BIOGENIX

STANDARD OPERATIONAL PROCEDURES FOR SARS-COV-2 VIRUS IGG ANTIBODY

	NAME	DESIGNATION	SIGNATURE	DATE
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2. REVISION HISTORY

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

3. REVIEW HISTORY

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4. PURPOSE

The SARS-CoV-2 IgG assay is an indirect method (ELISA) used for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum and plasma in vitro on the URANUS AE Automated ELISA system Assay Analyzer. 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. Antibody detection in serum can provide a convenient metric to confirm SARS-Cov-2 exposure.

5. TEST PRINCIPLE

This kit uses an indirect method (ELISA) to detect IgG antibodies against SARS-Cov-2 virus in human serum or plasma.

First, the patient sample is added to plate, which is pre-coated with purified antigen. An incubation step facilitates patient IgG antibodies to bind to viral antigens, while unbound components are removed by subsequent wash steps. Next, an enzyme-labeled mouse anti-human IgG is added and another incubation allows these detection antibodies to bind with any SAR-CoV-2 virus specific IgG antibodies that were present in the original sample. This procedure ultimately allows a complex of coated antigen-IgG antibody-anti-human IgG enzyme conjugate to be formed. After the plate is washed again, substrate A and substrate B are added, in the presence of the coated antigen, IgG antibody and anti-human IgG enzyme conjugate, the linked HRP will catalyze a chromogenic reaction and produce a blue chemical complex. Upon addition of stop buffer, the color will change to yellow, indicating that SAR-CoV-2 virus IgG antibodies have been detected in the original sample. The absence of color indicates that no SAR-CoV-2 virus IgG antibody was detected in the original sample.

The OD value is measured on a microplate reader or an enzyme immunoassay system, and the presence of SAR-Cov-2 virus IgG antibody will be determined by the OD value.

6. PERFORMANCE CHARACTERISTICS

6.1 This test is verified with accuracy and precision

6.2 Please refer method verification file

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

7.1. SAMPLE TYPE

Specimen Type	Stability & Storage
Serum (yellow top, red top)	Room temperature (15 to 30°C) 2 days Stable for 3 Days at 2-8°C Stable for -20°C long term storage
Plasmas: Potassium EDTA (purple top)	Room temperature (15 to 30°C) 2 days Stable for 3 Days at 2-8°C Stable for -20°C long term storage

7.2. HANDLING OF SPECIMENS

7.2.1. Centrifuge serum samples after complete clot formation (1500-2000 rpm/15 minutes)

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

7.3.1. Grossly hemolyzed (> 500 mg/dL hemoglobin)

7.3.2. Obvious microbial contamination

7.3.3. Fungal growth

7.3.4. Heat-inactivated specimens

7.3.5. Pooled specimens

8. PATIENT PREPARATION

8.1. NO SPECIAL PATIENT PREPARATION

8.2. REQUIRED EQUIPMENT AND REAGENT

8.2.1 Reagents

SARS-CoV-2 IgG coated plate	The plate coated with the purified SARS-CoV-2 virus antigen.
SARS-CoV-2 IgG Positive control	Human serum with SARS-CoV-2 IgG antibody with stabilizer and preservatives.
Negative Control	Human serum with SARS-CoV-2 IgG antibody with stabilizer and preservatives.
SARS-CoV-2 IgG Enzyme Solution	Horseradish peroxidase-labelled anti-human IgG antibody with preservatives.
Concentrated washing buffer	PBST with appropriate amount of preservatives
Sample Buffer	
Substrate A	Urea Peroxidase solution
Substrate B	TMB solution, stored avoiding light
Stop Buffer	Diluted H2SO4

8.2.2 Universal Plate washer
8.2.3 Purified water
8.2.4 Measuring cylinder
8.2.5 Storage and Stability:

	Storage Temperature	**Maximum Storage Time**	**Additional Storage Instructions**
Unopened	2 to 8°C	Until expiration date	Store in upright position.
Opened	2 to 8°C	Valid until 6 months	

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Wash Buffer	10-30°C	1 week	If crystal appear in the concentrated washing buffer heat the buffer to 37°C to fully dissolve the crystals and mix.

9. ENVIRONMENT & SAFETY CONTROL

9.1. Humidity / Temperature
9.2. In vitro diagnostic use
9.3. Exercise the standard precautions required for handling all Laboratory reagents.
9.4. Disposal of all waste material in accordance with Procedure for Waste Management
9.5. Avoid the formation of foam with all reagents and sample types (specimens, Calibrators, and controls).
9.6. For environmental and safety precautions in using SARS-COV-2 IgG reagent go to MSDS file.

10. CALIBRATION

10.1. CALIBRATION FREQUENCY

- Every 30 days.
- A reagent kit with a new lot number is used.
- Daily quality control results are outside of quality control limits used to monitor and control system performance.
- This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.

10.2. TRACEABILITY

10.3. CONTENTS

10.4. CALIBRATOR STORAGE & STABILITY

11. QUALITY CONTROL

11.1. QC MATERIALS

11.1.1 2 levels of QC supplied by the manufacturer will be run per batch of samples.

- Negative
- Positive

11.2. FREQUENCY OF RUNNING INTERNAL QC

Every batch of sample processed

11.3. EXTERNAL QC:

Enrolled in CAP Pt program.

12. PROCEDURE

12.1 Follow standard Personnel Protective equipment precautions.

12.2 Check the request for Routine or urgent, Confirm the label on the tube and bar-coded sticker with accompanying requisition form.

12.3 Prepare the sample as per our Procedure for Sample Handling, Preparation and Storage

12.4 Check for all consumables and reagent needed before processing the sample.

12.5 Click on the “Initialize” Button to Initialize the system.

12.6 After Initialization, Click the Washer application program to maintenance the washed.

12.7 Connect the system liquid tube in the tank buffer island and click “Rinse” Button to flush the fluidic tubing for 60 seconds, check if there is any blockage on the manifold.

12.8 Clean up the waste liquid container and waste tip bucket.

12.9 Refill the disposable tips.

12.10 Place the required reagents and controls according to position, check the volume and make sure there are no bubbles.

12.11 Prepare washing buffer: Dilute concentrated washing buffer with purified water (dilution ratio 1:9)

12.12 Position the pre-dilution plates and wells.

12.13 Position the samples on the sample racks, barcode label facing the scanner.

12.14 Click “Add SMPs” to go to test program page, select test program and enter the number of samples.

12.15 Click “Next” to go to barcode scanning page and pushing the rack slowly forward.

12.16 Click “Next” to turn the page presenting the details of samples and corresponding program

12.17 Click “Next” to turn the page to show the position of assay plate that display in red.

12.18 Click ‘Complete” and check the preparation and click “OK” button to confirm, then Click “Run” icon to start the process.

12.19 Schedule monitoring page will be shown to check the status of sample processing.

12.20 Machine will alarm when test is done and to view the result by clicking the “Reader” button.

13. INTERFERENCE

13.1. 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.

13.2. 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.

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

14. CALCULATION

If the OD value of the tested sample is greater that the cut off value, the result is considered positive for IgG antibody against SAR-CoV-2. If the ID value of a tested sample is less than the cut off value, the result is considered negative for IgG antibody against SARS-CoV-2.

15. BIOLOGICAL REFERENCE INTERVALS

15.1. The cut off value 0.10 mean of negative control (calculated as 0.05 if mean OD value of negative control is less than 0.05).

15.2. Negative test results indicate that an individual has not mounted a sufficient immune response to SARS-CoV-2.

15.3. Positive test results indicate that an individual may have been exposed to SARS-CoV-2 and should be combined with clinical symptoms and other diagnostic results for further confirmation.

15.4. DILUTIONS

N/A

16. CRITICAL VALUE

16.1. CRITICAL VALUE: N/A

17. LABORATORY CLINICAL INTERPRETATION

17.1. POINTS TO BE NOTED BEFORE RELEASING RESULTS:

17.2. RESULT EVALUATION:

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

17.3. RESULT CONFIRMATION:

- Result is confirmed by revising the patient identification from the request with the sticker on the sample
- The laboratory technical staff confirms the acceptability of quality control results prior to reporting patient results.
- Patients with previous Laboratory records, check first the latest results before releasing the current results.
- Confirm and repeat any High / low result.
- Review the results for any Flags on the system.

18. POTENTIAL SOURCES OF VARIATION

18.1. PERSONAL:

- Competent of staff.

18.2. MACHINE /EQUIPMENT:

- Centrifuge
- Maintenance
- PPM
- Pipette

18.3. REAGENT:

- Stability of reagent and expiry date
- Temperature of refrigerator

19. REFERENCES

19.1. USER MANUAL FOR URANUS AE AUTOMATED ELISA ASSAY ANALYZER

19.2. KIT INSERT OF SARS-COV-2 IGG.

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Thank You