March 18, 2022

Abbott Ireland Diagnostics Division
Suzanne Cheang
Regulatory Affairs Manager
Lisnamuck
Longford, Ireland

Re: K203530
Trade/Device Name: Albumin BCP2
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Code: CJW
Dated: December 17, 2021
Received: December 20, 2021

Dear Suzanne Cheang:

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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
k203530

Device Name
Albumin BCP2

Indications for Use *(Describe)*
The Albumin BCP2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The Albumin BCP2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily 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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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

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

I. 510(k) Number

k203530

II. Applicant Name

Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Longford, IE

Primary contact person for all communications:

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Date Summary Prepared: December 16, 2021

III. Device Name

Albumin BCP2

Reagents

Trade Name: Albumin BCP2
Device Classification: Class II
Classification Name: Albumin test system
Governing Regulation Number: 21 CFR 862.1035
Product Code: CJW

IV. Predicate Device

Albumin BCP (k981814)

V. Description of Device

A. Principles of the Procedure

The Albumin BCP2 assay is an automated clinical chemistry assay. The Albumin BCP2 procedure is based on the binding of bromocresol purple specifically with human albumin to produce a colored complex. The absorbance of the complex at 604 nm is directly proportional to the albumin concentration in the sample.

Methodology: Colorimetric (Bromocresol Purple)

B. Reagents

The various kit configurations of the Albumin BCP2 reagent kits are described below.

	List Number	
	04U4520	**04U4530**
Tests per cartridge	150	550
Number of cartridges per kit	4	4
Tests per kit	600	2200
Reagent 1 (R1)	15.8 mL	49.9 mL

Reagent 1 Active ingredient: Bromocresol Purple 0.154 g/L. Inactive ingredients: sodium hydroxide/acetic acid (pH 5.4) and detergent/surfactant (0.8%). Preservatives: ProClin 300 and ProClin 950.

VI. Intended Use of the Device

The Albumin BCP2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The Albumin BCP2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

VII. Comparison of Technological Characteristics

The Albumin BCP2 assay (subject device) is an automated clinical chemistry assay for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Comparison of Subject Device (Albumin BCP2) to Predicate Device (Albumin BCP)

Characteristics	Subject Device Albumin BCP2 (List No. 04U45)	Predicate Device Albumin BCP (k981814; List No. 7D54)
Intended Use and Indications for Use	The Albumin BCP2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System. The Albumin BCP2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.	The Albumin BCP assay is used for the quantitation of albumin in human serum or plasma.
Platform	ARCHITECT c System	Same[a]
Methodology	Colorimetric (Bromocresol Purple)	Same
Specimen Type	Human serum or plasma	Same
Assay Principle / Principle of Procedure	The Albumin BCP2 procedure is based on the binding of bromocresol purple specifically with human albumin to produce a colored complex. The absorbance of the complex at 604 nm is directly proportional to the albumin concentration in the sample.	Same
Standardization	ERM-DA470/IFCC	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same
Assay Range	Analytical Measuring Interval: 0.3 – 9.0 g/dL Extended Measuring Interval: 9.0 – 22.4 g/dL Reportable Interval: 0.3 – 22.4 g/dL	Measuring Interval: 0.31 to 11.0 g/dL

[a] In accordance with FDA Guidance Document "Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagent for Automated Analyzers", issued June 10, 1996, the assay equivalency study on ARCHITECT c System vs. the original platform, AEROSET, was performed and submitted under k980367/A005 in May 2002.

ERM = European Reference Materials Standard Reference Material

IFCC - International Federation of Clinical Chemistry and Laboratory Medicine

Characteristics	Subject Device Albumin BCP2 (List No. 04U45)	Predicate Device Albumin BCP (k981814; List No. 7D54)
Precision	Samples with albumin concentrations between 0.4 and 8.2 g/dL were evaluated. The samples demonstrated % coefficients of variation (%CV) ≤ 1.7% and standard deviations (SD) ≤ 0.04 g/dL.	Samples with albumin concentrations between 2.4 and 3.7 g/dL demonstrated %CVs ranging from 1.2% to 1.4%.
Lower Limits of Measurement	Limit of Blank: 0.0 g/dL Limit of Detection: 0.3 g/dL Limit of Quantitation: 0.3 g/dL	Limit of Detection: 0.3 g/dL Limit of Quantitation: 0.31 g/dL
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Dipotassium EDTA tubes - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Glass or plastic tubes with or without gel barrier Plasma: - Glass or plastic lithium heparin tubes (with or without gel barrier) - Glass or plastic sodium heparin tubes

VIII. Summary of Nonclinical Performance

A. Reportable Interval

Based on the limit of detection (LoD), limit of quantitation (LoQ), precision, and linearity, the ranges over which results can be reported are provided below according to the definitions from Clinical and Laboratory Standards Institute (CLSI) EP34, 1st ed.*

	g/dL
Analytical Measuring Interval (AMI)[a]	0.3 - 9.0
Extended Measuring Interval (EMI)[b]	9.0 - 22.4
Reportable Interval[c]	0.3 - 22.4

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in g/dL that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The EMI extends from the ULoQ to the ULoQ × dilution factor.

[c] The reportable interval extends from the LoD to the upper limit of the EMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the Analytical Measuring Interval (AMI), and result values below 0.3 g/dL are reported as "<0.3 g/dL".

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking. 1st ed*. CLSI Document EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[†] Testing was conducted using 3 lots of the Albumin BCP2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**n**	**Mean (g/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	80	3.7	0.04	1.1	0.05 (0.05 – 0.05)	1.4 (1.3 – 1.4)
Control Level 2	80	2.5	0.04	1.6	0.04 (0.04 – 0.04)	1.6 (1.4 – 1.7)
Panel 1	80	0.4	0.02	5.3	0.04 (0.02 - 0.04)	10.4 (5.5 - 10.4)
Panel 2	80	5.3	0.05	1.0	0.05 (0.03 – 0.06)	1.0 (0.6 – 1.0)
Panel 3	80	8.2	0.03	0.3	0.05 (0.05 – 0.07)	0.7 (0.7 – 0.9)

[a] Includes within-run, between-run, and between-day variability.

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

C. Accuracy

A study was performed to estimate the bias of the Albumin BCP2 assay relative to a standard reference material (ERM - DA470k/IFCC). Testing was conducted using 2 lots of the Albumin BCP2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias was within ± 2.8%.

[†] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[‡] Testing was conducted using 3 lots of the Albumin BCP2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	g/dL
LoB[a]	0.0
LoD[b]	0.3
LoQ[c]	0.3

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20% CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

E. Linearity

A study was performed based on guidance from CLSI EP06-A.[§] The assay was demonstrated to be linear across the analytical measuring interval of 0.3 to 9.0 g/dL.

[‡] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

[§] Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.

F. Potentially Interfering Endogenous and Exogenous Substances

A study was performed based on guidance from CLSI EP07-A2.[**] Each substance was tested at 2 levels of the analyte (approximately 3.5 g/dL and 5.0 g/dL).

No significant interference (interference within ± 10%) was observed at the following concentrations.

Potentially Interfering Endogenous Substances

	Interferent Level
Potentially Interfering Substance	**Default Units**
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Hemoglobin	2000 mg/dL
Triglycerides	3025 mg/dL

[**] Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* CLSI Document EP07-A2. Wayne, PA: CLSI; 2005.

Potentially Interfering Exogenous Substances

	Interferent Level
Potentially Interfering Substance	**Default Units**
Acetaminophen	250 mg/L
Acetylcysteine	1663 mg/L
Acetylsalicylic Acid	1000 mg/L
Aminosalicylic Acid	80 mg/dL
Ampicillin-Na	1000 mg/L
Ascorbic Acid	300 mg/L
Ca-dobesilate	200 mg/L
Cefotaxime	31 mg/dL
Cefoxitin	2500 mg/L
Cyclosporine	5 mg/L
Desacetylcefotaxime	6 mg/dL
Doxycycline	50 mg/L
Ibuprofen	500 mg/L
Levodopa	20 mg/L
Methyldopa	20 mg/L
Metronidazole	200 mg/L
Phenylbutazone	400 mg/L
Rifampicin	60 mg/L
Sodium Heparin	10 U/mL
Theophylline (1,3-dimethylxanthine)	100 mg/L

G. Method Comparison

A study was performed based on guidance from CLSI EP09-A3[††] using the Passing-Bablok regression method.

Albumin BCP2 vs Albumin BCP on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	127	g/dL	1.00	-0.20	1.00	0.6 – 9.6

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Albumin BCP2 assay. Samples were collected from a minimum of 40 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Albumin BCP2 assay:

- Serum tubes
- Serum separator tubes
- Dipotassium EDTA tubes
- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

[††] Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

I. Dilution Verification

A study was performed to evaluate the performance of the Albumin BCP2 automated dilution protocol relative to the manual dilution procedure on the ARCHITECT c System. Five human serum samples were prepared by spiking human serum albumin (HSA) stock solution into reagent grade water to obtain the target concentration values of 10.0 g/dL, 12.5 g/dL, 15.0 g/dL, 17.5 g/dL, and 20.0 g/dL. Each sample was divided into multiple aliquots. An aliquot of each sample was tested using the 1:2.5 automated dilution protocol on the ARCHITECT c System. The additional aliquots were used to prepare 6 sets of manual dilutions (1:2.5 dilution with saline) of each sample and the manually diluted samples were tested.

The % difference values for the automated dilution protocol versus the manual dilution procedure ranged from of -2.9% to -1.5% and therefore, demonstrated acceptable performance.

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) pre-market notification demonstrate that the performance of the subject device, Albumin BCP2 (List No. 04U45), is substantially equivalent to the predicate device, Albumin BCP (List No. 7D54, k981814).

The similarities and differences between the subject device and predicate device are presented in Section 5-VII.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Albumin BCP2 reagent package insert instructions.