BIOGENIX

SOP FOR SARS-COV-IGG ASSAY (ALINITY)

	NAME	DESIGNATION	SIGNATURE	DATE
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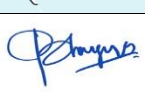
Reviewed by	Dr Bhagyashree Thakre	Deputy Lab Director		01/07/2020
Approved by	Dr Sally Abdulla Ibrahim	Lab Director		01/07/2020

1. Table of Content

2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

4. PURPOSE

The SARS-CoV-2 IgG assay is a chemiluminescent micro particle immunoassay (CMIA) used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma on the ARCHITECT i System.
The SARS-CoV-2 IgG assay is to be used as an aid in the diagnosis of SARS-CoV-2 infection in conjunction with clinical presentation and other laboratory tests. Results from the SARS-CoV-2 IgG assay should not be used as the sole basis for diagnosis.

5. TEST 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.

6. PERFORMANCE CHARACTERISTICS

This test is verified with (accuracy and precision)

6.1. Precision

Complex precision: Precision evaluation experiments evaluate the degree to which repeated measurements show the same result under a specified set of conditions.

Run 3 levels of QC (negative, positive +, Positive 2+) five times for five days.

6.2. Linearity

Linearity studies is performed as in order to determine linear reportable range. Calibrators is tested in the same manner as patient samples. Testing is performed in triplicate

6.3. Comparison

A set of 25 patients' samples already processed on the using Alinity i of another laboratory are processed to do comparison studies.

6.4. For detailed reports Please refer to method verification file.

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7. TYPE OF SAMPLE/CONTAINER/ADDITIVE/PATIENT PREPARATION

7.1. SAMPLE TYPE

Sample type, Storage, and Stability:

Specimen Type	Stability & Storage
Serum	Room temperature (15 to 30°C) 2 days Stable for 7 Days at 2-8°C
Plasmas: Potassium EDTA	Room temperature (15 to 30°C) 2 days Stable for 7 days at 2-8°C

7.2. HANDLING OF SPECIMENS

7.2.1. Centrifuge serum samples after complete clot formation (3500rpm/15minutes)

7.2.2. Ensure the patients' samples are at ambient temperature (20-25°C) before measurement.

7.2.3. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation

7.3. SAMPLE ACCEPTANCE AND REJECTION CRITERIA

Do not use specimens with the following conditions:

7.3.1. Heat -inactivated
7.3.2. Pooled
7.3.3. Grossly hemolysed (> 500 mg/dL hemoglobin)
7.3.4. Obvious microbial contamination
7.3.5. Fungal growth

8. PATIENT PREPARATION

No special patient preparation required for the test.

9. REQUIRED EQUIPMENT AND REAGENT

9.1. Trigger / Pre Trigger
9.2. Probe conditioning solution
9.3. Wash Buffer
9.4. Sample Cups
9.5. RV's
9.6. Control
9.7. Calibration
9.8. Printer paper
9.9. D/W
9.10. COV -2 IgG Reagent from Abbott consist of:

Micro particle	Purified SARS-CoV-2 recombinant antigen coated microparticles in TRIS buffer with surfactant. Minimum concentration: 0.045% solids. Preservatives: ProClin 950 and sodium azide.
Conjugate	Anti-human IgG (mouse, monoclonal) acridinium-labeled conjugate in MES buffer with surfactant and protein (bovine) stabilizer. Minimum concentration: 4ng/mL. Preservatives: ProClin 300 and antimicrobial agents.
Assay diluents	TRIS buffer and detergent. Preservatives: ProClin 950 and sodium azide.

10. ENVIRONMENT & SAFETY CONTROL

10.1. Humidity / Temperature

10.2. In vitro diagnostic use
10.3. Exercise the standard precautions required for handling all Laboratory reagents.
10.4. Disposal of all waste material in accordance with Procedure for Waste Management
10.5. Avoid the formation of foam with all reagents and sample types (specimens, Calibrators, and controls).

For environmental and safety precautions in using COV-2 IgG reagent go to MSDS sheet file no 7.

11. CALIBRATION

11.1. PROCEDURE:

11.1.1. Thaw completely before use.
11.1.2. Prior to each use, mix by gentle inversion.
11.1.3. CoV 2 IgG calibrator: test calibrator's in replicates of 3. The calibrators should be priority loaded.
11.1.4. Hold the bottle vertically, and dispense 4 drops of the calibrator in to sample cup in the assigned position, if the calibration uses bar-coded samples, the position is not required, and we can load it directly.
11.1.5. Calibration must be performed once per new reagent lot
11.1.6. As required: e.g. quality control findings outside the defined limits.

11.2. CALIBRATION FREQUENCY

Once a calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:

11.2.1. A reagent kit with a new lot number is used.
11.2.2. Daily quality control results are outside of quality control limits used to monitor and control system performance.
11.2.3. This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

11.3. TRACEABILITY

There is currently no internationally recognized reference method or reference material for standardization. The SARS-CoV-2 IgG calibrator is traceable to internal reference standards.

11.4. CONTENTS

The calibrator contains inactivated, cell-free, human blood-derived material, reactive for anti-SARS-CoV-2 IgG. Preservatives: sodium azide and antimicrobial agents.

11.5. CALIBRATOR STORAGE & STABILITY

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Onboard	System Temperature	7 days	
Opened	2 to 8°C	Until expiration date	Store in upright position. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.

12. QUALITY CONTROL

12.1. QC MATERIALS

Two levels of QC supplied by the manufacturer will be run daily before running patient's samples:

12.1.1Negative

12.1.2 Positive

12.2. FREQUENCY OF RUNNING INTERNAL QC

12.2.1. Once every 24 hours when the test is in use.

12.2.2. On Opening of new reagent kit.

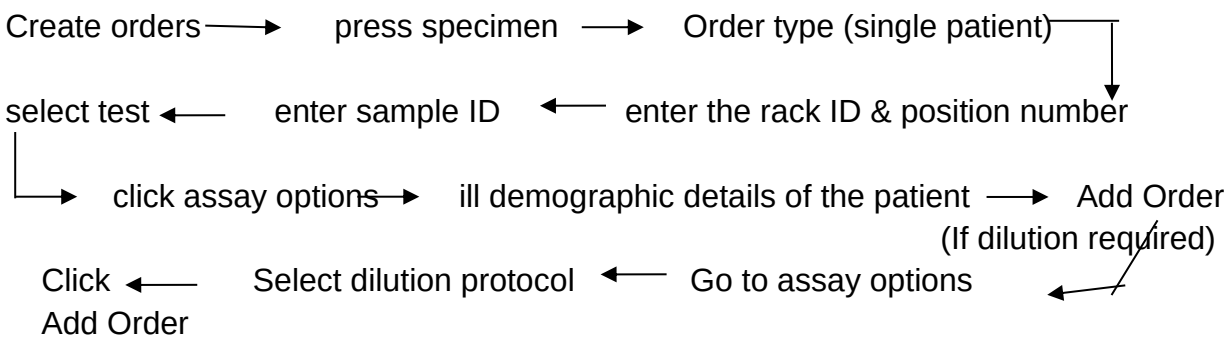
12.2.3. After every calibration.

12.2.4. Patient samples not run unless IQC result is acceptable / refer to Procedure for Ensuring Quality of Examination Results

12.2.5. Refer to General SOP/for Allinity startup, running control, calibrating, and machine shut down procedures

13. PROCEDURE:

13.1. Follow standard Personnel Protective equipments precautions.
13.2. Check the request for Routine or urgent, Confirm the label on the tube and bar-coded sticker with accompanying requisition form.
13.3. Prepare the sample as per our Procedure for Sample Handling, Preparation and Storage
13.4. Take the Request form and check all the Demographic details and Test order in LIS;
13.5. Check the sample for Barcode;
13.6. Check for the daily and weekly maintenance, if pending perform it first and then proceed for the test;
13.7. Check for all consumables and reagent needed before processing the sample.
13.8. After checking the validity of controls and calibrators process samples using LIS or manual entry
13.9. LIS method: Take sample carrier, position the tube by barcode facing outside, machine will automatically take the rack and start to run the test.
13.10. If LIS is not working or any problem with LIS we process samples manually, place the tube in appropriate sample carrier, in main menu:



13.11. Place the rack in the sample loading area
13.12. Machine will automatically start performing the tests
13.13. After some time, it will give results.
13.14. If barcoded samples are used, the rack ID and position number are not required.
13.15. In case of Bar-coded Batch, select bar-coded batch, scan the first sample ID then the last Sample ID, name the batch, select assay then Add Order.

14. EXTERNAL QC

14.1. We are enrolled in CAP proficiency

15. INTERFERENCE

15.1. Do not use:

15.1.1. heat-inactivated specimens
15.1.2. pooled specimens
15.1.3. grossly hemolyzed specimens
15.1.4. specimens with obvious microbial contamination
15.1.5. specimens with fungal growth

15.2. For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.

15.3. Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

15.4. To ensure consistency in results, recentrifuge specimens prior to testing if they contain fibrin, red blood cells, or other particulate matter.

16. CALCULATION

16.1. The Allinity COV 2IgG assay calculates results automatically based on ng/mL (nmol/L) The Allinity System calculates the calibrator mean chemiluminescent signal from 3 calibrator replicates and stores the result. Results are reported by dividing the sample result by the stored calibrator result. The default result unit for the SARS-CoV-2 IgG assay is Index (S/C).

17. BIOLOGICAL REFERENCE INTERVALS

17.1. The cutoff is 1.4 Index (S/C).

17.2. As with all analyte determinations, the result should be used in conjunction with information available from clinical evaluation and other diagnostic procedures.

Index (S/C)	Interpretation
< 1.4	Negative
≥ 1.4	Positive

18. DILUTIONS

Dilution of samples for the SARS-CoV-2 IgG assay has not been verified.

19. CRITICAL VALUE

N.A.

20. LABORATORY CLINICAL INTERPRETATION

20.1. Result evaluation:

20.1.1. Result of the patient evaluated according to provisional diagnosis of the patient and the type of the sample.

20.2. Result confirmation:

20.2.1. Result is confirmed by revising the patient identification from the request with the sticker on the sample

20.2.2. The laboratory technical staff confirms the acceptability of quality control results prior to reporting patient results.

20.2.3. Patients with previous Laboratory records, check first the latest results before releasing the current results.

20.2.4. Confirm and repeat any High / low result.

20.2.5. Review the results for any Flags on the system.

21. POTENTIAL SOURCES OF VARIATION

21.1. PERSONAL:

- Competency of staff.

21.2. MACHINE /EQUIPMENT:

21.2.1. Centrifuge

21.2.2. Maintenance
21.2.3. PPM
21.2.4. Pipette

21.3. REAGENT:

21.3.1. Stability of reagent and expiry date
21.3.2. Temperature of refrigerator

22. REFERENCES

22.1. Operational Manual for Allinity.
22.2. Kit insert of SARS-CoV-2 IgG.
22.3. Insert of Calibrators for SARS-CoV-2 IgG.

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Thank You