Albumin BCG2

FOR USE WITH
Alinity c

en
AlbBCG2
04U30
G93169R03
B4U300

Revised September 2020.

REF 04U3020

REF 04U3030

Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

For laboratory professional use only.

NAME

Albumin BCG2 (also referred to as AlbBCG2)

INTENDED USE

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

SUMMARY AND EXPLANATION OF THE TEST

Albumin is the major serum protein in normal individuals. Elevated serum albumin levels are usually the result of dehydration.

Decreased albumin levels are found in a wide variety of conditions, including kidney disease, liver disease, malabsorption, malnutrition, severe burns, infections, and cancer.

PRINCIPLES OF THE PROCEDURE

The Albumin BCG2 assay is an automated 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.

Methodology: Colorimetric (Bromocresol Green)

For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3.

REAGENTS

Kit Contents

Albumin BCG2 Reagent Kit 04U30

NOTE: Some kit sizes may not be available. Please contact your local distributor.

Volumes (mL) listed in the following table indicate the volume per cartridge.

REF	04U3020	04U3030
Tests per cartridge	261	780
Number of cartridges per kit	4	4
Tests per kit	1044	3120
R1	26.0 mL	68.0 mL

R1 Active ingredient: bromocresol green 0.320 g/L. Preservative: ProClin 300.

Warnings and Precautions

- IVD
- For *In Vitro* Diagnostic Use
- Rx ONLY

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials and all consumables contaminated with potentially infectious materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate regional, national, and institutional biosafety practices should be used for materials that contain, are suspected of containing, or are contaminated with infectious agents.[1-4]

The following warnings and precautions apply to: R1

WARNING	Contains methylisothiazolones.
H317	May cause an allergic skin reaction.
H402*	Harmful to aquatic life.
H412	Harmful to aquatic life with long lasting effects.
Prevention	
P261	Avoid breathing mist / vapors / spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves / protective clothing / eye protection.
P273	Avoid release to the environment.
Response	
P302+P352	IF ON SKIN: Wash with plenty of water.
P333+P313	If skin irritation or rash occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

* Not applicable where regulation EC 1272/2008 (CLP) has been implemented.

Follow local chemical disposal regulations based on your location along with recommendations and content in the Safety Data Sheet to determine the safe disposal of this product.

For the most current hazard information, see the product Safety Data Sheet.

Safety Data Sheets are available at www.corelaboratory.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 8.

Reagent Handling

- Upon receipt, place reagent cartridges in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity ci-series Operations Manual, Section 7.

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Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	15 to 30˚C	Until expiration date	Store in upright position.
Onboard	System Temperature	42 days	
Opened	15 to 30˚C	Until expiration date	Store in upright position. Do not reuse original reagent caps or replacement caps due to the risk of contamination and the potential to compromise reagent performance.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 15 to 30˚C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity ci-series Operations Manual, Section 5.

Indications of Reagent Deterioration

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The Albumin BCG2 assay file must be installed on the Alinity c system prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity ci-series Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity ci-series Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity ci-series Operations Manual.

Alternate Result Units

Edit assay parameter "Result Units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default Result Unit	Conversion Factor	Alternate Result Unit
g/dL	10	g/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen types listed below were verified for use with this assay.

Other specimen types and collection tube types have not been verified with this assay.

Specimen Types	Collection Tubes
Serum	Serum Serum separator
Plasma	Dipotassium EDTA Lithium heparin Lithium heparin separator Sodium heparin

- Liquid anticoagulants may have a dilution effect resulting in lower concentration values for individual specimens.

The instrument does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- Follow the tube manufacturer's processing instructions for collection tubes. Gravity separation is not sufficient for specimen preparation.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

To ensure consistency in results, recentrifuge specimens prior to testing if

- they contain fibrin, red blood cells, or other particulate matter.

NOTE: If fibrin, red blood cells, or other particulate matter are observed, mix by low speed vortex or by inverting 10 times prior to recentrifugation.

Prepare frozen specimens as follows:

- Frozen specimens must be completely thawed before mixing.
- Mix thawed specimens thoroughly by low speed vortex or by inverting 10 times.
- Visually inspect the specimens. If layering or stratification is observed, mix until specimens are visibly homogeneous.
- If specimens are not mixed thoroughly, inconsistent results may be obtained.
- Recentrifuge specimens.

Recentrifugation of Specimens

- Transfer specimens to a centrifuge tube and centrifuge.
- Transfer clarified specimen to a sample cup or secondary tube for testing. For centrifuged specimens with a lipid layer, transfer only the clarified specimen and not the lipemic material.

Specimen Storage

Specimen Type	Temperature	Maximum Storage Time
Serum/Plasma	Room temperature (20 to 25˚C)	7 days[5]
	2 to 8˚C	7 days[5]
	-20˚C	3 months[6]

Avoid multiple freeze/thaw cycles.[6]

It is the responsibility of the individual laboratory to determine specific specimen stability criteria for their laboratory per their laboratory workflow.

For additional information on sample handling and processing, refer to CLSI GP44-A4.[7] The storage information provided here is based on references or data maintained by the manufacturer.

Each laboratory may establish a range around -20˚C from either the freezer manufacturer's specifications or your laboratory standard operating procedure(s) for specimen storage.

Stored specimens must be inspected for particulates. If present, mix with a low speed vortex or by inversion and centrifuge the specimen to remove particulates prior to testing.

Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

04U30 Albumin BCG2 Reagent Kit

Materials Required but not Provided

- Albumin BCG2 assay file
- 04V6201 Consolidated Chemistry Calibrator
- Controls containing albumin

For information on materials required for operation of the instrument, refer to the Alinity ci-series Operations Manual, Section 1.

For information on materials required for maintenance procedures, refer to the Alinity ci-series Operations Manual, Section 9.

Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity ci-series Operations Manual, Section 5.

- If using primary or aliquot tubes, refer to the Alinity ci-series Operations Manual, Section 4 to ensure sufficient specimen is present.
- Minimum sample cup volume is calculated by the system and printed on the Order List report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Minimum sample volume requirements:
  - Sample volume for single test: 1.6 µL.

    NOTE: This amount does not include the dead volume plus the additional over-aspiration volume. For total sample volume requirements, refer to the Alinity ci-series Operations Manual, Section 4.
- Refer to the Consolidated Chemistry Calibrator package insert REF 04V6201 and/or commercially available control material package insert for preparation and usage.
- For general operating procedures, refer to the Alinity ci-series Operations Manual, Section 5.
- For optimal performance, it is important to perform routine maintenance as described in the Alinity ci-series Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Sample Dilution Procedures

Sample dilutions have not been evaluated for the Albumin BCG2 assay. Samples with an albumin concentration of > 9.4 g/dL (> 94 g/L) are flagged as "> 9.4 g/dL" ("> 94 g/L"). The standard dilution factor for the Albumin BCG2 assay is 1:1.68.

For details on configuring automated dilutions, refer to the Alinity ci-series Operations Manual, Section 2.

Calibration

For instructions on performing a calibration, refer to the Alinity ci-series Operations Manual, Section 5.

Calibration is stable for approximately 42 days (1008 hours), but is required with each change in reagent lot. Verify calibration with at least 2 levels of controls according to the established quality control requirements for your laboratory. If control results fall outside acceptable ranges, recalibration may be necessary.

This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

Quality Control Procedures

As appropriate, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions.

- At least 2 levels of controls (low and high) are to be run every 24 hours.
- If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.
- If quality control results do not meet the acceptance criteria defined by your laboratory, sample results may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary. For troubleshooting information, refer to the Alinity ci-series Operations Manual, Section 10.
- Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

Controls should be used according to the guidelines and recommendations of the control manufacturer. Concentration ranges provided in the control package insert should be used only for guidance.

For any control material in use, the laboratory should ensure that the matrix of the control material is suitable for use in the assay per the assay package insert.

Quality Control Guidance

Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.[8]

Verification of Assay Claims

For protocols to verify package insert claims, refer to Verification of Assay Claims in the Alinity ci-series Operations Manual.

RESULTS

Calculation

The Albumin BCG2 assay utilizes the Linear data reduction method to generate a calibration and results.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the Alinity ci-series Operations Manual, Section 5.

Reportable Interval

Based on representative data for the limit of quantitation (LoQ) and the limit of detection (LoD), the ranges over which results can be reported are provided below according to the definitions from CLSI EP34, 1st ed.[9]

	g/dL	g/L
Analytical Measuring Interval (AMI)[a]	0.3 - 9.4	3 - 94
Reportable Interval[b]	0.3 - 9.4	3 - 94

[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 (g/L) that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the reportable interval.

LIMITATIONS OF THE PROCEDURE

- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS, Analytical Specificity, Interference section of this package insert.

EXPECTED VALUES

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

Reference Range (Serum)

Age	Range (g/dL)	Range* (g/L)
0 - 4 days[10]	2.8 - 4.4	28 - 44
4 days - 14 years[10]	3.8 - 5.4	38 - 54
Adult[10]	3.5 - 5.0	35 - 50
60 - 90 years[11]	3.2 - 4.6	32 - 46
> 90 years[11]	2.9 - 4.5	29 - 45

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

Abbott has not evaluated reference ranges in the pediatric population.

SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

The Alinity c system and the ARCHITECT c System utilize the same reagents and sample/reagent ratios.

Unless otherwise specified, all studies were performed on the Alinity c system.

Precision

Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.[12] 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 1 instrument. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot 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	90	4.0	0.03	0.9	0.06 (0.06 - 0.07)	1.4 (1.4 - 1.6)
Control Level 2	90	2.6	0.04	1.6	0.05 (0.03 - 0.05)	2.0 (1.1 - 2.0)
Panel 1	90	0.4	0.00	0.0	0.00 (0.00 - 0.00)	0.0 (0.0 - 0.0)
Panel 2	90	5.5	0.03	0.5	0.04 (0.04 - 0.07)	0.8 (0.8 - 1.2)
Panel 3	90	9.2	0.03	0.4	0.07 (0.06 - 0.07)	0.7 (0.7 - 0.7)

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

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

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	n	Mean (g/L)	SD	%CV	SD (Range[b])	%CV (Range[b])
Control Level 1	90	40	0.3	0.9	0.6 (0.6 - 0.7)	1.4 (1.4 - 1.6)
Control Level 2	90	26	0.4	1.6	0.5 (0.3 - 0.5)	2.0 (1.1 - 2.0)
Panel 1	90	4	0.0	0.0	0.0 (0.0 - 0.0)	0.0 (0.0 - 0.0)
Panel 2	90	55	0.3	0.5	0.4 (0.4 - 0.7)	0.8 (0.8 - 1.2)
Panel 3	90	92	0.3	0.4	0.7 (0.6 - 0.7)	0.7 (0.7 - 0.7)

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

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

Accuracy

A study was performed to estimate the bias of the Albumin BCG2 assay relative to standard reference material (ERM - DA470k/IFCC). Testing was conducted using 1 lot of the Albumin BCG2 reagent, 1 lot of the Consolidated Chemistry Calibrator, and 1 instrument. The bias was 4.8%.

Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.[13] Testing was conducted using 3 lots of the Albumin BCG2 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	g/L
LoB[a]	0.0	0
LoD[b]	0.3	3
LoQ[c]	0.3	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.

Linearity

A study was performed based on guidance from CLSI EP06-A.[14]

This assay is linear across the analytical measuring interval of 0.3 to 9.4 g/dL (3 to 94 g/L).

Analytical Specificity

Interference

This study was performed on the ARCHITECT c System.

A study was performed based on guidance from CLSI EP07-A2.[15] Each substance was tested at 2 levels of the analyte (approximately 3.5 g/dL and 5.0 g/dL).

Potentially Interfering Endogenous Substances

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

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	Default Units	Alternate Units
Conjugated Bilirubin	60 mg/dL	712 µmol/L
Unconjugated Bilirubin	60 mg/dL	1026 µmol/L
Hemoglobin	750 mg/dL	7.5 g/L
Triglycerides	3000 mg/dL	33.9 mmol/L

Potentially Interfering Exogenous Substances

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

No Significant Interference (Interference within ± 10%)		
	Interferent Level	
Potentially Interfering Substance	**Default Units**	**Alternate Units**
Acetaminophen	250 mg/L	1655 µmol/L
Acetylcysteine	1663 mg/L	10 194 µmol/L
Acetylsalicylic Acid	1000 mg/L	5550 µmol/L
Aminosalicylic Acid	80 mg/dL	5232 µmol/L
Ampicillin-Na	1000 mg/L	2693 µmol/L
Ascorbic Acid	300 mg/L	1704 µmol/L
Calcium Dobesilate	200 mg/L	478 µmol/L
Cefotaxime	31 mg/dL	682 µmol/L
Cefoxitin	2500 mg/L	5850 µmol/L
Cyclosporine	5 mg/L	4.2 µmol/L
Desacetylcefotaxime	6 mg/dL	145 µmol/L
Doxycycline	50 mg/L	113 µmol/L
Ibuprofen	500 mg/L	2425 µmol/L
Levodopa	20 mg/L	101 µmol/L
Methyldopa	20 mg/L	95 µmol/L
Metronidazole	200 mg/L	1168 µmol/L
Penicillin	18 000 mg/L	48.3 mmol/L
Phenylbutazone	400 mg/L	1296 µmol/L
Rifampicin	60 mg/L	73 µmol/L
Sodium Heparin	10 U/mL	N/A
Theophylline (1,3-dimethylxanthine)	100 mg/L	555 µmol/L

N/A = Not applicable

Interferences from medication or endogenous substances may affect results.[16]

Method Comparison

A study was performed based on guidance from CLSI EP09-A3[17] using the Passing-Bablok regression method.

Albumin BCG2 vs Albumin BCG on the ARCHITECT c System						
	n	**Units**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Serum	128	g/dL	1.00	0.03	1.03	0.4 - 8.1
		(g/L)		(0.30)		(4 - 81)

Albumin BCG2 on Alinity c vs Albumin BCG2 on ARCHITECT						
	n	**Units**	**Correlation Coefficient**	**Intercept**	**Slope**	**Concentration Range**
Serum	133	g/dL	1.00	0.00	1.00	1.0 - 9.1
		(g/L)		(0.00)		(10 - 91)

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Key to Symbols

ISO 15223 Symbols	
	Consult instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
REF	List Number
SN	Serial number

Other Symbols	
FOR USE WITH	Identifies products to be used together
PRODUCT OF IRELAND	Product of Ireland
R1	Reagent 1
Rx ONLY	For use by or on the order of a physician only (applicable to USA classification only).

Note for number formatting:

- A space is used as thousands separator (example: 10 000 specimens).
- A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

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CE

Customer Service: Contact your local representative or find country-specific contact information on www.corelaboratory.abbott

For customers in the European Union: if, in the course of using this device, you have reason to believe that a serious incident has occurred, please report it to the manufacturer and to your national authority.

Revised September 2020.

Cruz Bella Rose Navarro

Digitally signed by Cruz Bella Rose Navarro
DN: c=VN, st=THÀNH PHỐ HÀ NỘI, o=Văn phòng đại diện ABBOTT LABORATORIES GMBH tại thành phố Hà Nội, title=Trưởng Đại Diện, cn=Cruz Bella Rose Navarro, 0.9.2342.19200300.100.1.1=MST:P5954425A
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