BIOGENIX

SOP FOR OPERATING & MAINTENANCE OF URANUS AE

	NAME	DESIGNATION	SIGNATURE	DATE
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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

This SOP describes the URANUS AE Automatic Elisa Analyzer and provides information required for safe operation and maintenance of the analyzer.

5. TEST PRINCIPLE

ELISA is based on the immobilized antigen or antibody and marked enzyme. The combined antigen or antibody on the surface of solid phase carrier maintains its immunological activities; the enzyme labeled antigen or antibody has retained its immunological activity and enzyme activity.

While testing, the inspected samples reacts with the antigen or antibody on the surface of solid carrier. Through washing, the antigen-antibody complex on the solid carrier separates from other substances in the liquid. Then add the enzyme marked antigen or antibody, which sticks on the solid carrier. The number of enzymes is proportional to the inspected substances.

After adding the color development reagent, the reagent is catalyzed to colored substances, whose number is directly related to that of the inspected substances. Therefore, qualitative or quantitative analysis can be made according to the color of the colored substances.

The theory of OD formula is Beer-Lambert's Law

A=lgI0/I=-lgT

“A” stands for absorbance
“T” stands for transmittance
“I0” stands for intensity of emitted light
“I” stands for the intensity of transmission light

6. PERFORMANCE CHARACTERISTICS

Test run on URANUS verified with Simple precision, Complex precision and method comparison.

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

7.1. SAMPLE TYPE

7.1.1. Serum

7.1.2. EDTA Plasma

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 (3000 rpm/10minutes)

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 Pooled specimens

7.3.2 Grossly hemolyzed specimens.

7.3.3 Inspect all samples for bubbles.

7.3.4 Improper labeling

7.3.5 Insufficient quantity

7.3.6 Obvious microbial contamination

7.3.7 Body fluids other than human serum and plasma

8 PATIENT PREPARATION

8.1 PATIENT PREPARATION

N.A.

8.2 REQUIRED EQUIPMENT AND REAGENT

8.2.1 SARS-COV-2 Virus IgG Antibody Detection Kit (ELISA)
8.2.2 SAR-COV-2 Virus IgM Antibody Detection Kit (ELISA)
8.2.3 Transfer Pipettes
8.2.4 8.2.5 Purified water
8.2.5 Measuring cylinder
8.2.6 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	
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 uses.
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 for using reagent for Uranus refer to MSDS file.

10 CALIBRATION

N.A.

11 QUALITY CONTROL

11.1 QC MATERIALS

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

- Negative Control
- Positive Control

11.2 FREQUENCY OF RUNNING INTERNAL QC

Every batch sample running

11.3 EXTERNAL QC

Enrolled in CAP Proficiency testing program

12 PROCEDURE

12.1 MACHINE START UP

12.1.1. Make sure the instrument power cord is connected properly;

12.1.2. Make sure the power cord of PC is connected properly;

12.1.3. Make sure the communication cable between PC and instrument is connected correctly;

12.1.4. Switch on the instrument by pressing the ON button from the back of the machine, green button in front, switch on the PC.

12.1.5. Click 

the “TOP” icon on the desktop to enter the system

12.1.6. Double click “TOP” icon, input “1” as username, access to the system;

12.2. Processing of Sample

12.2.1. MAINTENANCE BEFORE RUNNING

12.2.1.1. Click the “initialize” button to initialize the system.

12.2.2. After initialization, go to the washer application program to maintenance the washer,

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

12.2.4. (Refer daily maintenance form: BG/REC/GEN/062)

12.2.2. EQUIPMENT PREPARATION

12.3.1. Clean up waste liquid container and waste tip bucket;

12.3.2. Fill up disposable tips;

12.3.3. Get required reagents and controls ready for use, make sure there is no bubble and the volume are enough.

12.3.4. Place the samples on sample rack, ensure there is no clot and the volume are sufficient, if there are barcode labels on the tube, turn the tubes to the position that the label are facing to the scanner.

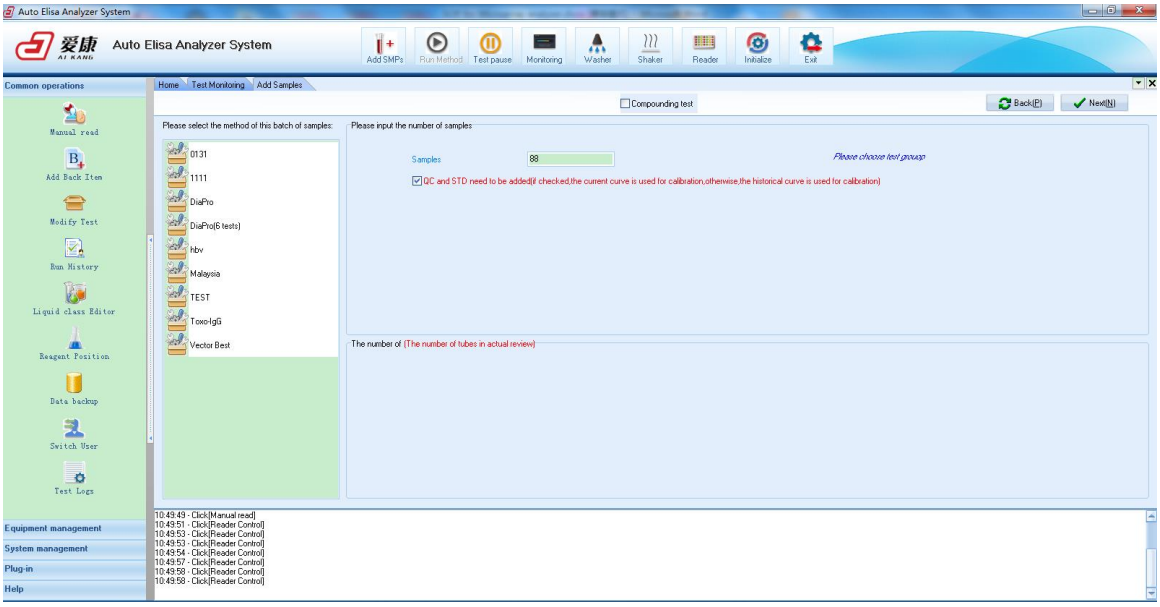
12.3.5. Prepare enough washing solution for use.

12.3.6. Get pre-dilution plate ready at its position.

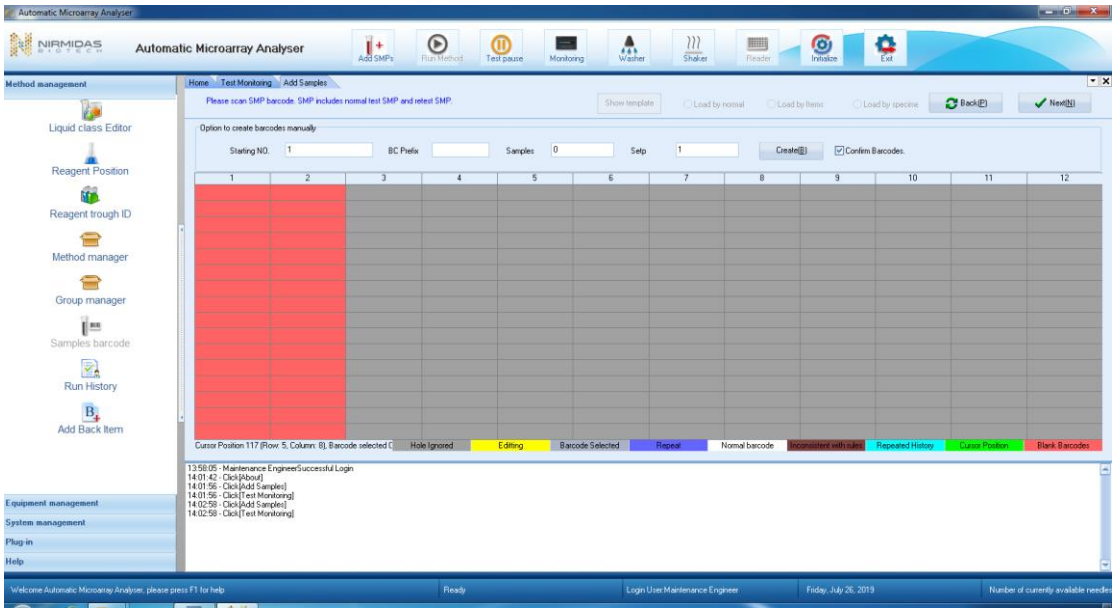
12.4. SAMPLE PROCESSING

12.4.1. Click “Add SMPs” icon to go to test programs page, select test program and input sample number;

Program list page

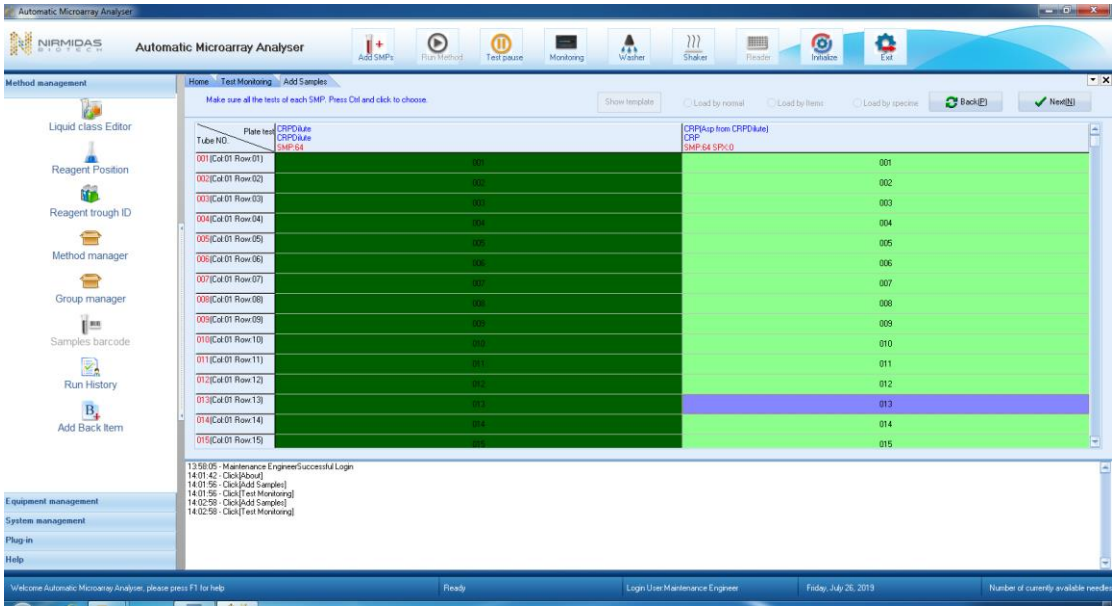


12.4.2. Then click “Next” to go to the barcode scanning page, user can scan the sample barcode in this page by pushing the tube rack slowly forward. If there is no barcode to scan, user can create barcode by clicking the “Create B” button.



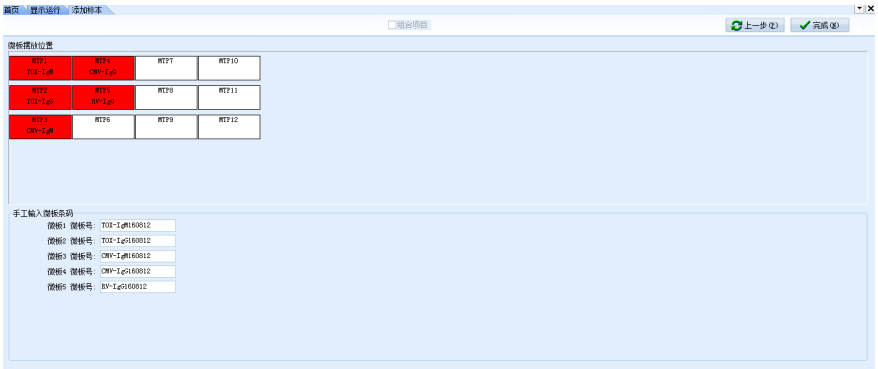
Scanning sample barcode page

12.4.3. Click “Next” to turn to the page presenting details info of samples and corresponding program, in this page, user can disable samples or program that don’t need to be tested by double clicking related columns.



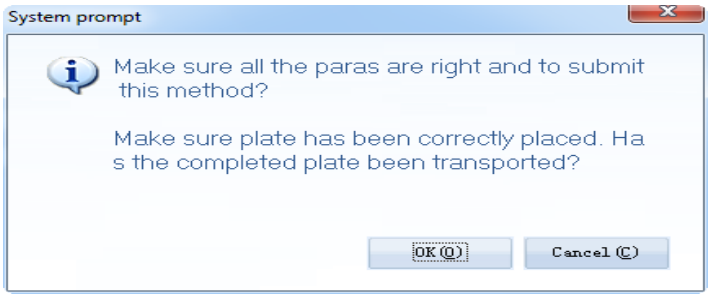
Disable/enable samples

13. After confirming the samples that would be tested, click “Next” to go the page which will show the distributing position of the assay plate, place the assay plates on the positions that are displayed in red.



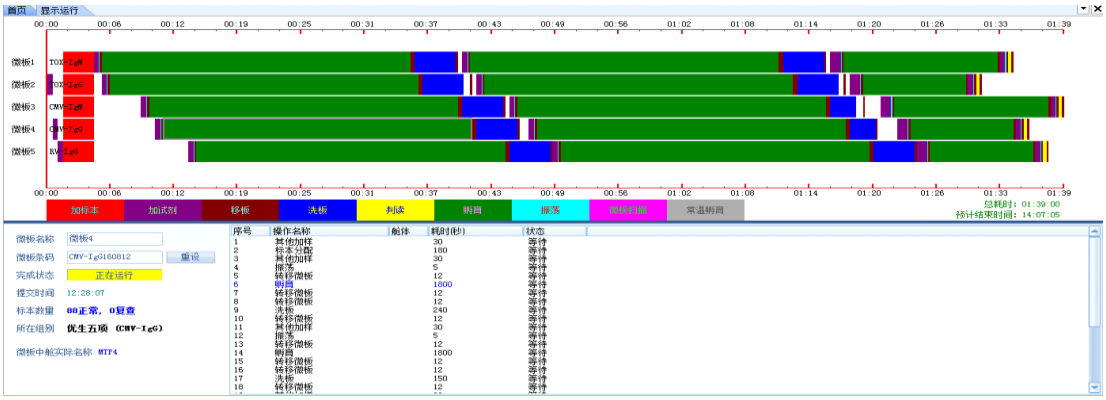
Distribution of assay plates

14. Click “Complete” and check all the preparation again, then click “OK” on the pop-up window to submit the test run.



Confirm all items are ready

15. Then the schedule monitoring page will be shown.



Test schedule monitoring

16. Check the scheduled plans, if there is any mistake, user can delete all the arrangements and submit from the beginning. Check all the items (samples, assay plate, reagent, tip, pre-dilution plate, washing solution etc.) that were prepared.

17. click “Run” icon to start the running.

17.1EVALUATING RESULTS

17.1.1Click on the “Reader” icon to show the test results

12.1.2 Print or Save the test results.

17.2 POST TEST MAINTENANCE

17.2.1 Rinse the washer because the aggregation of material in the needles, may result in clogged needles. So, the manifold of the microplate washer must be rinsed after usage.
17.2.2 Rinse the washer with distilled water for 3-5 times and ensure the water stays in the tubing to soak.
17.2.3 Clean the worktable, take the accessories down from the worktable: tube racks, reagent troughs, tip containers, lids and grippers. Carefully clean the worktable with warm water and then with 75% ethyl alcohol. For those racks that cannot be taken from the worktable, rinse directly with warm water and 75% ethyl alcohol.
17.2.4 Cleaning of the wash buffer containers. The dirt and impurities in the wash buffer container may cause tubing blocking and thus affecting the results. clean the container every two days.
17.2.5 Empty the waste containers for liquid and tip.
17.2.6 Disinfect and clean the waste containers. Pour the waste liquid to the designated location and disinfect it with disinfectant.

17.2.7 Rinse the reagent racks with distilled water.

17.2.8 For the reagents that cannot be preserved in the refrigerator, rinse the reagent racks first and then with distilled water, after than dry it.

17.3MACHINE SHUT DOWN

17.3.1 Quit “TOP” system, Shutdown PC and switch off the instrument from front green button to back OFF switch.

18. INTERFERENCE

18.1 Please make sure there are enough wash buffer in the bottle before testing.
18.2 Do not mix reagent troughs, otherwise it will cause contamination and affect the results. 2.
18.3 The size of reagent trough couldn’t be changed at will when several different sizes of troughs are used on the instrument; otherwise missing addition of the reagent or false alarm for insufficient volume would happen.
18.4 Make sure there are no bubble in the reagent trough.

12.5 CHANGE THE REAGENT IF IT STAYS IN THE REAGENT TROUGH FOR MORE THAN 3 DAYS.

18.6 Rinse the trough with distilled water before changing it.
18.7 Some reagents like the stop solution is corrosive, which might cause personal injury or corrode
the instrument.

19. CALCULATION

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

20. BIOLOGICAL REFERENCE INTERVALS

20.1 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).

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

20.3. 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.

21. DILUTIONS

Dilution: N/A

22. CRITICAL VALUE

Critical value: N/A

23. LABORATORY CLINICAL INTERPRETATION

23.1. POINTS TO BE NOTED BEFORE RELEASING RESULTS:

23.2. RESULT EVALUATION:

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

23.3. RESULT CONFIRMATION:

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

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

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

23.3.4 Confirm and repeat any High / low result.

23.3.5 Review the results for any Flags on the system.

24. POTENTIAL SOURCES OF VARIATION

24.1. PERSONAL:

24.1.1 Competence of staff.

24.2. MACHINE /EQUIPMENT:

24.2.1 Centrifuge

24.2.2 Maintenance

24.2.3 PPM

24.2.4 Pipette

24.3. REAGENT:

24.3.1Stability of reagent and expiry date

24.3.2 Temperature of refrigerator

25. REFERENCES

25.1 Product Manual for Uranus AE Automated ELISA Assay Analyzer

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Thank You