December 30, 2025

Truvian Health
Tho Tran
Head of Quality Assurance & Regulatory Affairs
10300 Campus Point Drive
Suite 190
San Diego, CA 92121

Re: K251091
Trade/Device Name: Lipids
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (Total) Test System
Regulatory Class: Class I, meets the limitations of exemptions in 21 CFR 862.9(c)(4)
Product Code: CHH, JGY
Dated: December 2, 2025
Received: December 4, 2025

Dear Tho Tran:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251091

Device Name
Lipids

Indications for Use *(Describe)*
Lipids is part of the TruWellness Panel™ and is intended for use on the TruVerus™. Lipids (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Total Cholesterol (TChol) and Triglycerides (TRIG) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings. From the TRIG determination, Very Low-Density Lipoprotein Cholesterol (VLDL) is calculated by the analyzer.

Lipids (part of the TruWellness Panel™) is an in vitro diagnostic test system that aids the physician in the diagnosis and treatment of the following disorders in adults 18 years of age or older:

Total Cholesterol (TChol): Excess cholesterol in the blood and lipid and lipoprotein disorders.
Triglyceride (TRIG): Diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism; various endocrine disorders.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K251091 510(k) Summary

[In accordance with 21 CFR 807.92]

1 Submitter

Sponsor Name:	Truvian Health
Address:	10300 Campus Point Drive, Suite 190 San Diego, CA 92121
Phone:	(760) 710-9712
Contact Person:	Tho Tran
Date Prepared:	December 30, 2025

2 Devices

Name of Devices: Lipids

Classification Name	Regulation Number	Product Code / Class
Cholesterol (total) test system	862.1175	CHH / Class 1, 510(k) Exempt*
Triglyceride test system	862.1705	JGY / Class 1, 510(k) Exempt*

* Meets limitations of exemption per 21 CFR § 862.9 (c)(4)

3 Predicate Devices

Primary Predicate Devices: Piccolo Total Cholesterol Test System (K023642)

Secondary Predicate Devices: Piccolo Triglycerides Test System (K023639)

4 Device Description

The TruSystem is an automated, integrated in vitro diagnostic platform consisting of the TruVerus™ and the TruWellness Panel™, a Single-Use Consumable Kit that includes a Disc and a Support Pack. Designed for point-of-care and clinical laboratory use, the system enables the simultaneous measurement of clinical chemistry, immunoassay, and hematology parameters from a lithium-heparinized venous whole blood sample in a single run. The TruSystem delivers quantitative results for routine clinical chemistry and immunoassay analytes as well as a complete blood count (CBC) with a 3-part differential, all without the need for specialized operating skills, external calibration, or complex infrastructure.

The TruVerus™ is a benchtop instrument that fully automates sample processing, assay execution, and result reporting. Its touchscreen interface allows operators to control workflows, initiate tests, and review results with minimal training. The Single-Use Consumable Kit and blood sample are loaded into the analyzer drawer, where all necessary processing takes place. Internally, the TruVerus™ integrates:

- A high-precision pipettor for automated sample and reagent handling.
- An onboard centrifuge to separate whole blood into plasma.
- A closed-loop thermal control system to maintain precise assay temperatures.
- A motion control system to fully automate sample processing.
- Dedicated detection modules for clinical chemistry, immunoassay, and hematology testing.
- A high-definition camera used to collect assay readings, image capture, and instrument quality control checks.
- An electronics board to manage individual module boards and associated firmware.
- An integrated computer running the instrument software, accessible via the touchscreen user interface.

The TruVerus™ is factory-calibrated and continuously monitors its performance using optical sensing and electronic feedback mechanisms. Every time the analyzer is powered on or a Single-Use Consumable Kit (TruWellness Panel™) is loaded, the system runs an automated self-test to verify that it remains within calibration and is functioning properly. Internal quality control (QC) checks occur throughout the testing process to ensure the integrity of the analyzer, Disc, and Support Pack. If any self-test or QC check fails to meet system specifications, the TruVerus™ will display an error code and next steps on the touchscreen interface.

The Single-Use Consumable Kit (TruWellness Panel™) houses all the components needed to process as well as analyze samples on the TruVerus™, including dried reagents, internal process control solutions, barcodes that manage the identity of the kit lot (e.g., Disc and Support Pack ID), calibration information, dilution buffers, and single-use plastic pipette tips. It also serves as a waste container which the user discards of at the end of the run.

Lipids is part of the TruWellness Panel™ and is intended for use on the TruVerus™. Lipids (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Total Cholesterol (TChol) and Triglycerides (TRIG) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings. From the TRIG determination, Very Low-Density Lipoprotein Cholesterol (VLDL) is calculated by the analyzer.

5 Indications for Use

Lipids is part of the TruWellness Panel™ and is intended for use on the TruVerus™. Lipids (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Total Cholesterol (TChol) and Triglycerides (TRIG) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings. From the TRIG determination, Very Low-Density Lipoprotein Cholesterol (VLDL) is calculated by the analyzer.

Lipids (part of the TruWellness Panel™) is an in vitro diagnostic test system that aids the physician in the diagnosis and treatment of the following disorders in adults 18 years of age or older:

Total Cholesterol (TChol):	Excess cholesterol in the blood and lipid and lipoprotein disorders.
Triglyceride (TRIG):	Diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism; various endocrine disorders.

6 Comparison of Technological Characteristics with the Predicate Device

The tables below compare the similarities and differences between the technological characteristics of Lipids (part of the TruWellness Panel™) and TruVerus™ to the legally marketed predicate devices.

Substantial equivalence was demonstrated through performance testing for the following performance characteristics: precision / reproducibility, linearity, detection limits, interferences, assay measuring ranges, reference ranges, and method comparison. Performance data for the subject device shows acceptable results compared to the predicate devices.

Table 1. Lipids (Part of the TruWellness Panel™) Comparison Chart

Characteristic	Subject Device Lipids (Part of the TruWellness Panel™)	Primary Predicate Device K023642	Secondary Predicate Device K023639
Measured Analytes	TChol, TRIG	TChol	TRIG
Product Code	TChol: CHH TRIG: JGY	CHH	JGY
Intended Use	In vitro quantitative determination of Total Cholesterol (TChol), and Triglycerides (TRIG) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.	In vitro quantitative determination of Total Cholesterol in heparinized whole blood, heparinized plasma, or serum in clinical laboratory setting or point-of-care location.	In vitro quantitative determination of Triglycerides in heparinized whole blood, heparinized plasma, or serum in clinical laboratory setting or point-of-care location.
Intended Use Setting	Clinical laboratory or point-of-care setting	Same	Same
Specimen Type	Lithium-heparinized venous whole blood	Heparinized whole blood, heparinized plasma, and serum	Heparinized whole blood, heparinized plasma, and serum
Detection Method	Photometric / Colorimetric	Same	Same
Detection Wavelength	TChol: 510 nm TRIG: 540 nm	340 nm, 405 nm	500 nm, 850 nm
Reagent Storage	2-8ºC (36-45ºF) or 15-25ºC (59-77ºF) for up to 14 days	2-8ºC (36-45ºF)	2-8ºC (36-45ºF)
Analytical Measuring Range	TChol: 20 – 520 mg/dL TRIG: 20 – 700 mg/dL	TChol: 20 – 520 mg/dL	TRIG: 20 – 500 mg/dL

Table 2. TruVerus™ Comparison Chart

Characteristic	Subject Device TruVerus™	Primary Predicate Device K171971	Secondary Predicate Device K942782
Product Code	JJG	Same	Same
Intended Use	In vitro quantitative determination of clinical chemistry, immunoassays, and hematology analytes in lithium-heparinized venous whole blood. It is for clinical laboratory or point-of-care use.	In-vitro diagnostic device for the quantitative determination of clinical chemistry analytes in lithium-heparinized venous whole blood, heparinized plasma, or serum. It is for clinical laboratory and point-of-care use.	Quantitative in-vitro determinations of clinical chemistry analytes in lithium-heparinized whole blood, heparinized plasma, or serum.
Form Factor	Benchtop	Same	Same
User Interface	Touch screen interface	Same	Same
Blood Separation Function	Centrifugation technology integrated into the instrument	Same	Same
Detection Method	Photometric / Colorimetric	Same	Same
Light Source	Xenon-arc stroboscopic lamp	LED	Same
Detector	CMOS array detector	Photodiode	Photodiode
Power Supply	120-240 volts AC; 50/60 Hz; 700 W	100-240 volts AC; 50-60 Hz; or 12 volts DC, 5.0A	100-240 volts AC; 50-60 Hz; or 15 volts DC, 5.0A
Assay Temperature	37 °C (98.6 °F)	Same	Same
Operating Temperature	15-30°C (59-86°F)	10-32°C (50-90°F)	15-32°C (59-90°F)
Test Time	≤ 30 minutes	15 minutes	12 minutes
Sample Volume	300 µL (aspiration volume)	200 µL	100 µL

7 Recognized Consensus Standards

The following recognized consensus standards were used as a basis for analytical performance testing:

- CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06 Ed.2, Evaluation of the Linearity of Quantitative Measurement Procedures
- CLSI EP07 Ed.3, Interference Testing in Clinical Chemistry
- CLSI EP09c Ed.3, Measurement Procedure Comparison and Bias Estimation Using Patient Samples
- CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline–Second Edition
- CLSI EP25 Ed.2, Evaluation of Stability of In Vitro Medical Laboratory Test Reagents
- CLSI EP37 Ed.1, Supplemental Tables for Interference Testing in Clinical Chemistry

8 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

8.1 Precision / Reproducibility

Precision studies were performed in accordance with CLSI document EP05-A3. The total precision (reproducibility), as well as within-run, between-day, and between-site precision, was assessed by testing three levels of control samples (low, medium, and high) across three sites. At least three operators performed testing per site, and each site utilized three instruments. Each site performed a minimum of 90 valid replicates for each control level over a 5-day period (2 runs per day, 3 replicates per run) on one lot of Single-Use Consumable Kits. Summary results are provided in the table below.

Analyte	Level	n	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total*	
				SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Total Cholesterol (mg/dL)	Low	92	82	2.1	2.6	0.0	0.0	0.0	0.0	1.2	1.5	2.5	3.0
Total Cholesterol (mg/dL)	Med	91	189	4.4	2.3	0.7	0.4	0.0	0.0	1.9	1.0	4.8	2.6
Total Cholesterol (mg/dL)	High	92	228	3.5	1.5	0.0	0.0	0.0	0.0	2.4	1.1	4.2	1.9
Triglycerides (mg/dL)	Low	92	88	1.6	1.8	0.0	0.0	0.0	0.0	0.8	0.9	1.8	2.0
Triglycerides (mg/dL)	Med	91	136	2.8	2.1	0.6	0.4	0.8	0.6	0.4	0.3	3.0	2.2
Triglycerides (mg/dL)	High	92	452	4.8	1.1	0.0	0.0	1.2	0.3	0.7	0.2	5.0	1.1

* Total Precision represents reproducibility, which is the sum of all variance components.

8.1.1 Whole Blood Precision

Whole blood precision was evaluated using Li-Hep whole blood samples collected across five sites from the intended use population with normal and abnormal blood chemistry analyte levels. For each test subject, eight replicates were measured across four instruments and two operators. The SD and CV% were calculated per subject. These variances were pooled across subjects for the defined analyte ranges and summarized in the table below.

Analyte	Range	n	Mean	Median	SD	CV%
Total Cholesterol (mg/dL)	20–200	93	140	144	3.5	2.5
Total Cholesterol (mg/dL)	200–240	10	214	215	4.8	2.3
Total Cholesterol (mg/dL)	240–520	9	313	319	8.2	2.6
Triglycerides (mg/dL)	20–150	69	91	95	2.2	2.9
Triglycerides (mg/dL)	150–250	25	184	177	3.6	1.9
Triglycerides (mg/dL)	250–700	9	339	302	5.7	1.6

8.2 Linearity

Linearity testing was performed in accordance with CLSI document EP06-Ed2. Whole blood-based linearity panels, consisting of numerous sample levels including at least one sample level below the assay lower limit linearity interval and one sample level above the assay upper limit linearity interval, were tested across multiple instruments and kit lots.

Summary results are provided in the table below.

Analyte	Tested Linear Range	Claimed Linear Range
Total Cholesterol (mg/dL)	2–590	20–520
Triglycerides (mg/dL)	11–843	20–700

8.3 Detection Limits

Detection limits were determined in accordance with CLSI document EP17-A2. The Limit of Blank (LoB) corresponds to the highest measurement result that is likely to be observed for a blank sample. The assay is designed to have a LoB ≤ Limit of Detection (LoD).

The Limit of Detection (LoD) corresponds to the lowest concentration of analyte that can be detected with a probability of 95%. The assay is designed to have an LoD ≤ Limit of Quantitation (LoQ).

The Limit of Quantitation (LoQ) corresponds to the lowest concentration of analyte in a sample that had a CV ≤ 20%. Detection limits are provided in the table below.

LoD and LoQ were established in Li-Hep whole blood samples.

Analyte	LoB	LoD	LoQ
Total Cholesterol (mg/dL)	3.76	6	7
Triglycerides (mg/dL)	12.45	14	16

8.4 Analytical Measuring Range

The analytical measuring range (AMR) was established based on the LoQ and the linear range data of each analyte. The TruVerus™ will report results within the AMR as listed in the table below.

Analyte	AMR
Total Cholesterol (mg/dL)	20–520
Triglycerides (mg/dL)	20–700

8.5 Risk Classification Intervals

The risk classification intervals were established based on scientific literature[1]. These ranges in the table below are provided as guidelines only.

Analyte		Reference Range	Units
Total Cholesterol	Desirable	< 200	mg/dL
	Borderline High	200 – 239	mg/dL
	High	≥ 240	mg/dL
Triglycerides	Normal	< 150	mg/dL
	Borderline High	150 – 199	mg/dL
	High	200 – 499	mg/dL
	Very High	≥ 500	mg/dL

[1] *National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 01-3670, May 2001.*

8.6 Interferences

Following CLSI documents EP07 and EP37, endogenous and exogenous substances were spiked into samples to assess potential interference. All testing was performed using contrived whole blood samples at two targeted analyte concentration levels. Interference is defined as the analyte result shifted by more than 10% or by a fixed value consistent with CLSI EP07 section 3.1.2, whichever is greater. Summary results are provided in the tables below.

Summary of Endogenous Substances

Substance	Max Concentration without Interference			
	Total Cholesterol	Triglycerides		Units
Hemolysis	122	154		mg/dL
Conjugated Bilirubin	4.1	< 200 mg/dL	2.1*	mg/dL
		>200 mg/dL	2.3	mg/dL
Unconjugated Bilirubin	5.0	<200 mg/dL	2.1	mg/dL
		>200 mg/dL	4.9	mg/dL
Triglycerides	1,814	N/A		mg/dL

** Low level Conjugated Bilirubin testing showed ≤11% bias*

Summary of Exogenous Substances

Substance	Max Concentration without Interference		
	Total Cholesterol	Triglycerides	Units
Acetaminophen	15.6	15.6	mg/dL
Acetylsalicylic acid	3.0	3.0	mg/dL
Ampicillin	7.5	7.5	mg/dL
Cefoxitin	495	660	mg/dL
Cyclosporine	0.18	0.18	mg/dL
Doxycycline	1.8	1.8	mg/dL
Heparin	3,300	3,300	U/L
Ibuprofen	10.95	21.9	mg/dL
Levodopa (L-Dopa)	0.75	0.3	mg/dL
Methyldopa	1.12	0.78	mg/dL
Metronidazole	12.3	12.3	mg/dL
Phenylbutazone	16.05	24.08	mg/dL
Rifampicin	4.8	4.8	mg/dL
Theophylline	6	6	mg/dL
Acetylcysteine	15	5	mg/dL

Substance	Max Concentration without Interference		
	Total Cholesterol	Triglycerides	Units
Ascorbic Acid	5.25	1.75	mg/dL
Calcium Dobesilate	3.0	1.5	mg/dL
Acetoacetate	20	20	mg/dL
Atorvastatin	0.075	0.075	mg/dL
Beta-Hydroxybutyrate	333	750	mg/dL
Caffeine	10.8	10.8	mg/dL
Cefotaxime	52.8	52.8	mg/dL
Cephalothin (Keflin)	180	180	mg/dL
Cimetidine	3.0	3.0	mg/dL
Creatinine	15	15	mg/dL
Cysteine	10	5	mg/dL
Digoxin	0.0039	0.0039	mg/dL
Dipyrone	3.3	3.3	mg/dL
Dobutamine	0.121	0.121	mg/dL
Fenofibrate	4.5	4.5	mg/dL
Fructose	18	18	mg/dL
Gemfibrozil (Lopid)	13.8	13.8	mg/dL
Glutathione	15	3.75	mg/dL
Isoniazide	6	6	mg/dL
Lactate Lithium	90	90	mg/dL
Lactose	100	100	mg/dL
Lidocaine	1.5	1.5	mg/dL
Lovastatin (Mevacor)	0.021	0.021	mg/dL
Methotrexate	102	54.4	mg/dL
Nicotinic Acid (Niacin)	10	10	mg/dL
Phenytoin	6	6	mg/dL
Pravastatin	0.0207	0.0207	mg/dL
Rosuvastatin	0.0111	0.0111	mg/dL
Salicylic Acid	2.86	2.86	mg/dL
Simvastatin	0.168	0.168	mg/dL
Sodium Methicillin	7.5	7.5	mg/dL
Urea	120	120	mg/dL
Uric Acid	23.5	23.5	mg/dL

8.7 Traceability

The assay calibrators are traceable to the reference materials in the table below. The calibration parameters for each analyte are established internally and the assigned values for calibrators are unique for each reagent lot. The calibration information is barcoded on each Single-Use Consumable Kit.

Assay	Traceable Material
Total Cholesterol	NIST SRM1950
Triglycerides	ID/MS→Roche Cobas

8.8 Method Comparison Study

Whole blood specimens were prospectively collected from subjects at five external sites. For each subject, two Li-Hep (no gel) tubes of whole blood and one EDTA tube were collected. One Li-Hep tube was analyzed on the TruVerus™, while the other was centrifuged shortly after collection to obtain Li-Hep plasma. The Li-Hep plasma and the EDTA sample were then shipped to a central laboratory for analysis using FDA-cleared comparator methods. Additionally, contrived samples were used sparingly to address extremely rare high and low target analytes. Truvian results were compared with results from the Roche Cobas Chemistry (c module) analyzer. Summary results are provided in the table below.

Analyte	Units	N	Range	Slope	Intercept	R
Total Cholesterol	mg/dL	326	23–488	1.00	-4.00	0.995
Triglycerides	mg/dL	313	29–687	1.00	-6.00	0.998

8.9 EMC and Safety

The TruVerus™ has been tested and complies with the following internationally recognized consensus standards for electromagnetic compatibility and safety:

- IEC 61326-2-6: 2020
- IEC 61326-1: 2020
- ETSI EN 301 489-1 V2.2.3 (2019-11)
- ETSI EN 301 489-17 V3.2.4 (2020-09)
- CFR47 FCC Part 15, Subpart B (Class A)
- ICES-003 Issue 7 October 2020
- CFR47 FCC Part 15, Subpart C, 15.247
- RSS-Gen – Issue 5, April 2018 including Amendment 1 (March 2019) and Amendment 2 (February 2021)
- ETSI EN 300 328 V2.2.2. (2019-07)
- ETSI EN 301 893 V2.1.1 (2017-05)

9 Conclusions

The performance data confirm that the subject device performs as intended and is as safe and effective as the predicate devices. Thus, the equivalence assessment and performance data demonstrate substantial equivalence to the predicates in terms of safety and effectiveness.