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

A. 510(k) Number:

k160282

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose, cholesterol, triglycerides, high density cholesterol (HDL)

D. Type of Test:

Lipids: Quantitative, Colorimetric
Glucose: Quantitative, electrochemical using glucose oxidase

E. Applicant:

SD Biosensor, Inc.

F. Proprietary and Established Names:

SD LipidoCare Home System
SD LipidoCare BT Home System
SD LipidoCare Professional System
SD LipidoCare BT Professional System

G. Regulatory Information:

Regulation	Test Name	Classification	Procode	Panel
21 CFR 862.1345	Glucose Test System	Class II	NBW	Chemistry (75)
21 CFR 862.1175	Cholesterol (total) Test System	Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4)	CHH	Chemistry (75)
21 CFR 862.1705	Triglyceride Test System	Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4)	JGY	Chemistry (75)

21 CFR 862.1475	Lipoprotein Test System	Class I, meet limitations of exemptions per 21 CFR 862.9 (c)(4)	LBR	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below

2. Indication(s) for use:

   SD LipidoCare Home System
   SD LipidoCare Home System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm; and to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Home System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use).

   The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein 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. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

   SD LipidoCare Home Blood Glucose Test Strips are for use with SD LipidoCare Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare Home Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by a single person and should not be shared.

   SD LipidoCare BT Home System:
   SD LipidoCare BT Home System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm; and to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Home System is

intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use).

The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Home System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein 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. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Home Blood Glucose Test Strips are for use with SD LipidoCare BT Home Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by a single person and should not be shared. SD LipidoCare BT Home Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Home Analyzer to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by a single person and should not be shared.

<u>SD LipidoCare Professional System:</u>
SD LipidoCare Professional System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm; and to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare Professional System is intended to be used by lay-users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein 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. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL

cholesterol, and triglycerides.

SD LipidoCare Professional Blood Glucose Test Strips are for use with SD LipidoCare Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and me medical professionals. SD LipidoCare Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals.

SD LipidoCare BT Professional System:
SD LipidoCare BT Professional System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood from fingertip, palm, forearm or upper arm; and to measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood from the fingertip. SD LipidoCare BT Professional System is intended to be used by lay users and medical professionals. It is intended to be used by a single person and should not be shared. It is intended for testing outside the body (in vitro diagnostic use).

The glucose testing system is for people with diabetes as an aid to monitor the effectiveness of diabetes control. Glucose testing with the SD LipidoCare BT Professional System should not be used for the diagnosis of or screening for diabetes and is not for use in neonates. For glucose testing, alternative site testing should be done only during steady-state times (when glucose is not changing rapidly). Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein 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. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

SD LipidoCare BT Professional Blood Glucose Test Strips are for use with SD LipidoCare BT Professional Analyzer to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip, palm, forearm, or upper arm by lay users and medical professionals. SD LipidoCare BT Professional Lipid Profile Test Strips are intended for use with the SD LipidoCare BT Professional Analyzer to be used to quantitatively measure total cholesterol (TC), triglycerides (TG), and HDL cholesterol (HDL) in capillary whole blood by lay users and medical professionals. Use the lipid profile test system at the frequency your doctor recommends testing for total cholesterol, HDL cholesterol, and triglycerides.

3. Special conditions for use statement(s):
   Applicable to Cholesterol, Triglyceride, HDL, and Glucose Testing for all four test systems:
   - Over-the-counter
   - Single-patient use only
   - Do not use this analyzer to measure cholesterol, triglycerides, HDL and glucose in people who are experiencing cardiovascular collapse (severe shock) or decreased peripheral blood flow.
   - Extremes in hematocrit may affect test results. For glucose testing, a hematocrit level below 20% and above 60% has been shown to affect the accuracy of the glucose measurement with this device. For TC, TG, and HDL testing, a hematocrit below 30% and above 52% has been shown to affect the accuracy of the test results with this device.
   - Severe dehydration (excessive water loss) may cause false low results. If you believe you are suffering from dehydration, consult your healthcare professional right away.
   - Inaccurate results may occur in severely hypotensive individuals.
   - Alternative site testing (AST) is intended only for glucose measurement with this device. Do not perform TC, TG and HDL testing using blood from alternative testing sites.
   - This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

   Applicable to Glucose Testing only:
   - Not intended for screening or diagnosis of diabetes, or for use on neonates.
   - Inaccurate glucose results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis.
   - Inaccurate results may occur in severely hypotensive individuals or patients in shock.
   - This device should not be used in critically ill patients.
   - Alternative site testing (AST) for glucose measurement should not be done within 2 hours of a meal, exercise, or medication.
   - Results from AST testing should not be used to calibrate continuous glucose monitors (CGMs).
   - Results from AST testing should not be used for insulin dosing calculations.
   - AST testing should not be done if your AST results do not match the way you feel.
   - AST should only be done at times when the patient's blood glucose is not rising or falling rapidly.
   - The glucose test results may be inaccurate beyond 12,388 ft. (3,776m).

4. Special instrument requirements:
   SD LipidoCare Professional Analyzer
   SD LipidoCare Home Analyzer

SD LipidoCare BT Professional Analyzer
SD LipidoCare BT Home Analyzer

I. Device Description:

The SD LipidoCare Professional System and the SD LipidoCare Home System are the same devices except the device name. The only difference between the SD LipidoCare Home/Professional Systems and SD LipidoCare BT Home/BT Professional Systems is the Bluetooth technology used to transfer data to a personal computer. The Bluetooth function is present in the two 'BT' versions. All four systems in this submission are for single-patient use only.

The SD LipidoCare test system consists of a portable LipidoCare Analyzer (meter), SD LipidoCare Lipid Profile Test Strips, SD LipidoCare Glucose Test Strips, SD Lipid Check Strip, SD Glucose Check Strip, a Code Chip, User Manual, and Quick Guide. The SD Glucose Test Strip is used in the measurement of capillary whole blood glucose. The SD Lipid Profile Test Strip is used in the measurement of capillary whole blood total cholesterol (TC), high density lipoprotein cholesterol (HDL), and triglyceride (TG). LDL value is calculated from TC, HDL and TG values using the numerical formula LDL=TC-HDL-(TG/5). When TG is over 400 mg/dL, LDL is not calculated.

Test Strips: The LipidoCare Glucose and Lipid Profile Test Strips are supplied in individual pouches with individual desiccants.

SD Ezi Tube+: The SD Ezi Tube+ capillary tubes (35 µL) are included in the Lipid Profile Test Strips box (25 count). The SD Ezi Tube+ is a disposable plastic capillary pipet, used to collect and transfer 35 µL of blood for the lipid profile testing.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   PTS PANELS Lipid Panel Test Strips
   SmartLink GOLD Blood Glucose Monitoring System

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

   k023558
   k100398

3. Comparison with predicate:
   The SD LipidoCare Professional System and the SD LipidoCare Home System are the same devices except the device name. The only difference between the SD LipidoCare Home/Professional Systems and SD LipidoCare BT Home/Professional Systems is the Bluetooth technology present in the two 'BT' versions.

Similarities and Differences			
Item	Candidate Device SD LipidoCare Test Systems (k160282)	Predicate SmartLink GOLD Blood Glucose Monitoring System (k100398)	Predicate Device PTS PANELS Lipid Panel Test Strips (k023558)
Intended use (lipid test system)	To measure total cholesterol, triglycerides and HDL cholesterol in capillary whole blood	Not applicable	Same
Intended use (glucose test system)	For the quantitative measurement of glucose in capillary whole blood. The glucose testing system is for use by people with diabetes at home as an aid to monitor the effectiveness of diabetes control	Same	Not applicable
Detection Method (lipid test system)	Colorimetric	Not applicable	Same
Detection Method (glucose test system)	Electrochemical	Same	Not applicable
Hematocrit	TC, TG, HDL: 30-52% Glucose: 20-60%	Same for glucose	TC, TG, HDL: 30-45%

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

CLSI EP05-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, Approved Guideline.

CLSI EP07-A2, Interferences Testing in Clinical Chemistry; Approved Guideline-Second Edition.

ISO 23640:2011, In vitro diagnostic medical devices-Evaluation of stability of in vitro diagnostic reagents.

ISO 14971:2007, Medical Devices-Application of Risk Management to Medical Devices

L. Test Principle:

The SD LipidoCare System combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL cholesterol, and triglycerides. A capillary whole blood sample is applied to an SD LipidoCare test strip. The test strip is then placed into the SD LipidoCare Analyzer, where a unique system on the test strip separates the plasma from the blood cells. A portion of the sample flows to the bottom layer of the test strip and is transferred to the total cholesterol, triglyceride, and HDL cholesterol reaction pads. The LipidoCare analyzer measures TC, TG, and HDL by an enzymatic method which causes a color change in the test area of the strip. The color changes are proportional to the lipid concentration in the sample. LDL value is calculated from TC, HDL and TG values using the numerical formula LDL=TC-HDL-(TG/5). Calculated LDL-cholesterol values are reported only when triglycerides are ≤400 mg/dL; when triglycerides are > 400 mg/dL, the calculated LDL-cholesterol is not reported.

The SD LipidoCare Blood Glucose Test Systems quantitatively measure glucose in a capillary whole blood sample by detecting a small electrical current that results from a chemical reaction of glucose in the blood with glucose oxidase present on the glucose test strip. The amount of current created depends on how much glucose is in the blood. The resulting current is converted to a blood glucose value for display to the user.

M. Performance Characteristics (if/when applicable):

The four systems are identical except for the device name and Bluetooth technology present in the two 'BT' versions (SD LipidoCare BT Home/BT Professional Systems); therefore only one set of performance data is presented below, which is representative of the performance of each of the four systems.

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Total Cholesterol, Triglycerides, and HDL Cholesterol:
   A within-run precision study was performed using three levels of Na-Heparin venous whole blood samples. Each level of blood samples was tested using 3 lots of test strips with 10 analyzers in one day. Ten replicates were tested per analyzer, test strip lot, and level for a total of 100 measurements per level/lot. Each of the 3 lots tested yielded similar within-run precision results. Results for one representative lot are summarized below:

   Total Cholesterol (TC), Triglycerides (TG), and HDL Within-Run Precision (n=100)

Analyte	Mean (mg/dL)	SD (mg/dL)	%CV
TC Level 1	174.2	4.7	2.7
TC Level 2	216.0	6.0	2.8

Analyte	Mean (mg/dL)	SD (mg/dL)	%CV
TC Level 3	263.7	7.1	2.7
TG Level 1	109.3	3.0	2.8
TG Level 2	180.8	5.1	2.8
TG Level 3	371.2	9.9	2.7
HDL Level 1	35.4	1.0	2.9
HDL Level 2	53.0	1.5	2.9
HDL Level 3	79.7	2.2	2.8

The between-run precision study was performed using 2 levels of control solutions and three lots of test strips and ten analyzers, testing 10 replicates per day for 10 days for a total of 100 results per level/lot. Each of the 3 lots tested yielded similar between-run precision results. Results for one representative lot are summarized below:

TC, TG, and HDL Between-run Precision (n=100)

Analyte	Mean (mg/dL)	SD (mg/dL)	%CV
TC Level 1	152.1	4.1	2.7
TC Level 2	239.1	6.5	2.7
TG Level 1	124.9	3.3	2.6
TG Level 2	239.6	7.1	2.9
HDL Level 1	45.2	1.2	2.7
HDL Level 2	77.4	2.1	2.7

Glucose:
A within-run precision study was performed venous whole blood samples adjusted to five glucose concentrations (approximately 50, 85, 150, 350, and 540 mg/dL). Each blood samples was tested using 3 lots of test strips with 10 analyzers in one day. Ten replicates were tested per analyzer, test strip lot, and level for a total of 100 measurements per glucose level and test strip lot. The within-run results are summarized below:

Glucose within-run precision Glucose Level	Strip lot	n	Mean Glucose (mg/dL)	SD	%CV
1	1	100	51.6	2.3	4.4
	2	100	51.4	2.2	4.2
	3	100	51.9	2.3	4.4
2	1	100	85.9	2.5	2.9
	2	100	86.0	2.6	2.4
	3	100	87.3	2.4	2.8
3	1	100	149.3	4.2	2.8
	2	100	149.7	4.0	2.7

Glucose within-run precision Glucose Level	Strip lot	n	Mean Glucose (mg/dL)	SD	%CV
	3	100	147.6	4.0	2.7
4	1	100	352.1	6.3	1.7
	2	100	355.2	6.3	1.8
	3	100	357.2	6.0	1.7
5	1	100	539.5	6.6	1.2
	2	100	542.1	6.1	1.1
	3	100	543.3	6.6	1.2

The between-run precision study was performed using 3 Levels of control solutions approximately 65, 125, and 330 mg/dL) testing 10 replicates per day for 10 days on ten analyzers for a total of 100 results per glucose level and test strip lot. Results are summarized below:

Glucose Between-run precision Glucose Level	Strip lot	n	Mean Glucose (mg/dL)	SD	%CV
1	1	100	64.2	2.1	3.2
	2	100	64.7	2.2	3.3
	3	100	64.7	2.2	3.3
2	1	100	124.5	3.3	2.7
	2	100	125.5	3.2	2.6
	3	100	125.5	3.3	2.6
3	1	100	331.2	8.7	2.6
	2	100	332.3	7.8	2.5
	3	100	332.9	8.4	2.5

b. Linearity/assay reportable range:

Lipid Profile:
Linearity was evaluated by diluting a venous Na-heparin whole blood sample with high concentrations of each analyte (Total Cholesterol, Triglycerides, and HDL) with a venous Na-heparin whole blood sample containing low concentrations of each analyte to obtain 9 intermediate dilution samples (TC 90-460 mg/dL, TG 35- 720 mg/dL, and HDL 22-100 mg/dL). Each sample was run in replicates of 5 on the candidate device. Each result obtained by the candidate device was compared to the expected value for each level. The resulting linear regression equations for each analyte are presented below:

Total Cholesterol: $y = 0.9904\ x - 3.8170$, $R^2 = 0.997$

Triglycerides: $y = 1.0275 x - 13.84$, $R^2 = 0.998$
HDL: $y = 0.9343 + 3.341$, $R^2 = 0.996$

Glucose test:
Linearity was evaluated by diluting a venous whole blood sample with a high concentration of glucose with a venous whole blood sample with a low concentration of glucose. The resulting glucose concentrations as determined by YSI comparator method were: 16.1, 23.7, 56.6, 86.5, 156.3, 227.5, 300.3, 363.8, 435.0, 508.8, 572.8, 645.0, and 725.0 mg/dL. Each sample was run in replicates of 5 on the candidate device and compared to the results from the comparator analyzer. The resulting linear regression equations for Glucose are presented below:

Lot 1: $y = 1.005x - 0.6884$, $R^2 = 0.999$
Lot 2: $y = 1.000x + 0.014$, $R^2 = 0.999$
Lot 3: $y = 1.006x - 0.765$, $R^2 = 0.999$

The linearity studies support the claimed measuring ranges below:
Total Cholesterol: 100-450 mg/dL
Triglycerides: 45-650 mg/dL
HDL: 25-95 mg/dL
Glucose: 20-600 mg/dL

The meter will display "LO" when the results are below the measuring range for each analyte and will display "HI" when the results are above the measuring range for each analyte. The sponsor validated the "LO" and "HI" functions and demonstrated that they functioned as intended.

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

The SD LipidoCare Total Cholesterol is traceable to the primary reference measurement procedure, Proton NMR spectroscopy using the NIST standardized reference material, SRM 911c.

The SD LipidoCare Triglyceride and HDL test system is traceable to the glycerol kinase-pyruvate kinase-lactate dehydrogenase UV method using the primary calibrator, COA of JCCRM 224-6.

The SD LipidoCare Total cholesterol and HDL-cholesterol test systems were certified by the Cholesterol Reference Method Laboratory Network (CRMLN) as meeting the National Cholesterol Education Program's (NCEP) performance criteria for accuracy and precision in capillary whole blood samples.

The SD LipidoCare Glucose test system is traceable to the NIST certified reference material, SRM 917c. Method comparison performance demonstrated accuracy to YSI 2300 analyzer.

Stability:
The stability study protocols and acceptance criteria for the LipidoCare Test Strips for all the analytes measured (total cholesterol, triglyceride, HDL-cholesterol, and glucose) were reviewed and found to be acceptable to support the sponsor's labeled stability claims:

SD LipidoCare Lipid Profile Test Strips are stable for 18 months unopened when stored at 36-90^{o}F (2-32^{o}C) and 10-90% relative humidity. Each Lipid Profile Test Strip is individually wrapped with a desiccant pack and the labeling indicates to perform the testing immediately after opening.

The SD LipidoCare Glucose test strips are stable for 24 months when stored unopened at 36-90^{o}F (2-32^{o}C) and 10-90% relative humidity. Each Glucose Test Strip is individually wrapped with a desiccant pack and the labeling indicates to perform the testing immediately after opening.

d. *Detection limit:*
Detection limit studies for the Total Cholesterol, Triglyceride, and HDL analytes were performed in accordance to CLSI EP17-A2 using two SD LipidoCare Analyzers and two lots of SD LipidoCare Lipid Profile Test Strips.

The Limit of Blank (LoB) was determined for TC, TG, and HDL by testing in vitro blank serum samples not containing the analyte being measured. Each sample was assayed in two runs over 15 days using two analyzers with two test strip lots (one lot per analyzer) for a total of 60 measurements. The following equation was used to determine the LoB for each analyte: $LoB = \text{mean}_{blank} + 1.645 (SD_{blank})$.

The Limit of Detection (LoD) was determined for TC, TG, and HDL by measuring 4 low levels of venous NaHep whole blood samples for each analyte in two runs over 15 days using two analyzers with two test strip lots (one per analyzer) to give a total of 60 measurements. The following equation was used to determine the LoD for each analyte: $LoD = LoB + 1.645 (SD_{\text{low concentration sample}})$.

The Limit of Quantitation (LoQ) was determined for TC, TG, and HDL by measuring 5 low levels of venous NaHep whole blood samples over 15 days using two analyzers with two test strip lots (one lot per analyzer) to give a total of 60 results measurements. The sponsor defines LoQ as the lowest concentration at which an imprecision goal of CV < 10% can be met.

The results of the detection limit studies are summarized below:

Analyte	LoB	LoD	LoQ
Total Cholesterol	47.5 mg/dL	51.7 mg/dL	100 mg/dL
Triglycerides	26.6 mg/dL	29.0 mg/dL	45.0 mg/dL
HDL	18.6 mg/dL	21.2 mg/dL	25.0 mg/dL

The measuring ranges for the SD LipidoCare System lipid panel are as follows:

TC: 100-450 mg/dL
TG: 45-650 mg/dL
HDL: 25-95 mg/dL

The measuring range for the SD LipidoCare System glucose measurement is 20-600 mg/dL and is supported by the linearity assay study above (M.1.b).

e. Analytical specificity:

Glucose interference study:
To assess the effect of potential interfering substances on the performance of the SD LipidoCare System glucose measurement, venous whole blood samples with low and high glucose concentrations of approximately 65 mg/dL and 250 mg/dL (as measured on the YSI 2300 STAT Plus comparator method)were spiked with two to three levels of each potential interferent. The samples were run in replicates of nine. The results of the spiked samples were compared to the results of control samples (as measured on the YSI 2300 STAT Plus comparator method) which did not contain any interferent substance. The sponsor defined significant interference as ≥ ± 10% bias between the individual spiked sample concentrations and the mean concentration of the control sample. The results are summarized below:

Substance	Highest concentration of substance tested which demonstrated no significant interference
Acetaminophen	6.6 mg/dL
Acetyl-salicylic acid	132 mg/dL
Ascorbic acid	4.4 mg/dL
Bilirubin, conjugated	35 mg/dL
Bilirubin, unconjugated	38.5 mg/dL
Creatinine	33 mg/dL
Dopamine	2.75 mg/dL
Ethanol	410 mg/dL
Fructose	16.5 mg/dL
Galactose	66 mg/dL
Gentisic acid	2 mg/dL
Glutathione	5.0 mg/dL
Hemoglobin	220 mg/dL
Ibuprofen	55 mg/dL
Lactose	27.5 mg/dL
Levodopa	4.4 mg/dL
Maltose	550 mg/dL
Maltotetraose	132 mg/dL
Maltotriose	264 mg/dL

Substance	Highest concentration of substance tested which demonstrated no significant interference
Mannitol	810 mg/dL
Mannose	5.5 mg/dL
Methly-dopa	2.2 mg/dL
Sodium salicylate	70 mg/dL
Sorbitol	11 mg/dl
Tetracycline	5.5 mg/dL
Tolbutamide	110 mg/dL
Tolazamide	5.5 mg/dL
Total Cholesterol	550 mg/dL
Triglyceride	1650 mg/dL
Urea	510 mg/dL
Uric acid	5.5 mg/dL
Warfarin	1.1 mg/dL
Xylitol	26 mg/dL
Xylose	55 mg/dL

The sponsor has included the following language in the labeling:

- If you are taking acetaminophen or acetaminophen containing drugs (for example Tylenol; at blood concentrations >6.6 mg/dL) you may get inaccurate results with this system.
- If you have a disease or condition in which uric acid levels in your blood may be elevated (>5.5 mg/dL), such as gout, you may get inaccurate results with this system.
- Do not use this device during or shortly after receiving xylose absorption therapy since xylose in your blood may cause inaccurate results with this system.

Lipids interference study:

To assess the effect of potential interfering substances on the performance of the SD LipidoCare System lipid panel measurement, sodium heparin venous whole blood samples with low and high concentrations of total cholesterol (175 and 240 mg/dL), triglyceride (175 and 325 mg/dL) and HDL (36 and 68 mg/dL) were spiked with two or three levels of each potential interferent. The samples were run in replicates of five. The results of the spiked samples were compared to the results of control samples which did not contain any interferent substance. The sponsor defined significant interference as $\geq \pm$ 10% bias between the individual spiked sample concentrations and the mean concentration of the control sample.

The results are summarized below:

	Highest concentration of substance tested which demonstrated no interference	
Substance	Total Cholesterol and Triglycerides	HDL-Cholesterol
Hemoglobin	300 mg/dL	300 mg/dL
L-Dopa	1.6 mg/dL	1.6 mg/dL
Ascorbic acid	3.5 mg/dL	3.5 mg/dL
Urea	700 mg/dL	700 mg/dL
Fructose	30 mg/dL	30 mg/dL
Creatinine	30 mg/dL	30 mg/dL
Gentisic acid	1 mg/dL	1 mg/dL
Glutathione	2 mg/dL	2 mg/dL
Oxytetracycline	10 mg/dL	10 mg/dL
Lactose	100 mg/dL	50 mg/dL
Cysteine	2.5 mg/dL	2.5 mg/dL
Bilirubin, conjugated	35 mg/dL	35 mg/dL
Bilirubin, unconjugated	50 mg/dL	50 mg/dL
α- methyldopa	2 mg/dL	2 mg/dL
Nicotinic acid	30 mg/dL	30 mg/dL
Dipyrone	30 mg/dL	30 mg/dL
Dopamine	2 mg/dL	2 mg/dL
Acetaminophen	20 mg/dL	20 mg/dL
Ibuprofen	40 mg/dL	40 mg/dL
Salicylate	50 mg/dL	50 mg/dL
Uric acid	20 mg/dL	20 mg/dL
Triglycerides	650 mg/dL	650 mg/dL
Total cholesterol	521 mg/dL	539 mg/dL

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

LipidoCare Glucose test Method Comparison Study:
To assess system accuracy, a method comparison study was performed by healthcare professionals at three external sites with capillary samples collected from the fingertip. Testing was performed on SD LipidoCare analyzers at each site for a total of 9 analyzers using 3 lots of SD LipidoCare Glucose test strips (one lot at each site). A total of 596 glucose samples were obtained (200 from site 1, 199 from site 2, and

197 from site 3). The results obtained on the SD LipidoCare system were compared to the YSI 2300 STAT Plus glucose results performed by a laboratory professional. The glucose range tested was 21.4 to 503 mg/dL as measured on the YSI 2300 STAT Plus. Five samples with glucose concentrations below 50 mg/dL (0.8%) and 5 samples with glucose concentrations above 400 mg/dL (0.8%) were contrived samples. The linear regressions obtained from the 3 glucose test strip lots for a total of 596 glucose results were as follows:

	Lot 1	Lot 2	Lot 3	Combined sites/Lots
Slope	1.0058	1.0033	1.0086	1.0057
Intercept	1.5988	-0.0288	-0.1308	0.5124
R	0.9946	0.9932	0.9935	0.9937
N	200	199	197	596
LipidoCareTest range for glucose (mg/dL)	30-478	24-478	42-479	24-479

The candidate results relative to the comparator method are summarized in the tables below for the 3 glucose strip lots:

Fingertip: System accuracy for blood glucose concentration <75 mg/dL

Lot #	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	11/18 (61.1%)	18/18 (100.0%)	18/18 (100.0%)
2	13/16 (81.3%)	16/16 (100.0%)	16/16 (100.0%)
3	12/19 (63.2%)	19/19 (100.0%)	19/19 (100.0%)

Fingertip: System accuracy for blood glucose concentration ≥ 75 mg/dL

Lot #	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ±20 %
1	107/182 (58.8%)	179/182 (98.4%)	182/182 (100%)	182/182 (100%)
2	101/183 (55.2%)	175/183 (95.6%)	183/183 (100%)	183/183 (100%)
3	101/178 (56.7%)	171/178 (96.1%)	178/178 (100%)	178/178 (100%)

Alternative site testing was conducted immediately after the fingertip testing (within 15 minutes). For the alternative site testing, capillary blood was taken from the palm, forearm and upper arm and tested on the candidate analyzer. The results from the candidate device were compared to the fingertip capillary blood results tested on the YSI 2300 comparator method. The linear regressions obtained from the 3 glucose test strip lots were as follows:

Palm	lot 1	lot 2	lot 3	Combined lots
Slope	1.0006	1.0032	1.0089	1.0042
Intercept	-0.4655	-0.3375	-0.6393	-0.4734
R	0.9943	0.9949	0.9931	0.9941
N	196	195	195	586
Test range (mg/dL)	58-414	59-416	61-425	58-425
Forearm	lot 1	lot 2	lot 3	Combined lots
Slope	1.0087	1.0014	1.0088	1.0060
Intercept	-0.5464	-1.1739	-0.6919	-0.7555
R	0.9923	0.9938	0.9929	0.9930
N	196	195	195	586
Test range (mg/dL)	64-426	63-420	62-424	62-426
Upper arm	lot 1	lot 2	lot 3	Combined lots
Slope	1.0034	1.0033	1.0089	1.0050
Intercept	-0.9712	-1.4912	-1.2255	-1.2054
R	0.9921	0.9943	0.9928	0.9931
N	196	195	195	586
Test range (mg/dL)	65-413	61-415	56-424	56-424

The agreement charts for the alternate site testing from each of the 3 glucose strip lots are provided below:

Palm System accuracy for blood glucose concentration <75 mg/dL

Lot #	Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	16	11/16 (68.8%)	16/16 (100.0%)	16/16 (100.0%)
2	14	11/14 (78.6%)	14/14 (100.0%)	14/14 (100.0%)
3	18	11/18 (61.1%)	18/18 (100.0%)	18/18 (100.0%)

Palm System accuracy for blood glucose concentration ≥ 75 mg/dL

Lot #	Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ±20 %
1	180	90/180 (50.0%)	175/180 (97.2%)	180/180 (100.0%)	180/180 (100.0%)
2	181	91/181 (50.3%)	173/181 (95.6%)	181/181 (100.0%)	181/181 (100.0%)
3	177	92/177 (52.0%)	169/177 (95.5%)	177/177 (100.0%)	177/177 (100.0%)

Forearm System accuracy for blood glucose concentration <75 mg/dL

Lot #	Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	16	10/16 (62.5%)	16/16 (100.0%)	16/16 (100.0%)
2	14	12/14 (85.7%)	14/14 (100.0%)	14/14 (100.0%)
3	18	11/18 (61.1%)	18/18 (100.0%)	18/18 (100.0%)

Forearm System accuracy for blood glucose concentration ≥ 75 mg/dL

Lot #	Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ±20 %
1	180	83/180 (46.1%)	177/180 (98.3%)	180/180 (100.0%)	180/180 (100.0%)
2	181	89/181 (49.5%)	171/181 (94.5%)	181/181 (100.0%)	181/181 (100.0%)
3	177	86/177 (48.6%)	166/177 (93.8%)	177/177 (100.0%)	177/177 (100.0%)

Upper arm System accuracy for blood glucose concentration <75 mg/dL

Lot #	Number of test results	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
1	16	10/16 (62.5%)	16/16 (100.0%)	16/16 (100.0%)
2	14	8/14 (57.1%)	14/14 (100.0%)	14/14 (100.0%)
3	18	11/18 (61.1%)	18/18 (100.0%)	18/18 (100.0%)

Upper arm System accuracy for blood glucose concentration ≥ 75 mg/dL

Lot #	Number of test results	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ±20 %
1	180	89/180 (49.4%)	172/180 (95.6%)	180/180 (100.0%)	180/180 (100.0%)
2	181	88/181 (48.6%)	177/181 (97.8%)	181/181 (100.0%)	181/181 (100.0%)
3	177	87/177 (49.2%)	168/177 (94.9%)	177/177 (100.0%)	177/177 (100.0%)

LipidoCare Lipid Profile Professional Method Comparison Study:
A method comparison study was performed by healthcare professionals at three external sites with capillary samples collected from the fingertip and a venous sample collected in a Na-heparin tube. The capillary and venous whole blood samples were tested on 3 different SD LipidoCare analyzers at each site for a total of 9 SD LipidoCare analyzers using 3 lots of SD LipidoCare Lipid Profile test strips (one lot/site). Samples which exceed the lower and higher end of the candidate device measuring range were excluded from the analysis. A total of 355 total cholesterol, 356 triglyceride results, and 358 HDL results were obtained from the 3 test sites. The candidate capillary whole blood test results were compared to test results obtained from Na-heparin venous plasma tested using Roche Cobas Ready Total Cholesterol, Roche HDL Cholesterol, and Roche Cobas Ready Triglyceride reagent by a laboratory professional. All samples were unmodified. The regression analysis results are summarized below:

Total Cholesterol candidate capillary results vs Cobas Ready Total Cholesterol results

	Site/Lot 1	Site/Lot 2	Site/Lot 3	Combined sites/lots
Slope	1.0056	1.0088	0.9945	1.0037
Intercept	-1.2959	-0.0525	2.1842	0.1245
R	0.9925	0.9902	0.9895	0.9905
N	120	119	116	355
Test range (mg/dL)	111-408	109-437	114-415	109-437

Triglyceride candidate capillary results vs. Roche Cobas Ready Triglyceride results

	Site/Lot 1	Site/Lot 2	Site/Lot 3	Combined sites/lots
Slope	0.9961	0.9951	0.9950	0.9954
Intercept	1.4773	0.6068	1.2699	1.1103
R	0.9988	0.9983	0.9979	0.9983
N	120	120	116	356
Test Range (mg/dL)	58-621	59-642	63-588	58-642

HDL candidate capillary results vs Roche HDL Cholesterol results

	Site/Lot 1	Site/Lot 2	Site/Lot 3	Combined sites/lots
Slope	0.9945	1.0095	0.9806	0.9944
Intercept	0.4465	-0.0479	1.2347	0.5609
R	0.9946	0.9889	0.9878	0.9904
N	120	119	119	358
Test range (mg/dL)	25-93	25-91	26-90	25-93

b. Matrix comparison:

Not applicable. The device is intended for use with capillary whole blood only.

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):

Lay-User Performance study:

Lipid Profile Test:

The accuracy of the SD LipidoCare system when used by the lay-user was evaluated by 600 lay-user participants at 3 external medical sites (200 users per site). Testing was performed using a total of 15 analyzers (5 per site) and 3 lots of SD Lipid Profile test strips (one lot per site). The lay-user participants were provided with the SD LipidoCare user manual. A healthcare professional then collected a blood sample from the participant's fingertip and obtained results using the comparator device (Roche Cobas Ready Total Cholesterol, Roche HDL Cholesterol, and Roche Cobas Ready Triglyceride reagent). The participants were given a survey for feedback on the user manual and the candidate device. The accuracy data from each of the 3 test sites was similar. A total of 10 HDL results were excluded at the 3 sites from the data analysis due to being outside the measuring range of the candidate device.

Site 1 Lay user with candidate device vs. healthcare professional with comparator

	Total Cholesterol	Triglycerides	HDL Cholesterol
Slope	0.9994	0.9971	0.9909
Intercept	0.9151	-1.2282	-1.0871
R^2	0.9969	0.9969	0.9891
N	200	200	194
Test range (mg/dL)	115-281	61-606	25-93

Site 2 Lay user with candidate device vs. healthcare professional with comparator

	Total Cholesterol	Triglycerides	HDL Cholesterol
Slope	1.0035	0.9974	1.0003
Intercept	-.3735	-0.3017	-0.8972
R^2	0.9758	0.9955	0.9883
N	200	200	198
Test range (mg/dL)	109-305	71-613	26-94

Site 3 Lay user with candidate device vs. healthcare professional with comparator

	Total Cholesterol	Triglycerides	HDL Cholesterol
Slope	1.0097	1.0038	1.0011
Intercept	-0.2851	-1.13510	0.2544
R^2	0.9692	0.9965	0.9890
N	200	200	198
Test range (mg/dL)	104-301	62-628	25-94

The following regression equations were obtained from the combined site data for total cholesterol, triglycerides, and HDL cholesterol:

Lay user with candidate device vs. healthcare professional with comparator device for capillary whole blood (all sites combined).

	Total Cholesterol	Triglycerides	HDL Cholesterol
Slope	1.0041	0.9995	0.9964
Intercept	0.1023	-0.9847	-0.5121
R^2	0.9720	0.9963	0.9871
N	600	600	590
Test range (mg/dL)	104-305	61-628	25-94

The difference analysis for the SD Lipid Profile test and comparator method is presented below:

Site 1

Analyte	Within ±5%	Within ±10%	Within ±15%
TC	157/200 (78.5%)	197/200 (98.5%)	200/200 (100%)
TG	171/200 (85.5%)	198/200 (99.0%)	200/200 (100%)
HDL	132/194 (68.0%)	190/194 (97.9%)	194/194 (100%)

Site 2

Analyte	Within ±5%	Within ±10%	Within ±15%
TC	166/200 (83.0%)	197/200 (98.5%)	200/200 (100%)
TG	166/200 (83.0%)	197/200 (98.5%)	200/200 (100%)
HDL	146/198 (73.7%)	194/198 (98.0%)	198/198 (100%)

Site 3

Analyte	Within ±5%	Within ±10%	Within ±15%
TC	157/200 (78.5%)	197/200 (98.5%)	200/200 (100%)
TG	169/200 (84.5%)	197/200 (98.5%)	200/200 (100%)
HDL	159/198 (79.5%)	198/198 (100.0%)	198/198 (100%)

Lay-user results (candidate) vs. comparator method

Glucose Test:

To assess accuracy of the SD LipidoCare system in the hands of the intended users the sponsor performed a study with 586 lay-user participants at 3 external sites. The number of lay-user participants at each site were as follows: site 1: n=196, site 2: n=195, and site 3: n=195. Testing was performed using 3 lots of SD Glucose test strips (one lot per site). The lay-user participants were provided with the SD LipidoCare user manual in English. The lay-users collected their own fingertip capillary blood using the SD LipidoCare Home System first and then from alternative sites (palm, forearm, and upper arm) and recorded their own results. A healthcare professional then collected the participant's capillary blood sample from the fingertip and tested the blood using the comparator device (YSI 2300). The participants were given a survey for feedback on the user manual and the candidate device. The following regression equations were obtained from one representative site for glucose measurement:

Lay user with candidate device vs. healthcare professional with comparator device:

Glucose	Finger	Palm	Forearm	Upper arm
Slope	1.0060	1.0057	1.0062	0.9983
Intercept	-0.6221	-1.0499	-0.5060	0.3568
R^2	0.9939	0.9930	0.9914	0.9928
N	196	196	196	196
Test range (mg/dL)	59-418	57-418	60-419	54-414

The difference analysis for the SD Glucose test and comparator method is presented below:

Glucose concentrations <75 mg/dL

Site	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
Fingertip	35/48 (79.2%)	48/48 (100.0%)	48/48 (100.0%)
Palm	29/48 (60.4%)	48/48 (100.0%)	48/48 (100.0%)
Forearm	26/48 (54.2%)	48/48 (100.0%)	48/48 (100.0%)
Upper arm	28/48 (58.3%)	48/48 (100.0%)	48/48 (100.0%)

Glucose concentrations ≥75 mg/dL

Site	Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
Fingertip	292/538 (54.3%)	510/538 (94.8%)	538/538 (100.0%)	538/538 (100.0%)
Palm	277/538 (51.5%)	500/538 (92.9%)	538/538 (100.0%)	538/538 (100.0%)
Forearm	275/538 (51.1%)	498/538 (92.6%)	538/538 (100.0%)	538/538 (100.0%)
Upper arm	274/538 (50.9%)	497/538 (92.4%)	538/538 (100.0%)	538/538 (100.0%)

A Flesch-Kincaid reading assessment was performed on the test strip inserts and user manuals demonstrating that the proposed labeling used in the lay-user studies is at an 8^{th} grade reading level or lower.

Usability study:

The SD LipidoCare System and its instructions for use were surveyed by lay users after the user studies by means of a questionnaire during the lay user studies. The questionnaire included questions regarding the user friendliness of the system, the clarity of the user instructions. The survey results demonstrated that the lay users found the instructions and the use of the system to be satisfactory.

4. Clinical cut-off**:**

Not applicable.

6. Expected values/Reference range:

Total cholesterol, Triglycerides, and HDL:
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 in May 2001. The APT III report presented the NCEP's updated clinical guidelines for cholesterol testing and management and described the following classifications for cholesterol and triglyceride testing:

	Range (mg/dL)	Classification
Total Cholesterol	<200	Desirable
	200-239	Borderline High
	≥ 240	High
HDL Cholesterol	<40	Low
	≥ 60	High
LDL Cholesterol	<100	Optimal
	100-129	Near Optimal
	130-159	Borderline High
	160-189	High
	≥ 190	Very High
Triglyceride	<150	Normal
	150-199	Borderline High
	200-499	High
	≥ 500	Very High

Glucose:

Expected blood glucose values for non-diabetic adults are as follows:
Before eating <100 mg/dL
One to two hours after meals <140 mg/dL

Reference: American Diabetes Association: Diabetes Care, 2015; 38 (suppl. 1): S8-S16.

N. Instrument Name:

SD LipidoCare Professional Analyzer
SD LipidoCare Home Analyzer
SD LipidoCare BT Professional Analyzer
SD LipidoCare BT Home Analyzer

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and must be replaced with a new strip for additional readings. There are two separate test strip insertion ports. The glucose test strip port is located at the top of the meter and the lipid profile test strip port is located at the bottom of the meter.

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 function with this device. Samples are applied directly to the test strip as they are collected. The SD LipidoCare System will store up to 500 patient results including control solution results. The results include the date and time the sample was run.

4. Specimen Sampling and Handling:
   The SD LipidoCare System is intended to be used with capillary whole blood from the finger, palm, forearm, and upper arm for glucose measurement; and capillary whole blood from the fingertip for lipid measurement. The whole blood sample is applied directly to the test strip and there is no special handling or storage required. The glucose test strip requires a sample volume is 0.9 µL of whole blood and the lipid profile test strip requires 35 µL of whole blood.

5. Calibration:
   There is no user calibration required to perform the LipidoCare lipid profile and glucose tests; however, a lot specific code chip is provided with each Lipid Profile test strip package. Lipid Profile test calibrations were performed in-house and parameters were coded into the code chip. The user inserts the code chip into the meter's code chip portal. The meter turns on automatically. A three-digit code number appears in the display window. The user must check that the number on the display window matches with the number on the test strip box. The calibration procedure programs the meter with the lot number, expiration date and test strip technology. The blood glucose testing requires no coding.

6. Quality Control:
   The SD LipidoCare Professional and Home Systems User Manual states to use only SD Lipid Control Solution and the SD Glucose Control Solution with this system. The SD Lipid Control Solution consists of two levels of controls and is used as quality control for the total cholesterol, triglyceride and HDL cholesterol measurements on the SD LipidoCare Professional and Home Systems. The SD Glucose Control Solution consists of two levels of controls for the glucose measurement on the SD LipidoCare Professional

and Home Systems. The SD Lipid Control Solutions and SD Glucose Control Solutions are sold separately from the SD LipidoCare Professional and Home System. Instructions on how to order the control solutions are included in the user manual. The meter has a function for the user to select that they wish to run a control solution to prevent control results from being stored in the internal memory as patient results. Recommendations on when to test the control materials are provided in the labeling. The control solution readings are not included in the average of the patient results when the measurements are performed in the "control solution mode". An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. Sample volume study
   Glucose: The SD LipidoCare Test system was tested with venous blood at three glucose concentrations (approximately 50, 150, and 350 mg/dL) and seven specimen volumes (0.2, 0.3, 0.5, 0.7, 0.9, 1.0 and 1.1 µL). Each sample was measured in five replicates on the candidate device and the results compared to those obtained with by an established laboratory comparator method (YSI 2300 analyzer)). Results support the claimed minimum sample volume of 0.5 µL and the meter error code for insufficient sample volume.

   Lipid Profile: The SD LipidoCare Test system was tested with venous blood at three total cholesterol levels (approximately 150, 194, and 253 mg/dL), three triglyceride levels (approximately 92, 182, and 266 mg/dL) and three HDL levels (approximately 38, 54, and 82 mg/dL) and nine specimen volumes (10, 20, 25, 30, 31, 32, 33, 34 and 35 µL). Each sample was measured in triplicate on the candidate device and compared to the results obtained using the laboratory comparator method (YSI). Results support the claimed minimum sample volume of 35 µL and the meter error code for insufficient sample volume.

2. Altitude study:
   A study was performed by the sponsor to evaluate the effect of altitude on the performance of the SD LipidoCare glucose test. Venous whole blood samples with concentrations of glucose approximately 45, 110 and 350 mg/dL were exposed to conditions simulating sea level (0ft), 3,280 feet, 6,561 feet, and 13,120 ft. The results from the candidate device were compared to YSI to support the claims in the labeling that altitudes from sea level up to 12,388 feet have no significant effect on blood glucose measurements from the SD LipidoCare system.

3. Hematocrit study:
   The sponsor evaluated the effect of hematocrit on three concentrations of total cholesterol (150, 220, and 260 mg/dL), triglyceride (120, 185, and 520 mg/dL), and HDL (35, 50, and 75 mg/dL); and five concentrations of Glucose (40, 80, 125, 355, and 520 mg/dL) in

venous whole blood. The blood samples were adjusted to the following hematocrit levels:

To assess the effects of hematocrit on TC and TG: 25, 30, 50, 52, 55 and 60%
To assess the effects of hematocrit on HDL: 25, 30, 50, 52, and 55%
To assess the effects of hematocrit on Glucose: 15, 20, 30, 40, 50, 60, and 65%

The samples were run on eight 8 SD LipidoCare analyzers (one test strip per analyzer for TC, TG, HDL and Glucose) and the results were compared to control sample with a hematocrit of 40% containing the same concentrations of analyte as the test samples. The sponsor concluded that a hematocrit range between 30-55% for TC and TG, 30-52% for HDL, and 20-60% for Glucose did not show any significant hematocrit effects.

4. Test System Operating Conditions Study:

Glucose test: The sponsor performed temperature and humidity studies using venous blood samples with five glucose concentrations (60, 108, 205, 300 and 475 mg/dL) to evaluate the effects of temperatures ranging from 50^{o}F to 113ºF (10-45 ºC) and relative humidity conditions from 10% to 90%. Five temperature and humidity combinations were tested: low temperature/low humidity, low temperature/high humidity, average temperature/average humidity, high temperature/low humidity and high temperature/high humidity. Meter results were compared to YSI comparator analyzer. The results support the claims in the labeling that the system can be used in conditions of 50-113°F (10-45 ºC) with relative humidity of 10 to 90% for glucose testing.
Lipid Profile test: The sponsor performed temperature and humidity studies using two concentrations of venous blood samples for total cholesterol (approximately 180 and 270 mg/dL), triglycerides (approximately 120 and 180 mg/dL) and HDL cholesterol (approximately 50 and 80 mg/dL) to evaluate the effects of temperatures ranging from 64^{o}F to 90ºF (18-32 ºC) and relative humidity from 10% to 90%. Meter results were compared to the comparator method. Five temperature and humidity combinations were tested: low temperature/low humidity, low temperature/high humidity, average temperature/average humidity, high temperature/low humidity and high temperature/high humidity. No significant effect (relative to the comparator method) was observed with the temperature and humidity combinations tested. The results support the claims in the labeling that the system can be used in conditions of 64-90°F (18-32 ºC) with relative humidity of 10 to 90% for lipid testing.

The final operational temperature range for the test system for measuring glucose and the lipid profile tests is 64-90°F (18-32 ºC), which is the narrower of the glucose operating condition ranges. The meters will display an error code (E- 4) and a thermal icon to prevent a test result from being displayed when the system is outside of 64-90^{o}F.

5. Infection Control Studies:
The four devices in this submission (SD LipidoCare Home, SD LipidoCare Professional, SD LipidoCare BT Home, and SD LipidoCare BT Professional Systems)are for single patient use only. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing laboratory demonstrating

complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Discide Ultra Disinfecting Towelettes (EPA registration #10492-4). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials of the meter after 260 cleaning and disinfection cycles simulating weekly single-patient use cleaning and disinfection over the 5 year use life of the meter. The subject device labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC Testing
   The sponsor provided appropriate documentation certifying that electromagnetic testing (EMC) has been performed on the SD LipidoCare Analyzer (both Bluetooth and non-Bluetooth models) and was found to be compliant.

7. This device was reviewed after the FDA issued final guidance documents for prescription use blood glucose monitoring systems (BGMS) and over-the-counter use blood glucose monitoring systems (SMBG). However, the recommendations in the guidance documents were not followed for this device since the submission was received prior to finalization of the guidance documents.

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.