| **Prealbumin** |
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| **Purpose** | This procedure provides instructions for performing PREALBUMIN ON ABBOTT INSTRUMENTATION. The Alinity c Prealbumin assay is used for the quantitation of prealbumin in human serum on the Alinity c analyzer. |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Alinity c at Children’s Minnesota Laboratory. |
| **Principle** | The prealbumin assay is an immunoturbidimetric procedure that measures increasing sample turbidity caused by the formation of insoluble immune complexes when antibody to prealbumin is added to the sample. Sample containing prealbumin is incubated with a buffer (R1) and a sample blank determination is performed prior to the addition of prealbumin antibody (R2). In the presence of an appropriate antibody in excess, the prealbumin concentration is measured as a function of turbidity.**Methodology**: Immunoturbidimetric |
| **Clinical Significance** | Prealbumin (transthyretin or thyroxin-binding prealbumin) is synthesized in the liver and is involved in triiodothyronine (T3), thyroxine (T4), and vitamin A transport. Prealbumin is capable of binding two separate ligands at unique binding sites. Each tetrameric prealbumin molecule binds one molecule of retinol-binding protein (which complexes with vitamin A) at one site and up to two molecules of T3 or T4 at another site. Prealbumin is secondary to thyroxine-binding globulin in the transport of T3 and T4.Because prealbumin has an extremely short half-life, quantitation of prealbumin serum levels can provide a more timely and sensitive assessment of protein malnutrition or liver dysfunction than transferrin or albumin.Prealbumin is a very sensitive negative acute phase protein (or acute phase reactant); decreased levels are associated with inflammation, malignancy, liver cirrhosis, and protein diseases of the gut or kidneys. Prealbumin levels also fall during periods of calorie/ protein malnutrition; therefore, during inflammatory processes with concomitant malnutrition, levels fall rapidly and markedly. Decreased prealbumin levels are also associated with cystic fibrosis, chronic illness, and some forms of hereditary amyloidosis.Although the presence of acute or chronic inflammation may limit its specificity, prealbumin can be a useful marker for assessing protein-energy nutritional status of maintenance dialysis patients. In 2000, the Kidney Disease Outcomes Quality Initiative (K/DOQI) recommended a prealbumin goal of ≥ 30 mg/dL, stating, “An individual with predialysis or stabilized serum prealbumin of less than 30 mg/dL should be evaluated for protein-energy malnutrition”. It has been reported that serum prealbumin is higher in peritoneal dialysis patients than in hemodialysis patients.Elevated prealbumin levels are associated with high doses of corticosteroids, high levels of endogenous steroids secondary to adrenal hyperactivity, high doses of nonsteroidal anti-inflammatory medication, and Hodgkin’s disease. |
| **Analyzer** | **Minneapolis: Abbott Alinity c (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code: SALIC)** |
| **Sunquest Test Codes** | **PRAB** |
| **Specimen** | Sample: Serum **Preferred**: SST**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum**Stability when separated from cells/gel:** **2 to 8°C 3 Days****-20°C** 6 months (repeated freeze thaw cycles discouraged)**Rejection criteria:** Unlabeled tube, sample type other than serum**Preparation:** 1. Whole blood specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis.
2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection.
3. Specimens should be free of particulate matter.
4. Transfer serum or plasma to a properly labeled pilot tube.
5. Architect and Alinity systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
6. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** Upon receipt, place reagent cartridges in an upright position for 8 hours before use to allow bubbles that may have formed to dissipate. If a reagent cartridge is dropped, place in an upright position for 8 hours 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. Use a pipette to remove all bubbles prior to loading on the Alinity or Architect system.* Do not use reagents beyond the expiration date.
* Do not pool reagents within a kit or between kits.
* Do not use components from one lot with components from another lot.
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| Prealbumin Reagent Kit | **09P8620** | **Store at:** 2 to 8°C**Unopened:** Until expiration Date**On-board**: 57 days |
| Prealbumin Calibrator Kit | **04S0101** | **Store at:** 2 to 8°C**Unopened:** Until expiration Date**Opened expiration:** .30 Days |

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| **Risk and Safety** | This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. The following warnings and precautions apply to: R1 ,R2Contains sodium azide, alcohols, C12- 14-secondary, ethoxylated, and trishydroxymethyl aminomethane. Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 5.0 to 60.0 mg/dL  |
| Reference Material: | Abbott Alinity c Prealbumin Calibrator Kit  |
| Suggested Calibration Levels: | Lot-specific calibrator values are listed in the Alinity c PrealbuminCalibrator Kit Value Sheet, packaged with the calibrators |
| Calibration Scheme: | Calibrators 1-5, Linear reduction |
| Calibration Frequency: | 57 days  |
| AMR | AMR is verified with each calibration |

The upper AMR for Prealbumin has been set lower than the typical highest calibrator concentration so that the AMR is constant and does not change with each calibrator lot. |
| **Quality Control** | **QC Material:** Bio-Rad Liquichek Immunology Control Levels 1 and 3**Frequency:** 2 Levels daily**Stability:** Once thawed, opened, and stored tightly capped at 2 to 8°C, product will be labeled with an expiration date equal to the shortest stability of the included analytes, which is **10 days.** **Preparation**: This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used. • To thaw the product, allow it to stand at room temperature (18° to 25°C) until completely thawed but no longer than one (1) hour. • After thawing, the product MUST be gently swirled and inverted several times to ensure homogeneity.• For optimal analyte stability in the thawed state, promptly return to 2 to 8°C storage after each use and minimize the time at room temperature to no more than 20 minutes daily.• Before each use, gently swirl the contents until homogeneous with no visible signs of precipitate.**Acceptable ranges:** * Non-Bio-Rad controls will utilize manufacturer ranges and 2 SD Westgard rules.
* New lots of Bio-Rad controls should be run for 20 days in parallel with the current lot whenever possible prior to switching to the new lot.
* Refer to the Westgard Rules in Chemistry procedure for current Westgard rules in place for each analyte.
* **Acceptable ranges are current in Unity Real Time only.** Quality Control results must be rejected in Sunquest when the results cross the interface.
* In the event of a QC failure, refer to the [Unity Real Time QC Review, General User](https://starnet.childrenshc.org/References/labsop/chem/quality/ch-2.17-unity-real-time-qc-review-general-user.pdf) and navigate to the QC Troubleshooting section.
* Do not load or release patients until QC is acceptable in Unity Real Time.
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| **Interferences** |  **Hemolysis, Icterus & Lipemia (HIL) Index Values:**

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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”Clarify specimens by ultracentrifugation if turbid. If turbidity does not clear by ultracentrifugation, consider line contamination. Interference is less than 10%:* Hemoglobin: up to 500 mg/dL
* Interlipids up to 1000mg/dL
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| **Reference Intervals** | Prealbumin in mg/dL:  0 to < 15 Days: 2 - 12 15 Days to < 1 Year: 5 -24 1 to < 5 Years: 12 - 22 5 to < 13 Years: 14 - 26 13 to < 16 Years: 18 - 31 Female 16 to < 19 Years: 17 - 33 Male 16 to < 19 Years: 20 - 35 Male and Female Adults: 20 - 42 |
| **Critical Values** | None specified |
| **Limitations** | * Turbidity and particles in the samples can interfere with the assay. Therefore, particulate matter should be removed by centrifugation prior to running the assay.
* Samples containing paraproteins (abnormal monoclonal antibodies) may interfere with test results.
* Samples with elevated total protein concentrations or samples from patients with suspected paraproteinemia can be screened using other laboratory methods such as protein electrophoresis
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| **Dilutions** |

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| Max Auto Dilution: |  1:4  |
| Maximum Manual Dilution: | None |
|  | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated dilutions. The system will automatically calculate the concentration of the sample and report the result. If a diluted sample result is less than the lower value of the measuring interval of 5, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | * Results between 5 and 60 without error messages are released
* Results below 5 without error messages are reported as < 5 mg/dL
* Results > 60 should be diluted using the onboard automated 1:4 dilution. Release results without error messages following this dilution.
* Results > 240 following automated dilution are reported as > 240 mg/dL.
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in a specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 14 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Prealbumin Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
2. Abbott Alinity c Prealbumin Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised April 2018
3. Bio-Rad Liquichek Immunology Control Package Insert, Bio-Rad Laboratories, Irvine CA, USA.
4. [CALIPER Reference Range Studies.](https://caliper.research.sickkids.ca/#/)  Accessed October 27, 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Stephen Gripentrog |  | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added AMR, changed calibrator levels, added reference intervals, references, interferences, and corrected Alinity in Mpls. |