 35 µL | 35-40 µL |
| Analytical measurement range for total cholesterol, HDL cholesterol, and triglycerides | CHO: 100-400mg/dL (2.59-10.36 mmol/L)<br><br>HDL: 15-100 mg/dL (0.39-2.59 mmol/L)<br><br>TRIG: 45-650 mg/dL (0.51-7.34 mmol/L) | CHO: 100-400mg/dL (2.59-10.36 mmol/L)<br><br>HDL: 15-100 mg/dL (0.39-2.59 mmol/L)<br><br>TRIG: 50-500 mg/dL (0.57-5.65 mmol/L) |

| Similarities | | |
|---|---|---|
| Item | Candidate Device, Mission Cholesterol Pro Monitoring System k163406 | Predicate Device, CardioChek Plus Test System, k140068 |
| Intended use | For the quantitative determination of total cholesterol, HDL cholesterol and triglycerides | Same |
| Methodology | Enzymatic, reflectance photometry | Same |
| LDL cholesterol | Calculated | Same |
| Test cartridge storage temperature | 36-86°F (2-30°C) | Same |

| Differences | | |
|---|---|---|
| Item | Candidate Device, Mission Cholesterol Pro Monitoring System k163406 | Predicate Device, CardioChek Plus Test System, k140068 |
| Hematocrit range | 30 to 50% | 30 to 45% |
| System operating conditions | 59-104ºF (15-40ºC), 20-90% RH | 50-104ºF (10-40 ºC), 20-80% RH |
| Specimen volume | 35 µL | 35-40 µL |
| Analytical measurement range for total cholesterol, HDL cholesterol, and triglycerides | CHO: 100-400mg/dL (2.59-10.36 mmol/L)<br><br>HDL: 15-100 mg/dL (0.39-2.59 mmol/L)<br><br>TRIG: 45-650 mg/dL (0.51-7.34 mmol/L) | CHO: 100-400mg/dL (2.59-10.36 mmol/L)<br><br>HDL: 15-100 mg/dL (0.39-2.59 mmol/L)<br><br>TRIG: 50-500 mg/dL (0.57-5.65 mmol/L) |

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

CLSI Guideline EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second 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 EP09-A2: Method Comparison and Bias Estimation Using Patient Samples.

CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use. July 13, 1995 revision.

General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002.

ISO 14971:2009 Medical devices - Application of Risk management to medical devices.

IEC 61010-1:2001 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use. Part 1: General Requirements.

## L. Test Principle:

Mission Cholesterol and Mission Cholesterol Pro Meter:
The Mission Cholesterol/Mission Cholesterol Pro Meter consists of a reflectance photometer that measures the intensity of light reflected from the reagent area of a test strip. The meter reads the Test Cartridges along with the lot-specific code chip.

Test Cartridge:
The Mission Cholesterol/Mission Cholesterol Pro Test Cartridge is a lipid panel test device used to measure concentrations of total cholesterol, HDL cholesterol, and triglycerides in whole blood. The cartridge is a plastic housing into which multilayers of dry reagents are applied . The test cartridge contains three distinct and separated reagent areas for total cholesterol, HDL and triglycerides. After whole blood is applied into the test cartridge, blood cells are separated by a glass fiber layer and a membrane. The plasma then enters the color membrane layer and the analytes in the plasma react with the enzymes to affect a color change. The color change is measured as a reflectance by the meter.

Total cholesterol:
Trinder reaction - Cholesterol esterase hydrolyzes cholesterol esters to free cholesterol and fatty acids. The free cholesterol is oxidized to cholesten-3-one and hydrogen peroxide by cholesterol oxidase. Peroxidase catalyzes the reaction of hydrogen peroxide with 4-aminoantipyrine and phenol to produce a colored quinoneimine product.

HDL:
The dextran sulphate/$Mg^{2+}$ on the test device precipitates the chylomicrons, VLDL and LDL, leaving HDL in the sample. The HDL cholesterol concentration is then determined enzymatically by the Trinder reaction.

Triglycerides:
Triglycerides in the sample are hydrolyzed to glycerol and free fatty acids by the action of lipase. A sequence of three coupled enzymatic steps using glycerol kinase, glycerophosphate

oxidase, and horseradish peroxidase causes the oxidative coupling of 4-aminoantipyrine to form a blue dye.

Calculated LDL:
When the concentration of triglycerides in the specimen is ≤ 400 mg/dL, the LDL concentration is calculated by the Friedewald equation:

LDL cholesterol, mg/dL = total cholesterol - HDL cholesterol - triglycerides/5

**M. Performance Characteristics:**

1. Analytical performance:
   The analytical performance studies were conducted using with the Mission Cholesterol Monitoring System. The meters are identical and the only differences between the Mission Cholesterol Monitoring System and Mission Cholesterol Pro Monitoring System are the intended use with associated sample types and labeling.

   *a. Precision/Reproducibility:*

   Three separate point-of-care (POC) studies were performed to evaluate the precision of the Mission Cholesterol Monitoring System.

   #1 Precision using whole blood samples
   A precision study was performed at three POC sites using freshly collected lithium heparin venous whole blood samples. In order to cover the analytical measurement range, whole blood samples with three concentration levels of total cholesterol, HDL cholesterol and triglycerides were tested.

   To minimize the effects of whole blood aging on the results, all samples were tested within 4 hours from preparation. Each POC site used the same whole blood sample as three aliquots from the same stock were taken to the three sites.

   At each POC site, 3 operators performed the study. Each operator used a different lot of cartridges; three lots per site. The same three lots were used at all three sites. Each operator used 2 different meters to conduct a run of 25 replicates with each meter; total of 3 operators x 2 meters x 25 replicates per meter =150 measurements per level per site, and 450 measurements per level across all sites. Each operator tested all three concentration levels.

   Total precision represents the sum of all variabilities; the variance of total precision was calculated by taking the sum of the between-site, between-operator, between-lot, between-meter, and repeatability variances. The data was analyzed by ANOVA and the results are summarized below:

Total cholesterol, n=450

| | | Repeatability | | Between lot | | Between operator | | Between site | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 120 | 1.6 | 1.3 | 0.0 | 0.0 | 1.0 | 0.9 | 0.7 | 0.5 | 1.6 | 1.3 |
| level 2 | 219 | 3.0 | 1.4 | 0.9 | 0.4 | 1.4 | 0.6 | 1.7 | 0.8 | 3.0 | 1.4 |
| level 3 | 364 | 4.8 | 1.3 | 0.0 | 0.0 | 0.4 | 0.1 | 0.0 | 0.0 | 4.9 | 1.3 |

HDL cholesterol, n=450

| | | Repeatability | | Between lot | | Between operator | | Between site | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 25 | 0.6 | 2.4 | 0.0 | 0.0 | 0.2 | 0.9 | 0.0 | 0.0 | 0.6 | 2.5 |
| level 2 | 46 | 0.7 | 1.6 | 0.0 | 0.0 | 0.1 | 0.2 | 1.1 | 2.3 | 0.7 | 1.6 |
| level 3 | 79 | 1.1 | 1.4 | 0.1 | 0.1 | 0.0 | 0.0 | 0.5 | 0.6 | 1.1 | 1.4 |

Triglycerides, n=450

| | | Repeatability | | Between lot | | Between operator | | Between site | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 74 | 1.1 | 1.4 | 0.3 | 0.4 | 0.4 | 0.5 | 0.0 | 0.0 | 1.1 | 1.5 |
| level 2 | 222 | 3.5 | 1.6 | 1.1 | 0.5 | 1.2 | 0.6 | 0.9 | 0.4 | 3.5 | 1.6 |
| level 3 | 490 | 6.8 | 1.4 | 0.5 | 0.1 | 0.0 | 0.0 | 3.2 | 0.7 | 6.8 | 1.4 |

#2 Precision using control materials

A second precision study was performed at three POC sites using control material. At each clinical site, 2 operators performed the study with 1 meter, 1 run of two replicates for each operator per day, over a total of 20 days for a total of 240 replicates per level across the sites. Each site used a different lot of test cartridges. The control material was from one lot and common to all three sites.

The precision study was designed as a three factorial design with site/lot/meter, operator/run, and day as the factors of interest. Total precision represents the sum of all of these variabilities. The data was analyzed by ANOVA and the results are summarized below:

Total cholesterol, n=240

| | | Repeatability | | Between day | | Between operator/run | | Between site/lot/meter | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 139 | 1.2 | 0.8 | 1.8 | 1.3 | 0.3 | 0.2 | 0.9 | 0.7 | 1.2 | 0.8 |
| level 2 | 316 | 3.1 | 1.0 | 2.8 | 0.9 | 0.5 | 0.2 | 3.2 | 1.0 | 3.5 | 1.1 |

HDL cholesterol, n=240

| | | Repeatability | | Between day | | Between operator/run | | Between site/lot/meter | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 37 | 0.5 | 1.5 | 0.2 | 0.6 | 0.0 | 0.0 | 0.2 | 0.7 | 0.5 | 1.5 |
| level 2 | 79 | 0.9 | 1.1 | 0.9 | 1.1 | 0.0 | 0.0 | 0.9 | 1.1 | 0.9 | 1.1 |

Triglycerides, n=240

| | | Repeatability | | Between day | | Between operator/run | | Between site/lot/meter | | Total Precision | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 147 | 1.1 | 0.8 | 1.0 | 0.7 | 0.0 | 0.0 | 0.3 | 0.2 | 1.2 | 0.8 |
| level 2 | 291 | 3.8 | 1.3 | 3.6 | 1.2 | 0.8 | 0.3 | 4.6 | 1.6 | 3.9 | 1.3 |

#3 Multi- site precision study with control solutions

A third precision study was performed at three POC sites using control material in accordance with CLSI EP05-A3.

At each clinical site, 1 operator performed the study with 1 meter, 1 run of 5 replicates per day, over a total of 5 days for a total of 75 replicates per level across the sites. Each site used the same lot of test cartridges. The control material was from 1 lot and common to all 3 sites. The data was analyzed by ANOVA and the results are summarized below. Reproducibility represents the contribution to imprecision from site-to-site variance. Within device precision represents the contributions to imprecision from between-day and repeatability.

Total cholesterol, n=75

| | | Repeatability | | Within Device Precision | | Reproducibility | |
|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 140 | 2.1 | 1.5 | 2.9 | 2.0 | 2.0 | 1.4 |
| level 2 | 316 | 5.0 | 1.6 | 5.7 | 1.8 | 2.8 | 0.9 |
| | | | | | | | |
| level 1 | 140 | 1.6 | 1.8 | 2.0 | 1.5 | Site 1 | |
| level 2 | 315 | 3.7 | 1.8 | 6.2 | 2.0 | | |
| | | | | | | | |
| level 1 | 141 | 2.2 | 1.5 | 2.3 | 1.6 | Site 2 | |
| level 2 | 316 | 5.1 | 1.6 | 5.1 | 1.6 | | |
| | | | | | | | |
| level 1 | 140 | 2.4 | 1.7 | 4.0 | 2.8 | Site 3 | |
| level 2 | 316 | 5.9 | 1.9 | 6.1 | 1.9 | | |

HDL cholesterol, n=75

| | | Repeatability | | Within Device Precision | | Reproducibility | |
|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 37 | 0.8 | 2.0 | 0.8 | 2.2 | 0.5 | 1.4 |
| level 2 | 79 | 1.3 | 1.6 | 1.4 | 1.8 | 1.1 | 1.4 |
| | | | | | | | |
| level 1 | 37 | 0.4 | 1.2 | 0.7 | 1.8 | Site 1 | |
| level 2 | 78 | 1.2 | 1.6 | 1.5 | 1.9 | | |
| | | | | | | | |
| level 1 | 38 | 0.8 | 2.2 | 0.9 | 2.3 | Site 2 | |
| level 2 | 80 | 1.4 | 1.8 | 1.6 | 1.9 | | |
| | | | | | | | |
| level 1 | 37 | 0.9 | 2.5 | 0.9 | 2.5 | Site 3 | |
| level 2 | 79 | 1.2 | 1.5 | 1.2 | 1.5 | | |

Triglycerides, n=75

| | | Repeatability | | Within Device Precision | | Reproducibility | |
|---|---|---|---|---|---|---|---|
| **Sample** | **Mean** | **SD** | **%CV** | **SD** | **%CV** | **SD** | **%CV** |
| level 1 | 145 | 1.9 | 1.3 | 2.4 | 1.7 | 1.5 | 1.0 |
| level 2 | 290 | 4.7 | 1.6 | 5.4 | 1.9 | 1.0 | 0.3 |
| | | | | | | | |
| level 1 | 147 | 1.0 | 0.7 | 2.0 | 1.4 | Site 1 | |
| level 2 | 290 | 4.6 | 1.6 | 5.8 | 2.0 | | |
| | | | | | | | |
| level 1 | 144 | 2.7 | 1.9 | 2.9 | 2.0 | Site 2 | |
| level 2 | 289 | 5.2 | 1.8 | 5.2 | 1.8 | | |
| | | | | | | | |
| level 1 | 145 | 1.7 | 1.1 | 2.3 | 1.6 | Site 3 | |
| level 2 | 293 | 4.2 | 1.4 | 5.3 | 1.8 | | |

The following precision information is provided in the labeling from study #2. Precision estimates were derived by fitting the data set to a Mixed Effects Model using a commercial software package.

| | %CV | | | | | |
|---|---|---|---|---|---|---|
| | Total Cholesterol | | High Density Lipoprotein | | Triglycerides | |
| | Level 1 | Level 2 | Level 1 | Level 2 | Level 1 | Level 2 |
| Repeatability | 1.5% | 1.6% | 2.0% | 1.6% | 1.3% | 1.6% |
| Total precision | 2.0% | 1.8% | 2.7% | 2.3% | 2.0% | 1.9% |

*b. Linearity/assay reportable range:*

A linearity study was conducted on the Mission Cholesterol Monitoring System in accordance to CLSI EP6-A.

To challenge the analytical measuring range for total cholesterol, HDL cholesterol, and triglycerides a linear dilution series of 9 levels was prepared from a high and a low sample pool. A high sample pool was prepared by spiking each analyte into a lithium heparin whole blood sample. The low pool was a native lithium heparin whole blood sample. Each sample of the dilution series was tested in replicates of 10 on each of three lots of test cartridges for a total of n=30 measurements at each level.

Linearity was assessed by a polynomial evaluation of linearity. For total cholesterol, regression analysis found statistically significant coefficients for second order and third order polynomial fits which indicated possible non-linearity. The degree of nonlinearity was further assessed by comparing the deviation of the second order and third order polynomial regression lines from linearity. At each level, the deviation from linearity by either the second order and third order polynomial was ≤ 2%.

For HDL cholesterol, regression analysis found a statistically significant coefficient for a third order polynomial fit which indicated possible non-linearity. The degree of nonlinearity was further assessed by comparing the deviation of the regression line for the third order polynomial from linearity. At each level, the deviation from linearity was ≤ 1%.

For triglycerides, regression analysis found statistically significant coefficients for a second order and third order polynomial fit which indicated possible non-linearity. The degree of nonlinearity was further assessed by comparing the deviation of the second order and third order polynomial regression lines from linearity. At each level, the deviation from linearity by either the second order and third order polynomial was ≤ 5%.

The linear regression results are given in the table below:

| Analyte | Slope | Intercept | $R^2$ | Tested Range, mg/dL |
|---|---|---|---|---|
| Total cholesterol | 1.005 | -0.12 | 0.9989 | ~ 100 to 500 |
| HDL cholesterol | 0.996 | 0.039 | 0.9985 | ~ 15 to 115 |
| Triglycerides | 1.007 | 0.46 | 0.9993 | ~ 45 to 695 |

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

- 100 to 400 mg/dL for total cholesterol
- 15 to 100 mg/dL for HDL cholesterol
- 45 to 650 mg/dL for triglycerides

Readings outside of reportable range:
Bench studies and software verification studies were provided to demonstrate that if a total cholesterol, HDL cholesterol, or triglycerides measurement was less than the lower end of the analytical measurement range, a '<' indicator is displayed preceding the lower limit; e.g. <100 mg/dL for total cholesterol. If a measurement exceeded the upper end of the analytical measurement range a '>' indicator is displayed preceding the upper limit; e.g. >400 mg/dL for total cholesterol.

LDL cholesterol
The LDL cholesterol concentration is derived by calculation using the Friedewald equation. Software verification studies were provided to demonstrate that the reported LDL concentration is calculated according to the Friedewald equation when the triglycerides concentration is ≤ 400mg/dL.

Software verification studies were provided to demonstrate that if the triglycerides concentration is > 400 mg/dL, the LDL cholesterol result will not be calculated, and the meter will display "--".

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

Traceability
Mission Cholesterol Monitoring System is CRMLN certified for total cholesterol and HDL cholesterol using whole blood samples. The total cholesterol assay is traceable to the National Reference System for Cholesterol. The HDL cholesterol assay is traceable to the National Cholesterol Education Program. The accuracy and precision performance in lithium heparin venous whole blood met the NCEP's performance criteria. The triglyceride assay is traceable to NIST certified reference material 1951c.

Test cartridge shelf life stability

The shelf life stability of the Mission Cholesterol Test Cartridges in foil pouches was assessed in a real-time stability study; test cartridges are provided in individual foil pouches. The study protocol and acceptance criteria were reviewed and found acceptable to support the product shelf life under the recommended storage conditions of 36°F to 86°F (2 to 30°C). The sponsor can currently support a shelf life claim of 6 months.

Test cartridge stability under shipping conditions

The Mission Cholesterol Meter and Test Cartridges were stressed under conditions to simulate the range of possible conditions experienced during actual shipping. The study protocol and acceptance criteria were reviewed and found acceptable.

*d. Detection limit:*

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantification (LoQ) for the Mission Cholesterol Monitoring System were conducted in accordance with CLSI EP17-A2.

LoB: To estimate the LoB, the sponsor tested analyte free venous blood samples using two reagent lots and two meters. The samples were tested in replicates of 10 on each meter/lot across each of three testing days for a total of 60 replicates per lot. LoB was derived using the parametric approach, and where the value was derived from the $95^{th}$ percentile of a normal distribution.

LoD: To estimate the LoD, the sponsor prepared five low level venous blood samples with analyte concentrations ranging from the LoB to approximately 4 x LoB. Each samples was tested in replicates of 10 on two reagent lots each, with one meter per lot for a total of 20 replicates per level. The data was analyzed to calculate LOD using a parametric analysis recommended in the CLSI guideline EP17-A2.

LoQ: To estimate the LoQ, the sponsor prepared four venous blood samples with concentrations spanning the anticipated LoQ. The samples were tested using two lots of test cartridges and two meters. Each sample was tested in replicates of 10 on each instrument/ lot across two runs for a total of 40 replicates per sample. LOQ was derived based upon a total error goal as described in CLSI EP17-A2:

Total error goals

Total cholesterol ≤9%
HDL cholesterol ≤12%
Triglycerides ≤13%

The detection limit results are summarized as follows:

| Analyte | LoB | LoD | LoQ |
|---|---|---|---|
| Total cholesterol, mg/dL | 3.4 | 3.7 | 92 |
| HDL cholesterol, mg/dL | 0.6 | 0.9 | 14.5 |
| Triglycerides, mg/dL | 3.7 | 4.0 | 33 |

e. *Analytical specificity:*

Interference testing on the Mission Cholesterol Monitoring System was evaluated in accordance with CLSI EP7-A2.

Interference testing was performed to evaluate exogenous and endogenous substances using lithium heparin venous whole blood spiked at two concentrations of each analyte: total cholesterol 150 and 250 mg/dL, HDL cholesterol 35 and 70 mg/dL, and triglycerides 150 and 500 mg/dL. The samples were divided into two aliquots: control with no added interferent and test with added interferent. Each sample was measured in five replicates using five meters and three test cartridge lots.

The sponsor defined no significant interference according to the following for total cholesterol, HDL cholesterol, and triglycerides:

Average Bias vs. Actual Level $\leq \pm 10\%$
Individual Bias vs. Actual Level $\leq \pm 15\%$

The following table lists the concentration of each substance at which no significant interference was detected.

| Substance | Highest concentration tested at which no significant interference was observed. |
|---|---|
| Exogenous Substances | |
| Acetaminophen | 20 mg/dL |
| Acetylsalicylic acid | 65 mg/dL |
| Ampicillin | 5.3 mg/dL |
| Ascorbic acid | 10 mg/dL |
| Atorvastatin | 0.06 mg/dL |
| Bezafibrate | 10 mg/dL |
| Dopamine | 0.09 mg/dL |
| Furosemide | 6 mg/dL |
| Gentisic acid | 1.8 mg/dL |
| Glybenclamide | 1 mg/dL |
| Ibuprofen | 50 mg/dL |
| Indomethacin | 3.6 mg/dL |
| Methyldopa | 1.5 mg/dL |

| Substance | Highest concentration tested at which no significant interference was observed. |
|---|---|
| Nicotinic acid | 0.1 mg/dL |
| Probenecid | 60 mg/dL |
| Quindine hydrochloride monohydrate | 1.2 mg/dL |
| Salicylic acid | 60 mg/dL |
| Sulfamethoxazole | 40 mg/dL |
| Trimethoprim | 4 mg/dL |
| Endogenous Substances | |
| Conjugated Bilirubin | 15 mg/dL |
| Creatinine | 5 mg/dL |
| Hemoglobin | 500 mg/dL |
| Uric acid | 12 mg/dL |
| Total Cholesterol (for Triglycerides only) | 502 mg/dL |
| Triglycerides (for Total and HDL only) | 649 mg/dL |

To address potential interference from bilirubin and uric acid, the labeling contains the following statements:

- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for the total cholesterol and HDL cholesterol.

- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for the total cholesterol and HDL cholesterol.

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

POC method comparison studies were performed to establish the accuracy performance of the Mission Cholesterol Monitoring System at three POC sites. The study data was analyzed in accordance with CLSI EP09-A2. A total of 369 patients were recruited for the study at three physician office laboratory sites located in different geographical locations. Participants included male and female adults, aged 18 years or older, across diverse ethnicities, educations, and occupations in the US.

The accuracy assessment for total cholesterol, HDL cholesterol, and triglycerides comprised a comparison of an FDA cleared comparator method using plasma samples to the Mission Cholesterol Monitoring System using samples of: (1) fingertip

capillary collection by the lay user, (2) fingertip capillary collection by the professional, and (3) venous draw into lithium heparin collection tube by the professional. No contrived or altered samples were tested in this clinical POC study. The comparator methods used lithium heparin plasma samples from the same venous draw.

Capillary collection and self testing

For self-testing, the lay user followed the OTC product labeling and performed the test with their capillary fingertip blood using the Mission Cholesterol Monitoring System.

Capillary collection and testing by professional

For each participant following their self collection/testing, a medical professional performed the test with the Mission Cholesterol Monitoring System from a second fingertip puncture.

Venous draw and testing by professional

For each participant, a venous draw was collected by a phlebotomy professional. A medical professional then mixed by inversion the collection tube, and used the transfer tube to collect 35 µL venous blood from the collection tube, and dispense blood to the Mission Cholesterol test cartridge. A total of three different operators per site conducted the test. The plasma from the venous collection was stored at -70°C, and sent to a clinical laboratory to run on the comparator method.

The results of the method comparison studies are summarized as follows.

Linear regression analysis

*Total Cholesterol – all sites combined*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.9994 | 0.0293 | 0.9846 | 102 - 399 mg/dL |
| Professional | Capillary | 1.0016 | -0.5139 | 0.9883 | 101 - 379 mg/dL |
| Professional | Venous | 0.9889 | 0.8070 | 0.9863 | 102 - 392 mg/dL |

*Total Cholesterol – site 1*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.990 | 1.257 | 0.989 | 102 - 375 mg/dL |
| Professional | Capillary | 1.009 | -2.6849 | 0.990 | 101 - 379 mg/dL |
| Professional | Venous | 0.979 | 2.160 | 0.987 | 102 - 380 mg/dL |

*Total Cholesterol – site 2*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 1.007 | -1.816 | 0.9783 | 103 - 399 mg/dL |
| Professional | Capillary | 0.90 | 1.148 | 0.9826 | 106 - 372 mg/dL |
| Professional | Venous | 0.989 | 1.148 | 0.9826 | 106 - 392 mg/dL |

*Total Cholesterol – site 3*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.9947 | 2.038 | 0.9840 | 112 - 364 mg/dL |
| Professional | Capillary | 0.999 | 0.505 | 0.9875 | 112 - 360 mg/dL |
| Professional | Venous | 0.997 | -0.969 | 0.9873 | 109 - 378 mg/dL |

*HDL Cholesterol– all sites combined*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.9900 | 0.0989 | 0.9768 | 15 - 100 mg/dL |
| Professional | Capillary | 1.0015 | -0.1705 | 0.9778 | 15 - 99 mg/dL |
| Professional | Venous | 0.9929 | 1.052 | 0.9790 | 15 - 100 mg/dL |

*HDL Cholesterol – site 1*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.993 | -0.233 | 0.9831 | 16 - 97 mg/dL |
| Professional | Capillary | 1.009 | -0.779 | 0.9827 | 16 - 99 mg/dL |
| Professional | Venous | 0.993 | 0.738 | 0.9852 | 15 - 97 mg/dL |

*HDL Cholesterol – site 2*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.978 | -0.085 | 0.9790 | 15 - 98 mg/dL |
| Professional | Capillary | 0.987 | 0.371 | 0.9767 | 16 - 96 mg/dL |
| Professional | Venous | 0.991 | 0.823 | 0.977 | 18 - 100 mg/dL |

*HDL Cholesterol – site 3*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 1.001 | 0.539 | 0.9731 | 16 - 100 mg/dL |
| Professional | Capillary | 1.003 | 0.222 | 0.9736 | 16 - 97 mg/dL |
| Professional | Venous | 0.991 | 1.736 | 0.975 | 19 - 96 mg/dL |

*Triglycerides – all sites combined*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.9983 | 0.8927 | 0.9934 | 45 - 600 mg/dL |
| Professional | Capillary | 0.9965 | 0.9441 | 0.9948 | 45 - 616 mg/dL |
| Professional | Venous | 0.9901 | -1.2099 | 0.9936 | 45 - 596 mg/dL |

*Triglycerides – site 1*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.999 | -0.521 | 0.9961 | 46 - 600 mg/dL |
| Professional | Capillary | 1.007 | -0.374 | 0.9935 | 45 - 606 mg/dL |
| Professional | Venous | 0.990 | -1.848 | 0.9960 | 45 - 596 mg/dL |

*Triglycerides – site 2*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 0.997 | 1.521 | 0.9917 | 45 - 595 mg/dL |
| Professional | Capillary | 0.992 | 1.838 | 0.9944 | 45 - 616 mg/dL |
| Professional | Venous | 0.991 | -1.776 | 0.9933 | 45 - 576 mg/dL |

*Triglycerides – site 3*

| Operator | Specimen | Slope | Intercept | $R^2$ | Range |
|---|---|---|---|---|---|
| Lay user | Capillary | 1.000 | 1.368 | 0.9929 | 45 - 595 mg/dL |
| Professional | Capillary | 0.990 | 1.361 | 0.9946 | 45 - 616 mg/dL |
| Professional | Venous | 0.990 | -0.191 | 0.9913 | 45 - 576 mg/dL |

Individual bias (all sites combined)

*Total cholesterol*

| Specimen/operator | Within ±5% | Within ±10% | Within ±15% |
|---|---|---|---|
| Capillary / lay user | 87.5% (321/367) | 99.5% (365/367) | 100% (367/367) |
| Capillary / professional | 90.2% (331/367) | 99.7% (366/367) | 100% (367/367) |
| Venous / professional | 88.0% (323/367) | 100% (367/367) | 100% (367/367) |

*HDL cholesterol*

| Specimen/operator | Within ±5% | Within ±10% | Within ±15% |
|---|---|---|---|
| Capillary / lay user | 79.1% (288/364) | 93.6% (341/364) | 99.7% (363/364) |
| Capillary / professional | 66.3% 240/362) | 95.9% (347/362) | 99.4% (360/362) |
| Venous / professional | 68.4% (249/364) | 94.8% (345/364) | 98.9% (360/364) |

*Triglycerides*

| Specimen/operator | Within ±5% | Within ±10% | Within ±15% |
|---|---|---|---|
| Capillary / lay user | 66.3% (236/356) | 93.0% (331/356) | 98.6% (351/356) |
| Capillary / professional | 68.1% (243/357) | 92.2% (329/357) | 98.0% (350/357) |
| Venous / professional | 61.4% (218/355) | 91.3% (324/355) | 99.2% (352/355) |

Predicted Bias at Medical Decision Points (all sites combined)

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.

*Total cholesterol*

| | **Predicated bias at Medical decision points** | |
|---|---|---|
| **Specimen/operator** | **200 mg/dL** | **240 mg/dL** |
| Capillary / lay user | 0.0% | 0.0% |
| Capillary / professional | -0.1% | -0.1% |
| Venous / professional | -0.7% | -0.8% |

*HDL cholesterol*

| | **Predicated bias at Medical decision points** | |
|---|---|---|
| **Specimen/operator** | **40 mg/dL** | **60 mg/dL** |
| Capillary / lay user | -0.8% | -0.8% |
| Capillary / professional | -0.3% | -0.1% |
| Venous / professional | 1.9% | 1.0% |

*Triglycerides*

| | **Predicated bias at Medical decision points** | | |
|---|---|---|---|
| **Specimen/operator** | **150 mg/dL** | **200 mg/dL** | **500 mg/dL** |
| Capillary / lay user | 0.4% | 0.2% | 0.0% |
| Capillary / professional | 0.3% | 0.0% | -0.2% |
| Venous / professional | -1.8% | -1.5% | -1.2% |

Misclassification Analysis

Individual results were compared to the reference results to determine if the results were correctly classified per NCEP Working Group recommendations.

*Total cholesterol*

| **Specimen/operator** | **Correctly classified with 240 mg/dL cut-off** |
|---|---|
| Capillary / lay user | 98.1% (362/369) |
| Capillary / professional | 97.8% (361/369) |
| Venous / professional | 97.3% (359/369) |

*HDL cholesterol*

| **Specimen/operator** | **Correctly classified with 40 mg/dL cut-off** |
|---|---|
| Capillary / lay user | 96.7% (357/369) |
| Capillary / professional | 96.5% (356/369) |
| Venous / professional | 97.0% (358/369) |

*Triglycerides*

| Specimen/operator | Correctly classified with 200 mg/dL cut-off |
|---|---|
| Capillary / lay user | 97.8% (361/369) |
| Capillary / professional | 97.8% (361/369) |
| Venous / professional | 97.3% (361/369) |

Usability survey

Lay users were surveyed after the study by means of a questionnaire on the usability of the Mission Cholesterol Monitoring System and the instructions for use. The questionnaire included user responses regarding ease of use of the system and clarity of the user instructions. The survey results demonstrated that lay users found the system and instructions for use to be adequate.

*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:

The National Heart, Lung and Blood Institute issued the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III) in 2002. The ATP III report presents NCEP's clinical guidelines for cholesterol testing and management, and recommends the following classifications for cholesterol and triglycerides concentration levels:

| Analyte | Concentration, mg/dL | ATP 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 |
| LDL cholesterol | <100 | Optimal |
| | 100 - 129 | Near optimal/above optimal |
| | 130 - 159 | Borderline high |
| | 160 - 189 | High |
| | ≥ 190 | Very high |

Source: *Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (ATP III). National Cholesterol Education Program, National Heart, Lung, and Blood Institute, National Institutes of Health, NIH Publication No. 02-5215, September 2002.*

**N. Instrument Name:**

Mission Cholesterol Meter
Mission Cholesterol Pro Meter

**O. System Descriptions:**

1. Modes of Operation:
   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _x_ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X____

2. Software:
   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:
   There is no sample identification by this device.

4. Specimen Sampling and Handling:
   For capillary specimens, following a lancing procedure, the user applies a drop (35 µL) of fingerstick whole blood to the specimen application area of the test cartridge using the capillary transfer tube.

   For venous specimens, the user draws 35 µL venous whole blood from collection tube using the capillary transfer tube and dispense to the specimen application area of the test cartridge.

5. Calibration:
   The Mission Cholesterol Monitoring System and Mission Cholesterol Pro Monitoring System are factory calibrated and not user adjustable. Calibration information for the test cartridges is stored in the code chip, which is provided with each lot of test cartridges and is required to run the test. The meter reads the code chip automatically when inserted into the meter. The concentrations of CHOL, HDL and TRIG based on a standard curve is programmed into the code chip.

6. Quality Control:
   The Mission Cholesterol and Mission Cholesterol Pro Monitoring Systems include two levels of control solutions with known concentrations of total cholesterol, HDL cholesterol, and triglycerides.

   The Mission Cholesterol and Mission Cholesterol Pro Monitoring System also include an optical verifier that checks the proper operation of the meter's optical detection system.

## P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study:
   The effect of hematocrit was evaluated with two samples of lithium heparin venous whole blood with total cholesterol at 150 and 300 md/dL, HDL at 35 and 80 mg/dL, and triglycerides at 150 and 300 mg/dL. The hematocrit of each sample was adjusted to 30%, 35%, 42%, 50%, 55%, and 60%. Each sample was tested in 10 replicates with each of three lots of the test cartridges (n=30). The % bias of each sample relative to a plasma sample of the same concentration run on the comparator method, and the average % bias at each hematocrit level relative to 42% was calculated. The bias results supported the sponsor's claimed acceptable hematocrit range of 30 to 50% for the Mission Cholesterol Monitoring System.

2. Temperature and Humidity Studies:

   a. To verify the operating temperature range (15 to 40°C) of the Mission Cholesterol Monitoring System, the system was tested at the following temperatures: 15, 20, 25, 30, 35, and 40°C. Lithium heparin venous whole blood samples with cholesterol at 150 and 350 mg/dL, HDL at 30 and 80 mg/dL, and triglycerides at 120 and 450 mg/dL were tested in 5 replicates on each of three cartridge lots (n=15) at each of the temperatures. The results relative to the comparator method supported the sponsor's claim that the test results are not significantly impacted by temperatures ranging from 15 to 40°C.

   b. To verify the operating humidity range (20 to 90% RH) of the Mission Cholesterol Monitoring System, the system was tested at 20%, 50%, and 90% RH and at room temperature (23-25°C). Lithium heparin venous whole blood samples with cholesterol at 150 and 350 mg/dL, HDL at 30 and 80 mg/dL, and triglycerides at 120 and 450 mg/dL were tested in 5 replicates on each of three cartridge lots (n=15) at each of humidity level. The results relative to the comparator method supported the sponsor's claim that the test results are not significantly impacted by humidity ranging from 20% to 90% RH.

   c. A study was performed to test the device at different combinations of temperature and humidity. The operating temperature range and humidity range for the Mission Cholesterol Monitoring System were evaluated using 5 meters and one lot of test cartridges, and with lithium heparin venous whole blood samples at total cholesterol of 120, 200, 350 mg/dL, HDL cholesterol of 35, 50, 70 mg/dL, and triglycerides 85,150, 300 mg/dL. The following four combination temperature and humidity extreme conditions were evaluated:

      15°C (59°F) and 20% RH
      15°C (59°F)and 90% RH
      40ºC (104ºF) and 20% RH
      40ºC (104ºF) and 90% RH

      The results support the claimed operating temperature range of 15°C (59°F) to 40ºC (104ºF) and operating relative humidity range of 20 to 90%.

   d. Validation studies were provided to demonstrate that when the ambient room temperature is below 15°C or higher than 40°C, the meter will display "LO.t" or "HI.t", and is disabled so to not conduct a measurement.

3. Sample Volume Study:
   A sample volume study was conducted on the Mission Cholesterol Monitoring System to verify the robustness of the system to variations in the intended 35 µL sample volume applied to the cartridge using capillary transfer tube. A lithium heparin venous whole blood sample was spiked to a total cholesterol of 200 mg/dL, HDL cholesterol of 50 mg/dL, and triglycerides of 200 mg/dL, as measured by the comparator methods. The

effect of different sample volumes (20, 25, 30, 35, 40, 45, and 50 µL) on the accuracy performance of the device was measured on the sample in replicates of 5 on each of three lots of test cartridges and using 5 meters. The bias results relative to the comparator method supported the claims that the device performance is not impacted by sample volumes ranging from 25-50 µL.

An additional study was conducted to verify that when the sample volume applied to the cartridge is insufficient to return an accurate result the meter displays an "E-5" error due to insufficient sample volume.

4. Infection Control Studies:
   The virucidal disinfection efficacy for the Mission Cholesterol Meter was established in k122553 using the Mission Plus Hb Meter.

   Disinfection robustness testing on the Mission Cholesterol Monitoring System was performed using Oxivir® TB wipes for 10,950 cleaning and 10,950 disinfection cycles (one cycle includes one cleaning wipe plus one disinfecting wipe) to simulate 3 years of device use cycles (10 tests/disinfection per day, 365 working days per year for 3 year, 10 x 365 x 3 =10950). After 10950 cycles of disinfection, the meter exterior was found to be unchanged in appearance, the meter passed a basic functional test, and a performance evaluation found no significant change in %bias relative to a comparator method using spiked lithium heparin venous whole blood samples. The labeling was reviewed for adequate instructions for the cleaning and disinfection procedures.

5. Electromagnetic Compatibility:
   The sponsor provided appropriate documentation certifying that electromagnetic (EMC) testing was performed and the device systems were found to be compliant.

6. Electrical Safety:
   The sponsor provided adequate documentation certifying that electrical safety testing was performed and that all requirements for electrical safety were met.

7. Readability Evaluation:
   A readability study was conducted on the User's Manual, all package inserts, and Quick Reference Guide for the Mission Cholesterol Monitoring System. The grade reading levels were found to be at an $8^{th}$ grade level or less.

8. Altitude study:
   The sponsor made no claims of operating altitude or oxygen dependency for the Mission Cholesterol Monitoring System.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

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