



BioCheck SARS-CoV-2 IgM Antibody Test Kit

Instructions for Use

For Use under an Emergency Use Authorization (EUA) Only
For Prescription Use Only
For *in vitro* Diagnostic Use Only

REF BCM-1003

IVD

Σ 10



Table of Contents

Symbols List	4
Intended Use	5
Background.....	5
Summary and Principles of the Procedure	6
Warnings and Precautions	7
Materials Provided	9
Kit Components.....	9
Components of the Test Cartridge.....	9
Materials Required But Not Provided	10
Reagent Storage, Handling and Stability.....	10
Sample Requirements.....	10
Sample Collection and Preparation	10
Sample Stability and Handling.....	11
Quality Control	11
External Controls (Positive and Negative Controls)	11
Positive and Negative Quality Control (QC) Testing	11
Procedure	14
Sample Testing	14
Interpretation of Results	15
Cut-Off.....	15
Valid Results	15
Invalid Runs.....	15
Limitations of the Procedure.....	15
Conditions of Authorization for the Laboratory	16
Performance Characteristics	17
Clinical Performance	17
Analytical Performance.....	18
Cross-Reactivity.....	18
Interference.....	19
Reproducibility	19
References	20



BioCheck, Inc.

425 Eccles Avenue
South San Francisco, CA 94080 USA
Tel: (650) 573-1968
Fax: (650) 573-1969
www.biocheckinc.com



Accelerate Diagnostics, Inc.

3950 S. Country Club Road, Suite 470
Tucson, AZ 85714 USA
E-mail: support@axdx.com
Technical Support: 1-888-586-2939
Fax: 1-520-269-6580
www.axdx.com
















Most Recent Labeling Documents



www.adx.com/support
Keycode: ADX15343

Symbols List

The following symbols may appear on the product labels or instructions for use.

Symbol	Description	Symbol	Description
	In vitro diagnostic equipment		Catalog Number
	Batch Code	SN	Serial Number
	Power on	○	Power off
	Do Not Re-Use		Contains Sufficient for <n> Tests
CE	CE-Marking of Conformity	EC REP	Authorized Representative in the European Community
	Temperature Limit		Use-By Date
	Consult Electronic Instructions for Use	Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Manufacturer		Date of Manufacture
	Distributor		Importer
	High temperature, do not touch these areas		Biological hazard
	Caution: General Warning		



For Use Under Emergency Use Authorization Only
For *in vitro* diagnostic use.
For prescription use only.

Intended Use

The BioCheck SARS-CoV-2 IgM Antibody Test Kit is a chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum using the MS-Fast Automated Chemiluminescent Immunoassay Analyzing System.

The BioCheck SARS-CoV-2 IgM Antibody Test Kit 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 BioCheck SARS-CoV-2 IgM Test should not be used to diagnose acute SARS CoV-2 infection.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests.

Results are for the detection and differentiation of SARS-CoV-2 IgM antibodies. The IgM 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 results to the appropriate public health authorities.

The sensitivity of BioCheck SARS-CoV-2 IgM Antibody Test Kit 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 BioCheck SARS-CoV-2 IgM Antibody Test Kit may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgM assay.

The BioCheck SARS-CoV-2 IgM Antibody Test Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

Background

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a new virus strain that has not been previously identified in humans and belongs to the coronavirus subfamily of the Coronaviridae family. Although it has better sequence conservation compared with the SARS virus in 2003 and MERS virus in 2012, it has low structural homology in the partial protein primary structure of the 19 proteins encoded. Combined with the recently published epidemiological and toxicological evidence, it is suggested that SARS-CoV-2 belongs to a relatively specific coronavirus, and current research shows that the new virus has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). This bat SARS-like coronavirus presents the characteristics of strong infection ability, fast transmission speed, and a large number of infections.



SARS-CoV-2 is highly contagious, and the human population is generally susceptible. It is mainly transmitted through respiratory droplets and contact routes, and the virus infects human cells via binding to angiotensin converting enzyme 2 (ACE2).^{1,2} People who are infected with SARS-CoV-2 may be asymptomatic or express signs and symptoms of lower respiratory tract infection such as dry cough, fever, and dyspnea (shortness of breath). In severe cases, the virus can cause acute respiratory distress syndrome (ARDS) and sepsis. Symptomatic, pre-symptomatic, and asymptomatic SARS-CoV-2 carriers all can be potential sources for viral transmission.³ Real-time reverse transcription polymerase chain reaction (rRT-PCR) detection of viral genes is the current gold standard for the diagnosis of COVID-19. Upper respiratory specimens, such as nasopharyngeal swabs and oropharyngeal swabs, are commonly used for diagnostic testing.²

The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, rapid detection of cases and contacts, appropriate clinical management and infection control, and implementation of community mitigation efforts are critical.

The BioCheck SARS-CoV-2 IgM Antibody Test Kit is intended for the qualitative detection of antibodies which could be indicative recent or prior infection.

Summary and Principles of the Procedure

The BioCheck SARS-CoV-2 IgM Antibody Test Kit uses an indirect method to determine the presence of SARS-CoV-2 IgM and antibodies in a human serum.

In the cassette from the IgM component of the kit, the SARS-CoV-2 IgM antibodies in a patient serum sample bind to biotinylated SARS-CoV-2 S1 antigens. Excess streptavidin coated magnetic beads bind with high affinity to biotinylated SARS-CoV-2 S1 antigen to form complexes. After incubation at 37°C for 10 minutes, the non-specific components in the serum are removed by washing. Next, alkaline phosphatase labeled anti-human IgM antibodies are added to the complexes for incubation at 37°C for 10 minutes, during which time the anti-human IgM antibodies bind to the complexes. This is followed by a second wash to remove excess alkaline phosphatase labeled anti-human IgM antibodies. A luminescent substrate is added, and the enzymes in the complexes catalyze the luminescent substrate to form unstable excited state intermediates. When the excited intermediates return to the ground state, photons are emitted. The number of photons produced is positively correlated with the level of SARS-CoV-2 IgM antibodies in the sample. The more SARS-CoV-2 IgM antibodies present in the sample, the more IgM antibodies that are captured and enzyme-labeled. Producing more enzymes to catalyze substrates, during which more photons (RLU) will be produced. The number of photons (RLU) produced is directly correlated with the level of SAR-CoV-2 IgM antibodies in the sample.

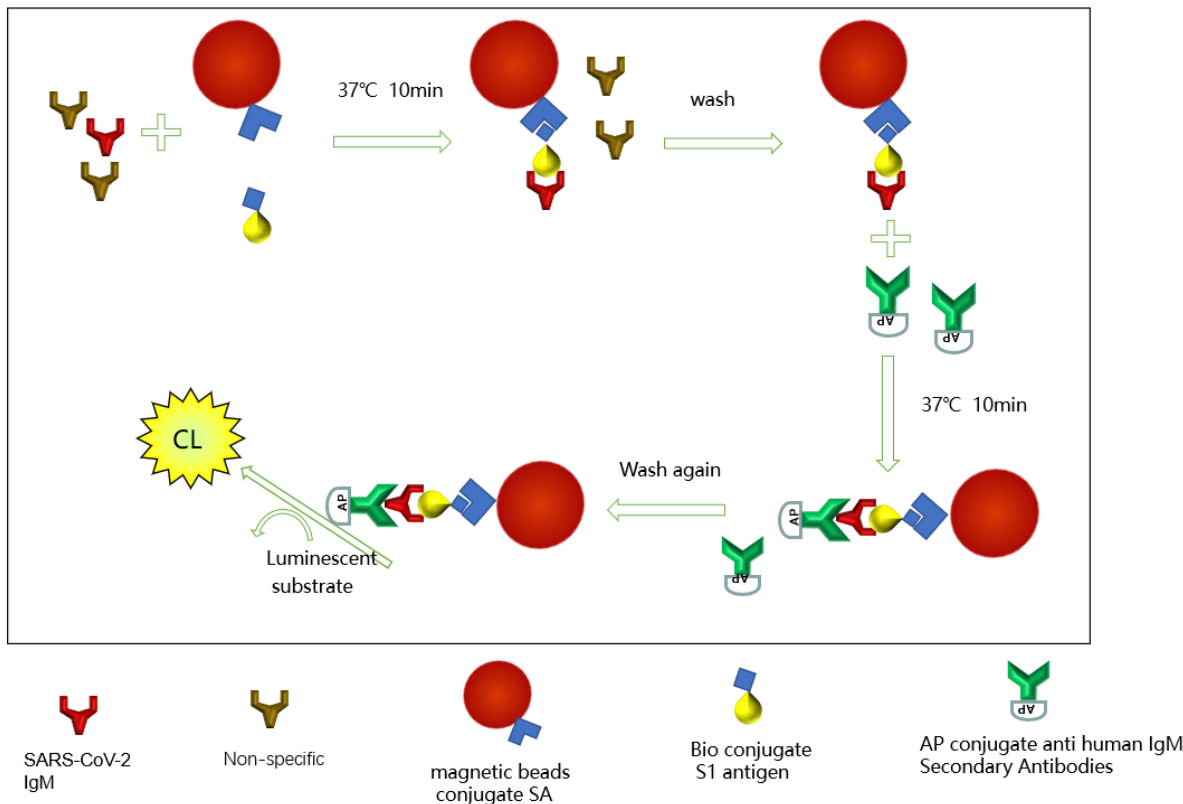


Figure 1: Schematic Diagram of the Reaction Principle of BioCheck SARS-CoV-2 IgM Antibody Test Kit

Warnings and Precautions

General Precautions

- For *in vitro* diagnostic use under the FDA Emergency Use Authorization.
- For Prescription Use Only
- For *in vitro* Diagnostic Use Only
- *Caution:* Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA and meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.



- Negative results do not rule out acute SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Testing with a molecular diagnostic should be performed to evaluate for acute infection in symptomatic individuals.
- The BioCheck SARS-CoV-2 IgM Antibody Test Kit is intended for single use only. Do not reuse.
- 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.
- Consider any materials of human origin as infectious and handle using standard biosafety procedures. No test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), human immunodeficiency virus (HIV 1+2) or other infectious agents are absent.
- Handle, use, store, and dispose of solid and liquid waste from samples and test components in accordance with procedures defined by appropriate national biohazard safety guidelines or regulations.
- The entire test procedure should be performed according to general biosafety guidelines of clinical labs. Protect cuts, abrasions and other skin damages and mucosa from contamination and infection.
- The BioCheck SARS-CoV-2 IgM Antibody Test Kit contain ProClin 300 (CAS 55965-84-9), which may cause an allergic skin reaction. Wear protective gloves when handling the kits. If skin contact occurs, wash with plenty of soap and water. If skin irritation or rash occurs, get medical advice/attention. Wash contaminated clothing before reuse.
- Do not substitute or mix reagents from different kit lots or from other manufacturers. In each kit, sufficient quantities of each component are provided.
- Test result of the same sample using kits from different manufacturers may have variations due to differences in factors such as methodology or antibody specificity.
- Contaminated or suspected contaminated serum specimens or reagents can produce erroneous results.
- Testing must comply with standard laboratory guidelines to prevent cross-contamination.
- Do not use kit after the expiration date.
- Read the package insert and operation manual carefully prior to performing test.

Safety Precautions

- Trained, qualified laboratory personnel should wear appropriate protective gear (gloves, lab coat, safety goggles) and exercise standard precautions for handling and disposing of infectious or potentially infectious materials (e.g. patient samples or consumables).
- All human source materials used in the preparation of the negative control have tested negative for antibodies to HIV 1&2, Hepatitis C and Hepatitis B surface antigen. However, no test method can ensure 100% efficiency. Therefore, all human controls and antigen should be handled as potentially infectious material. The Centers for Disease Control and Prevention and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.
- Materials used in the tests, including reagent cartridges and the sample collection device, should be disposed of according to federal, state and local regulations.
- Safety Data Sheets (SDS) are available upon request. If the product is a kit or is supplied with more than one component, please refer to the SDS for each component for hazard information.



CAUTION: You must have read and understood the contents of the instructions for use before attempting to run this assay. The contents of this document may be modified by BioCheck at any time. Check www.biocheckinc.com for the latest information.

Materials Provided

The BioCheck SARS-CoV-2 IgM Antibody Test Kit contains the following materials sufficient to perform ten (10) tests.

Kit Components

Table 1. Key Components of the SARS-CoV-2 IgM Antibody Test Kit

Kit Components	Quantity	Description
Cartridge	10 IgM cartridges	See Table 2.
Positive Control IgM	200 μ L \times 1	BSA-containing buffer with human SARS-CoV-2 S1 IgM antibody. Batch specific
Negative control IgM	200 μ L \times 1	BSA-containing buffer. Batch specific
QR code label	label	Contain positive controls and negative control reference values for IgM on the side of the kit box

Components of the Test Cartridge

The BioCheck SARS-CoV-2 IgM Antibody Test Kit cartridges (Figure 2) contain all the reagent components and accessories needed to run a test as shown in Table 2.

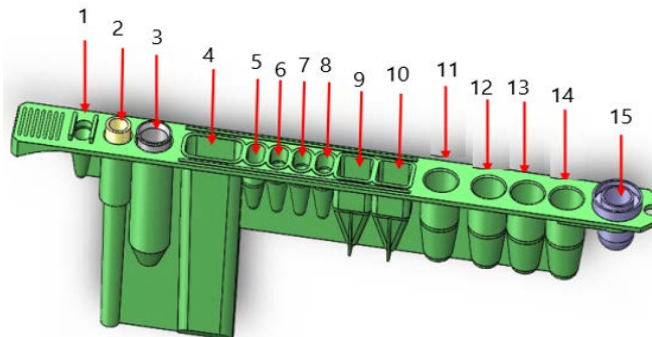


Figure 2. Schematic Diagram of Cartridge

Table 2. Components of the BioCheck SARS-CoV-2 IgM Antibody Test Kit Cartridges

#	Test Cartridge Components	Quantity	Main Composition
1	Sample Well	1	N/A
2	Pipette tip	1	N/A
3	Eluting sleeve	1	N/A
4	Wash buffer	4mL	0.95% Tween-20, 0.17%, Proclin 300 in Tris buffer
5	Luminescent substrate	180 μ L	APS-5 substrate
6	Magnetic separation reagent	60 μ L	Streptavidin labeled magnetic beads in PBS buffer

#	Test Cartridge Components	Quantity	Main Composition
7	Reagent A	80µL	Biotinylated SARS-CoV-2 S1 antigen, 0.1% Proclin 300 in Tris buffer
8	Reagent B IgM	130µL	ALP labeled Anti-human IgM antibody, 0.1% Proclin 300 in Tris buffer
9	Sample diluent	540µL	0.9% NaCl in buffer
10	Sample diluent	405µL	0.9% NaCl in buffer
11	Empty	N/A	Reaction Well
12	Empty	N/A	Wash Well
13	Empty	N/A	Wash Well
14	Empty	N/A	Reaction Well
15	Reading aperture	1	N/A

Materials Required But Not Provided

REF T-1001 MS Fast Chemiluminescent Immunoassay Analyzing System (MS Fast Analyzer) manufactured by Sophonix Co., Ltd. in Beijing, China

- Micropipette and tips for sample addition
- Sample collection materials and centrifuge

Reagent Storage, Handling and Stability

Proper storage and handling of reagents and samples are essential for the performance of the BioCheck SARS-CoV-2 IgM a Antibody Test Kits.

- Inspect package upon arrival. Kit components should be intact and complete with no leaking, damage, or contamination. All labels should be legible.
- If the foil seals are pierced, do not use the test cartridge.
- Remove kit from the shipping box and immediately store in a dark environment at temperatures between 2-8°C.
- Positive and negative controls are stable for 7 days at 2-8°C after opening.
- Test must be used immediately after opening.
- Do not use the kit after the expiration date. See the packaging label for the product expiration date.

Sample Requirements

Sample Collection and Preparation

- The BioCheck SARS-CoV-2 IgM Antibody Test Kit should only be performed on human serum samples.
- Collect specimens using universal precautions.⁴
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.⁵
- Follow instructions provided with your collection device for use and processing of the sample.⁶
- Ensure that complete clot formation in specimens has taken place prior to centrifugation.⁷
- Carefully transfer serum to a tightly sealed sterile container for storage.⁷



- Avoid use of icteric, hyperlipemic, hemolyzed, or contaminated sera which may cause erroneous results.

Sample Stability and Handling

- Serum samples should be tested within 4 hours at room temperature (approximate range 15-30°C (59-86°F)) after blood collection. If testing cannot be performed immediately, store the serum samples at 2-8°C for up to 24 hours.
- For long-term storage, store small aliquots of samples below -20°C. Avoid repeated freeze/thaw cycles of aliquots. Freeze-thaw damage can result if specimens are frozen in self-defrosting freezers. Thaw and mix samples well prior to use.

Quality Control

External Controls (Positive and Negative Controls)

QC should be performed upon receipt of each new lot or shipment. The detected positive control Relative Light Units (RLU) will be calculated with the standard RLU of the positive control in the QR code to obtain a correction coefficient (M , $M = b / a$). If the RLU of the negative control after correction by the correction coefficient falls within the specified range of the negative control, the correction proved to be accurate, thus reducing the error caused by different instruments.

The RLU of the sample corrected by the correction coefficient is compared with the cut-off value of the product, and the result is judged to be negative or positive. The above calculation process will be completed automatically by MS-Fast Analyzer, and the result will be reported. The negative and positive controls should result in negative and positive test results, respectively.

If the quality control test results of the positive or negative controls are not within the expected range, repeat the failed control test under the same conditions. A new QC test should be run to obtain the expected positive or negative result. If QC test failure persists, stop using the kit lot and contact the U.S distributor, Accelerate Diagnostics.

Positive and Negative Quality Control (QC) Testing

1. A rack of QC cartridges will take 30 minutes from test start until result acquisition.
2. Unpack the BioCheck SARS-CoV-2 Antibody Test Kit QC contents and equilibrate all materials to room temperature (15-30° C (59-86°F)) before use.
3. Insert four cartridges (two cartridges for positive controls, two cartridges for negative controls) into the reagent rack.



Figure 3: Inserting Controls Cartridges into Reagent Rack

- Using a micropipette with a fresh tip for each control, add 80 μ L of the appropriate controls to the corresponding sample wells of the cartridges.



Figure 4: Adding Controls to the Cartridge

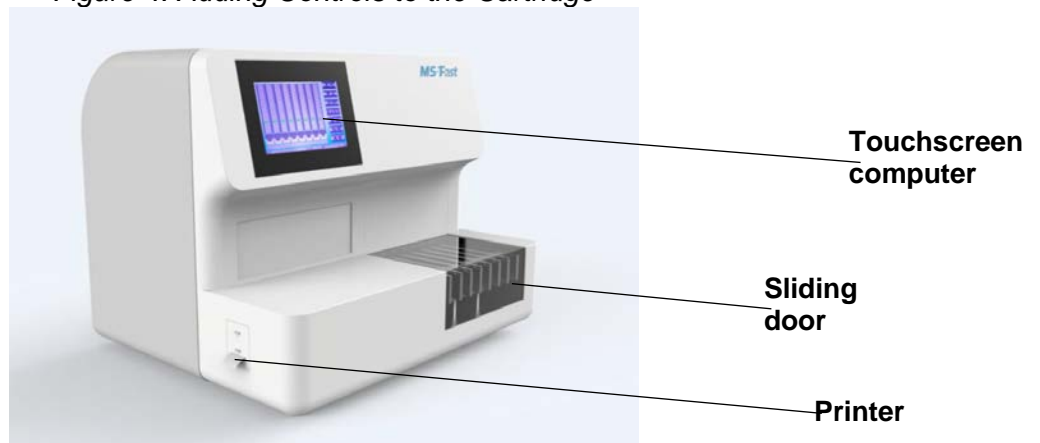


Figure 5: MS Fast Analyzer

- Open the door of the MS Fast Analyzer by sliding it to the left as shown in Figure 6.

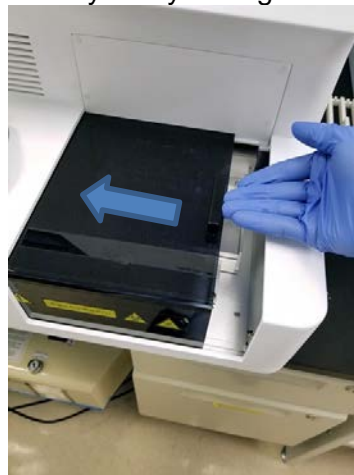


Figure 6: Opening Instrument Door

6. Insert the reagent rack, then close the sliding door as shown in Figure 7.

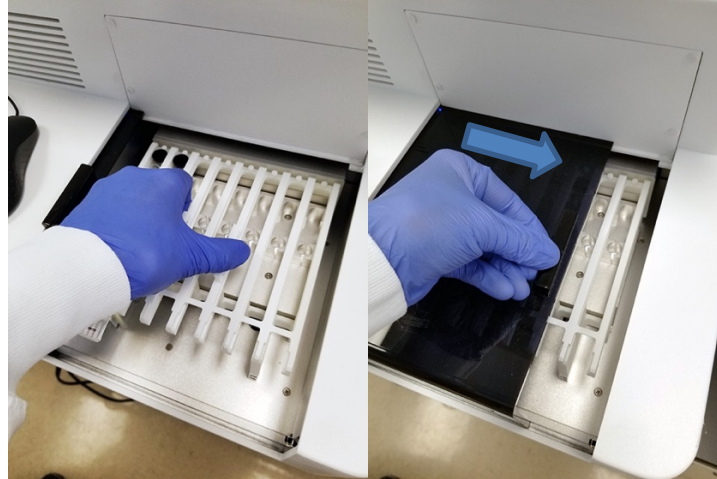


Figure 7: Inserting Rack and Closing Instrument Door



NOTE: The test result of the Negative Control must be negative (-) and the test result of the Positive Control must be positive (+). Otherwise, the kit is invalid, and troubleshooting is necessary to ensure proper function of the instrument reagents, control materials, or parameter settings.

NOTE: If this is the first time the lot or shipment is run:

- a. From the Main Window, select “Setting”.
 - b. In the Setting Window, select “Reagent Management”.
 - c. Select “SARS-CoV-2 IgM”.
 - d. Click “New batch”.
 - e. Scan each of the QR code labels on the side of the box with the handheld scanner. If the label cannot be scanned, the information can be manually input using the “Manual Input” button.
 - f. Select “Save Data”.
 - g. Repeat for the other antibody kit. Click “Back” when both QR code labels’ information has been saved.
7. From the “Run” screen, double click column corresponding to the cartridge position.
 8. Confirm the detected position is correct, then select the project name, lot number, and sample type (i.e., QC).
 9. Select positive or negative control and then click “Confirm”. The system will populate the required fields for IgM. Repeat until all controls have been entered.
 10. Click “Run” on the Home screen. The MS-Fast Analyzer will automatically identify the test project. When the run is complete, the QC results will automatically print. The QC report can be exported and reprinted.
 11. The MS-Fast report will indicate whether the control is valid or not. If the control is valid, the serum sample can be tested next. If the control is not valid, cause for the invalid control should be determined. See the MS-Fast User Manual for more information.

The expected test results for valid negative and positive controls are given below in Table 3.

Table 3. Expected RLU of IgM Positive and Negative Controls for Valid Runs

IgM Control	RLU	Interpretation and Next Steps
If both QC Negative Controls	<16,000	Valid QC Result
If one QC Negative Control	<16,000	Invalid QC Result. Repeat in duplicate
	≥16,000	
If both QC Negative Controls	≥16,000	Invalid QC Result. Repeat in duplicate
If both QC Positive Control	20,000 to 130,000	Valid QC Result
If one QC Positive Control	<20,000 or >130,000	Invalid QC Result. Repeat in duplicate
	20,000 to 130,000	
If both QC Positive Control	<20,000 or >130,000	Invalid QC Result. Repeat in duplicate



NOTE: When the negative QC and/or positive QC is not within range of the expected Relative Light Unit (RLU), the instrument should not be used to test samples. The QC should be repeated and if the QC fails again, please contact Accelerate Diagnostics Technical Support. The negative and positive controls should show correct results in order to have valid runs.

Procedure

Sample Testing

1. A rack of samples will take 30 minutes from test start until result acquisition.
2. The instrument can run up to eight samples at a time.
3. Unpack the IgM test cartridges and equilibrate all materials to room temperature (15-30° C (59-86°F) before use. Return all unused reagents to the refrigerator.
4. Insert one cartridge for each sample into the reagent rack. Ensure that test strips are locked into the rack (user should hear a click when inserted properly).
5. Using a micropipette, add 80µL serum to the sample well of each cartridge as shown in Figure 8.

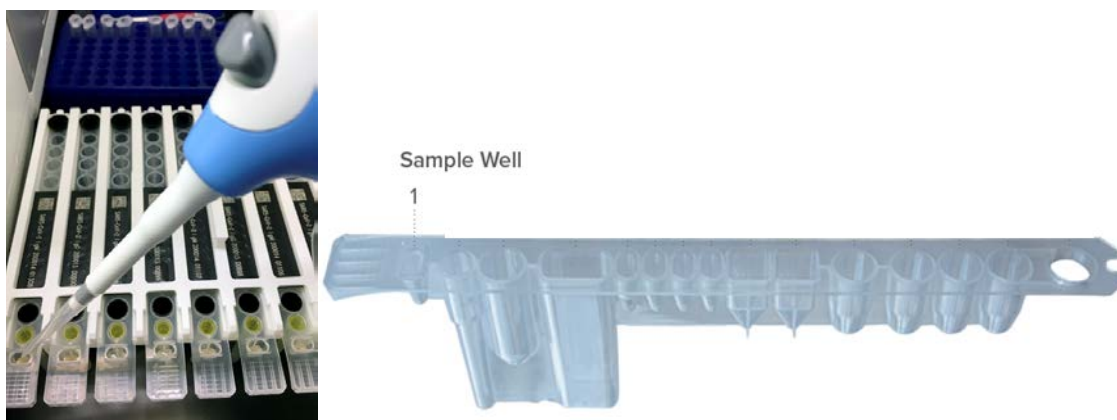


Figure 8: Test Cartridge Showing Sample Well

6. Slide door of the instrument to the left to open.
7. Insert the reagent rack.



8. From the Sample screen select the SARS-CoV-2 IgM project icon.
9. If using patient or sample barcodes, highlight the “Scan” field and scan in the unique patient (or sample) identifier barcodes using the external barcode scanner. Scan each barcode in the order of the samples in the rack. Click “Exit”.
10. If using manual sample entry, enter the number of samples to test in the “Sample #” field.
11. Push “add data” and double click the “Sample ID” field to manually edit the “Sample ID” field.
12. Click “Done” when complete and then click “Exit”.
13. Close the sliding door and click on “Run”. The MS-Fast Analyzer will automatically identify the test project and provide the final result when testing is complete.

Interpretation of Results

Cut-Off

The BioCheck SARS-CoV-2 IgM Antibody Test Kit assay uses the receiver operating characteristic (ROC) curve method to determine the positive cut-off value based on a selection of 157 clinically diagnosed serum specimens, including 52 positive serum samples and 105 negative serum samples. Statistical processing was performed to obtain the ROC curve, and the point with the largest Youden index was selected as the critical point, which is the positive cut-off value of the kit. The RLU corresponding to the SARS-CoV-2 IgM cut-off is 18500. When the RLU of the sample test result is ≥ 18500 , the result is positive. When the RLU of the sample test result is < 18500 , the result is judged as negative.

Valid Results

The MS-Fast Analyzer produces the test result when the assay run is complete. Patient sample test results should only be interpreted if the QC test result was valid. The expected test results for valid negative and positive QC results are given in Table 4.

Table 4. Interpretation

IgM Test		Test Result Interpretation
Result Reported	RLU Expected	
Positive	≥ 18500	Positive for SARS-CoV-2 IgM antibodies
Negative	< 18500	Negative for SARS-CoV-2 IgM antibodies

Invalid Runs

When the negative control or positive control is not within range of the expected RLU, the test result is not valid and, therefore, the assay should not be used to report results. The positive and negative controls should show passing results prior to running patient specimens.

Limitations of the Procedure

- The product can only be used with MS-Fast Automated Chemiluminescent Immunoassay Analyzing System.
- The BioCheck SARS-CoV-2 IgM Antibody Test Kit has not been evaluated for specimens other than human serum.
- Samples that are contaminated or suspected of contamination cannot be used for testing.



- The assay should not be used to diagnose or exclude acute infection. Results are not intended to be used as the sole basis for patient management decisions.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- A negative or non-reactive result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody detected by the test.
- The clinical significance of the test results of the kit needs to be analyzed in combination with other test indicators and clinical manifestations.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, alternative serology test to confirm an immune response.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.
- Assay performance characteristics have not been established for testing cord blood, for testing neonates, for prenatal screening, or for general population screening.
- Results from immunosuppressed patients must be interpreted with caution.
- Failure to observe proper procedures for sample collection, preparation, storage, handling, and/or transportation may cause incorrect results.
- The kit has not been tested with all types of blood collection tubes that are commercially available. For different blood collection tubes from different manufacturers, different results may be obtained due to different raw materials and additives.
- Not for the screening of donated blood.

Conditions of Authorization for the Laboratory

The BioCheck SARS-CoV-2 IgM Antibody Test Kit Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

Authorized laboratories using the BioCheck SARS-CoV-2 IgM Antibody Test Kit must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

- Authorized laboratories^a using the BioCheck SARS-CoV-2 IgM Antibody Test Kit will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories will use the BioCheck SARS-CoV-2 IgM Antibody Test Kit as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the product are not permitted.
- Authorized laboratories that receive the BioCheck SARS-CoV-2 IgM Antibody Test Kit will notify the relevant public health authorities of their intent to run the assay prior to initiating testing.



- Authorized laboratories using the BioCheck SARS-CoV-2 IgM Antibody Test Kit will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the BioCheck SARS-CoV-2 IgM Antibody Test Kit and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH.EUA.Reporting@fda.hhs.gov) and Biocheck Technical Support (<https://BioCheckInc.com>) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of the assay of which they become aware.
- All laboratory personnel using the BioCheck SARS-CoV-2 IgM Antibody Test Kit must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the BioCheck SARS-CoV-2 IgM Antibody Test Kit in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the the BioCheck SARS-CoV-2 IgM Antibody Test Kit.
- BioCheck Inc., authorized distributors, and authorized laboratories using the BioCheck SARS-CoV-2 IgM Antibody Test Kit will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

^a The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate and high complexity tests" as "authorized laboratories".

Performance Characteristics

Clinical Performance

Clinical studies were conducted using a total of two hundred fifty-three (253) patient samples obtained from China and the United States. One hundred fifty-three (153) of the samples were collected from individuals at two clinical trial institutions in China. Of the 153 samples, 110 had tested positive for SARS-CoV-2 and the other 43 samples tested negative for SARS-CoV-2, both using a comparator PCR testing method. An additional one hundred (100) known negative samples collected in the United States prior to December 2019 from a biobank tested negative for SARS-CoV-2 using a comparator PCR testing method.

For the 110 positive samples obtained from clinical trial institutions in China, 105 IgM test results were positive. For the 143 negative samples, comprising 43 pre-pandemic samples from China and 100 pre-pandemic samples from the United States, 139 IgM test results were negative.

By comparing with the diagnostic results of a nucleic acid detection method, the positive percent agreement (PPA) and negative percent agreement (NPA) of the BioCheck SARS-CoV-2 IgM Antibody Test Kit were determined and shown in Table 5 and Table 6.

Table 5. IgM PPA

Days Post Symptom Onset	# PCR Positive At Any Time	BioCheck SARS-CoV-2 IgM Antibody Test Kit		
		# Of Positive Results	PPA	95%CI
≤7	7	7	100%	64.57% -100%
8-14	16	15	93.75%	71.67% - 98.89%
≥15	9	8	88.89%	56.50% - 98.01%
unknown	78	75	96.15%	89.29% - 98.68%

Overall IgM PPA: 95.45% (105/110); [95% (89.80% - 98.04%)]

Table 6. IgM NPA

# PCR Negative	BioCheck SARS-CoV-2 IgM Antibody Test Kit		
	# Of Negative Results	NPA	95%CI
143	139	97.20%	93.0% - 99.2%

Analytical Performance

Cross-Reactivity

Cross-reactivity of the BioCheck SARS-CoV-2 IgM Antibody Test Kit was evaluated by judging positive and negative results of specimens serologically positive for other known coronaviruses, respiratory pathogens (both bacterial and viral), and other blood-borne pathogens against the SARS-CoV-2 IgM test.

No cross-reactivity was detected when anti-sera for the following infectious agents was tested on the SARS-CoV-2 IgM test: Human coronavirus panel 229E/HKU1, Human coronavirus panel OC43/NL63, Parainfluenza 1, Parainfluenza 3, Parainfluenza 4, Adenovirus, Rhinovirus, *Mycoplasma pneumonia*, HBV, HCV, Influenza A, Influenza B, and Respiratory Syncytial Virus.

Table 7. Cross-Reactivity

Conditions	Number of Samples
anti-influenza A IgM	5
anti-influenza B IgM	5
anti-HCV IgM	5
anti-HBV IgM	5
anti-Haemophilus influenzae IgM	5
Human coronavirus panel 229E/HKU1	5
Human coronavirus panel OC43/NL63	5
ANA	5
anti-respiratory syncytial virus IgM	5

In addition, one hundred (100) known negative samples were collected in the US prior to December 2019 from a population with a high prevalence of vaccination and/or infection and were tested to evaluate potential cross-reactivity. The specificity of IgM test was 96%.

Interference

Low titer SARS-CoV-2 IgM antibody positive serum samples and SARS-CoV-2 IgM antibody negative serum samples were spiked with one of the following substances to specified concentrations. No false-positivity or false-negativity was found.

Table 8. Interference

Interfering Substance	Concentration IgM
Hemoglobin	10 mg/mL
Bilirubin, conjugated	0.4 mg/mL
Bilirubin, unconjugated	0.4 mg/mL
Triglycerides	15 mg/mL
Cholesterol	4 mg/mL
Human anti-mouse antibody	800 ng/mL
Rheumatoid factor	2000 IU/mL
Human serum albumin	60 mg/mL
Histamine hydrochloride	4 mg/mL
α-IFN	200 mg/L
Zanamivir	1 mg/L
Oseltamivir carboxylate	1 mg/L
Abidol	40 mg/L
Levofloxacin	200 mg/L
Ceftriaxone	400 mg/L
Meropenem	200 mg/L
Tobramycin	10 mg/L
Ribavirin	40 mg/L
Biotin	3500 ng/mL

Reproducibility

For the BioCheck SARS-CoV-2 IgM Antibody Test Kit, five (5) positive samples and two (2) negative samples, respectively, were selected and each sample was tested in duplicate by two (2) different operators at two (2) different labs with three (3) different lots/batches of kits for five (5) consecutive days, resulting in a total of 30 test results per sample. Inter/ intra assay, inter-lab, and inter-lot reproducibility was determined and shown in Table 9.

Table 9. IgM Reproducibility

			Inter- assay		Intra-assay		Between-Days		Between-Lot		Total Precision	
Sample ID	Mean Value	N	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Low Positive	25489	30	1845	7.24	1838	7.16	266	1.04	1821	7.15	2053	8.1
Moderate Positive	83086	30	5405	6.51	4182	5.07	2308	2.78	5379	6.47	5504	6.6
High Positive	203001	30	15794	7.78	12383	6.15	8783	4.33	14595	7.19	18413	9.1
Positive	112485	30	8943	7.95	8224	7.30	2185	1.94	8875	7.89	9708	8.6
Positive	65574	30	5312	8.10	4741	7.24	2419	3.69	5377	8.20	5620	8.6
Negative	5674	30	375	6.60	319	5.64	176	3.10	387	6.82	406	7..2
Negative	14027	30	879	6.27	801	5.72	268	1.91	878	6.26	930	6.6

References

1. Modes of transmission of virus causing COVID-19: implications for IPC precaution recommendations (<https://www.who.int/news-room/commentaries/detail/modes-of-transmission-of-virus-causing-covid-19-implications-for-ipcprecaution-recommendations>)
2. IFCC Information Guide on COVID-19 (<https://www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/>)
3. Lai et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and coronavirus disease-2019 (COVID-19): The epidemic and the challenges. *International Journal of Antimicrobial Agents*. 55:3; 2020.
4. Clinical and Laboratory Standards Institute. *Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2014. CLSI Document M29-A4.
5. Clinical and Laboratory Standards Institute. *Collection of Diagnostic Venous Blood Specimens. Seventh Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2017. CLSI Document GP41.
6. Clinical and Laboratory Standards Institute. *Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard-Sixth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2017. CLSI Document GP39-A6.
7. Clinical and Laboratory Standards Institute. *Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*. Wayne, PA: Clinical and Laboratory Standards Institute; 2010. CLSI Document GP44-A4.

MS-Fast

Automated Chemiluminescent Immunoassay Analyzing System Manual



**For Use under an Emergency Use Authorization
(EUA) Only**
FOR *IN VITRO* DIAGNOSTIC USE

REF

T-1001 or A01



Sophonix Co.,Ltd.

Address: 301 Building #19, #8
Liangshuihe 2nd Street
Economical & Technological
Development Zone
100176 Beijing
Tel: 010-67898607
Fax: 010-67898607-8018
www.sophonix.net



Europe, Middle East, and Africa

Accelerate Diagnostics S.L.

08007 Barcelona- Spain
E-mail: support.emea@axdx.com
Technical Support:

+34 932204547 (Spain)
+46 844683447 (Sweden)
+44 2080680697 (United Kingdom)
+33 411920245 (France)
+31 718080145 (Netherlands)
+39 0694802890 (Italy)
+43 800 291257 (Austria)
+351 220280007 (Portugal)
+49 8001813437 (Germany)

Fax: +34 935207582
www.axdx.com



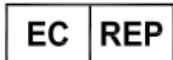
BioCheck, Inc.

Address: 425 Eccles Avenue
South San Francisco, CA 94080 USA
Tel: (650)573-1968
Fax: (650)573-1969
www.biocheckinc.com



Accelerate Diagnostics, Inc.

Carrer Consell de Cent 333- 7ª planta
3950 S. Country Club Road, Suite 470
Tucson, AZ 85714 USA
E-mail: support@axdx.com
Technical Support: 1-888-586-2939
Fax: 1-520-269-6580



CMC MEDICAL DEVICES & DRUGS S.L.

C/ Horacio Lengo Nº 18, CP 29006
Málaga, Spain
Tel: +34 951 214 054
Email: info@cmcmmedicaldevices.com

Most Recent Labeling Documents
















www.adx.com/support
Keycode: ADX41446




Table of Contents

Symbols List.....	1
1 About this manual.....	3
2 About MS-Fast	3
2.1 Intended Use	3
2.2 Specifications and performance.....	4
3 Details of MS-Fast.....	4
3.1 Principle of detection.....	4
3.2 MS-Fast components.....	5
4 Storage and Operation of the Equipment	7
4.1 Environmental conditions and placement instructions	7
5 Software Description	8
5.1 Software Overview.....	8
5.2 System startup.....	8
5.3 Log in.....	9
5.4 Initialization check.....	10
5.5 Main window.....	11
5.6 Run window	11
5.7 Sample window.....	13
5.8 Result window.....	16
5.9 Setting window.....	20
5.10 Start initialization.....	24
5.11 Shut down.....	24
6 Instrument warnings and precautions	25
6.1 Precautions.....	25

7 Troubleshooting	26
8 Equipment maintenance.....	27
8.1 Weekly maintenance.....	27
8.2 Monthly maintenance.....	28
8.3 Recommended regular maintenance	28
8.4 Replacing the internal printer paper	28

Symbols List

Symbol	Description	Symbol	Description
	In vitro diagnostic equipment		Catalog Number
	Batch Code	SN	Serial Number
	Power on	○	Power off
	Do Not Re-Use		Contains Sufficient for <n> Tests
CE	CE-Marking of Conformity		Authorized Representative in the European Community
	Temperature Limit		Use-By Date
	Consult Electronic Instructions for Use	Rx only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Manufacturer		Date of Manufacture
	Distributor		Importer

Symbol	Description	Symbol	Description
	High temperature, do not touch these areas		Biological hazard
	Note, refer to the attached file		

1 About this manual

This manual contains the MS-Fast Automated Chemiluminescent Immunoassay Analyzing System (hereinafter referred to as "MS-Fast") produced by Sophonix Co.,Ltd. and distributed by Accelerate Diagnostics, Inc. Please read this manual carefully before attempting to operate MS-Fast.

2 About MS-Fast

This section includes the intended use, operating characteristics, and instrument performance of the MS-Fast Analyzer.

2.1 Intended Use

The MS-Fast Analyzer is an automated discrete loading chemiluminescence enzyme-linked immunosorbent assay (CLEIA) and magnetic particle separation analyzing system that uses indirect chemiluminescence based, on a chemiluminescent substrate (APS-5) and alkaline phosphatase. The BioCheck SARS-CoV-2 IgM and IgG Antibody Combo Test Kit is for qualitative detection and differentiation of IgG and IgM antibodies to SARS-CoV-2 in human serum using the MS-Fast Automated Chemiluminescent Immunoassay Analyzing System. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

- The BioCheck SARS-CoV-2 IgM and IgG Antibody Combo Test Kit has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA and meets requirements to perform moderate or high complexity tests.
- The BioCheck SARS-CoV-2 IgM and IgG Antibody Combo Test Kit has been authorized only for the presence of IgG or IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- The BioCheck SARS-CoV-2 IgM and IgG Antibody Combo Test Kit is only authorized for the duration of the declaration that circumstances exist justifying the authorization of

emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

2.2 Specifications and performance

Instrument type	Automated chemiluminescent immunoassay analyzing system
Model	MS-Fast Analyzer
Detection batch	8-channel parallel detection
Sample material	Serum
Sample volume	80ul
Wavelength	300-650nm
Data storage	Patient data: more than 100,000 samples (tests)
QC data	More than 100,000 results
Size	508 (W) x 586 (D) x 343 (H) mm
Weight	40 kg
Electrical requirements	110/220 VAC
Rated power supply	110/220V 60/50 Hz 200W
Printer	Built in
Computer	Built in
Screen	7 in LCD touch screen (800 x 600) px
Operating System	Microsoft Windows10 Professional

3 Details of MS-Fast

This section describes the measurement principle, equipment structure, and accessories used in MS-Fast.

3.1 Principle of detection

The detection principle used by MS-Fast is Chemiluminescent Enzyme Immunoassay (CLEIA), and the reagents used in each test are stored in a special, individually packaged cassette sealed with aluminum foil.

The MS-Fast detection principle is described by applying the sandwich immunoassay reaction mode. The sample is combined with an alkaline phosphatase-labeled antibody and a biotinylated antibody to form a sandwich structure. The excess streptavidin-coated magnetic particles form a complex with the biotinylated antibody, and after washing, the luminescent substrate is

catalytically cleaved by an enzyme in the complex to form an unstable excited intermediate.

When the particle returns to the ground state, it emits photons. The light intensity of the reaction is detected by a photomultiplier tube, and the luminescence intensity of the analyte is converted into relative light units (RLU) by the instrument operating software.

3.2 MS-Fast components

This section describes the components of the MS-Fast and their functions.

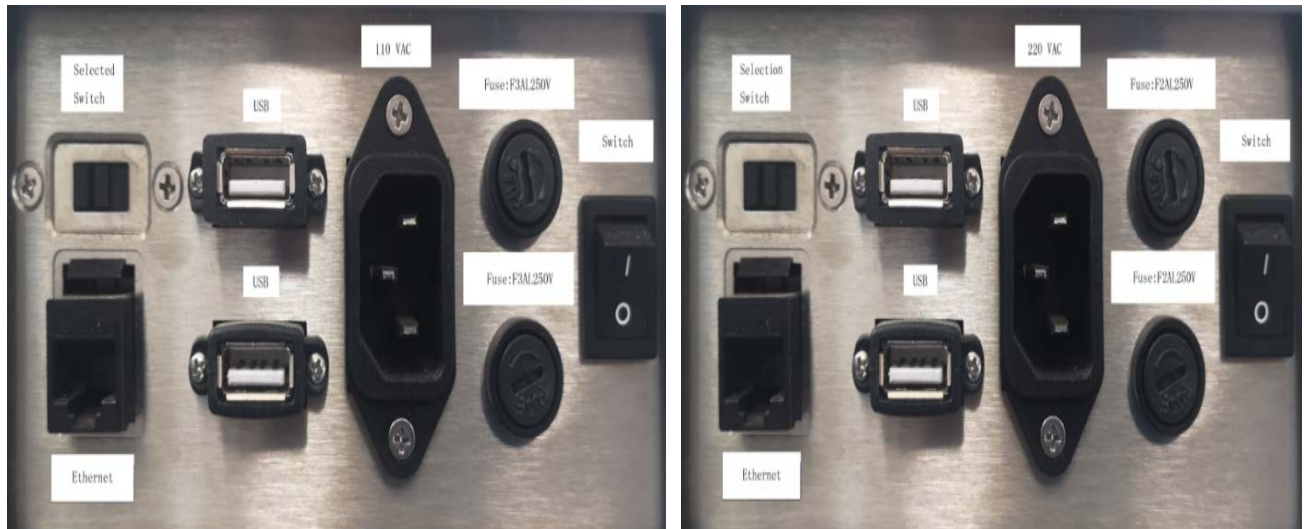
3.2.1 Front of the Device

The necessary components for operating the MS-Fast are located at the front and side of the unit; see the figure below. Component names and functions are described as follows:



- **Touchscreen computer** - Displays various information about the MS-Fast Analyzer and accepts input from the user operating the device. Select the appropriate program.
- **Sliding door** - Slide to the left to open; insert the rack after opening. The instrument automatically scans the barcode, and the user can read the cassette information and select the appropriate program.
- **Printer** - Prints results and other information.

3.2.2 Back of the Device



Supply voltage = 110VAC

Supply voltage = 220VAC

The input and output ports of the device are mainly located on the back of the device, as shown in the figure above.

- **Switch** – This is the main power switch of the device. After the instrument is turned on, the computer powers up in about 1 minute.
- **USB** – Provides connection to the internal instrument computer.
- **110/220 VAC** – Provides connection to the power cable.
- **Fuse: F2AL250V/F3AL250V** – Protects the internal circuitry of the instrument.
- **Selected Switch** – For use by manufacturer or distributor

3.2.3 Accessories

Information on the main MS-Fast accessories is shown in the table below.

Main Accessories Description	Quantity	Remarks
Power cord	1	Standard
Fuse: F2AL250V/F3AL250V	2	Alternate replacement
Cartridge rack	1	Standard



4 Storage and Operation of the Equipment

4.1 Environmental conditions and placement instructions

4.1.1 Normal working conditions

- 1) Altitude: no more than 2000m
- 2) Power supply voltage: 110-220V 50/60 Hz 200W
- 3) Ambient temperature: 10 ° C ~ 30 ° C;
- 4) Relative humidity: ≤70%;
- 5) Atmospheric pressure: 85.0 kPa to 106.0 kPa;
- 6) Keep away from magnetic field interference sources, e.g., MRIs;

4.1.2 Placement instructions

- 1) The instrument should be placed on a flat, stable surface.
- 2) The rear panel of the instrument requires a distance of >200 mm for access the power switch and ventilation.
- 3) Avoid placing the MS-Fast in a place where it is exposed to direct sunlight, air conditioning, or other equipment.
- 4) Do not block the device vents, and ensure that there is no paper or other objects that may affect the air circulation in this area.
- 5) MS-Fast is placed at an altitude of no more than 2000 meters.

5 Software Description

5.1 Software Overview

This section describes the software used with MS-Fast.

5.1.1 Software Environment

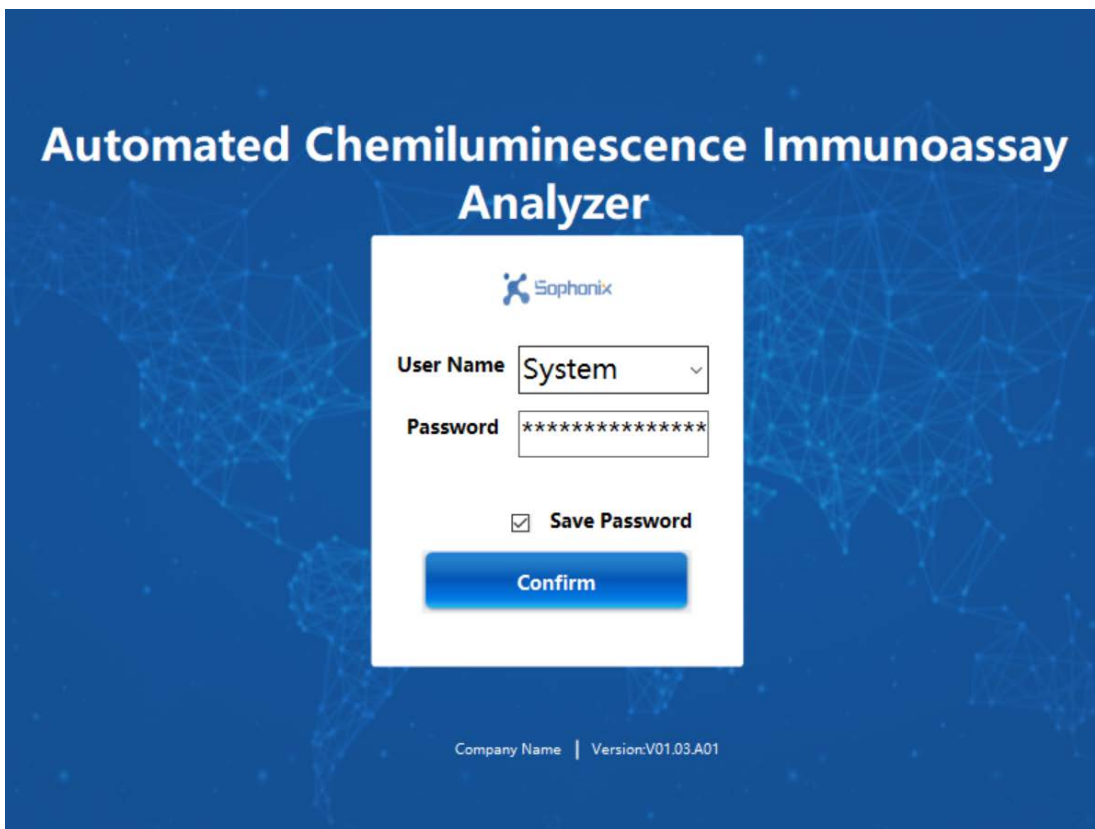
- 1) Uses a custom 7-inch touch screen, with a resolution of 800X600 px
- 2) Microsoft Windows10 Professional operating system.

5.2 System startup

Power on the system using the power switch. If the Sophonix software does not automatically start, double-click the desktop shortcut “POCT_Soft Ware”.



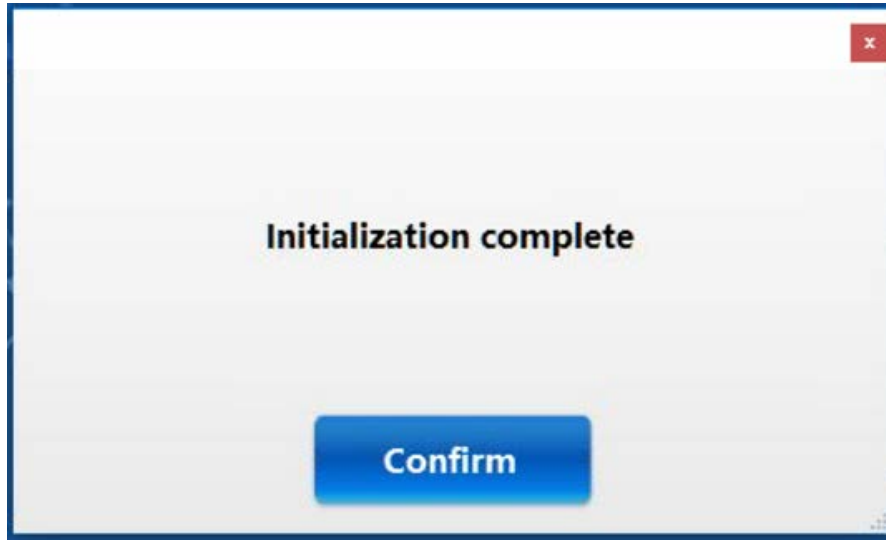
5.3 Log in



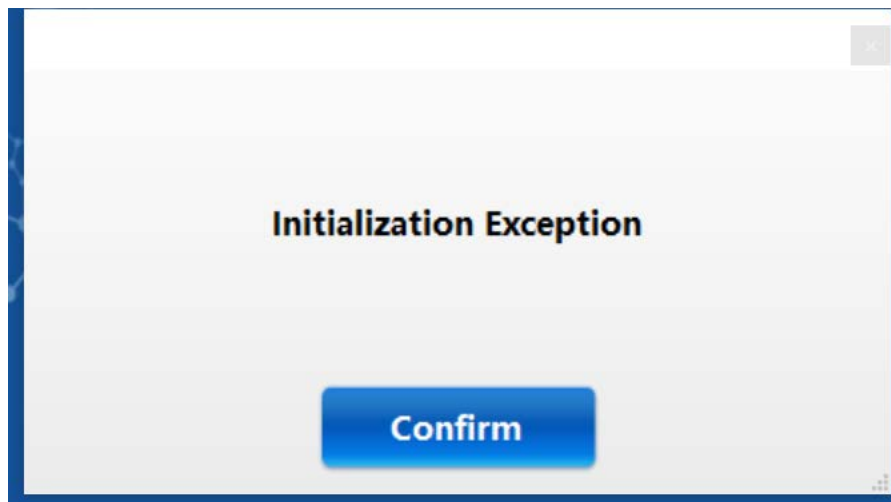
- 1) To log in, enter the username and password, you can select whether to save the password. When the "Confirm" button is clicked, the system checks the username and password, and then login to the system is completed after meeting the system requirements.
- 2) Usernames are used to distinguish system permissions: user permissions are divided into four levels: A, B, C, and D.
 - Permission A and B: for manufacturing or distributor use
 - Permission C: administrative permissions (user permissions, user settings, re-collection of calibration curves, etc.)
 - Permission D: user permission (sample detection, calibration, quality control, result query, report printing, adding new batch of reagents)

5.4 Initialization check

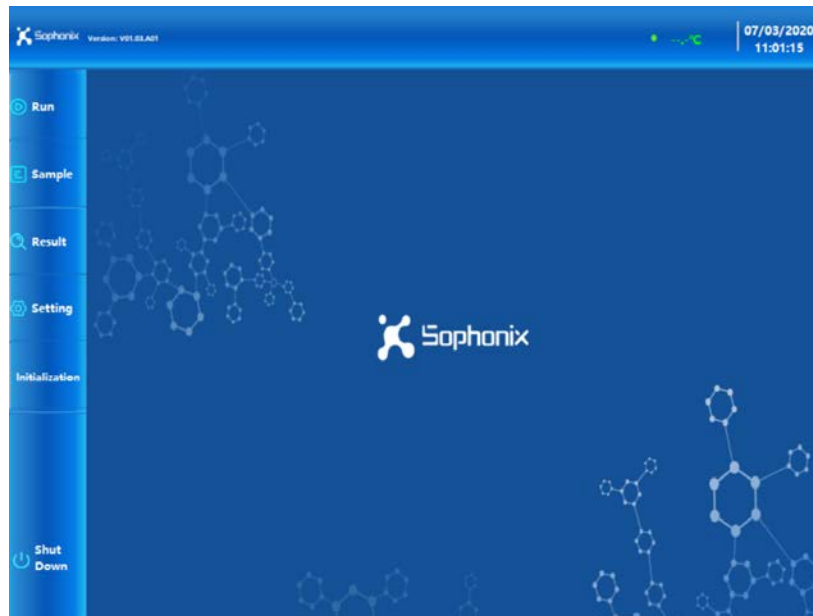
- 1) After login the system will initialize. A dialogue box will show “Initialization complete”, and click on the “Confirm” box to access the main window.



- 2) If an error, like the ones below, is encountered contact customer support.



5.5 Main window



- 1) Click "Run" to enter the device running window
- 2) Click on "Sample" to go to the Edit Samples window
- 3) Click "Result" to enter the results query window
- 4) Click "Setting" to enter the settings window.

5.6 Run window

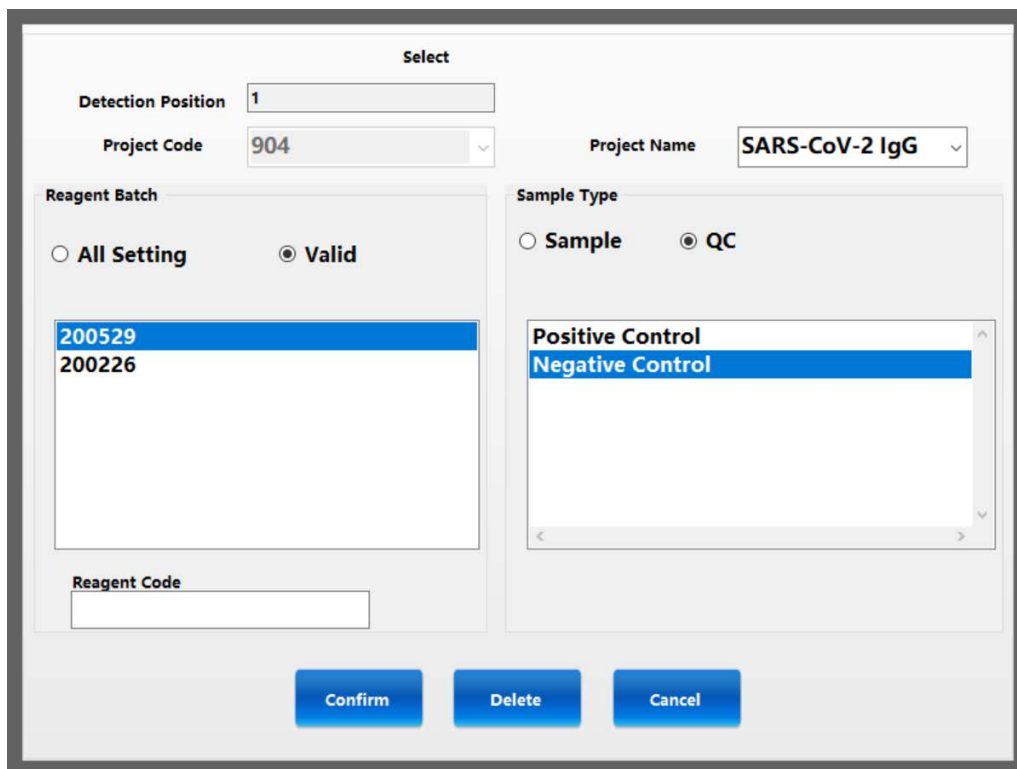
The "Run" window is the core part of the normal operation and shows the status of the instrument. The whole operation process is carried out in this window.



5.6.1 Routine detection settings

All pertinent information, such as the project, sample, and batch number can be manually added on a channel by channel basis from the "Run" Window.

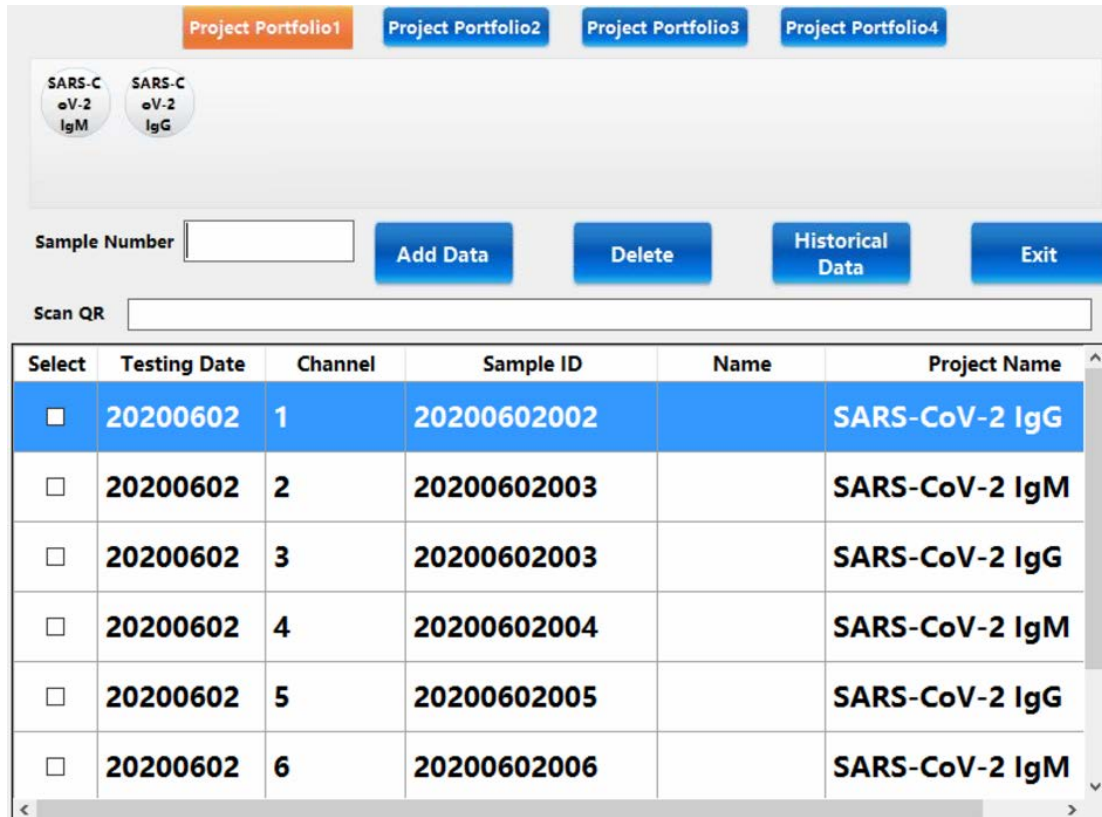
- 1) Double-click the "Project" or "Sample" positions to pop up a window for selection.



- 2) Confirm detection position is correct, and then select the project name, batch number, and sample type (Sample or QC).

5.7 Sample window

The “Sample” window allows you to add the sample and project information for the cassettes, as well as display sample and project information that has been set, edit patient information for samples, and more.



Select	Testing Date	Channel	Sample ID	Name	Project Name
<input type="checkbox"/>	20200602	1	20200602002		SARS-CoV-2 IgG
<input type="checkbox"/>	20200602	2	20200602003		SARS-CoV-2 IgM
<input type="checkbox"/>	20200602	3	20200602003		SARS-CoV-2 IgG
<input type="checkbox"/>	20200602	4	20200602004		SARS-CoV-2 IgM
<input type="checkbox"/>	20200602	5	20200602005		SARS-CoV-2 IgG
<input type="checkbox"/>	20200602	6	20200602006		SARS-CoV-2 IgM

5.7.1 Scan Accession number

- 1) Select the project(s) for the cassette and then scan the accession number into the “Scan QR” toolbar.
- 2) If you do not want to wish to add an accession number, the cassette QR code can be scanned instead or use the “Add Data” button shown below.

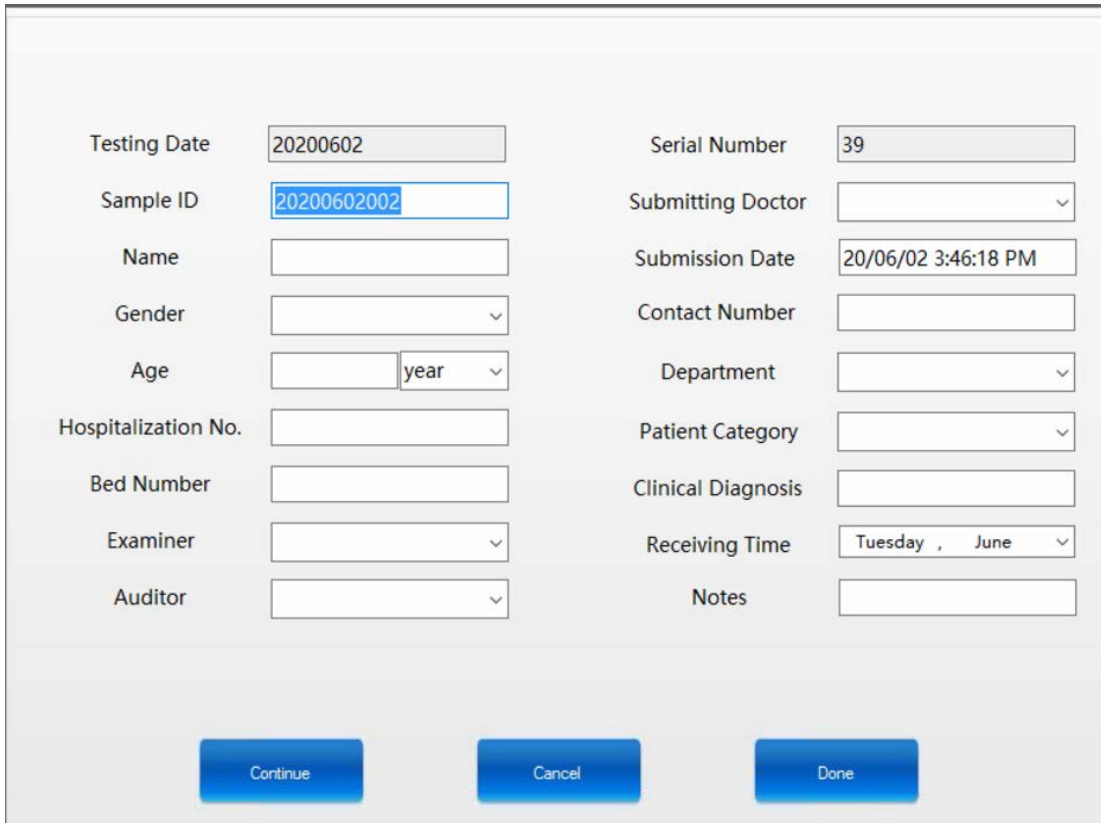
- 3) Add data 

Select the project and enter the number of samples. Click "Add Data" to automatically fill in "Testing Date", "Channel", "Sample ID".

NOTE: Date of testing and results follow the Year-Month-Day format.

5.7.2 Edit record

- 1) Double-click the record to go to the edit information interface.

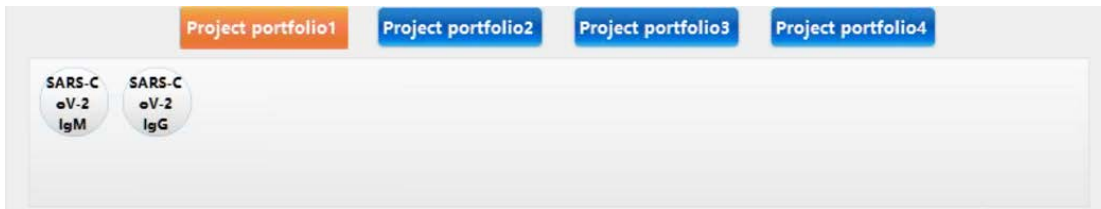


The screenshot displays a form for editing a record. The form is organized into two columns of fields. The left column includes: Testing Date (20200602), Sample ID (20200602002), Name, Gender, Age (with a 'year' dropdown), Hospitalization No., Bed Number, Examiner, and Auditor. The right column includes: Serial Number (39), Submitting Doctor, Submission Date (20/06/02 3:46:18 PM), Contact Number, Department, Patient Category, Clinical Diagnosis, Receiving Time (Tuesday, June), and Notes. At the bottom of the form are three blue buttons: 'Continue', 'Cancel', and 'Done'.

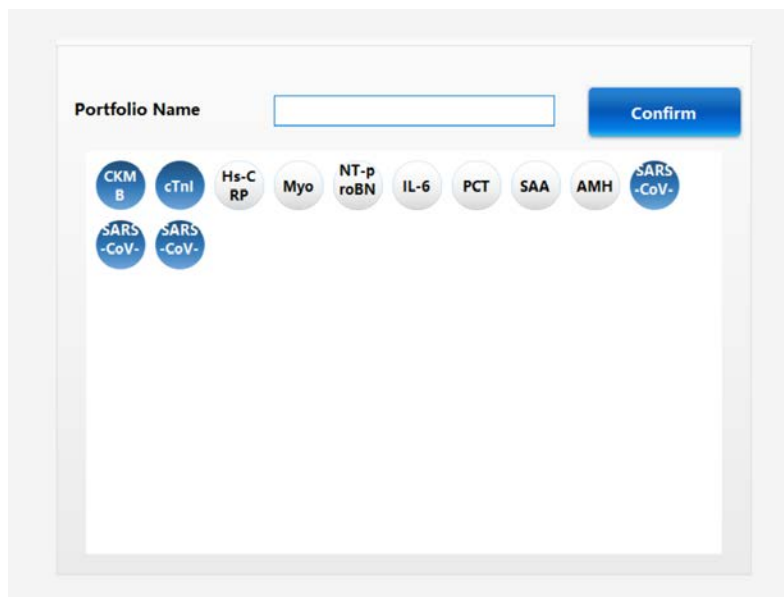
- 2) Fill in the corresponding data, click the "Continue" button to save the current data, and load the data for the next cassette slot.
- 3) Click the "Cancel" button to cancel the current operation.
- 4) Click the "Done" button to close the current interface and return to the previous interface.

5.7.2 Set up project portfolio

- 1) Double-click the project portfolio button at the top to enter the portfolio Settings window.



- 2) Go to the portfolio settings.



- 3) Modify the combination name and select or deselect the project name, blue is selected, white is deselect. Click the "Confirm" button to save the current setting item information.



5.7.3 Delete data

Select a row record and click the "Delete" button to delete the selected record data.



5.7.4 Historical data

- 1) Click to enter the history interface for querying sample information. Update the testing date range and click search.

Testing Date: Friday, May 29, -- Tuesday, June 2

Search **Exit**

Testing Date	Channel	Sample ID	Name	Age	Gender	Project N.
20200602	1	20200602001				SARS-Co
20200602	2	20200602001				SARS-Co
20200602	1	192020_01				SARS-Co
20200602	2	192020_01				SARS-Co
20200602	3	192020_03				SARS-Co
20200602	4	192020_03				SARS-Co
20200602	5	192020_04				SARS-Co
20200602	6	192020_04				SARS-Co

- 2) According to the date of detection, query all sample information for the period of time.
 Double-click the record to go to the edit Information screen.



5.7.5 Exit

Exit the current interface

5.8 Result window

In the "Result" window, you can query the experimental results, including the test results, the calibration results and quality control results.

Find Sample
Find Calibration
Find QC
Exit

Testing Date Tuesday , June 2, ▾ -- Tuesday , June 2, ▾

Project ▾

Sample ID **Name**

Search
Upload to Host
Print Result
Print List
Export
PDF
Export-Excel

All Select

Select	Testing Date	Submission Time	Detection Time	Channel	Sample ID

5.8.1 Find Sample

Find Sample

- 1) After entering the " Result " window, the software automatically displays to the "Find Sample" interface.

Find Sample
Find Calibration
Find QC
Exit

Testing Date Tuesday , May 26, ▾ -- Tuesday , June 2, ▾

Project ▾

Sample ID Name

Search
Upload to Host
Print Result
Print List
Export
PDF
Export-Excel

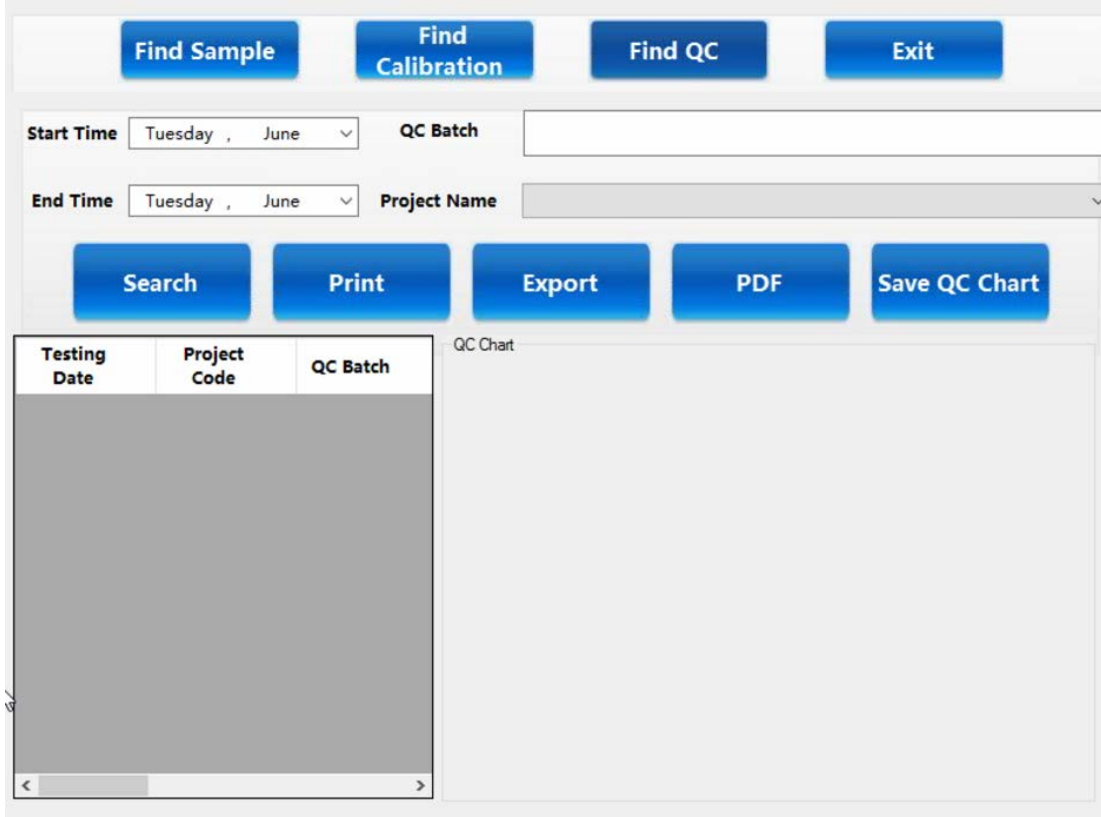
All Select

Select	Testing Date	Submission Time	Detection Time	Channel	Sample
<input checked="" type="checkbox"/>	20200602	2020-06-02 10:33:22	2020-06-02 10:50:22	1	2020060200
<input checked="" type="checkbox"/>	20200602	2020-06-02 10:33:22	2020-06-02 10:50:22	2	2020060200
<input checked="" type="checkbox"/>	20200602	2020-06-02 12:59:39	2020-06-02 13:33:00	1	192020_01
<input checked="" type="checkbox"/>	20200602	2020-06-02 12:59:39	2020-06-02 13:33:00	2	192020_01
<input checked="" type="checkbox"/>	20200602	2020-06-02 13:00:02	2020-06-02 13:33:00	2	192020_02

- 2) Under this interface, you can select the date of Detection, and “Project”, query by “Sample ID” or “Name”. The “Testing Date” is mandatory to see results, while all other search criteria is optional. If you do not enter information, you do not select the condition.
- 3) Click the “Search” button to retrieve the experimental results of all samples under the current selection condition and display them in the data area below.
- 4) Click “Upload to Host” to upload the results of the current query to the LIS system.
- 5) Click “Print List” to print the record of the current query by list.
- 6) Click “Export” to export the data and save the format as text.
- 7) Click “Export-Excel” to export the data and save the format as Excel.

5.8.2 Find QC Find QC

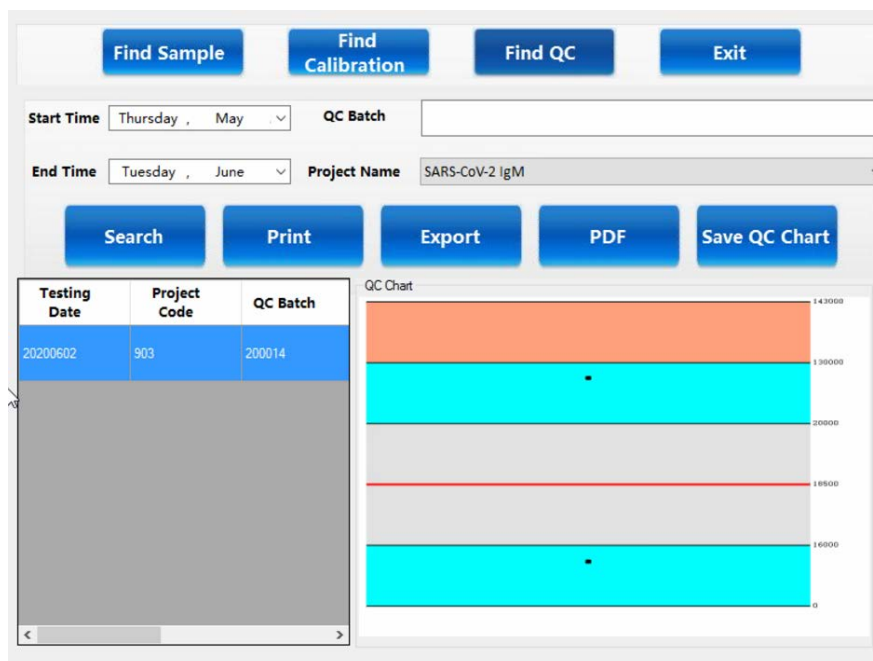
- 1) Click on “Find QC” to enter the “Find QC” window.



The interface includes the following elements:

- Buttons: Find Sample, Find Calibration, Find QC, Exit
- Start Time: Tuesday, June
- QC Batch: [Empty field]
- End Time: Tuesday, June
- Project Name: [Empty dropdown]
- Buttons: Search, Print, Export, PDF, Save QC Chart
- Table with columns: Testing Date, Project Code, QC Batch
- QC Chart area

- 2) "Project Name", "Start Time", and "End Time" are required items, the rest are optional.
- 3) Click the "Search" button to retrieve all the quality control results from the selected conditions.



The interface shows the following search results and chart:

Start Time: Thursday, May

QC Batch: [Empty field]

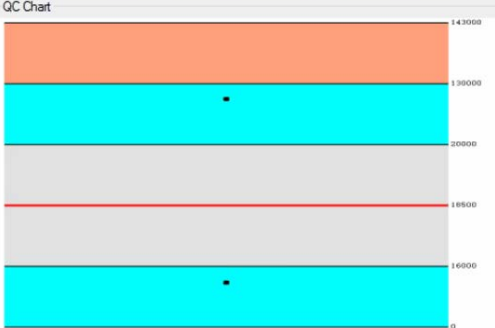
End Time: Tuesday, June

Project Name: SARS-CoV-2 IgM

Buttons: Search, Print, Export, PDF, Save QC Chart

Testing Date	Project Code	QC Batch
20200602	903	200014

QC Chart



The QC Chart displays a horizontal bar chart with a red line at 18500 and a cyan bar at 16000. The y-axis ranges from 0 to 140000.

4) Click “Save QC chart” to save the currently displayed quality control charts.

1) Print

Print list format.

2) PDF

Save as PDF

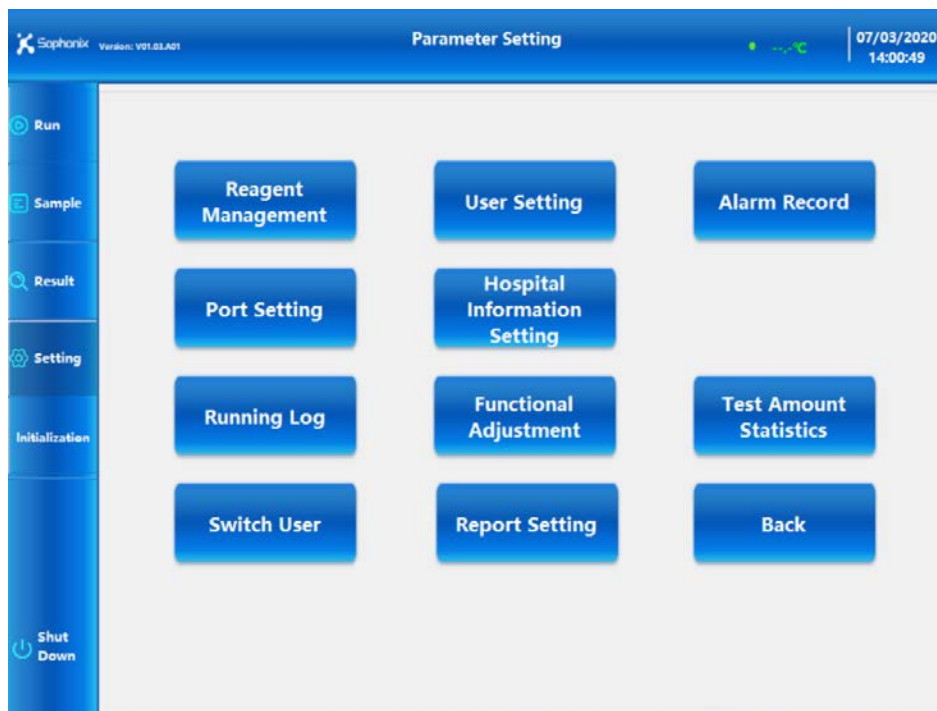
3) Export

Click the "Export" button to export the data and save the format as text.

5.9 Setting window

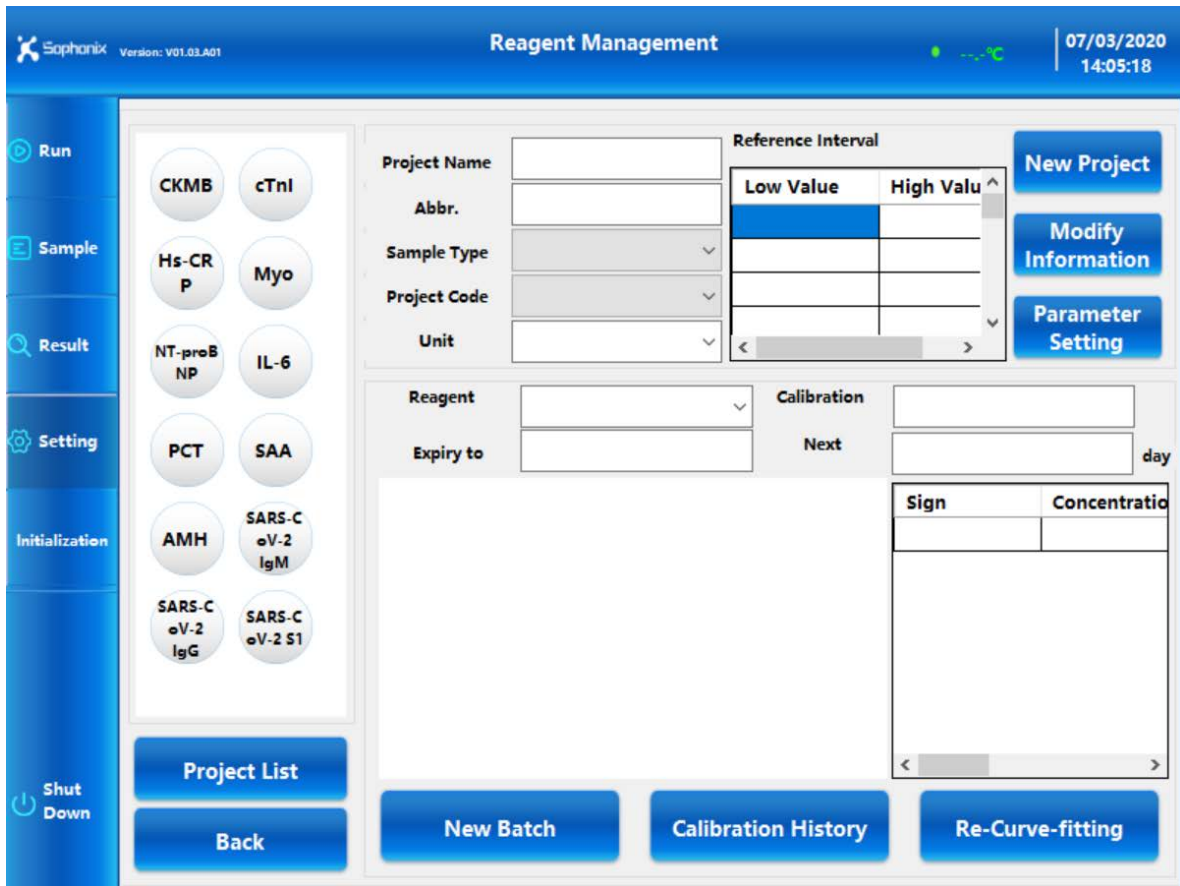
The “Setting” window includes Reagent Management, Hospital Information Setup, User Settings and Switch user.

1) Click the corresponding button to enter the corresponding window.



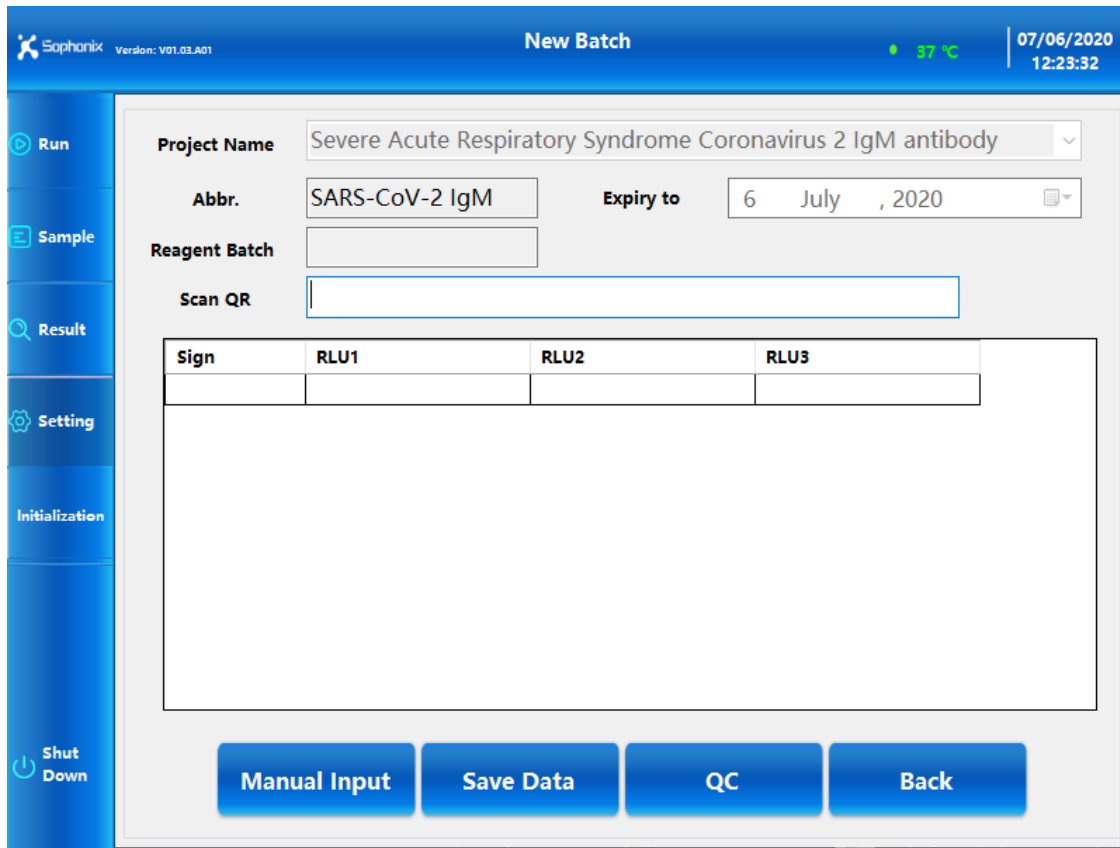
5.9.1 Reagent Management

In the “Reagent Management” interface, you can enable and disable projects; query project parameters; and add new batch reagents.



1) Add new batches

- Select the “Project List” on the left side of the screen, and the detailed information of the currently selected project will automatically be displayed.
- Click the “New Batch” button to select a new batch of the currently selected project.



Project Name Severe Acute Respiratory Syndrome Coronavirus 2 IgM antibody

Abbr. SARS-CoV-2 IgM **Expiry to** 6 July, 2020

Reagent Batch

Scan QR

Sign	RLU1	RLU2	RLU3

Manual Input **Save Data** **QC** **Back**

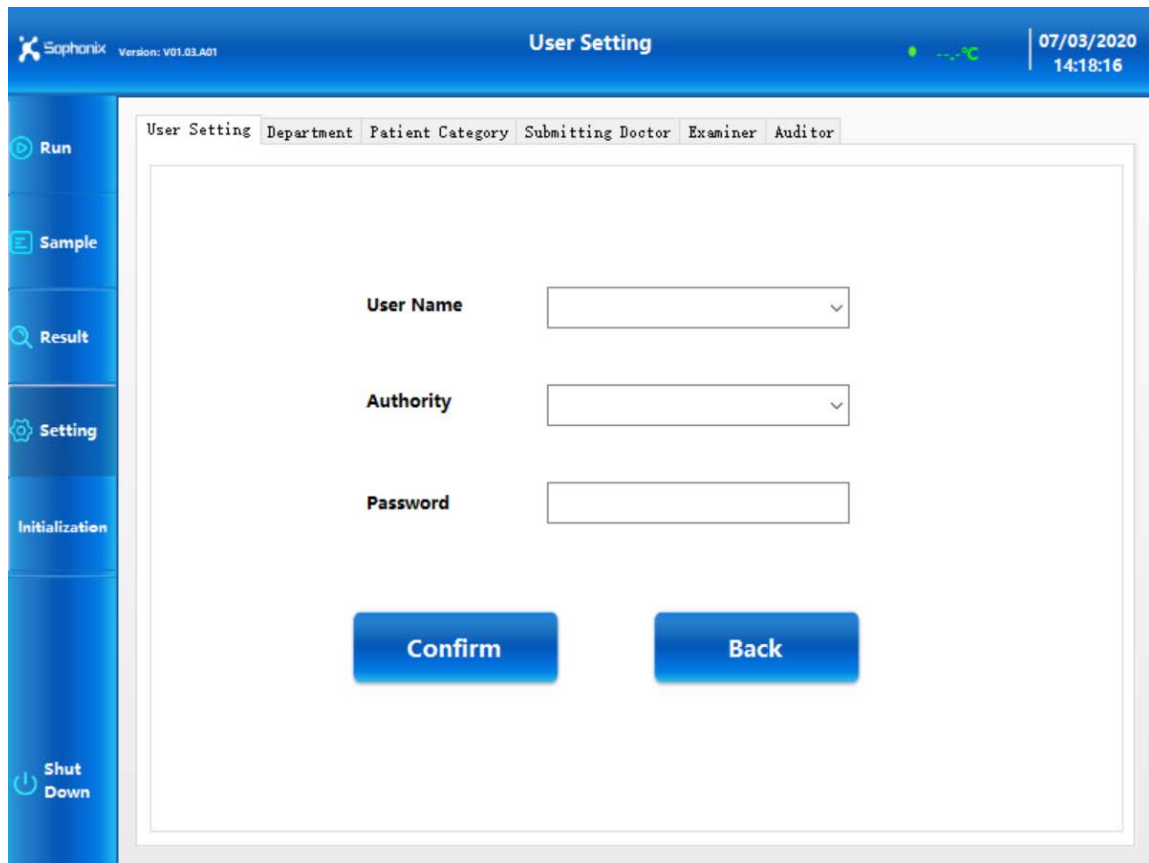
- **Scan QR:** When entering the interface, scan the QR code on the kit with the handheld scan code gun. After the scan is successful, the current scan information is automatically added.
- **Manual Input:** If unable to be scanned, the information can be manually added via the “Manual Input” button.

NOTE: After scanning or manually inputting the batch information, the “Reagent Batch” and “Expiry to” values are unable to be changed.

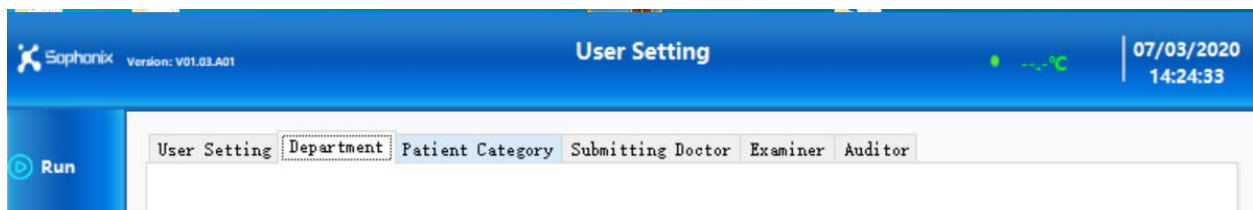
- After inputting, click the “Save Data” button to save the current batch data.
- You can also add multiple batches of information at once. Repeat the above operation.
- Click the "Back" button to exit the current interface and return to the reagent management interface.

2) Add a user

- In setting, select the "User Setting" button to add a user and password.

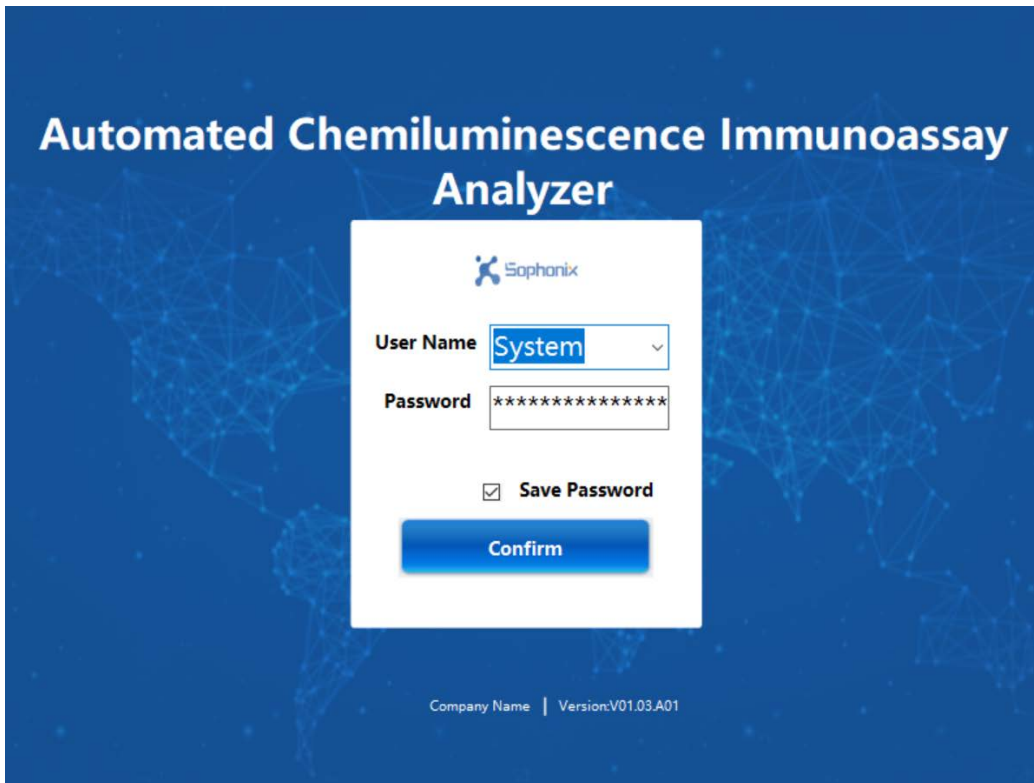


- "Authority ": A is the highest level and D is the lowest level.
- The current user's authority cannot be higher than the new User they are setting up.
- Modify the "Authority " and "Password" of the original users.
- Add a user, enter "User Name", select "Authority ", set "Password", the password can be empty.
- Click the "Confirm" button to save the current information.
- Click "Back" to close the current window and return to the settings window.

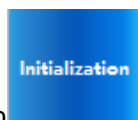


3) To update, modify, or delete

- Click on the corresponding tab to update a department, patient category, submitting Doctor, examiner, or auditor.
- Go back to the login window and enter your username and password. Re-register.



5.10 Start initialization

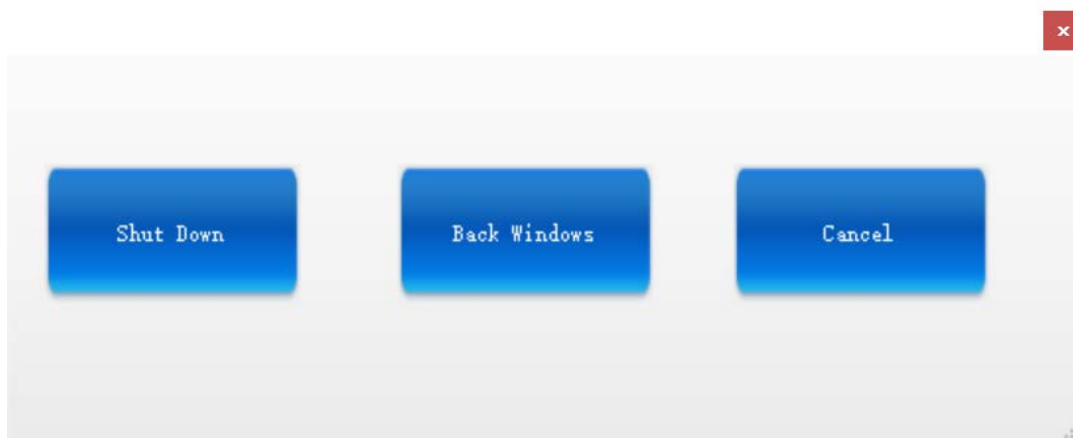


- Click the "Initialization " button  in the main window. System will be re-initialized.

5.11 Shut down



- Click the "Shut Down" button  in the main window to access the shutdown option.



- Click the "Shut Down" button to directly close the display interface.
- Click the "Back Windows" button to return directly to Windows, just close the current system.
- Click the "Cancel" button to cancel the current operation.

6 Instrument warnings and precautions

6.1 Precautions

- 1) Only trained, qualified laboratory personnel are authorized to use the instrument. Authorized personnel must wear appropriate protective gear (gloves, lab coat, safety goggles) and exercise standard precautions for handling and disposing of infectious or potentially infectious materials (e.g. patient samples or consumables).
- 2) The test cassette provided by the factory will not release toxic and harmful gases during the use of the instrument. The test sample is potentially infectious. The used test cassettes are treated according to the Medical Waste Management Regulations to avoid biohazard. . 4) If hazardous materials leak into the surface or inside the equipment, proper cleaning should be carried out (see section 8)
- 3) During cleaning of the instrument ensure that the instrument is in turned off. 7
- 4) The operator must follow the instructions in this manual in order to ensure safe operation.
- 5) MS-Fast is a medical analytical instrument for testing serum. Do not use the device for other purposes.

- 6) Do not use solvents, abrasive cleaning fluids, or rough cloth to clean any parts. Do not use cleaning agents or disinfectants that are not approved for cleaning or disinfections as specified in section 8.
- 7) The door should not be opened during the operation of the instrument to avoid injury caused by touching moving parts.
- 8) The user must not open service door or remove any covers from the instrument.

7 Troubleshooting

Error Alarm	Cause of Issue	Solution
Z motion abnormality	Magnetic rod motor or magnetic sleeve motor movement abnormal	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
TIP movement abnormality	TIP motor motion abnormality	<ol style="list-style-type: none"> 3. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 4. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
Abnormal pump motion	Sample pump motor movement is abnormal	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
PMT movement abnormality	PMT motor motion abnormality	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.

Error Alarm	Cause of Issue	Solution
Y-axis motion anomaly	Y-axis motor movement is abnormal	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
X-axis motion abnormality	X-axis motor movement is abnormal	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
Fitting exception, data processing is unsuccessful	Reagent related data processing exception	<ol style="list-style-type: none"> 1. The operator turns the machine on and off once, so that the instrument is reset again to see if the fault persists. 2. If the fault persists, please contact the factory after-sales engineer or an authorized technical service representative.
Open the serial port exception	Thermal printer communication is abnormal	Contact the manufacturer's after-sales engineer or an authorized technical service representative

8 Equipment maintenance

When servicing the equipment, turn off the power and wear appropriate safety clothing (gloves, test jackets, goggles, etc.) to keep the equipment accessories and reagent racks clean.

8.1 Weekly maintenance

1) Clean the Reagent Rack

- Gently clean the surface of the reagent rack with a lint free wipe soaked with disinfectant 70% alcohol.
- Ensure all channels are disinfected with 70% alcohol when cleaning the channels of the reagent rack.

8.2 Monthly maintenance

- 1) Clean the surface of the device with 70% alcohol.

8.3 Recommended regular maintenance

To ensure proper operation and reliability of the MS-Fast instrument, follow recommendation for periodic maintenance by the manufacturer's after-sales engineer or an authorized MS-Fast technical service representative.

8.4 Replacing the internal printer paper

- 1) Power off the instrument before replacing printer paper.
- 2) Pull the printer cover located at the lower left of the front of the unit.
- 3) Remove the used paper roll and install new paper roll.
- 4) Push the retaining plate back into place and use the paper cutter to cut off excess paper.