FAQ

MGI Products（CE-IVD）for COVID-19

A1.

Nucleic Acid Extraction Kit for COVID-19 testing

What products can we offer for COVID-19 virus extraction?

MGI could provide automatic extractor, virus nucleic acid extraction kit, and related consumables for COVID-19 virus extraction. MGI develops multiple nucleic acid extraction kits for different automatic extractor which could meet the requirements of different application and throughput. Please choose the extraction kits according to the automatic extraction platforms you already have or plan to purchase.

For MGISP-960 :

Class	Cat. No.	Product Name	Specification	Model	Certificate	Note
Equipment	900-000158-00	MGISP-960	EA	/	CE-IVD	/
Reagent	1000021043	Nucleic Acid Extraction Kit	1728 preps	T-1728	CE-IVD	Tube type
	1000021042	Nucleic Acid Extraction Kit	96 preps	T-96	CE-IVD	Tube type
	1000023877	Nucleic Acid Extraction Kit	96 preps	VDR02P-96	CE-IVD	Preload type

* Additional consumables are required during the experiment, please contact with the local sales or FAS to get the product information.

For NE32:

Class	Cat. No.	Product Name	Specification	Model	Certificate	Note
Equipment	950-000013-00	MGISP-NE32	EA	/	CE-IVD	/
Reagent	1000023937	Nucleic Acid Extraction Kit	32 preps	VDR03P-32	CE-IVD	Preload type
	1000022606	Nucleic Acid Extraction Kit	32 preps	OP02-32	CE-IVD	Preload type

For NE384:

Class	Cat. No.	Product Name	Specification	Model	Certificate	Note
Equipment	900-000359-00	MGISP-NE384	EA	/	CE-IVD	/
Reagent	1000021043	Nucleic Acid Extraction Kit	1728 preps	T-1728	CE-IVD	Tube type
	1000027006	Nucleic Acid Extraction Kit	96 preps	VDR01P-96	CE-IVD	Preload type
	1000024108	Nucleic Acid Extraction Kit	96 preps	VDR03P-96	CE-IVD	Preload type

*Additional consumables are required during the experiment, please contact with the local sales or FAS to get the product information.

Types of Samples Currently Applicable with Nucleic Acid Extraction Kit (Virus DNA/RNA Extraction)

Model	Applicable sample types	Application
T-1728/T-96	Oropharyngeal and nasopharyngeal swab, saliva, BALF, cervical swab and FTA card washing solution.	PCR， RT-qPCR
VDR01P-96	Oropharyngeal and nasopharyngeal swab，BALF	PCR， RT-qPCR
VDR02P-96	Oropharyngeal and nasopharyngeal swab	PCR， RT-qPCR, sequencing
VDR03P-32/VDR03P-96	Oropharyngeal and nasopharyngeal swab	PCR， RT-qPCR, sequencing
OP02-32	Swab, plasma， blood， body fluid (Only Swab is for IVD labelled)	PCR， RT-qPCR

*T-1728/T-96 and VDR01P-96 contain enhancer buffer which is carrier RNA. It will be reversed transcribed together with target viral RNA that result in waste of sequencing data. So, T-1728/T-96 and VDR01P-96 aren't recommended to sequence.

How to choose those extraction kits for COVID-19 testing?

MGI provide multiplex viral DNA and RNA Extraction Kits for COVID-19 testing. You could choose those kits based on the automatic extraction platforms in your lab.

When your lab has MGISP-960：

Model	T-1728/T-96	VDR02P-96
Highlight	Best extraction efficiency； Suitable to various sample types	Preload reagent， easy to use; Fully automatic extraction
Specification	1728 preps/96 preps	96 preps
Sample types	Oropharyngeal and nasopharyngeal swab, saliva, BALF, cervical swab and FTA card washing solution.	Oropharyngeal and nasopharyngeal swab
Hand work	Need prepare the lysis mixture by manual；	No manual steps are needed
TAT	192 samples/60min	192 samples/80min
Application	PCR， RT-qPCR	PCR, RT-qPCR, sequencing
Storage Condition	Box 1 except magnetic beads and proteinase K is stored in RT; Magnetic beads and proteinase K is stored in 2-8°C； Box2 is stored below -15°C.	Box1 is stored in RT; Box2 is stored in 2-8°C.
LOD with BGI COVID-19 RT-qPCR Kit	100 copies/mL	100 copies/mL
Max throughput per 24h	3000 samples	2500 samples

When your lab has MGISP-NE32 :

Model	OP02-32	VDR03P-32
Advantage	Preload reagent, easy to use; Widely sample type	Preload reagent, easy to use; Shorter TAT, More efficient, Compatible with sequencing;
Sample type	Swab, Saliva, BALF, Blood, Plasma, Body fluid	Swab
Hand work	Need to transfer sample and Proteinase K by manual	Need to transfer sample only by manual
TAT on NE32	8-16 samples/35min	8-16 samples/10min
Application	RT-PCR	RT-PCR, Sequencing
If contain alcohol	Yes	No
Storage condition	2-8°C	2-8°C
LOD with BGI COVID-19 RT-qPCR Ki	250 copies/mL	150 copies/mL
Max throughput per day	800 Samples	1500 Samples

When your lab has MGISP-NE384:

Model	VDR01P-96	VDR03P-96
Advantage	Best extraction efficiency;	Highest throughput;Preload reagent, easy to use; Shorter TAT; Compatible with sequencing;
Sample type	Swab	Swab
Hand work	Need to transfer sample only by manual or liquid handling workstation	Need to transfer sample only by manual or liquid handling workstation
TAT on NE384	96-384 samples/20min	96-384 samples/15min
Application	RT-PCR	RT-PCR, sequencing
Storage condition	Box 1: RT; Box 2: -20°C; Box 3: 2-8°C	2-8°C
LOD with RT-PCR	100 copies / mL	150 copies / mL
Max throughput per day	10000 samples	14000 samples

The principle of MGI Nucleic Acid Extraction （T-1728/T-96）?

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.

Do the samples for COVID-19 testing need to be inactivated?

For the COVI-19 samples have potential infection risk and need to be inactivated without special application. Please refer to local medical regulations and guidelines at first. Inactivated sample preservation solution with guanidine salts is recommended.

What does the extraction reagent extract, DNA or RNA?

T-1728/T-96/VDR01P-96/VDR02P-96/VDR03P-32/VDR03P-96/OP02-32 are for viral nucleic acid, including DNA and RNA.

Common problems of magnetic beads in use

1) The magnetic beads are stored below 0℃,

The best storage condition of magnetic beads is 2-8℃. The magnetic beads 'surface chemistry will be changed when stored below 0℃ which will result in agglomeration, and the extraction performance is reduced. If stored below 0℃, the magnetic beads aren't recommended to be used.

2) Magnetic beads sedimentation will be occasionally observed during Buffer MLB Mixture separation, how to deal with it?

The magnetic beads in T-1728/T-96 extraction kit have large particle size and are easy to sediment. If the phenomenon is found, please increase the mixing frequency.

Could the buffer MLB Mixture (T-1728/T-96) be prepared in advance and stored for long period?

Buffer MLB Mixture contains alcohol which will inhibit proteinase K performance. So, it is recommended to using the buffer MLB Mixture within 30 min （noted in use manual of T-1728/T-96 extraction kit as below.）; The alcohol also will cause the precipitation of guanidine salt and glycogen. The larger of the volume of preparation, the more obvious the phenomenon of precipitation is. So, the buffer MLB Mixture after preparation isn't recommended to being stored for long time.

Note: The prepared Buffer Mixtrue needs to dispense to the sample tube in 30 min.If need to prepare in advance,please add Proteinase K in the Buffer Mixture before dispensing,avoiding the proteinase inactivation.

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

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.)

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

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.

Is it only suitable for coronavirus or all viruses?

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

MGISP-960

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	Nucleic Acid Extract Kit	
Consumables	250 μL automated filter tips 1.3 mL U-bottom deep-well plate 0.2 mL 96 Well Half-skirt PCR Plate	

What operations are available with MGISP-960?

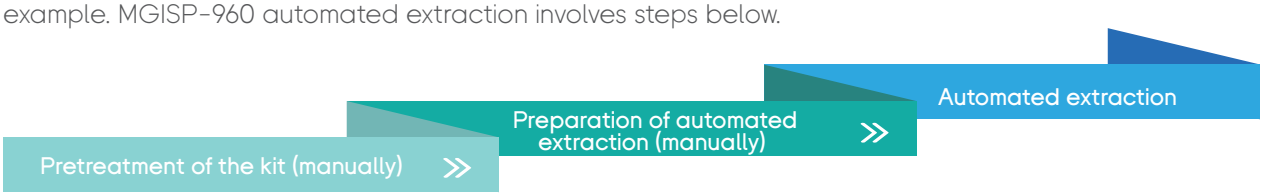
A: The detection of COVID-19 based on RT-PCR method requires the following 7 steps from sample collection to report output. MGISP-960 mainly completes the key automated extraction and RT-PCR reaction setup in this process. As for extraction, MGISP-960 offers 2 throughputs, of which one is to run 96 samples / run in 40 minutes, and the other is to run 192 samples / run in 60 minutes.

- Inactivation - It is recommended to inactivate at 56℃ for 30min (manually) （Please refer local regulations）;
- Sampling - Transfer the sample from the sample preservation tube to a 96-well plate (manually).
- Automated Preparation - Prepare consumables and reagents for automation (manually);
- Automated Extraction - Extract viral DNA/RNA (MGISP-960);
- RT-PCR Reaction Setup - Mix the extracted samples and detection reagents (MGISP-960 + partly manually);
- RT-PCR Reaction - Place the 96-well plate from step5 on the RT-PCR instrument (QPCR instrument);
- Report Analysis - Analyze based on test results and send reports accordingly.

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

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. MGISP-960 automated extraction involves steps below.



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.

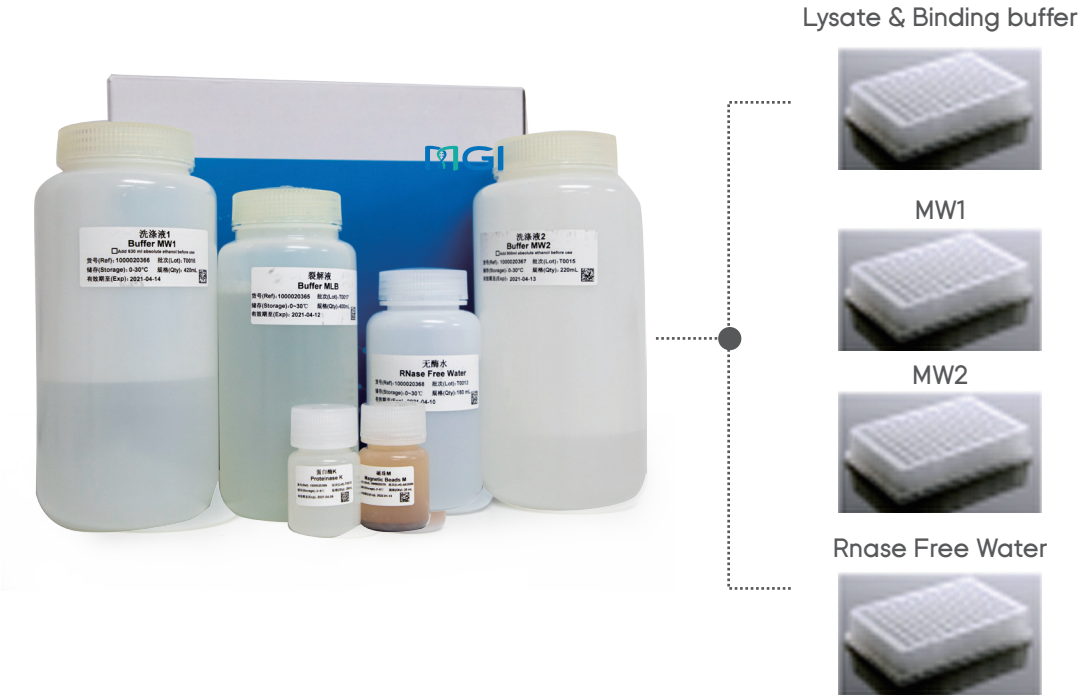
Add absolute ethanol into Butfer MW1 according to the label on the bottle only betore the first use,and then label the bottle.

Add absolute ethanol into Butfer MW2 according to the label on the bottle only betore the first use,and then label the bottle.

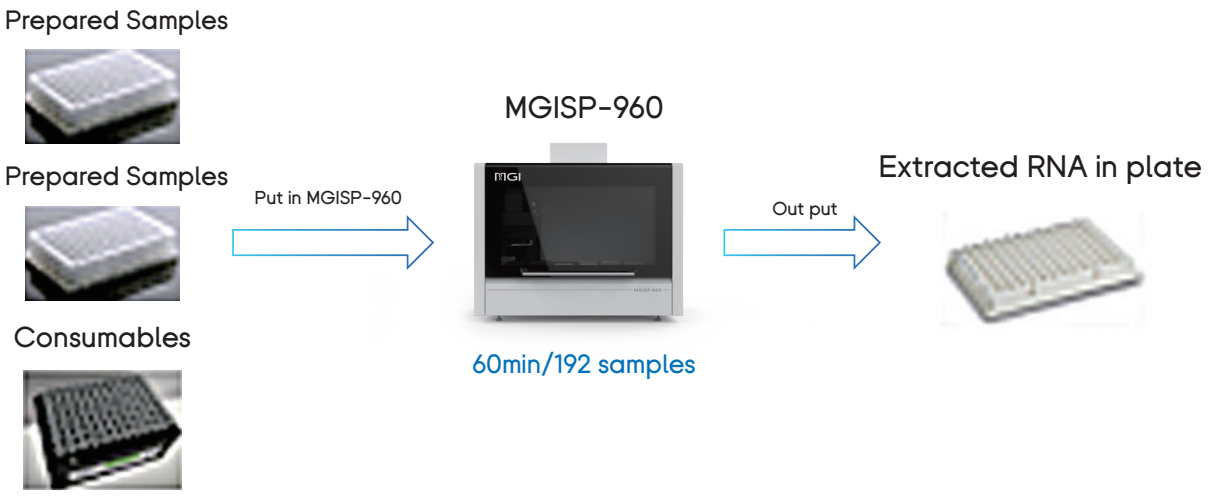
Step 2 - Preparation of automated extraction: Before preparing for extraction on MGISP-960, some preparations are required, including consumable preparation, sample preparation and reagent preparation.

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

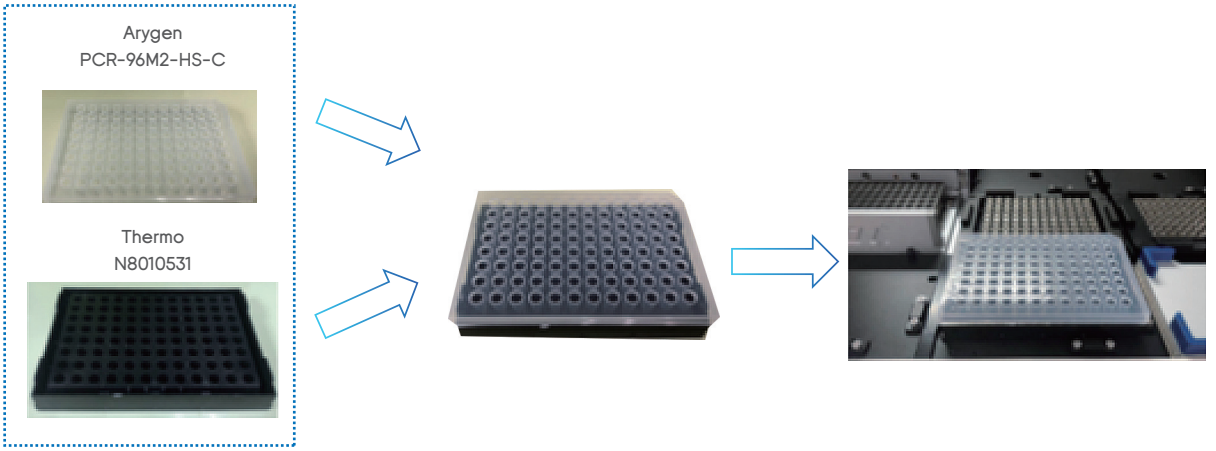
Reagent preparation - Transfer the reagent from the reagent bottle to a 96-well deep-well plate.



Step 3 - Automated extraction



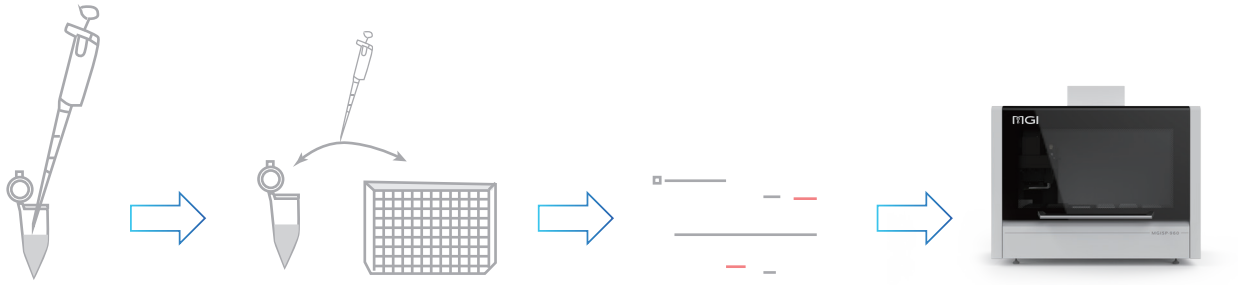
The above introduction is based on 96 samples / run as an example. The operation mode of 192 samples / run is quite similar and required only the selection of the corresponding script in the software.



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):



Prepare RT-PCR mix marualy

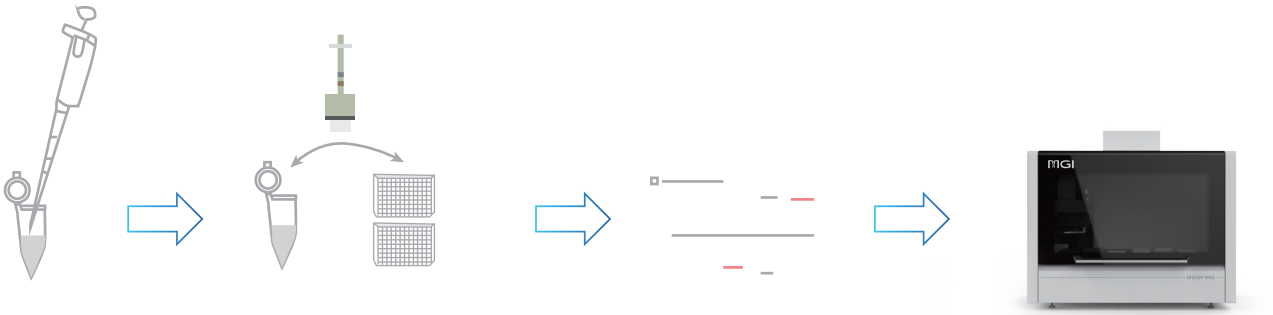
Dvide mix nto 1 column of 96 well plate manually

Waiting for the reminding POP-UP window of MGISP-960 to put in the 96-well plate

contirue to run MGISP-960 will divide mix from 1 column to 1 PCR plare and add samples to PCR plate

Here is flow chart of 192 samples / run operation.

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



Prepare RT-PCR mix marualy

Divide mix into 2 96 Well PCR Plate manually

Waiting for the reminding POP-UP window of MGISP-960 to put in the 96-wel plate

contirue to run MGISP-960 will add samples to PCR plate with reagent.

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.

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

A: Yes. MGISP-960 is a high-throughput pipetting station with two throughput, of which one is to complete 96 samples / run in 40 min, and the other is to complete 192 samples / run in 60 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.

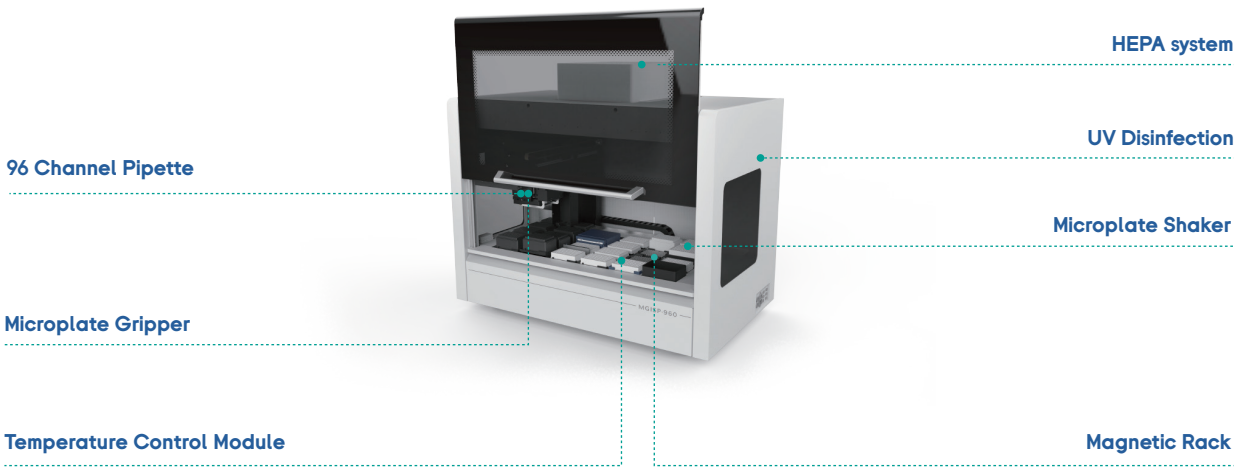
Is MGISP-960 automated sample preparation system avoiding the risks of cross-contamination?

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.

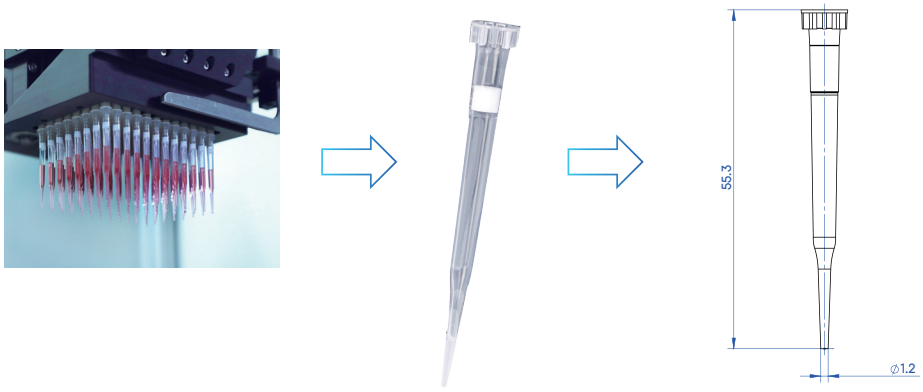
Meanwhile, pipette tips are designed with a filter element to minimize the risk of aerosol contamination in the pipettes.

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.

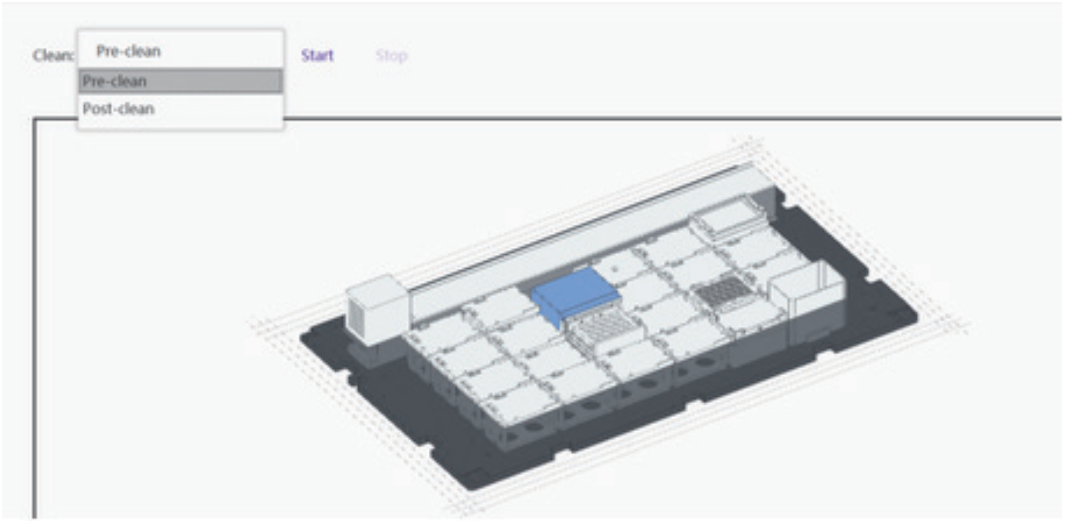
MGISP-960 Structure:



MGISP-960 Tips:



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



Is the MGI extraction kit compatible with other automated platforms?

MGIEasy Nucleic Acid Extraction Kit (T-1728/T-96) 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.

Is MGISP-960 applicable to other extraction reagents?

MGISP-960 is a versatile pipette workstation with diverse functions and stable operations. Presently, it has been compatible with MGIEasy Nucleic Acid Extraction Kit 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.

Can I connect MGI SP-960 with other LIMS?

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.

Contact Us

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*All Sequencers and Sequencing Reagents are not available in Germany, the US and Spain.