Albumin, Serum or Plasma

Purpose

This procedure provides instructions for ALBUMIN on Abbott Instrumentation. The Alinity c Albumin BCG2 assay is used for the quantification of albumin in human serum or plasma on the Alinity c analyzer.

Policy Statements

This procedure applies to all personnel responsible for operating the Abbott Alinity c at Children's Minnesota Laboratory.

Principle

Methodology: Colorimetric (Bromocresol Green)

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.[1]

Clinical Significance

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.[1]

Materials

Product Description	*Product Code*	*Stability*
Albumin BCG2 Reagent (1044 tests per box; each box contains 4 reagent sets of 261 tests). Each reagent set consists of an R1 component. Alinity c **R1:** Active Ingredient: bromocresol green (0.320 g/L). Preservatives: ProClin 300. Abbott Diagnostics	**MFR#** 04U3020 **CHC#** 32618	**Store at:** 15-30 °C **Unopened:** Until Expiration **Opened:** Stable 42 days onboard the analyzer. Stable until expiration if returned to 15-30 °C storage with replacement caps tightly secured and in upright position.
Albumin BCG2 Reagent (1044 tests per box; each box contains 4 reagent sets of 261 tests). Each reagent set consists of an R1 component. **R1:** Active Ingredient: bromocresol green (0.320 g/L). Preservatives: ProClin 300.	**MFR#** 04T3420 **CHC#** 32522	**Store at:** 15-30 °C **Unopened:** Until Expiration **Opened:** Stable 42 days onboard the analyzer. Stable until expiration if returned to 15-30 °C storage with replacement caps tightly secured and in upright position.

Abbott Diagnostics		
Consolidated Chemistry Calibrator (ConCC) Each calibrator set consists of 6 lyophilized calibrator vials and 6 empty barcode labeled vials. Abbott Diagnostics	**MFR#** 04V6201 **CHC#** TBD	**Store at:** 2-8 °C **Unopened:** Until Expiration **Reconstituted:** Stable 7 days if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.
Biorad MultiQual Controls Levels 1 and 3 Each box contains 12 5mL vials of control material. Biorad Laboratories	**Level 1 MFR#** 697 **Level 1 CHC#** 34574 **Level 3 MFR#** 699 **Level 3 CHC#** 34575	**Store at:** 2-8 °C **Unopened:** Until Expiration **Opened:** Stable 30 days onboard the analyzer. Stable until expiration if returned to 2-8 °C storage with replacement caps tightly secured and in upright position.

Special Safety Precautions

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.[1]

Calibration material contains human-sourced and/or potentially infectious components.[3]

Sample

Sample: Plasma collected with lithium heparin with or without gel barrier is preferred. Alternatively, serum collected with or without gel barrier is also accepted.

Stability: 7 days at room temperature, 7 days at 2-8 C, or up to 3 months frozen at –20 C or colder.

Test Code

LIS Test code: ALB for Albumin in Serum or Plasma.

Analyzer

Primary Analyzer or Method: MACC or MALIC (Minneapolis), SALIC or ARCH4 (St. Paul).

Backup: Each analyzer may act as a backup for the other.

Calibration

Calibration Information

Reference Material	ConCC; 04V6201
Calibration Frequency	Calibration is due every 42 days and with each new reagent lot.
Calibration Scheme	2-Point Calibration; 2 replicates per level. The Albumin BCG2 assay utilizes the Linear data reduction method to generate a calibration and results.

Quality Control

Material: Biorad Multiqual, Levels 1 and 3
Frequency: Run 2 levels, once per day.
Acceptable Ranges: Acceptable ranges are set in Unity Real Time software.

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 effect of evaporation, verify that adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
    - Sample volume for the first test: 1.6 uL + 50 uL for over-aspiration and dead volume
    - Sample volume for each additional test from the same sample cup: 1.6 uL

Dilutions

Do not dilute.

Calculations

Not applicable.

Interpretation and Resulting

Results will be reported to the first decimal (xx.x).
Results between 0.3 and 9.4 g/dL without error messages are released.
Results below 0.3 g/dL without error messages are reported as <0.3 g/dL.
Results greater than 9.4 g/dL without error messages are reported as >9.4 g/dL.

Reference Intervals

Critical Values: Not applicable.

Reference Ranges[2]

Age	*Sex*	*Reference Interval (g/dL)*
0 to <15 days	All	3.3-4.5
15 days to 1 year	All	2.8-4.7
1 to <8 years	All	3.8-4.7
8 to <15 years	All	4.1-4.8
12 to 18 years	Female Male	4.0-4.9 4.1-5.1
Adult	All	3.0-5.2

Method Performance Specifications

Analytical Measuring Range: 0.3-9.4 g/dL

AMR/Calibration Verification Frequency: Every 6 months

AMR recommended verification product: Maine Standards GC1
AMR proximity budget: 50% (low) or 20% (high)
AMR systematic error budget: 50%

Allowable Error: 8% (CAP)

Precision: 0.06 g/dL SD or 3.0% CV, whichever is greater

Limitations

HIL Indices Cutoff Values[1,4]				At HIL levels at or above the specified cutoff value, append the appropriate comment AFTER visually confirming presence of interferent: -HP for "Hemolysis present, may affect results." -BIN for "Bilirubin Interference" -LINT for "Lipid Interference"
Interpretation	H	I	L	
Quant (mg/dL)	N/A	N/A	N/A	
Semi Quant	N/A	N/A	N/A	

Interferences from medication or endogenous substances may affect results.[1]

Additional interference information can be found in reagent package insert, page 6.

References

1. Albumin BCG2 for Alinity c Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised September 2020
2. CALIPER Reference Interval Studies, accessed October 27 2020
3. ConCC for Alinity c Calibrator Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised December 2020
4. Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis. CLSI guideline C56-A, 1st Ed, Wayne, PA: CLSI, 2012
5. Albumin BCG2 for Architect Reagent Package Insert, Abbott Laboratories Diagnostic Division, Abbott Park, IL 60064, Revised October 2020

Appendices

Not applicable.

Training Plan/Competency Assessment

CH 1.04.T1 Abbott Alinity Training
QP 2.30 Orientation and Training
QP 2.40 Competency Assessment

Historical Record

Version	Author	Effective Date	Summary
1	Matt Johnson	11/17/2025	Initial Version