July 13, 2023

Siemens Healthcare Diagnostics Inc.
Anoop Joy
Clinical Regulatory Affairs Specialist
511 Benedict Avenue
Tarrytown, NY 10591

Re: K222116
Trade/Device Name: Atellica® CI Analyzer, Atellica® IMThyroid Stimulating Hormone 3-Ultra (TSH3-UL), Atellica® CH Albumin BCP (AlbP)
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW, CJW, JJE
Dated: December 31, 2022
Received: January 4, 2023

Dear Anoop Joy:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222116

Device Name
Atellica® CI Analyzer
Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
Atellica® CH Albumin BCP (AlbP)

Indications for Use *(Describe)*
The Atellica® CI Analyzer is an automated, integrated system designed to perform in vitro diagnostic tests on clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ionselective electrode technology for clinical use.

The Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Atellica® CI Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

The Atellica® CH Albumin BCP (AlbP) assay is for in vitro diagnostic use in the quantitative measurement of albumin in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CI Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.

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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510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K222116

1. APPLICANT

Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue,
Tarrytown, NY 10591 USA

Contact: Anoop Joy
Regulatory Clinical Affairs Specialist
Phone: (516) 232-3307
E-mail: anoop.joy@siemens-healthineers.com

Date Prepared: 06 July 2023

2. Regulatory Information

System: Atellica CI Analyzer
Regulation section: 21 CFR § 862.2160
Classification: Class I
Trade Name: Atellica® CI Analyzer
Product Code: JJE, Photometric Analyzer for Clinical Use
Panel: Clinical Chemistry

Assay: Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

Regulation section: 21 CFR § 862.1690
Classification: Class II
Trade Name: Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)
Product Code: JLW, Thyroid stimulating hormone test system
Panel: Clinical Chemistry

Assay: Atellica CH Albumin BCP (AlbP)

Classification Name: Bromocresol Purple Dye-Binding, Albumin
Regulation Section: 21CFR862.1035, Albumin Test system
Trade Name: Atellica® CH Albumin BCP (AlbP)
Classification: Class II
Product Code: CJW
Panel: Clinical Chemistry

3. PREDICATE DEVICE INFORMATION

Candidate Device	Predicate Device	510(k) #	Class	Code
Atellica CI Analyzer	Trinidad Immunoassay (IM) System	K151792	Class I	JJE
	Trinidad CH system	K151767	Class I	JJE
Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)	Trinidad IM Thyroid Stimulating Hormone (TSH) Assay	K151792	Class II	JLW
Atellica CH Albumin BCP (AlbP)	Trinidad CH Albumin BCP reagent (Alb_P)	K151767	Class II	CJW

4. DEVICE DESCRIPTION

4.1. Atellica CI Analyzer

The Atellica® CI Analyzer is an automated, integrated system designed to perform in vitro diagnostic tests on clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ionselective electrode technology for clinical use.

The Atellica CI Analyzer with Atellica® Rack Handler supports both clinical chemistry (CH) and Immunoassay (IM) features and contains all the necessary hardware, electronics, and software to automatically process samples and generate results, including sample and reagent dispensing, mixing, and incubating.

4.2. Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

The Atellica IM TSH3-UL assay is a third-generation assay that employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, an FITC-labeled anti-TSH capture mouse monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH mouse monoclonal antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection

4.3. Atellica CH Albumin BCP (AlbP)

The Atellica CH Albumin BCP (AlbP) assay is an adaptation of the bromocresol purple dy-e binding method reported by Carter and Louderback et al. In the Atellica CH AlbP assay, serum or plasma albumin quantitatively binds to BCP to form an albumin-BCP complex that is measured as an endpoint reaction at 596/694 nm coenzyme NAD+ functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

5. INTENDED USE

5.1 Atellica CI Analyzer

The Atellica® CI Analyzer is an automated, integrated system designed to perform in vitro diagnostic tests on clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ionselective electrode technology for clinical use.

5.2 Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

The Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Atellica® CI Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

5.3 Atellica CH Albumin BCP (AlbP)

The Atellica® CH Albumin BCP (AlbP) assay is for in vitro diagnostic use in the quantitative measurement of albumin in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CI Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.

6. INDICATIONS FOR USE

Same as Intended use

7. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table provides a comparison between the predicate and candidate device.

7.1. Atellica CI Analyzer

Feature	Trinidad CH system	Trinidad Immunoassay (IM) System	Atellica CI Analyzer	
			CH side	IM side
Intended Use	The Trinidad CH System is an automated, clinical chemistry analyzer designed to perform in vitro diagnostic tests on clinical specimens. The system's chemical and immunochemical assay applications utilize photometric, turbidimetric and ion-selective electrode technology for clinical use.	The Trinidad Immunoassay (IM) system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens. The Trinidad IM system's assay application utilizes chemiluminescents technology for clinical use.	The Atellica® CI Analyzer is an automated, integrated system designed to perform in vitro diagnostic tests on clinical specimens. The system is intended for the qualitative and quantitative analysis of various body fluids, using photometric, turbidimetric, chemiluminescent, and integrated ion selective electrode technology for clinical use.	

Feature	**Trinidad CH system**	**Trinidad Immunoassay (IM) System**	**Atellica CI Analyzer**	
			CH side	**IM side**
Operating Principle	Electrolyte, Photometric and Turbidimetric	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	Same as CH	Same as IM
Type of System	Random continuous access, batch, discrete processing		Same	
Analytical and Detection Technology	Electrolyte, Photometric and Turbidimetric	Chemiluminescence using magnetic-particle solid phase and chemiluminescent label	Same as CH	Same as IM
Pack capacity on-board	Up to 70 x 2	42 primary and 35 ancillary reagent packs	70 positions	40 positions (20 in the primary and 20 in the ancillary compartments).
Reagent Probes	4	3	3	1
Mixing	N/A	Centrifugal	N/A	Rocking
Throughput	1800 tests/hour, 1200 tests/hour colorimetric, 600 tests/hour ISE	220 to 440 tests/hr.	CH maximum throughput of up to 1000 assays/hour: 600 photometric assays/hour, 400 IMT assays/hour	120 IM Test / hour
Optical System	Water bath and cuvette optical path length (7 mm) 11 fixed wavelengths	PMT used in photon counting mode	Same as CH	Same as IM
Water Requirements	Special reagent water (SRW) typically through direct plumbing.		Same	
Water Consumption	Max 33 L/Hour	1600: Average of 6 L/hour 1300: 3.5 L/hour	18 L/hour	

Feature	Trinidad CH system	Trinidad Immunoassay (IM) System	Atellica CI Analyzer	
			CH side	IM side
Temperature Control	Water bath, 37°C	Stationary foil heaters	Same	Same
Liquid Level Sensing	Capacitance technology	Air pressure fluid sensing and disposable tip sensing; clog detection mechanism to alert operator to clogged sample probe	Same	Same
Dispense System	Sample Probe transfers an aliquot of diluted sample to reaction cuvette. Dilution probe picks up primary sample from primary tube or cup, and dispenses to dilution cuvette with diluent to dilute sample (except, IMT) Probes have clot detect, crash protect & liquid verification	-Disposable tips -Sample integrity check -10ul-100ul	Same as CH	Same as IM
Test Processing	Random continuous access, batch, discrete processing	Random continuous access, batch, discrete processing	Same as CH	Same as IM
Incubation Time	Dependent on Atellica CH assay	Dependent on Atellica IM assay	Same	Same

Feature	Trinidad CH system	Trinidad Immunoassay (IM) System	Atellica CI Analyzer	
			CH side	IM side
Human Interface (Data Input)	Universal Instrument Workstation, common to new Siemens IVD systems	Universal Instrument Workstation, common to new Siemens IVD systems	Same as CH	Same as IM
Specimens	Tubes - 5 mL, 7 mL, 10 mL Cups - 2 mL sample cups Whole blood, serum, plasma, CSF or urine	Tubes - 5 mL, 7 mL, 10 mL Cups - 2 mL sample cups Whole blood, serum, plasma, CSF or urine	Same as CH	Same as IM
Disposables	Reagent Cuvette Segment, Dilution Cuvette Segment,	Tips, cuvettes	Same as CH	Same as IM
Reagents	Atellica CH reagents	Atellica IM reagents	Same as CH	Same as IM
Altitude	Up to 2000 Meters	Up to 2000 Meters	Same	Same
Calibrators	Atellica CH Calibrators	Atellica IM Calibrators	Same	Same
Controls	Controls specified in assay IFU	Controls specified in assay IFU	Same	Same
Software	Atellica Solution Software	Atellica Solution Software	Atellica CI Software	Atellica CI Software
Weight	CH 470 kg DL 141.7 kg	IM 574 kg DL 141.7 kg	Atellica CI with Rack Handler 760 kg	
Dimension	CH 1156mm D X 1364mm H X 1491 mm W Direct Load 1100 mm D X 1360mm H X 425 mm W	IM 1155.5mm D X 1500mm H X 1491mm W Direct Load 1100 mm D X 1360mm H X 425 mm W	Atellica CI with Rack Handler 934mm D X 1610 mm H X 2138 mm W	
Electromagnetic Compatibility	CISPR 11 Class A IEC 61326-2-6		Same	

Feature	Trinidad CH system	Trinidad Immunoassay (IM) System	Atellica CI Analyzer	
			CH side	IM side
Photometer (CH Side Only)	11 fixed wavelengths	N/A	Same	N/A
Light Source (CH Side Only)	12 V, 50 W Halogen lamp	N/A	Same	N/A
Sample Tray	Samples identified and delivered by Direct Load - 60 positions		Same	
Bar Code	Reagent pack data matrix 2D		Same	
Reaction Tray	221	89	130	56
Reagent cooling	CH Module: 4-12° C	IM module: 4-8° C	Same	7±3° C
Reagent Dispense Volume	10-100 µl per test		Same	
Dispensing System	2 probes with liquid level sensing		Same	
Software	Atellica Solution		Atellica CI Software	

7.2. Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

Below is a features comparison for the Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay on the Atellica CI Analyzer and the predicate device Trinidad IM system.

Feature	**Predicate Device:** Atellica IM TSH3-UL on Trinidad IM system	**New Device:** Atellica IM TSH3-UL on Atellica CI Analyzer
Intended Use:	The Trinidad IM Thyroid Stimulating Hormone (TSH) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum, and plasma (EDTA and lithium heparin) using the Trinidad	The Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma

	IM system. Measurements of the thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	(EDTA and lithium heparin) using the Atellica® CI Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.
Indications for Use:	Measurements of the thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders	Same
Sample type	Serum and plasma	Same
Measurement	Quantitative	Same
Assay Principle	Sandwich immunoassay	Same
Technology	Chemiluminescence	Same
Detection Antibody	Monoclonal murine anti-TSH antibody BSA conjugate labeled with acridinium ester (AE)	Same
Capture Antibody	Anti-fluorescein labeled (FITC) monoclonal murine anti-TSH antibody covalently bound to paramagnetic particles (PMP)	Same
Assay Range	0.008–150.000 µIU/mL	Same
Calibration	2 Point	Same
Calibrators	Atellica IM TSH3-UL CAL	Same
Number of Calibrators	Two (2) levels	Same
Use of Controls	Yes (recommended)	Same
Traceability	Traceable to the World Health Organization (WHO) 3rd International standard for human TSH (IRP 81/565)	Same
Calibrators Packaging	Provided with reagent kit	Same
Expected Values	Infants: 0.87 - 6.15 µIU/mL Children:0.67 - 4.16 µIU/mL Adolescent: 0.48- 4.17 µIU/mL Adult: 0.55 – 4.78 µIU/mL	Same

7.3. Atellica CH Albumin BCP (AlbP)

Below is a features comparison for the Atellica CH AlbP assay on the Atellica CI Analyzer and the predicate device Trinidad CH System.

Feature	**Predicate Device:** Atellica CH AlbP on Trinidad CH System	**New Device:** Atellica CH AlbP on Atellica CI Analyzer
Intended Use :	The Trinidad CH Albumin BCP Reagent (Alb_P) is intended for in vitro diagnostic use in the quantitative measurement of albumin in human serum or plasma on Trinidad CH system. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.	The Atellica® CH Albumin BCP (AlbP) assay is for in vitro diagnostic use in the quantitative measurement of albumin in human serum and plasma (lithium heparin, potassium EDTA) using the Atellica® CI Analyzer. Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.
Indications for Use:	Albumin measurements are used in the diagnosis and treatment of numerous diseases primarily involving the liver or kidneys.	Same
Device Technology:	bromocresol purple (BCP) dye-binding method	Same
Sample Type:	Serum/plasma	Same
Analytical Measuring Interval:	ALBP : 0.5–8.0 g/dL	Same
Reference Interval:	3.4–5.0 g/dL	Same
Interferences:	Bilirubin (Conjugated) – 30 mg/dL Bilirubin (Unconjugated) – 30 mg/dL Lipemia – 500 mg/dL Hemoglobin – 600 mg/dL	Bilirubin (Conjugated) – same Bilirubin (Unconjugated) – same Lipemia – same Hemoglobin – 800 mg/dL
Traceability:	ERM-DA470k Reference Material	Same
Calibration Frequency:	Every 30 days	Same
Calibrators:	Albumin BCP Calibrator	Same
Calibrator Matrix:	ALBP: Human Serum	Same
Calibrator Form:	Lyophilized	Same
Number of Calibrator Levels:	ALBP: One	Same

8. PERFORMANCE CHARACTERISTICS DATA

8.1. Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

Detection Capability

Limit of Blank (LoB) 0.004 µIU/mL (mIU/L)
Limit of Detection (LoD) 0.008 µIU/mL (mIU/L)
Limit of Quantitation (LoQ) 0.008 µIU/mL (mIU/L)

The LoB corresponds to the highest measurement result likely to be observed for a blank sample with a probability of 95%. The LoD corresponds to the lowest concentration of TSH that can be detected with a probability of 95%. The LoQ corresponds to the lowest amount of Atellica IM TSH3-UL in a sample at which the within laboratory CV is ≤ 20%. Detection capability was determined in accordance with CLSI Document EP17-A2.18.

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed in duplicate in 2 runs per day for 20 days. The study was performed using calibrations before the first day and before the eleventh day of testing. The following results are representative of the performance of the assay:

			Repeatability		Within-Laboratory Precision	
Sample Type	N[a]	Mean µIU/mL (mIU/L)	SD[b] µIU/mL (mIU/L)	CV[c] (%)	SD µIU/mL (mIU/L)	CV (%)
Serum A	80	0.017	0.0009	N/A[d]	0.0015	N/A
Serum B	80	0.156	0.0018	1.2	0.0047	3.0
Serum C	80	1.129	0.0152	1.3	0.0262	2.3
Serum D	80	9.848	0.1213	1.2	0.1996	2.0
Serum E	80	58.362	0.6498	1.1	1.4346	2.5
Serum F	80	120.833	1.6610	1.4	3.5474	2.9
EDTA Plasma A	80	1.408	0.0170	1.2	0.0311	2.2
EDTA Plasma B	80	39.662	0.6028	1.5	0.9500	2.4
EDTA Plasma C	80	97.894	1.2965	1.3	2.8148	2.9
Heparin Plasma A	80	1.706	0.0230	1.3	0.0321	1.9
Heparin Plasma B	80	40.719	0.4539	1.1	0.8526	2.1
Heparin Plasma C	80	97.533	1.4809	1.5	3.1898	3.3

Sample Type	N[a]	Mean µIU/mL (mIU/L)	Repeatability SD[b] µIU/mL (mIU/L)	Repeatability CV[c] (%)	Within-Laboratory Precision SD µIU/mL (mIU/L)	Within-Laboratory Precision CV (%)
Control 1	80	0.387	0.0057	1.5	0.0091	2.4
Control 2	80	4.745	0.0812	1.7	0.1136	2.4
Control 3	80	32.012	0.4122	1.3	0.7244	2.3

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

Assay Comparison

Assay comparison was determined with the weighted Deming regression model in accordance with CLSI Document EP09c-ed3. Agreement of the assays may vary depending on the study design, comparative assay, and population tested.

Specimen Type	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica IM TSH3-UL on Atellica IM Analyzer	y = 0.96x - 0.001 µIU/mL (mIU/L)	0.013–144.030 µIU/mL (mIU/L)	112	0.996

[a] Number of samples tested.
[b] Correlation coefficient.

Interferences

Interference testing was performed in accordance with CLSI Document EP07-ed3.

Hemolysis, Icterus, and Lipemia (HIL)

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration µIU/mL (mIU/L)	Percent Bias
Hemoglobin	500 mg/dL (5.00 g/L)	0.820	-2
	500 mg/dL (5.00 g/L)	8.329	-3
Bilirubin, conjugated	40 mg/dL (474 µmol/L)	0.817	-0.1
	40 mg/dL (474 µmol/L)	8.361	-0.3
Bilirubin, unconjugated	40 mg/dL (684 µmol/L)	0.821	-1
	40 mg/dL (684 µmol/L)	8.363	0.3
Lipemia (Intralipid®)	1000 mg/dL (11.3 mmol/L)	0.816	-3
	1000 mg/dL (11.3 mmol/L)	8.258	-2

Other Substances

Interference testing was performed using the Atellica CI Analyzer in accordance with CLSI Document EP07-ed3 and EP37-ed1. The following substances do not interfere with the assay when present at the concentrations indicated. Bias due to these substances does not exceed 10% at TSH concentrations of approximately 0.800 µIU/mL(mIU/L) and 9.000 µIU/mL(mIU/L).

Substance	Substance Test Concentration	Substance	Substance Test Concentration
Biotin	0.35 mg/dL (14.3 µmol/L)	Ibuprofen	21.9 mg/dL (1,062 µmol/L)
Cholesterol	400 mg/dL (10.3 mmol/L)	Levodopa	0.75 mg/dL (38.0 µmol/L)
Protein	15 g/dL (150 g/L)	Levothyroxine	0.0429 mg/dL (0.552 µmol/L)
Rheumatoid Factor	1,500 IU/mL	Liothyronine	0.0075 mg/dL (0.116 µmol/L)
Acetaminophen	15.6 mg/dL (1,033 µmol/L)	Methimazole	8.0 mg/dL (701 µmol/L)
N-Acetylcysteine	15.0 mg/dL (920 µmol/L)	Methyldopa	2.25 mg/dL (107 µmol/L)
Acetylsalicylic acid	3.0 mg/dL (167 µmol/L)	Metronidazole	12.3 mg/dL (719 µmol/L)
Ampicillin	7.5 mg/dL (215 µmol/L)	Octreotide	0.03 mg/dL (0.294 µmol/L)
Ascorbic Acid	5.25 mg/dL (298 µmol/L)	Phenylbutazone	32.1 mg/dL (1,040 µmol/L)
Carbimazole	3.0 mg/dL (161 µmol/L)	Propranolol	24 mg/dL (926 µmol/L)
Cefoxitin	495 mg/dL (11,583 µmol/L)	Propylthiouracil	30 mg/dL (1,762 µmol/L)
Cyclosporine	0.18 mg/dL (1.50 µmol/L)	Rifampicin	4.8 mg/dL (58.6 µmol/L)
Doxycycline	1.8 mg/dL (40.5 µmol/L)	Theophylline	6.0 mg/dL (333 µmol/L)
Heparin	7,500 U/dL		

Specimen Equivalency

Specimen equivalency was determined using the weighted Deming regression model in accordance with CLSI Document EP09c-ed3. The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Plasma (Lithium heparin)	Serum	y = 1.00x + 0.001 µIU/mL (mIU/L)	0.023–134.942 µIU/mL (mIU/L)	64	1.00
Plasma (EDTA)	Serum	y = 1.00x - 0.001 µIU/mL (mIU/L)	0.023– 134.942 µIU/mL (mIU/L)	64	1.00

[a] Number of samples tested.
[b] Correlation coefficient.

High-Dose Hook Effect

High TSH concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with TSH concentrations as high as 3000 µIU/mL (mIU/L) will report > 150.000 µIU/mL (mIU/L).

Cross-Reactivity

Cross-reactivity was determined using the Atellica CI Analyzer in accordance with with CLSI Document EP07-ed3. The following substances do not interfere with the assay when present in serum at the concentrations indicated. Bias due to these substances does not exceed 5%.

Substance	Substance Test Concentration µIU/mL (mIU/L)	TSH Concerntration µIU/mL (mIU/L)	Percent Difference (%)
Human Chorinic Gonadotropin	200,000	0.323	0.3
		3.637	-2.1
		51.156	1.4
		114.932	1.6
Follicle Stimulating Hormone	1,500	0.323	-1.5
		3.637	0.1
		51.156	0.5
		114.932	1.7
Luteinizing Hormone	600	0.323	0.9
		3.637	-0.6
		51.156	0.3
		114.932	1.1

Onboard Dilution Recovery

Serum and plasma samples were diluted onboard the Atellica CI Analyzer with Atellica CI Multi-Diluent 15. The following results are representative of the performance of the assay:

Sample (Serum)	Dilution	Observed µIU/mL (mIU/L)	Expected µIU/mL (mIU/L)	Recovery (%)
1	1:2	279.994	277.025	101.1
2	1:2	282.326	286.927	98.4
3	1:2	250.056	253.858	98.5
Mean				99.3
1	1:5	281.490	277.025	101.6
2	1:5	284.370	286.927	99.1
3	1:5	252.720	253.858	99.6
Mean				100.1

Sample (Plasma)	Dilution	Observed µIU/mL (mIU/L)	Expected µIU/mL (mIU/L)	Recovery (%)
1	1:2	231.502	234.614	98.7
2	1:2	224.044	217.294	103.1
3	1:2	180.004	180.317	99.8
Mean				100.5
1	1:5	233.170	234.614	99.4
2	1:5	220.400	217.294	101.4
3	1:5	175.125	180.317	97.1
Mean				99.3

Linearity

Linearity studies were performed following CLSI EP06-ED2. Dilution series composed of at least 14 levels created by mixing the high and low serum samples. Measurements were made with N=5 replicates per level. The results of the linear regression analysis are summarized in the table below.

Sample	Linear Regression	Claimed Linear Range
Serum	Y=0.9945*X-0.0011	0.008–150.000 µIU/mL

The results demonstrated linearity of the claimed measuring range.

Traceability

The Atellica IM TSH3-UL assay and assigned values for calibrators are traceable to the World Health Organization (WHO) 3rd International Standard for human TSH (IRP 81/565).

8.2. Atellica CH Albumin BCP (AlbP)

Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2. The assay is designed to have a limit of blank (LoB) ≤ 0.1 g/dL (≤ 1 g/L), a limit of detection (LoD) ≤ 0.6 g/dL (≤ 6 g/L), and a limit of quantitation (LoQ) ≤ 0.6 g/dL (≤ 6 g/L).

The LoD corresponds to the lowest concentration of albumin that can be detected with a probability of 95%. The LoD for the Atellica CH AlbP assay is 0.5 g/dL (5 g/L), and was determined using 486 determinations, with 270 blank and 216 low level replicates, and a LoB of value 0.1 g/dL (1 g/L).

The LoQ corresponds to the lowest amount of analyte in a sample at which the within laboratory precision is ≤ 10%. The LoQ of the AlbP assay is 0.5 g/dL (5 g/L). All samples were assayed n = 5 using 3 reagent lots, over a period of 5 days.

Precision

Precision was determined in accordance with CLSI Document EP05-A3. Samples were assayed on an Atellica CI Analyzer in duplicate in 2 runs per day for at least 20 days (N ≥ 80 for each sample). The following results were obtained:

			Repeatability		Within-Laboratory Precision	
Sample Type	N	Mean g/dL (g/L)	SD[a] g/dL (g/L)	CV[b] (%)	SD[a] g/dL (g/L)	CV[b] (%)
Serum 1	80	2.7 (27)	0.03 (0.3)	1.1	0.06 (0.6)	2.2
Serum QC 1	80	3.1 (31)	0.04 (0.4)	1.3	0.08 (0.8)	2.6
Serum 2	80	3.6 (36)	0.03 (0.3)	0.8	0.09 (0.9)	2.5
Serum 3	80	7.1 (71)	0.04 (0.4)	0.6	0.12 (1.2)	1.7

[a] Standard deviation.
[b] Coefficient of variation.

Reproducibility

Reproducibility was determined in accordance with CLSI Document EP05-A3. Samples were assayed n=5 in 1 run for 5 days using 3 instruments and 3 reagent lots. The data were analyzed to calculate the following components of precision: repeatability, between-day, between-lot, between-instrument, and reproducibility (total). The following results were obtained:

			Repeatability		Between-Day		Between-Instrument		Between-Lot		Total Reproducibility	
Sample	N[a]	Mean g/dL (g/L)	SD[b] g/dL (g/L)	CV[c] (%)	SD g/dL (g/L)	CV (%)	SD g/dL (g/L)	CV (%)	SD g/dL (g/L)	CV (%)	SD g/dL (g/L)	CV (%)
Serum 1	225	2.7 (27)	0.03 (0.3)	1.2	0.03 (0.3)	1.3	0.02 (0.2)	0.7	0.01 (0.1)	0.2	0.05 (0.5)	1.9
Serum 2	225	3.7 (37)	0.03 (0.3)	0.9	0.03 (0.3)	0.9	0.01 (0.1)	0.4	0.01 (0.1)	0.3	0.05 (0.5)	1.4
Serum 3	225	7.1 (71)	0.04 (0.4)	0.6	0.06 (0.6)	0.9	0.00 (0.0)	0.0	0.07 (0.7)	1.1	0.11 (1.1)	1.5

[a] Number of results.
[b] Standard deviation.
[c] Coefficient of variation.

Assay Comparison

The performance of the Atellica CH AlbP assay on the Atellica CI Analyzer (y) was compared with the performance of the comparison assay on the indicated system (x) and is designed to have a correlation coefficient of > 0.960 and a slope of 1.00 ± 0.10. Assay comparison was determined using the Deming linear regression model in accordance with CLSI Document EP09c.13 The following results were obtained:

Specimen	Comparative Assay (x)	Regression Equation	Sample Interval	N[a]	r[b]
Serum	Atellica CH AlbP on Atellica CH Analyzer	y = 0.98x + 0.0 g/dL (y = 0.98x + 0 g/L)	0.6–7.5 g/dL (6–75 g/L)	106	0.999

[a] Number of samples tested.
[b] Correlation coefficient.

Specimen Equivalency

Specimen equivalency was determined using the Deming linear regression model in accordance with CLSI Document EP09c. The following results were obtained:

Specimen (y)	Reference Specimen (x)	Regression Equation	Sample Interval	N[a]	r[b]
Plasma (Lithium heparin)	Serum	y = 1.01x + 0.0 g/dL (y = 1.01x + 0 g/L)	0.5–7.9 g/dL (5–79 g/L)	76	0.995
Plasma (Potassium EDTA)	Serum	y = 0.99x + 0.0 g/dL (y = 0.99x + 0 g/L)	0.5–7.9 g/dL (5–79 g/L)	55	0.997

[a] Number of samples tested.
[b] Correlation coefficient.

Hemolysis, Icterus, and Lipemia (HIL)

The Atellica CH AlbP assay is designed to have ≤ 10% interference from hemoglobin, bilirubin, and lipemia. Interfering substances at the levels indicated in the table below were tested in accordance with CLSI Document EP07 using the Atellica CH AlbP assay.

Bias is the difference in the results between the control sample (does not contain the interferent) and the test sample (contains the interferent) expressed in percent. Bias > 10% is considered interference. Analyte results should not be corrected based on this bias.

Substance	Substance Test Concentration Common Units (SI Units)	Analyte Concentration g/dL (g/L)	Percent Bias[a]
Hemoglobin	800 mg/dL (8 g/L) 1000 mg/dL (10 g/L)	3.4 (34) 5.0 (50)	9 6
Bilirubin, conjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.4 (34) 5.0 (50)	-3 -4
Bilirubin, unconjugated	30 mg/dL (513 µmol/L) 30 mg/dL (513 µmol/L)	3.6 (36) 5.3 (53)	-3 -2
Lipemia (Trig Fraction)	2000 mg/dL (20 g/L) 2000 mg/dL (20 g/L)	3.3 (33) 4.8 (48)	6 6
Lipemia (Intralipid®)	500 mg/dL (5 g/L) 500 mg/dL (5 g/L)	3.6 (36) 5.3 (53)	8 4

[a] Analyte results should not be corrected based on this bias.

Non-Interfering Substances

The following substances do not interfere with the Atellica CH AlbP assay when present in serum, potassium EDTA plasma, and lithium heparin plasma at the concentrations indicated in the table below. Bias due to these substances is ≤ 10%.

Substance	Substance Test Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
N-Acetylcysteine	15 mg/dL (0.9 mmol/L) 15 mg/dL (0.9 mmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	-6 -4
Acetaminophen	15.6 mg/dL (1032 µmol/L) 15.6 mg/dL (1032 µmol/L)	3.4 g/dL (34 g/L) 5 g/dL (50 g/L)	3 0
Acetylsalicylic acid	3 mg/dL (166.7 µmol/L) 3 mg/dL (166.7 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	0 0
Ampicillin	7.5 mg/dL (214.9 µmol/L) 7.5 mg/dL (214.9 µmol/L)	3.4 g/dL (34 g/L) 5 g/dL (50 g/L)	3 0
Ascorbic acid	5.25 mg/dL (298.3 µmol/L) 5.25 mg/dL (298.3 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	-3 0
Biotin	0.351 ng/mL (1.4 nmol/L) 0.351 ng/mL (1.4 nmol/L)	3.6 g/dL (36 g/L) 5.1 g/dL (51 g/L)	0 -2
Cefoxitin	75 mg/dL (1756.4 µmol/L) 75 mg/dL (1756.4 µmol/L)	3.3 g/dL (33 g/L) 4.7 g/dL (47 g/L)	3 0

Substance	Substance Test Concentration Conventional Units (SI Units)	Analyte Concentration Conventional Units (SI Units)	Bias %
Cholestrol	400 mg/dL (10.3 mmol/L) 400 mg/dL (10.3 mmol/L)	3 g/dL (30 g/L) 4.3 g/dL (43 g/L)	7 2
Cyclosporine	0.18 mg/dL (1.5 µmol/L) 0.18 mg/dL (1.5 µmol/L)	3.6 g/dL (36 g/L) 5.1 g/dL (51 g/L)	3 2
Heparin	3300 IU/L 3300 IU/L	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	0 0
Ibuprofen	21.9 mg/dL (1063.1 µmol/L) 21.9 mg/dL (1063.1 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	3 2
Immunoglobin G	5 g/dL (50 g/L) 5 g/dL (50 g/L)	3.7 g/dL (37 g/L) 5.2 g/dL (52 g/L)	-3 -4
Levodopa	0.75 mg/dL (38.1 µmol/L) 0.75 mg/dL (38.1 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	0 0
Rheumatoid Factor	1500 IU/mL 1500 IU/mL	3 g/dL (30 g/L) 4.3 g/dL (43 g/L)	10 7
Rifampicin	4.8 mg/dL (58.3 µmol/L) 4.8 mg/dL (58.3 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	0 2
Theophylline	6 mg/dL (333.3 µmol/L) 6 mg/dL (333.3 µmol/L)	3.5 g/dL (35 g/L) 5 g/dL (50 g/L)	-3 0

Linearity

Linearity studies were performed following CLSI EP06-ED2. Dilution series composed of at least nine levels created by mixing the high and low pools of serum. Measurements were made with N=5 replicates per level. The results of the linear regression analysis are summarized in the table below.

Sample	Linear Regression	Claimed Linear Range
Serum	Y=0.9984*X+0.2891 (g/dL)	0.5–8.0 g/dL

The results demonstrated linearity of the claimed measuring range.

Traceability

The Atellica CH AlbP assay and assigned values for calibrators are traceable to ERM DA470k Reference Material.

9. CONCLUSION

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