510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251157

B Applicant

Truvian Health

C Proprietary and Established Names

Core Metabolic

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CIX	Class II	21 CFR 862.1035 - Albumin Test System	CH - Clinical Chemistry
CFR	Class II	21 CFR 862.1345 - Glucose test system	CH - Clinical Chemistry
CEK	Class II, 510(k) exempt*	21 CFR 862.1635 - Total Protein test system	CH - Clinical Chemistry

* Total Protein meets the limitations of exemptions per 21 CFR § 862.9 (c)(9)

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Glucose (GLU), Total Protein (TP), Albumin (ALB)

C Type of Test:

Quantitative, photometric/colorimetric

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The Core Metabolic panel is part of the TruWellness Panel™ and is intended for use on the TruVerus™. The Core Metabolic panel (part of the TruWellness Panel™) is an in vitro diagnostic device and intended to be used for the quantitative determination of Glucose (GLU), Total Protein (TP), and Albumin (ALB) in lithium-heparinized venous whole blood in clinical laboratory or point-of-care settings.

The Core Metabolic panel (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:

- Glucose (GLU): Carbohydrate metabolism disorders, including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

- Total Protein (TP): Variety of diseases involving the liver, kidney, or bone marrow, as well as other metabolic and nutritional disorders.

- Albumin (ALB): Numerous diseases involving primarily the liver and kidneys.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

The instrument was validated up to an altitude of 2,000 m (6562 ft). The Core Metabolic panel should not be used above 2,000 m (6562 ft).

D Special Instrument Requirements:

TruVersus ™

IV Device/System Characteristics:

A Device Description:

Core Metabolic contains the following reagents:

Core Metabolic	Quantity per single-use consumable kit
Adenosine-5'-Triphosphate	17.5 µg
Bromocresol Green	4.8 µg
Copper Sulfate	38.4 µg
Glucose-6-Phosphate Dehydrogenase	0.4 mU
Hexokinase	0.4 mU
Magnesium Aspartate	0.1 µg
Nicotinamide Adenine Dinucleotide	0.3 µg
Potassium Iodide	99.9 µg

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 at the end of the run. The Support Pack contains a feature to accept a standard 4 mL blood tube. The Support Pack also houses 22 pipette tips for transferring and mixing samples and reagents, 11 dilution wells to support reagent processing activities within the test system (e.g., sample dilution, reagent dilution, rehydration of dried reagents), and 6 x 2 ml tubes that contain additional wet and dry reagents.

B Principle of Operation:

Glucose: This assay measures glucose by employing the hexokinase (HK) glucose-6-phophate dehydrogenase (G-6-P-DH) method. Glucose is phosphorylated by adenosine-5'-triphosphate (ATP) in a reaction catalyzed by HK. The glucose-6-phosphate (G-6-P) formed is oxidized by G-6-P-DH to 6-phosphogluconate (6-PG), producing an equimolar amount of NADH. The amount of NADH formed in the second reaction is directly proportional to the concentration of glucose in the sample and is measured via absorbance at 340 nm.

$$\text{Glucose} + \text{ATP} \xrightarrow{\text{HK}} \text{G-6-P} + \text{ADP} \quad \text{G-6-P} + \text{NAD} \xrightarrow{\text{G-6-P-DH}} \text{6-PG} + \text{NADH}$$

Total Protein: This assay measures total protein via the biuret method. In alkaline solution, cupric ions react with all compounds with two amide or peptide bonds linked either directly or through an intermediate carbon atom to form a violet-colored complex. The absorbance of this colored complex at 550 nm is directly proportional to protein concentration.

$$\text{Cu} + \text{Protein} \rightarrow \text{Purple Complex}$$

Albumin: This assay measures albumin levels by monitoring the formation of a complex between albumin and bromocresol green (BCG). The blue-green color produced in the reaction is

measured at 628 nm, and its absorbance is directly proportional to the concentration of albumin in the sample.

BCG + Albumin→ Green Complex

V Substantial Equivalence Information:

A Predicate Device Name(s):
Medicon Hellas Albumin, Medicon Hellas Glucose

B Predicate 510(k) Number(s):
K200898

C Comparison with Predicate(s):

Primary Device Predicate

Device & Predicate Device(s):	K251157	K200898
Device Trade Name	Core Metabolic	Medicon Hellas Albumin, Medicon Hellas Glucose
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative determination of albumin and glucose	Same
General Device Characteristic Differences		
Specimen Type	Lithium-heparinized venous whole blood	Serum and urine

Secondary Device Predicate

Device & Predicate Device(s):	K251157	K950164
Device Trade Name	Core Metabolic	Abaxis Piccolo® Primary Health Panel Reagent Rotor
General Device Characteristic Similarities		
Intended Use/Indications For Use	Quantitative determination of total protein	Same
General Device Characteristic Differences		
Specimen Type	Lithium-heparinized venous whole blood	Heparinized whole blood, heparinized plasma, or serum
Analytical Measuring Range	2.0-11.5 mg/dL	2-14 mg/dL

VI Standards/Guidance Documents Referenced:

- Clinical & Laboratory Standards Institute (CLSI) EP05-A3 Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition
- CLSI EP06 Evaluation of the Linearity of Quantitative Measurement Procedures - Second Edition
- CLSI EP07 Interference Testing in Clinical Chemistry - Third Edition
- CLSI EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples -Third Edition
- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition
- CLSI EP37 Supplemental Tables for Interference Testing in Clinical Chemistry - First Edition

VII Performance Characteristics (if/when applicable):

1. Analytical Performance:

1. Precision/Reproducibility:

A. Reproducibility with control material: This study was designed according to CLSI EP05-A3. The study was conducted at 3 external point-of-care (POC) sites, with 3 analyzers per site and at least 3 POC operators per site. Testing was conducted over 5 days using a single lot of consumables and consisted of at least 3 levels of control samples, with 6 replicates run per day, 3 run in the morning and 3 run in the afternoon (each replicate is run on an individual instrument). Overall, there were at least 90 replicates for each precision control sample level (3 sites x 1 sample x 3 replicates per run x 2 runs per day x 5 days = 90 replicates). The total precision as well as within run, between day, and between site precision were estimated. Results are displayed below:

Analyte	N	Mean	Within-Run		Between-Run		Between-Day		Between-Site		Total Precision	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
GLU	92	60	1	1.9	0	0.0	0	0	0.1	0.2	1	1.9
GLU	91	114	3	2.7	0	0.0	0	0	1	1.2	3	3.0
GLU	92	274	5	1.7	0	0.0	1	0.3	1	0.3	5	1.7
GLU	90	399	6	1.6	2	0.4	1	0.4	4	1.1	8	2.0
TP	92	4.8	0.1	2.3	0.0	0.0	0.04	0.8	0.1	1.9	0.1	3.1
TP	91	6.5	0.2	2.4	0.0	0.0	0.0	0.0	0.04	0.6	0.2	2.5
TP	92	7.8	0.1	1.2	0.0	0.0	0.04	0.5	0.03	0.4	0.1	1.4
ALB	92	3.1	0.1	1.8	0.0	0.0	0.0	0.0	0.1	1.9	0.1	2.6
ALB	91	4.3	0.1	2.3	0.0	0.5	0.0	0.0	0.1	1.3	0.1	2.7
ALB	92	5.0	0.1	1.2	0.0	0.0	0.0	0.3	0.1	1.1	0.1	1.7

B. Whole Blood Precision: This study was evaluated at five sites collecting samples from the intended use population with normal and abnormal analyte levels. At least 20 subjects were enrolled at each site and for each test subject, eight replicates were measured across four instruments and two operators. The SD and CV% precision estimates were calculated by pooling subject standard deviations and/or % CV for predefined Low, Medium or High sub-intervals selected to represent normal and abnormal regions of the analytical measuring range and encompassing medical decision levels. Pooled imprecision is considered a representative estimate of reproducibility that include variability of sites, instruments, operators, days and repeatability.

Analyte	Range	Subject (N)	Replicate (N)	Mean	SD	CV%
GLU (mg/dL)	10–100	45	348	88.5	2.91	3.4%
GLU (mg/dL)	100–150	28	221	118.4	3.61	3.0%
GLU (mg/dL)	150–450	44	334	205.2	4.23	2.0%
TP (g/dL)	2.0–6.0	27	210	5.27	0.165	3.2%
TP (g/dL)	6.0–8.0	83	639	6.98	0.166	2.4%
TP (g/dL)	8.0–11.5	3	24	8.48	0.269	3.3%
ALB (g/dL)	1.0–3.5	53	409	2.92	0.108	3.7%
ALB (g/dL)	3.5–5.0	63	487	4.22	0.108	2.6%
ALB (g/dL)	5.0-6.5	1	8	5.15	0.076	1.5%

C. Whole Blood Between Lot Precision: 22 subjects consisting of 6 healthy individuals and 16 individuals in various disease states were enrolled at a single point-of-care clinical site and tested across 3 lots of the candidate panel on 3 TruVersus™ analyzers by 2 operators. A total of 6 replicates per subject participant, 2 replicates per lot, were tested by 1 of the 2 operators. Results below present the number of subjects evaluated, the % difference from the median, and pooled %CV by lot and by analyte.

Analyte	Subjects per Lot	Median relative difference %			Pooled % CV		
		Lot-A	Lot-B	Lot-C	Lot-A	Lot-B	Lot-C
GLU	22	0.8%	-0.5%	-0.3%	3.6%	2.8%	2.8%
TP	22	-0.2%	0.9%	-0.7%	2.5%	2.4%	1.9%
ALB	22	0.6%	0.5%	0.2%	2.4%	1.5%	1.6%

D. Control Between Lot Reproducibility: To evaluate the lot-to-lot reproducibility, 3 control samples (low, medium and high) were tested on 3 TruVersus™ analyzers using 3 lots of the candidate test. Each sample level was tested with at least 5 replicates on one TruVersus™ analyzer each day with each single-use consumable kit lot over 3 days to achieve a minimum of 15 replicates per sample level and kit lot. Results are displayed below:

Analyte	QC Level	N	Mean	Lot Mean			%CV		
				Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3
GLU (mg/dL)	Low	45	60.33	60.71	59.92	60.36	2.60%	2.20%	1.60%
	Medium	45	117.88	118.34	117.45	117.86	2.60%	2.10%	2.40%
	High	45	278.08	278.66	276.79	278.79	2.40%	3.00%	1.90%
TP (g/dL)	Low	45	4.73	4.79	4.68	4.71	2.10%	2.60%	1.60%
	Medium	45	6.53	6.53	6.49	6.56	1.70%	2.70%	1.50%
	High	45	7.79	7.93	7.63	7.80	6.10%*	3.70%	1.70%
ALB (g/dL)	Low	45	3.11	3.14	3.10	3.08	1.70%	2.50%	1.90%
	Medium	45	4.27	4.30	4.26	4.26	1.20%	1.20%	1.40%
	High	45	4.95	4.99	4.90	4.96	1.20%	2.80%	1.20%

*A replicate for TP Lot-1 was identified as a statistical outlier and the table below provides the results without the outlier included.

Analyte	QC Level	N	Mean	SD	%CV
TP (g/dL)	High	14	7.81	0.10	1.31

2. Linearity:

A linearity study was conducted in accordance with CLSI EP06 - 2nd Edition. Linearity was assessed with multiple panels of samples. The linear range for the GLU, TP, and ALB assays were determined by testing 9 samples containing varying concentrations of analyte. Each sample was tested in quadruplicate, using 1 kit lot, across 4 TruVersus™ analyzers, on a single day. The results of the study supported the claimed linear interval for GLU, TP, and ALB. Within the claimed analytical measuring range, the maximum observed deviation for GLU, TP, and ALB are 5%, 4%, and 9%, respectively.

3. Analytical Specificity/Interference:

This study was designed according to CLSI EP07-A3 and CLSI EP37, to verify and validate the effect of potentially interfering exogenous and endogenous substances on the GLU, TP, and ALB assays. Testing was performed with contrived lithium heparin whole blood samples from a healthy donor population, with 2 analyte concentration levels targeted based on recommended levels in CLSI EP07. Potentially interfering substances were prepared in the appropriate diluent and then added to the low and high contrived whole blood samples to create test samples. For any substances identified as an interferent, dose response testing and analysis was conducted to assess the highest concentration limit below which no significant interference was observed. The results are displayed below:

Endogenous compounds:

Substance (mg/dL)	Max Concentration without Interference		
	GLU	TP	ALB
Triglycerides	1,140	1,140	1,140
Hemoglobin	346	1,151	1,050
Conjugated Bilirubin	26.0	15.1	40
Unconjugated Bilirubin	37.9	17.5	40

Exogenous compounds:

Substance	Max Concentration without Interference			
	GLU	TP	ALB	Units
Acetaminophen	15.6	15.6	15.6	mg/dL
Acetylsalicylic acid	3.0	3.0	3.0	mg/dL
Ampicillin	7.5	7.5	7.5	mg/dL
Cefoxitin	660	495	660	mg/dL
Cyclosporine	0.18	0.18	0.18	mg/dL
Doxycycline	1.8	1.8	1.8	mg/dL
Heparin	3,300	3,300	3,300	U/L
Ibuprofen	21.9	21.9	21.9	mg/dL
Levodopa (L-Dopa)	0.75	0.75	0.75	mg/dL
Methyldopa	2.25	2.25	2.25	mg/dL
Metronidazole	12.3	12.3	12.3	mg/dL
Phenylbutazone	24.08	32.1	32.1	mg/dL
Rifampicin	4.8	4.8	4.8	mg/dL
Theophylline	6.0	6.0	6.0	mg/dL
Acetylcysteine	15	15	15	mg/dL
Ascorbic Acid	5.25	5.25	5.25	mg/dL
Calcium Dobesilate	6.0	6.0	6.0	mg/dL
α-ketoglutarate	N/A	N/A	5	mg/dL
α-1-acid Glycoprotein	N/A	N/A	500	mg/dL
Acetoacetate	20	N/A	20	mg/dL
Albumin	15,000	N/A	N/A	mg/dL
Caffeine	10.8	10.8	10.8	mg/dL
Calcium	N/A	N/A	20	mg/dL
Cefotaxime	N/A	N/A	52.8	mg/dL
Cephalothin	180	180	180	mg/dL
Chloramphenicol	7.8	N/A	N/A	mg/dL
Cimetidine	3.0	3.0	3.0	mg/dL
Desacetylcefotaxime	N/A	N/A	6	mg/dL
Dopamine	0.0621	N/A	N/A	mg/dL

Substance	Max Concentration without Interference			
	GLU	TP	ALB	Units
Eltrombopag	30	N/A	N/A	mg/dL
Glutathione	92	N/A	N/A	mg/dL
Hydrochlorothiazide	0.113	N/A	N/A	mg/dL
IgG	4,500	N/A	N/A	mg/dL
Lidocaine	1.5	N/A	N/A	mg/dL
Lithium	2.5	N/A	N/A	mg/dL
Methotrexate	136	68	N/A	mg/dL
Nitrofurantoin	0.213	0.213	0.213	mg/dL
Oxaloacetate	14.62	N/A	N/A	mg/dL
p-Aminosalicylic Acid	N/A	N/A	46.5	mg/dL
Penicillin G	N/A	900	1,800	mg/dL
Phenytoin	6	N/A	N/A	mg/dL
Proline	N/A	N/A	4	mg/dL
Pyruvate	5	N/A	N/A	mg/dL
Salicylic Acid	2.86	2.86	2.86	mg/dL
Sulfadiazine	N/A	25.5	25.5	mg/dL
Sulfanilamide	N/A	50	50	mg/dL
Uric acid	23.5	N/A	N/A	mg/dL

4. Detection Limit and Assay Reportable Range:

The Limit of Blank (LoB) was determined in accordance with the classical approach provided in section 5.3 of CLSI EP17-A2. LoB was determined by running four (4) blank samples on 4 TruVersus™ analyzers over 3 days of testing with 5 replicates per sample for a total of 60 tests for each single-use consumable kit lot.

The LoD (Limit of Detection) and LoQ (Limit of Quantitation) were determined based on recommendations from CLSI EP17-A2. The LoQ corresponds to the lowest concentration of analyte in a sample that had a CV ≤ 20%.

The results of the studies are summarized below and support the claimed range of analytes.

Assay	Reportable Analytical Measuring Range	LoQ
Glucose	10 - 450 mg/dL	6 mg/dL
Total Protein	2.0 - 11.5 g/dL	0.7 g/dL
Albumin	1.0 - 6.5 g/dL	0.2 g/dL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

A. Traceability: Core Metabolic assay calibrators are traceable to the reference materials in the table below:

Assay	Traceability
GLU	ID/MS→NIST SRM 1950
TP	NIST SRM1950
ALB	ERM-DA470k→Verichem 9466F

B. Sample Stability: Sample Stability studies performed demonstrate that samples measured on the candidate tests are stable for 60-minutes post-collection.

C. Altitude Effects: An altitude study was conducted to evaluate performance of GLU, TP, and ALB at sea-level and the results are acceptable. This study supports the device performance at altitudes of up to 2000 m.

6. Assay Cut-Off:

Not applicable.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was conducted to establish the performance characteristics of the Core Metabolic on the TruVersus™ when used to analyze lithium heparin whole blood clinical specimens. Whole blood samples from apparently healthy patient and from patients with acute or chronic health conditions were collected from 5 point-of-care sites, tested by at least 3 point-of-care operators per site, on at least 4 TruVersus™ per site, using 5 lots of reagents. Results compared against a legally marketed comparator are displayed below. The data demonstrated that accuracy was consistent across sites and differences at the medical decision points were reviewed and found acceptable.

Analyte	N	Range	Slope	Intercept	R
GLU (mg/dL)	341	50-441	0.95 (0.94, 0.96)	3.20 (1.73, 4.38)	0.998
TP (g/dL)	344	2.5-11.5	1.00 (1.00, 1.05)	-0.20 (-0.53, -0.10)	0.964
ALB (g/dL)	345	1.5-6.0	1.00 (1.00, 1.08)	0.00 (-0.28, 0.10)	0.969

2. Matrix Comparison:

Not applicable.

C. Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Clinical Cut-Off:

   Not applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable.

D. Expected Values/Reference Range:

The reference ranges are based on scientific literature.

Analyte	Reference Interval	Units
Glucose[1]	Adult fasting plasma glucose: <100 mg/dL (5.55 mmol/L)	mg/dL (mmol/L)
	<140 mg/dL (7.77 mmol/L) 1-2 hours after meals.	
Total Protein[2,3]	6–7.8	g/dL
Albumin[2,3]	3.5–5	g/dL

[1] ElSayed NA, Aleppo G, Aroda VR,et al, American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of Care in Diabetes-2023. Diabetes Care 2023; 46 (Suppl. 1):S19-S40
[2]Henry, J.B., Clinical Diagnosis and Management by Laboratory Methods. 20th Ed. W.B. Saunders Co., Philadelphia (1976).
[3]Tietz, N.W., Textbook of Clinical Chemistry. 2nd Ed. W.B. Saunders Co., Philadelphia (1994).

VIII Proposed Labeling:

The labeling does support the finding of substantial equivalence for this device.

IX Conclusion:

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