| **Microalbumin** |
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| **Purpose** | This procedure provides instructions for performing MICROALBUMIN ON ABBOTT INSTRUMENTATION. The Alinity c Microalbumin assay is used for the quantitative measurement of albumin in human urine 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 Microalbumin assay is a turbidimetric immunoassay that uses polyclonal antibodies against human albumin. When a specimen is mixed with the reagents, albumin in the specimen combines with the anti-human albumin antibody (goat) in the reagent to yield an insoluble aggregate that causes increased turbidity in the solution. The degree of turbidity is proportional to the concentration of albumin in the specimen, and can be measured optically. **Methodology**: Turbidimetric/Immunoturbidimetric For additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Microalbuminuria is a condition characterized by increased urinary excretion of albumin in the absence of overt nephropathy, and can be used to predict diabetic nephropathy. Diabetic nephropathy is a major cause of death in individuals with insulin-dependent diabetes; and because it is accompanied by irreversible kidney damage and persistent proteinuria, it is a major factor in the decision to initiate hemodialysis.Early detection of glomerular damage, when it is minimal and reversible, is extremely important. Monitoring urinary microalbumin is an important component of treatment for both Type I and Type II diabetes mellitus.3 Methods for monitoring microalbuminuria include measurement of protein excretion in 24 hour, timed, or overnight collections, and determination of the albumin:creatinine ratio in an untimed “spot” urine specimen. Twenty-four hour and timed urine collections may be associated with collection errors including improper timing, missed samples, and incomplete bladder emptying. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****St. Paul: Abbott Alinity c (Sunquest method code:SALIC)**Backup: Opposite campus |
| **Sunquest Test Codes** | **UMAR: Urine Microalbumin****UMAT: Urine Microalbumin on Timed Collection** |
| **Specimen** | Sample: Urine collected in a clean, unused plastic or class container**Minimum Volume:**1 mL Urine, centrifuged**Stability:**2 days at RT, 14 days at 2-8 °C,The use of frozen urine samples is not recommendedRejection Criteria: Unlabeled specimensNormal procedures for collecting urine may be used for samples to be analyzed by this method. The following samples are acceptable:* 24-hour collection
* Overnight (8-12-hour) collection
* 1-to 2-hour collection
* First-morning sample for simultaneous albumin and Creatinine measurement.

Samples should not be collected after exertion, in the presence of urinary tract infection, during acute illness, immediately after surgery, or after an acute fluid overload.Specimens should be collected without preservatives.**Preparation**Timed urine collections are measured for total volume, and the collection date and time recorded for the start and end of the collection. Enter collection information into Sunquest by ordering the test PV on the same accession number.**Each urine sample MUST BE CENTRIFUGED prior to analysis.** |
| **Reagents** | **Reagent Handling** Reagents are shipped refrigerated or on cold packs. 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 8 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. 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*** |
| Alinity c Microalbumin Reagent kit | 08P0420 | **Store at:** 2-8° C**Unopened:** Until manufacturer’s printed expiration date**On-board**: System temperature for 28 days |
| Alinity c Microalbumin Calibrators | 08P0401 | **Store at:** 2 to 8° C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** .2-8° C 6 months after opening. Store tightly capped with new replacement cap. Return to refrigerator promptly after use |

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| **Risk and Safety** | **Safety Precautions****CAUTION:** 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 Blood borne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.Reagent contains 4-morpholinopropanesulphonic acid and sodium azide.No special disposal 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: | 5 to 500 µg/mL |
| Reference Material: | Abbott Alinity c Microalbumin Calibrators |
| Suggested Calibration Levels: | CAL 1: 5CAL 2: 25CAL 3: 100CAL 4: 300CAL 5: 500 |
| Calibration Scheme: | 5 levels; Spline data reduction method |
| Calibration Frequency: | 28 days, with every new lot, after major instrument repair, or when quality control results indication a need for recalibration |
| AMR | AMR is verified with each calibration. |

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| **Quality Control** | **QC Material:** Bio-Rad Liquichek™ Urine Chemistry Control Levels 1 & 2**Frequency:** Two levels each day of use**Stability:** Once opened store tightly capped at 2 to 8°C, this product has a stability of 30 days once open unless lot expiration date comes first**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. * The product **MUST** be gently swirled and inverted several times to ensure homogeneity.
* For optimal analyte stability 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** | In some instances, falsely high or low results occur due to non-specific turbidity. Prozone may be observed at albumin concentrations greater than 10000 μg/mL. If a result is questionable, dilute the sample and repeat the analysis. |
| **Reference Intervals** | Random/24 hour: Normal < 30 mg/gMicroalbuminuria 30 to 299 mg/g Macro (clinical) albuminuria: ≥ 300 mg/g Albumin Excretion Rate: 0-19 mcg/minuteDue to variability in urinary albumin excretion, at least two of three test results measured within a 6-month period should show elevated levels before a patient is designated as having microalbuminuria.Exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, and marked hypertension may elevate urinary albumin excretion over baseline values. |
| **Calculations** | **Microalbumin Creatinine Ratio (UMAR)** = (urine Microalbumim/Urine Creatiine (UCRE)) X 100 **Albumin Excretion Rate (UAE)=** (Urine Microalbumin x total volume (mLs))/(Time in hours of collection x 60) |
| **Critical Values** | None specified |
| **Limitations** | Due to variability in urinary albumin excretion, at least two of three test results measured within a 6-month period should show elevated levels before a patient is designated as having microalbuminuria.Exercise within 24 hours, infection, fever, congestive heart failure, marked hyperglycemia, and marked hypertension may elevate urinary albumin excretion over baseline values.The Alinity c Microalbumin assay is prone to shifts in reagent lots when monitoring with quality control products that contain animal constituents. The Bio-Rad Liquichek Urine control contains both human and animal products. Therefore, shifts between reagent lots should be fully investigated with at least two previously tested microalbumin patient samples if any shift in lot number is seen. Notify the Technical Specialist immediately if such a shift is seen. Note: parallel testing between the current and new lot must not utilize frozen/thawed samples. |
| **Dilutions** |

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| Max Auto Dilution: | 1:4 |
| Maximum Manual Dilution: | 1:10 |
| Diluent: | Onboard diluent |
| 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 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 500 mg/L without error messages are released
* Results below 5 without error messages are reported as < 5 mg/L (orµg/mL)
* Results > 500 should be diluted using the onboard automated 1:4 dilution. Release results without error messages following this dilution.
* Results > 2000 following automated dilution are manually diluted 1:10 using saline. Results are released if no instrument flags are attached to the output.
* Results >5000 following manual dilution are reported as >5000.
* **mg/L is the same as µg/mL**
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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 7 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Microalbumin Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised February 2018
2. Abbott Alinity c Microalbumin Calibrator Package Insert, Abbott Diagnostics Division, Abbott Park, IL USA. Revised December 2017
3. Bio-Rad Liquichek Urine Chemistry Control Package Insert, Bio-Rad Laboratories, Irvine CA, USA.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | Michelle Anton |  | New Procedure for Abbott analyzers |
| 1 | Erin Bartos | October 28, 2020 | Added correct Alinity in Mpls, AMR, dilutions, reference intervals, calculations, references, calibrator info, processing info |