| **Rheumatoid Factor** |
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| **Purpose** | This procedure provides instructions for performing RHEUMATOID FACTOR on ABBOTT INSTRUMENTATION. The Alinity c Rheumatoid Factor (RF) assay is used for the quantitation of rheumatoid factor in human serum 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** | Alinity c Rheumatoid Factor is an *in vitro* diagnostic assay for the quantitative determination of rheumatoid factor in human serum. The Alinity c Rheumatoid Factor assay is a latex enhanced immunoturbidimetric assay that involves an antigen-antibody reaction between rheumatoid factor in the sample and denatured human IgG, which has been adsorbed to latex particles. The resulting agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of rheumatoid factor in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.**Methodology:** ImmunoturbidimetricFor additional information on system and assay technology, refer to the Alinity ci-series Operations Manual, Section 3. |
| **Clinical Significance** | Rheumatoid factor (RF) is an autoantibody against human immunoglobulin G (IgG) commonly present at a high concentration in sera of patients with certain conditions, particularly in patients with rheumatoid arthritis.The measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis. Rheumatoid factor may also be observed in systemic lupus erythematosus, Sjogren’s syndrome, cryoglobulinemia, chronic hepatic diseases and other autoimmune and inflammatory diseases. This assay is designed to accurately and reproducibly measure serum rheumatoid factor using latex agglutination. |
| **Analyzer** | **Minneapolis: Abbott Alinity ci (Sunquest method code: MACC)****Backup:** Hold samples until Alinity ci (MACC) is back in service. Samples may be sent to Mayo Medical Laboratories (MML) if directed by provider. |
| **Sunquest Test Codes** | **RF- Rheumatoid Factor** |
| **Specimen** | Sample: Serum (with or without gel barrier) **Preferred:** SST or red no gel**DO NOT USE PLASMA****Minimum sample volume:** 0.6 mL blood, 0.2 mL serum **Stability when separated from cells/gel:** **20 to 25°C:** 24 hours**2 to 8°C:** 3 days**-20°C**: 1 month **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 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** Reagents are shipped on wet ice or 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 1 hour before use to allow bubbles that may have formed to dissipate. **Immediately prior to loading on the analyzer, gently invert cartridge 5 times, ensuring no bubbles have formed in the process.**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 Rheumatoid Factor Reagent Kit | 04R9921 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**On-board**: 30 days |
| Alinity c Rheumatoid Factor Calibrator Kit | 04S0002 | **Store at:** 2 to 8°C**Unopened:** Until manufacturer’s printed expiration date**Opened expiration:** 90 days when stored tightly capped between uses and minimizing time at room temperatures |

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| **Risk and Safety** | This product contains human-sourced and/or potentially infectious components. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be 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 human-sourced material used in R2 is nonreactive for HBsAg, anti-HIV-1/HIV-2, anti-HCV, and HIV-1 Ag.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/) |
| **Calibration** |

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| Assay Range: | 13 to 200 IU/mL |
| Reference Material: | Abbott Alinity c Rheumatoid Factor Calibrator  |
| Suggested Calibration Levels: | CAL 1: 10CAL 2: 20CAL 3: 40CAL 4: 120 CAL 5: 200 |
| Calibration Scheme: | 5 Levels; Spline data reduction method |
| Calibration Frequency: | 60 days; with every new lot, or when instrument undergoes major maintenance, replacement of critical components, or as directed by Abbott field service. |
| AMR | AMR is verified with every calibration. |

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| **Quality Control** | **QC Material:** Bio-Rad Liquichek™ Immunology Control Levels 1 & 3**Frequency:** Two levels each day of use**Stability:** Stable until the expiration date when stored frozen between -20 and -40°C. Once thawed, opened, and stored tightly capped at 2 to 8°C, this product is stable for 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” Less than 6% interference is seen at these levels:* Hemoglobin up to 2000 mg/dL
* Bilirubin up to 60 mg/dL
* Intralipid up to 2000 mg/dL

Pharmaceuticals listed below may affect rheumatoid factor concentration.* Interferon Alfa-2a and methotrexate may decrease serum rheumatoid factor levels.
* Penicillamine, pentopril, and timegadine have no significant effect on serum rheumatoid factor levels.
* Methyldopa, oral contraceptives, and oxyphenisatin may increase serum rheumatoid factor levels.
* Nonsteroidal anti-inflammatory drugs may decrease or have no significant effect on serum rheumatoid factor levels.
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| **Reference Intervals** | **0 to < 15 Days**: 9 – 17.1**15 Days to < 19 Years**: <10**Adult**: <30Lower values should not be classed as “rheumatoid factor positive”. Even clinically unremarkable individuals may be found to have low levels of rheumatoid factor. Such persons generally exhibit low titers, with the incidence increasing with age, irrespective of sex. |
| **Critical Values** | None specified |
| **Limitations** | Pharmaceuticals listed below may affect rheumatoid factor concentration.* Interferon Alfa-2a and methotrexate may decrease serum rheumatoid factor levels.
* Penicillamine, pentopril, and timegadine have no significant effect on serum rheumatoid factor levels.
* Methyldopa, oral contraceptives, and oxyphenisatin may increase serum rheumatoid factor levels.
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| **Dilutions** |

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| Max Auto Dilution: | 1:5, 1:10 |
| Maximum Manual Dilution: | Not specified |
| Diluent: | Onboard saline |
| Automated 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.  |

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| **Result Reporting** | * Results between 13 and 200 IU/mL without error messages are released
* Results below 13 without error messages are reported as < 13 IU/mL.
* Results > 200 should be diluted using the onboard automated 1:5 dilution. Release results without error messages following this dilution.
* Results > 1000 following 1:5 automated dilution should be diluted using the onboard automated 1:10 dilution. Results without error messages are released.
* Results >2000 following this dilution, results are are reported as > 2000 IU/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 14 days in specimen storage freezer. |
| **References** | 1. Abbott Alinity c Rheumatoid Factor Reagent Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised April 2019
2. Abbott Alinity c Rheumatoid Factor Calibrator Kit Instructions for Use, Abbott Diagnostics Division, Abbott Park, IL USA. Revised August 2019
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 | Added AMR, references, reference intervals, interferences and limitations, calibrator, etc for new instrument. |