510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K203248

B Applicant

Abbott Ireland Diagnostics Division

C Proprietary and Established Names

Albumin BCG2

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CIX	Class II	21 CFR 862.1035 - Albumin Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Albumin

C Type of Test:

Quantitative, colorimetric

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Albumin BCG2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The Albumin BCG2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

ARCHITECT c8000 System

IV Device/System Characteristics:

A Device Description:

The Albumin BCG2 Reagent Kit consists of a single reagent R1. The active ingredient is bromocresol green at a concentration of 0.320 g/L. Inactive ingredients include sodium hydroxide/succinic acid buffer (pH 4.2) and detergents/surfactants (1.6%). The preservative is ProClin 300.

B Principle of Operation:

The Albumin BCG2 assay is an automated, colorimetric clinical chemistry assay. The Albumin BCG2 procedure is based on the binding of bromocresol green in the assay reagent specifically with albumin in the patient sample to produce a colored complex. The absorbance of the complex at 604 nm is directly proportional to the albumin concentration in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Albumin BCG (AlbG)

B Predicate 510(k) Number(s):

K981758

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203248 **Candidate Device:**	K981758 **Predicate Device:**
Device Trade Name	Albumin BCG2	Albumin BCG
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitation of albumin in human serum or plasma and it is used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.	Same
Methodology	Colorimetric (Bromocresol Green)	Same
Specimen Type	Human serum or plasma	Same
Standardization ERM-DA470/IFCC Same	Standardization ERM-DA470/IFCC Same	Same
Calibrator Levels	Two	Same
General Device Characteristic Differences		
Detection of colorimetric complex (absorbance)	604 nm	628 nm
Assay Range	0.3 – 9.4 g/dL	0.4 – 10.5 g/dL
Sample Types (Venous)	**Serum**: - Serum - Serum separator **Plasma**: - Dipotassium EDTA - Lithium heparin - Lithium heparin separator - Sodium heparin	**Serum**: - (with or without gel barrier) **Plasma**: - Lithium heparin (with or without gel barrier) - Sodium heparin

VI Standards/Guidance Documents Referenced:

- CLSI - EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.
- CLSI – EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guidance -Second Edition.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The Albumin BCG2 assay was evaluated in accordance with CLSI EP05-A3. Testing was conducted using 3 lots of the Albumin BCG2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Samples were prepared by spiking pooled normal human serum to a target concentration of 0.4 g/dL, 5.9 g/L and 9.5 g/dL. The samples were tested in 2 replicates, 2 times per day, for 20 days, for a total of 80 measurements.

Representative performance collected over 20 days using one instrument and one reagent lot is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory*	
Sample	n	Mean (g/dL)	SD	%CV	SD (Range†)	%CV (Range†)
Control Level 1	80	4.1	0.05	1.2	0.06 (0.05 – 0.06)	1.5 (1.3 – 1.6)
Control Level 2	80	2.6	0.03	1.3	0.04 (0.04 – 0.05)	1.4 (1.4 – 1.9)
Panel 1	80	0.4	0.00	0.0	0.00 (0.00 - 0.00)	0.0 (0.0 – 0.0)
Panel 2	80	5.7	0.06	1.0	0.06 (0.05 – 0.06)	1.0 (0.9 – 1.0)
Panel 3	80	9.4	0.07	0.8	0.07 (0.06 – 0.07)	0.8 (0.7 – 0.8)

*Includes within-run, between-run, and between-day variability.
†Minimum and maximum SD or %CV across all reagent lot and instrument combinations

2. Linearity:

The linearity for the Albumin BCG2 assay was evaluated by testing twelve unique sample levels (ranging from 0.0 – 11.6 g/dL) using 1 lot of the Albumin BCG2 reagent, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls on a single instrument and a single run. Two replicates were tested per sample/pool and all replicates were used in the analysis. The data was analyzed using linear regression as well as second and third order non-linear fitted polynomial regression with the third order model demonstrating the best fit. For all test samples, the absolute value of the degree of non-linearity met the sponsor's pre-defined acceptance criteria for deviation from linearity and the assay was demonstrated to be linear across the claimed analytical measuring interval of 0.3 to 9.4 g/dL.

3. Analytical Specificity/Interference:

The interference was evaluated in accordance with CLSI EP07-A2. Test samples were prepared by spiking each potentially interfering substance into a pooled human serum at the interferent level into low albumin (approximately 3.5 g/dL) and high albumin (approximately 5.0 g/dL) serum samples and analyzed 10 times. The sponsor states that interference is considered to be non-significant if the difference between the samples with and without interferent are less or equal to ± 10%.

The results of the highest concentration tested without significant interference are summarized in the table below.

Potentially Interfering Substance	**Highest concentration tested that did not show significant interference**
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Hemoglobin	750 mg/dL
Triglycerides	3000 mg/dL
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
Calcium 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
Penicillin	18,000 mg/L
Phenylbutazone	400 mg/L
Rifampicin	60 mg/L
Sodium Heparin	10 U/mL

Potentially Interfering Substance	Highest concentration tested that did not show significant interference
Theophylline (1,3-dimethylxanthine)	100 mg/L

4. Assay Reportable Range:

   The reportable and analytical measuring range of the assay is 0.3-9.4 g/dL. Samples with an albumin value below 0.3 g/dL are reported as "< 0.3 g/dL" and samples with an albumin value exceeding 9.4 g/dL (> 94 g/L) are flagged as "> 9.4 g/dL" ("> 94 g/L").

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

   Traceability: The Albumin BCG2 assay is traceable to the ERM-DA470/IFCC standard.

6. Detection Limit:

   The limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) studies were performed in accordance with CLSI EP17-A2.

   Limit of blank (LoB) study was performed by testing 4 blank samples (0 g/dL), using 3 reagent lots over 3 days on 2 different instruments. Each day, for each reagent lot, 5 replicate measurements were recorded (60 results). The LoB was calculated non-parametrically at the 95th percentile for each lot. The higher LoB for both reagent lots was chosen as the assay's LoB.

   Limit of detection (LoD) study was performed by testing 6 levels level samples using 3 reagent lots over 3 days on 2 instruments. Each day, for each reagent lot, 10 replicate measurements were recorded (60 results per reagent lot). LoD was calculated non-parametrically. The higher LoD of the 3 lots was chosen as the assay's LoD.

   Limit of quantitation (LoQ) study was performed using 6 low level human sera samples measured over 3 days on 2 instruments using 3 reagent lots. Each day, for each reagent lot, 10 replicate measurements were recorded (60 results total). The sponsor defined LoQ as the lowest concentration at which the maximum allowable precision of 20 %CV was met.

   The studies supported the following detection limit claims:

	g/dL
LoB	0.0
LoD	0.3
LoQ	0.3

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A method comparison study was performed in which human serum samples (n=128) spanning the analytical measuring interval of the assay (0.4-8.1 g/dL) were tested. For the candidate device, samples were tested internally using 3 lots of reagents and 1 lot each of calibrator and controls across 2 ARCHITECT c8000 instruments. For the predicate device, samples were tested internally using 1 lot each of reagents, calibrator, and controls across 2 ARCHITECT c8000 instruments. Each sample was tested in a minimum of 2 replicates using both methods and testing occurred over a minimum of 3 calendar days.

A Passing-Bablok evaluation was performed by comparing the first replicate result from the candidate device versus the mean result from the predicate device. The study results were considered acceptable if the subject device had a Passing-Bablok regression slope of 1.00 (± 0.08) and a correlation coefficient (r) ≥ 0.975 for samples across the analytical measuring interval of the assay when compared to the predicate device.

The results are summarized below:

Sample	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range (as measured by the predicate method)
Serum	128	g/dL	1.00	0.03	1.03	0.4 – 8.1

2. Matrix Comparison with Predicate device:

A matrix comparison study was performed to evaluate plasma samples and blood collection tube types suitable for use with the Albumin BCG2 assay. Samples containing 0.8-7.7 g/dL albumin were obtained from 74 matched donors in the control tube type (plain serum without serum separator tube) and in the evaluation tube types (K_2EDTA, lithium heparin, sodium heparin, lithium heparin separator tube, and serum separator tube).

All samples were processed according to the blood collection tube manufacturer's instructions. The samples were evaluated on the candidate device and tested in a minimum of 2 replicates using 1 lot of the Albumin BCG2 reagent, 1 lot of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and1 instrument. For the control tube type, all 3 replicates were analyzed. For the evaluation tube types, only the 1st replicate was analyzed.

The results are shown below:

Evaluation Tube Type	Slope	Intercept	R^2	Concentration tested
Dipotassium EDTA	0.96	0.19	0.99	0.8-7.6 g/dL

Lithium heparin	0.98	0.08	0.99	0.8-7.5 g/dL
Sodium heparin	0.97	0.13	0.98	0.8-7.6 g/dL
Lithium heparin (separator tube)	0.96	0.16	0.97	0.8-7.5 g/dL
Serum (separator tube)	0.99	0.09	0.99	0.8-7.7 g/dL

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

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

   Not applicable.

D Clinical Cut-Off:

Not applicable.

E Reference Range:

The following reference ranges, cited from the scientific literature, were included in the labeling.

Age	Range (g/dL)	Range* (g/L)
0 - 4 days	2.8 - 4.4	28 - 44
4 days - 14 years	3.8 - 5.4	38 - 54
14 – 18 years	3.2 – 4.5	32 - 45
Adult (20 – 60 years)	3.5 - 5.2	35 - 52
60 - 90 years	3.2 - 4.6	32 - 46
> 90 years	2.9 - 4.5	29 - 45

*Alternate result units were calculated by Abbott and are not included in the citation provided.

Burtis CA, Bruns DE, editors. Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, 7th ed. St Louis, MO: Saunders Elsevier; 2015.

VIII Proposed Labeling:

The labeling supports 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.