| **Transferrin** |
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| **Purpose** | This procedure provides instructions for performing TRANSFERRIN on ABBOTT INSTRUMENTATION. The Alinity c Transferrin assay is used for the quantitation of transferrin 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, Minneapolis. |
| **Principle** | The Alinity c Transferrin assay is an immunoturbidimetric procedure that measures increasing sample turbidity caused by the formation of insoluble immune complexes when antibody to transferrin is added to the sample. Sample containing transferrin is incubated with a buffer (R1) and a sample blank determination is performed prior to the addition of transferrin antibody (R2). In the presence of an appropriate antibody in excess, the transferrin concentration is measured as a function of turbidity.**Methodology:** ImmunoturbidimetricFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Transferrin is a β-globulin, synthesized primarily in the liver, which is the principal protein responsible for iron transport. Transferrin transports ferric ions from the iron stores of intracellular or mucosal ferritin to bone marrow where erythrocyte precursors and other cells have transferrin surface receptors. Transferrin is responsible for 50% to 70% of the iron binding capacity of serum. Since other proteins may bind iron, transferrin concentration correlates with, but is not identical to, Total Iron Binding Capacity (TIBC). Indications for transferrin quantitation include: screening for nutritional status; differential diagnosis of anemia; and monitoring anemia treatment. Iron deficiency and iron overload are best diagnosed using a combination of iron, transferrin, and ferritin determinations.Transferrin is considered to belong to a group of proteins, along with albumin, prealbumin, and β-lipoprotein, referred to as negative acute phase reactants (APRs). Negative APRs are found in decreased levels in response to inflammation, necrosis, or malignancy. Decreased levels of transferrin are also associated with conditions involving chronic liver disease, malnutrition, nephrotic syndrome, protein-losing enteropathies, iron overload due to multiple transfusion or hereditary hemochromatosis, and congenital atransferrinemia. Transferrin Index (calculated as serum iron/transferrin) has been suggested as a better screen for iron overload. Elevated levels of transferrin are associated with iron deficiency anemia where elevated transferrin often precedes the appearance of anemia by days to months. Transferrin levels are also elevated with increased estrogen due to pregnancy, oral contraceptives, etc. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****Backup:** Hold until instrument is back in service. Send to Mayo if directed by provider.   |
| **Sunquest Test Codes** | **TRAF** |
| **Specimen** | Sample: Plasma or Serum (with or without gel barrier) **Preferred:** Lithium Heparin**Alternative:** SST, Sodium Heparin, EDTA**Minimum sample volume:** 0.6 mL blood, 0.2 mL serum/plasma**Stability when separated from cells/gel:** **2 to 8°C:** 3 days**-20°C:** 6 months **Rejection criteria:** Unlabeled tube, sample type other than serum or acceptable plasma**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 directly 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*** |
| Abbott Alinity c Transferrin Reagent Kit  | 08P3820 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 57 days |
| Abbott Alinity c Specific Proteins Multiconstituent Calibrator Kit | 08P6201 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** 30 days after opening. Store tightly capped with new replacement caps. Return to refrigerated storage after use.Lot-specific calibrator values are listed in the Alinity c Specific Proteins Multiconstituent Calibrator Kit value sheet, packaged with the calibrator. Verify that the lot number listed on each calibrator carton agrees with the lot number printed on the value sheet. The last two digits of the lot numbers can vary. Do not change the AMR upper limit with every lot number; the chosen AMR should encompass all lots of calibrator material. Ensure the upper AMR limit does not change from that which is printed in this procedure. |

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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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.The following warnings and precautions apply to: R1 and R2**WARNING** Contains alcohols, C12-14-secondary ethoxylated, tris hydroxymethyl aminomethane and sodium azide.Causes serious eye irritation.Causes mild skin irritation.Harmful to aquatic life.Contact with acids liberates very toxic gas.No special disposal requirements indicated.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 19 – 500 mg/dL |
| Reference Material: | Specific Proteins Multiconstituent Calibrator |
| Suggested Calibration Levels: | These are approximate levels. Do not change the upper AMR with change in lot number. Ensure the upper AMR stays at 500.CAL 1: 0.2CAL 2: 82CAL 3: 162CAL 4: 270CAL 5: 540 |
| Calibration Scheme: | 5 Levels, Spline data reduction method |
| Calibration Frequency: | 57 days  |
| AMR | AMR verification meet regulatory requirements with each calibration using 5 calibrators that span the full measuring range.  |

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| **Quality Control** | **QC Material**: Bio-Rad Liquichek Immunology Control Levels 1 & 3**Frequency:** Two levels each day of use **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 products **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” Abbott performed studies at two medical decision levels for endogenous substances. No interference was noted. |
| **Reference Intervals** | 0 to < 9 Weeks: 104 - 224 9 Weeks to < 1 Year: 107 - 324 1 to < 19 Years: 220 - 337Adult: 174 – 382 |
| **Critical Values** | None specified |
| **Limitations** | * 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.
* Elevated fibrinogen levels in EDTA plasma samples may yield a depressed result. Transferrin results should be evaluated by comparing to other clinically relevant information.
* Turbidity and particles in the samples can interfere with the assay. Therefore, particulate matter should be removed by centrifugation prior to running the assay.
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| **Dilutions** |

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| Max Auto Dilution: | 1:2 |
| Maximum Manual Dilution: | 1:4 |
| Diluent: | Saline |
| Manual Dilution: | Follow Abbott [Alinity Operator’s Manual](https://starnet.childrenshc.org/References/labsop/chem/operator/alinity-ci-series-operations-manual.pdf) instructions for programming automated and manual 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 19 mg/dL, do not report the result. Rerun and/or investigate for other possible causes of error. |

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| **Result Reporting** | * Results between 19 and 500 mg/dL without error messages are released
* Results below 19 without error messages are reported as < 19.
* Results > 500 should be diluted using the onboard automated 1:2 dilution. Release results without error messages following this dilution.
* Results > 1000 should be diluted 1:4 with saline. Release results without error messages following this dilution.
* Results > 2000 following automated dilution are reported as > 2000.
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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 Transferrin Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
2. Abbott Alinity c Specific Proteins Multiconstituent Calibrators Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 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/#/search). Accessed October 27, 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Elauteria Earnhardt | April 23, 2020 | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Fixed errors, changed instrument, added AMR, dilutions, reporting, dilutions, interferences, title, etc for new analyzer. |