| **SARS-CoV-2 IgG** |
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| **Purpose** | This procedure provides instructions SARS-CoV-2 IgG on ABBOTT ALINITY INSTRUMENTATION.  |
| **Policy Statements** | This procedure applies to all personnel responsible for operating the Abbott Alinity ci at Children’s Minnesota Laboratory |
| **Principle** | This assay is an automated, two-step immunoassay for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.Sample, SARS-CoV-2 antigen coated paramagnetic microparticles, and assay diluent are combined and incubated. The IgG antibodies to SARS-CoV-2 present in the sample bind to the SARS-CoV-2 antigen coated microparticles. The mixture is washed. Anti-human IgG acridinium-labeled conjugate is added to create a reaction mixture and incubated. Following a wash cycle, Pre-Trigger and Trigger Solutions are added.The resulting chemiluminescent reaction is measured as a relative light unit (RLU). There is a direct relationship between the amount of IgG antibodies to SARS-CoV-2 in the sample and the RLU detected by the system optics. This relationship is reflected in the calculated Index (S/C). The presence or absence of IgG antibodies to SARS-CoV-2 in the sample is determined by comparing the chemiluminescent RLU in the reaction to the calibrator RLU.**Methodology**: Chemiluminescent Microparticle Immunoassay (CMIA) |
| **Clinical Significance** | The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin). The SARS-CoV-2 IgG assay is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The SARSCoV-2 IgG assay should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, to perform moderate or high complexity test. Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. The sensitivity of SARS-CoV-2 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.False positive results for SARS-CoV-2 IgG assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes.The SARS-CoV-2 IgG assay is only for use under the Food and Drug Administration’s Emergency Use Authorization. |
| **Analyzer** | **Minneapolis : Abbott Alinity ci (Sunquest Method Code** |
| **Sunquest Test Codes** | SARSG |
| **Specimen** | Sample: **Preferred**: lithium heparinized plasma, serum, SST or without gel**Alternative:** EDTA plasma**Minimum sample volume:** 0.6 mL blood, 0.2 ml serum/plasma**Stability when separated from cells/gel:** **20 to 25°C** 2 Days**2 to 8°C** 7 Days**-20°C** 7 Days**Rejection criteria:** Unlabeled tubes, sample type other than serum or plasma, grossly hemolyzed samples**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 gel/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 or aliquot cup. Architect systems utilize a specimen level detect mechanism, so special racks specific to tube-type are not required.
5. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
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| **Reagents** | **Reagent Handling** Immediately upon receipt in lab, unopened reagent kits must be be mixed by fully inverting and then returning right-side-up (180 degrees) 5 times with the green label stripe facing up and then 5 times with the green label facing down. This ensures that liquid covers all sides of the bottles within the cartridges. During reagent shipment, microparticles can settle on the reagent septum. Place a check in the square on the reagent kit to indicate to others that the inversions have been completed. After mixing, place reagent cartridges in an upright position for 1 hour 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.Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may produce erroneous results. Take every precaution to prevent this. Do not pool reagents within a kit or between kits.**IMPORTANT NOTE**: When handling conjugate vials, change gloves that have contacted human serum or plasma, since introduction of human IgG will result in a neutralized conjugate.Load and Remove reagent daily. Store in the refrigerator using clean cartridge caps. When the reagent is removed daily, it is estimated that the time onboard will be less than 4 hours and should therefore last refrigerated until expiration date on package insert.  |
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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| SARS-CoV-2 IgG Reagent | **06R9020** | **Store at:** 2 to 8°C**Unopened:** Until expiration date on package**On-board: 7 days** **Opened:** Until expiration date on package or until 168 hours onboard is reached, as tracked by the instrument system. **Load and remove reagent daily. Cover with clean cartridge caps. Store in the refrigerator.**  |
| SARS-CoV-2 IgG Control Kit | **06R9010** | **Unopened:** Store at -20°C or colder until the printed expiration date **Opened:** 2 to 8°C for up to 23 days |
| SARS-CoV-2 IgG Calibrator Kit | **06R9001** | **Unopened:** Store at -20°C or colder until the printed expiration date**Opened:** 2 to 8°C for up to 60 days |

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| **Risk and Safety**  | Contains methylisothiazolone and sodium azide at levels that do not require special handling.Dispose of unused reagents, controls, and calibrators in biohazard waste.Safety data sheets (MSDS/SDS) available on [Children’s Intranet](https://starnet.childrenshc.org/emergency-and-safety/)  |
| **Calibration** |

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| Assay Range: | 1.4 S/C (sample cutoff) |
| Reference Material: | SARS-CoV-2 IgG Calibrator Kit |
| Suggested Calibration Levels: | See lot-specific assay documentation |
| Calibration Scheme: | 1 Level |
| Calibration Frequency: | 7 days. Recalibrate with every new lot, whenever quality control results are out of range, every 6 months, or after major instrument maintenance  |
| AMR | AMR is not required on qualitative assays. |

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| **Quality Control** | **QC Material:** Abbott ArchitectSARS-CoV-2 IgG Control Kit, 06R9010**Frequency:** positive and negative every 24 hours of patient testing**Stability:** When opened and stored at 2-8°C, 23 days. Store frozen at <-20°C until printed manufacturer expiration date.**Preparation**: To obtain the recommended volume requirements for the controls, hold the bottle vertically, and dispense 4 drops of the negative control and 4 drops of the positive control into each sample cup in the assigned position.**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 (insert hyperlink) 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** | Specimens from patients who have received preparations of mouse monoclonoal antibodyies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA); such specimens may show either falsely elevated or depressed values when tested with this assay kit. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Rheumatoid Factor in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Refer to the package insert for potentially interfering disease states, located in the SPECIFIC PERFORMANCE CHARACTERISTICS section.  |
| **Reference Intervals** | < 1.4 Negative≥ 1.4 PositiveNegative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out early infection in these individuals.Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. |
| **Critical Values** | None |
| **Limitations** | Immunocompromised patients who have COVID-19 may have a delayed antibody response and produce levels of antibody which may not be detected as positive by the assay.This test has not been reviewed by the FDA.**•**Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.**•** Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**•** Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E. |
| **Dilutions** |

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| Max Auto Dilution: | N.A. |
| Maximum Manual Dilution: | Do not dilute. |
| Diluent: | N.A |

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| **Result Reporting** | * Results less than 1.4 without error messages are reported with the following comment:

“This test has not been reviewed by the FDA. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.” * Results 1.4 and above are reported as positive with the following comment:

“This test has not been reviewed by the FDA. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.” |
| **Specimen Storage** | Promptly stopper tested specimen and after each batch, remove to freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Architect SARS-CoV-2 IgG Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, September 2020.
2. Architect SARS-CoV-2 IgG Calibrator Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, April 2020.
3. Architect SARS-CoV-2 IgG Quality Control Package Insert, Abbott Laboratories Diagnostics Division, Abbott Park, IL 60064, April 2020.
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Stephen Gripentrog, Erin Bartos | 05/25/2020 | New Procedure  |
| 2 | Erin Bartps | 10/24/2020 | Updated for Alinity I system |