FAQ

MGI Automatic Virus DNA / RNA Extraction

Version: A0

MGI 华大智造

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Chapter I Testing

1. 1 Types of Samples Currently Applicable with MGIEasy Magnetic Beads Virus DNA / RNA Extraction (RUO)?

A: The Product is applicable to respiratory tract samples such as throat swab, nasopharyngeal swab and alveolar lavage fluid. It's also applicable to virus nucleic acid extraction from plasma and virus culture.

1.2 The principle of MGIEasy Magnetic Beads Virus DNA / RNA Extraction Kit?

A: The kit contains superparamagnetic beads which are efficiently bound to nucleic acids. The buffer MLB could lysis virus, and release virus DNA / RNA; After adding ethanol, the superparamagnetic beads could specifically adsorb the nucleic acid through hydrogen bonding and electrostatic interaction, without adsorbing protein and impurities. The beads bonding with nucleic acid are washed by the MW1 to remove non-specifically adsorption proteins or proteinase K, then washed by MW2 to remove the salts adsorbed on the beads. Finally, use the nuclease-free water to elute and obtain high-purity nucleic acid solution.

1.3 Virus inactivation approaches

A: Refer to related literature and guideline reports of China, it is recommended to detect after inactivation at 56 ℃ for 30 min.

1.4 Treatment before Extraction for different types of samples

A: 1) Throat swab sample: If the swab is stored in preservation fluid, please draw the supernatant for nucleic acid extraction; If no preservation fluid, please let the swab head dip into 500 μL of 1 × PBS buffer (pH Value of 7.4), mix by vortex evenly, and draw the supernatant for nucleic acid extraction.

2) BALF sample: Mix by vortex evenly and draw the supernatant for nucleic acid extraction.

3) Saliva sample: Saliva can be directly extracted. If it is relatively thick, it is recommended to centrifuge at 10,000 rpm for 2 min.

1.5 What does the extraction reagent extract, DNA or RNA?

A: The extraction steps provided herein mainly aim for viral nucleic acids, including DNA and RNA. However, the extraction steps are not applicable to nucleic acid extraction from other microorganisms.

The extracted product is the mixed solution of DNA and RNA. If the customers require RT-PCR detection of viral RNAs, quantitative PCR reaction may be performed directly. If customers intend to perform high-throughput sequencing, it is

recommended not to add enhancer buffer during extraction and lysate addition.

If it is needed to digest RNA, please add 10 μL RNase A (50 mg/ mL) (prepared by customer) to the sample before lysis, mix by vortexing, incubate at RT for 5 min, then add to the buffer mixture to subsequent operations.

If DNA digestion is needed, add 50 μL DNase I (1 U/ μL) (prepared by customer) after discarding the supernatant liquid of buffer mixture, then incubate at RT for 10 min and add Buffer MW1 to operate according to SOP.

1.6 Whether positive reference or standard substance is required when the nucleic acid extraction?

A: Generally, positive reference is not required in nucleic acid extraction, or the internal standard may be added just as required. (Normally corresponding components will be provided with the RT-PCR detection kit.)

1.7 Are nucleic acid extraction reagents applicable to viral RNA sequencing? If applicable, what is the input of sample and nucleic acid extraction conditions?

A: This extraction kit can be used for subsequent sequencing of viral RNA. Sample extraction for sequencing requires the following special operations.

Firstly, do not apply enhance buffer in lysing. Secondly, Ranse free water is required to replace the buffer for Magnetic Bead M to reduce background bacteria contamination of the buffer primers of Magnetic Bead M. For massively parallel sequencing, DO NOT add the enhancer into the buffer mixture.

Manual - In the step of preparation of buffer mixture (Step C-1), mixture 200 μL Buffer MLB, 250 μL absolute ethanol, 15 μL Proteinase K, and 15 μL Magnetic Beads M.

Automatic - In the step of preparation of buffer mixture (Step D-4-3), mixture 160 μL Buffer MLB, 200 μL absolute ethanol, 15 μL Proteinase K, and 15 μL Magnetic Beads M.

1.8 What are the treatments in case of agglomeration of magnetic beads during extraction?

A: The reaction system of the extraction kit has been optimized to improve capture efficiency of cell-free samples, especially with very low concentrations of nucleic acids. However, for protein -rich samples, such as blood and saliva, agglomeration of magnetic bead may occur. And such agglomeration will not affect the performance of nucleic acid extraction. If you worry about that, please centrifugate to remove the cells before extraction.

1.9 What is the purity of the extracted nucleic acid? How to ensure that nucleic acids from other species, such as bacteria, are not purified?

A: For most of clinical samples are cell-free and low content, the conventional quantitative method, such as OD260 / OD280 can't be used to determine the purity of virus nucleic acid exactly. If you want to know the content of virus, we recommend the method of qPCR to quantify.

The nucleic acid of other species will also be extracted. For the optimized chemistry and conditions, our kit could increase

the enrichment of virus nucleic acid and reduce the enrichment of other species.

1.10 Can I still use the magnetic beads stored in -20 ℃ by mistake?

A: The best storage condition of magnetic beads is 2-8 ℃. The freezing condition will reduce the performance. If the beads buffer become agglomeration after stored in -20 ℃, it is NOT recommended to be used.

1.11 Is it only suitable for coronavirus or all viruses?

A: The extraction kit is suitable for DNA and RNA extraction of all viruses, not just for coronavirus.

1.12 Could the buffer mixture be prepared in advance and stored for long period?

A: Buffer MLB and absolute ethanol could be prepared together in advance and can be stored for a long time. Other reagents, such as proteinase K, Magnetic Beads M, and enhancer are added before use. It is best to be used in 30 min. Buffer MW1 and buffer MW2, could be added absolute ethanol and stored for a long time.

Chapter II Market

2.1 What COVID-2019 RT-PCR Kit can work with this nucleic acid extraction reagent?

A: The nucleic acid extraction kit produced by MGI has undergone a large number of clinical trials with Real-time fluorescent RT-PCR kit for detecting 2019-nCOV produced by BGI Europe A/S. As nucleic acid extraction is a universal method, it is also applicable to RT-PCR detection methods for COVID-2019 of other companies.

2.2 Superiorities of this nucleic acid extraction reagent.

A: 1) The reagent is based on magnetic bead method, which is more conducive to automated and rapid nucleic acid extraction.

2) It offers automated nucleic acid extraction solutions, greatly reducing the contact time between the operator and the infectious samples. Safety protection for the operator are also guaranteed.

3) Subsequent different extraction scripts available can enable nucleic acid extraction for multiple types of samples.

2.3 How many types of MGI virus nucleic acid extraction kits are available for viral nucleic acid extraction?

A: Presently, there are 4 types of MGI extraction kit are available for viral nucleic acid extraction. Detailed information are as follows.

Product No.	Product Name	Product Specification	RUO or IVD	Remark
1000020261	MGIEasy Magnetic Beads Virus DNA / RNA Extraction Kit	1,728 preps	RUO	It is suitable for the automated nucleic acid extraction of MGI SP960 and SP-100.
1000020471	MGIEasy Magnetic Beads Virus DNA / RNA Extraction Kit	96 preps	RUO	Itis suitable for manual and automated SP960 and SP100 nucleic acid extraction.
1000021042	Virus DNA / RNA Extraction Kit	1,728 preps	CE-IVD	. It is suitable for the automated nucleic acid extraction of MGI SP960 and SP-100
1000021043	Virus DNA / RNA Extraction Kit	96 preps	CE-IVD	It is suitable for manual and automated SP960 and SP100 nucleic acid extraction.

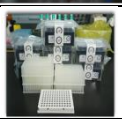
2.4 Are MGIEasy Magnetic Bead DNA/RNA Extraction Kit pre-loaded?

A: MGIEasy Magnetic Bead DNA / RNA Extraction Kit is not pre-loaded. Some reagents require configuration by the customers before nucleic acid extraction. Meanwhile, this kit is an open reagent, and is applicable to be used with universal automated nucleic acid extraction devices of other companies.

Chapter III MGISP-960

3.1 What kind of products are included in the MGISP-960 Automatic Virus DNA / RNA Extraction solution?

A: At present, MGISP-960 automatic virus DNA/RNA extraction solution include the following three types of products, all of which can be purchased from MGI.

Product Type	Product Name	Product Photo
Instrument	High-throughput Automated Sample Preparation System MGI SP-960 (Device & Computer)	
Reagent	MGIEasy Magnetic Beads Virus DNA / RNA Extraction	
Consumables	250 μL automated filter tips	
	1.3 mL U-bottom deep-well plate	
	Hard-shell thin-wall 96-well skirted PCR plates, white shell / clear well	

3.2 What operations are available with MGISP-960?

A: The detection of COVID-19 based on RT-PCR method requires the following 7 steps from sample collection to report output. MGISP-960 mainly completes the key automated extraction and RT-PCR reaction setup in this process. As for extraction, MGISP-960 offers 2 throughputs, of which one is to run 96 samples / run in 60 minutes, and the other is to run 192 samples / run in 80 minutes.

(1) Inactivation - It is recommended to inactivate at 56℃ for 30min (manually);

(2) Sampling - Transfer the sample from the throat swab tube to a 96-well plate (manually);

(3) Automated Preparation - Prepare consumables and reagents for automation (manually);

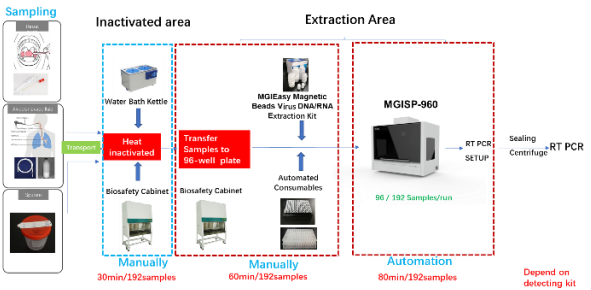
(4) Automated Extraction - Extract viral DNA/RNA (MGISP-960);

(5) RT-PCR Reaction Setup - Mix the extracted samples and detection reagents (MGISP-960 + partly manually);

(6) RT-PCR Reaction - Place the 96-well plate from step5 on the RT-PCR instrument (QPCR instrument);

⑦Report Analysis - Analyze based on test results and send reports accordingly.

Flow Chart of COVID-2019 Detection by RT-PCR Method:



3.3 What are the specific operations of MGISP-960 in automated extraction?

A: Description is made hereinafter with 96 samples / run extraction (excluding RT-PCR setup) as an example.

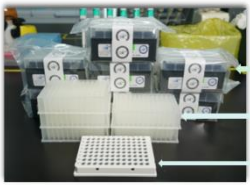
MGI SP-960 automated extraction involves steps below.

Step 1 - Pretreatment of the kit (manually) → Step 2 - Preparation of automated extraction (manually) → Step 3 - Automated extraction

Step1 - Pretreatment of the kit: When opening the kit for the first time, add absolute ethanol to the corresponding reagent bottle. It is only required when the test cassette is opened for the first time.

Step 2 - Preparation of automated extraction: Before preparing for extraction on MGI SP-960, some preparations are required, including consumable preparation, sample preparation and reagent preparation.

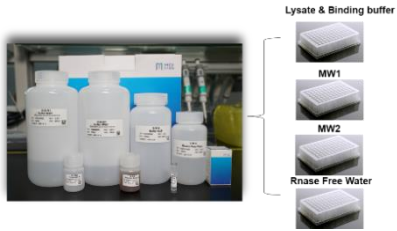
Consumable preparation: Take the corresponding number of automated consumables, as shown below.



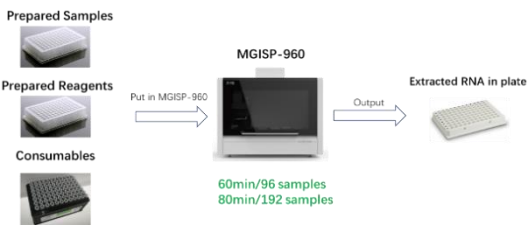
Item	Brand	Cat. No.	Quantity
250 μL automated filter tips	MGI	1000000723	7 boxes
1.3 mL U-bottom deep-well plate	MGI	1000004644	5 plates
Hard-shell thin-wall 96-well skirted PCR plates, white shell/clear well	MGI	1000012059	1 plate

Sample preparation - Manually transfer the inactivated samples from the throat swab tube to a deep-well plate.

Reagent preparation - Transfer the reagent from the reagent bottle to a 96-well deep-well plate.



Step 3 - Automated extraction

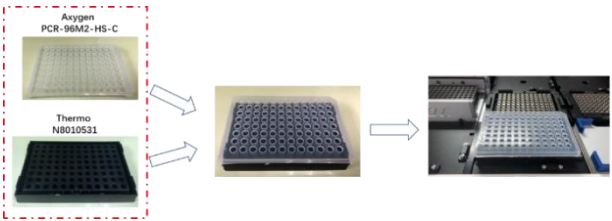


The above introduction is based on 96 samples / run as an example. The operation mode of 192 samples / run is quite similar and required only the selection of the corresponding script in the software.

3.4 Is MGI SP-960 configurable for RT-PCR reaction setup?

A: Yes. MGISP-960 is equipped with a 96-channel pipette head, which is available for 2 μl-200 μL pipetting as well as the configuration of RT-PCR system. Just select a script with PCR SETUP function when running MGISP-960 to enable this function.

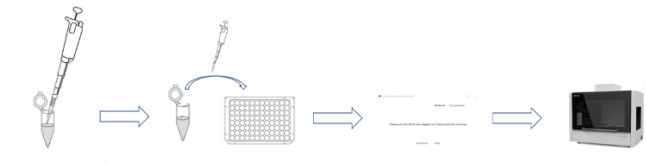
The following PCR plate for RT PCR is available to work with the scrips provided with MGI SP-960.



The specific operations are shown in the following figure. Manually preparation of the mix and packaging is required.

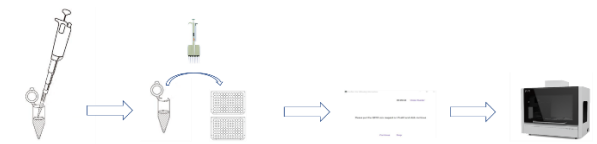
Below is the flow chart of 96 samples / run operation.

After MGISP-960 starting extraction(96 samples/run):



Here is flow chart of 192 samples / run operation.

After MGISP-960 starting extraction(192 samples/run):



Note: As different RT PCR Kits and QPCR instruments are used by different customers, the PCR plates and reaction systems vary accordingly. Therefore, customized scripts are required for such functions according to the PCR plates and RT PCR Kits of the customers. The customized scripts are available in 2 working days after the customer sends the brand/Part Number/picture and the SOP of the RT PCR Kits to MGI FAS.

3.5 Can the MGISP-960 be operated for less than 96 cases?

A: Yes. MGISP-960 is a high-throughput pipetting station with two extraction throughput, of which one is to complete 96 samples / run in 60 min, and the other is to complete 192 samples / run in 80 min. Specific operations in case of less than 96 samples:

1) When splitting the reagent, it is only required to add reagent to the corresponding wells with samples; even if there is only one sample, reagent may be added just for such sample.

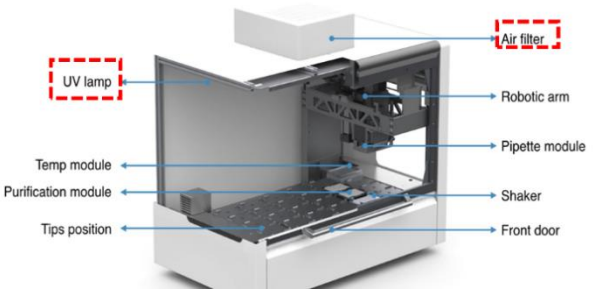
2) The entire extraction process runs completely according to practice for 96 samples/run, and consumables shall be prepared for 96 samples.

The amount of reagent used for the above method is same as the actual use without excessive loss of reagent. However, the consumption of consumables is consistent with the 96 samples, and consumables will be wasted.

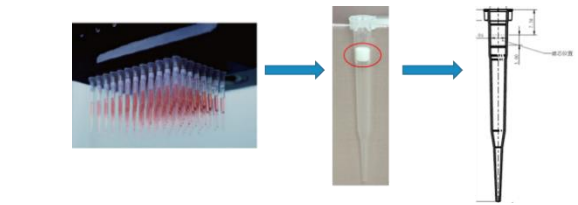
3.6 Is MGISP-960 automated sample preparation system avoiding the risks of cross-contamination?

A: To avoid cross-contamination, the MGISP-960 automated sample preparation system is integrated with the UV lamp and ISO5 positive pressure laminar flow hood, which can sterilize and filter the interior of the device before and after the experiment, so that the experimental environment inside the device is close to the ultra-clean workbench as possible. Meanwhile, pipette tips are designed with a filter element to minimize the risk of aerosol contamination in the pipettes. In addition, MGI SP-960 software has integrated pre-/ post-clean step. During this step, prompt will be given to clean the device and enable the operation of the UV lamp and laminar flow hood. Pre-clean and Post-clean are recommended to run daily.

MGISP-960 Structure:



MGISP-960 Tips:



MGISP-960 Software Pre-/Post-clean Step :

3.7 Is the MGI extraction kit compatible with other automated platforms?

A: MGIEasy Magnetic Beads Virus DNA / RNA Extraction is a user-friendly product with easy operations. It has been fully compatible with MGISP-100 and MGISP-960.

Theoretically, MGI extraction kits are applicable to pipette workstations and magnetic rod extraction devices. However, the effects of the specific application with different automated platforms are subject to evaluation and development test by the corresponding instrument manufacturers.

3.8 Is MGISP-960 applicable to other extraction reagents?

A: MGISP-960 is a versatile pipette workstation with diverse functions and stable operations. Presently, it has been

compatible with MGIEasy Magnetic Beads Virus DNA / RNA Extraction as well as other MGI extraction series kits for whole blood/white membrane layer / plasma / feces, *etc.*

In theory, the device can be compatible with most magnetic bead extraction kits. The customer may send the SOP and actual product of the kits to be suited to MGI and MGI may complete the development within about 1 month.

3.9 Can I connect MGI SP-960 with other LIMS?

A: MGI SP-960 provides a set of kafka interface protocols, through which other LIMS can be connected to MGISP-960. However, it must be declared that MGI is not responsible for the security of this interface protocol.

The information presently available with MGISP-960 interface includes device operation information, device error information, *etc.* and excludes sample information and detection information as sampling and detection are not completed on MGISP-960.

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■ Basic Information

Manufacturer - MGI Tech Co., Ltd.
Address - 2nd Floor, Building No. 11, Beishan Industrial Park, No. 146, Beishan Road, Yantian District, Shenzhen, 518083
Service Hotline - 4000-966-988
Website – http://www.mgitech.cn