

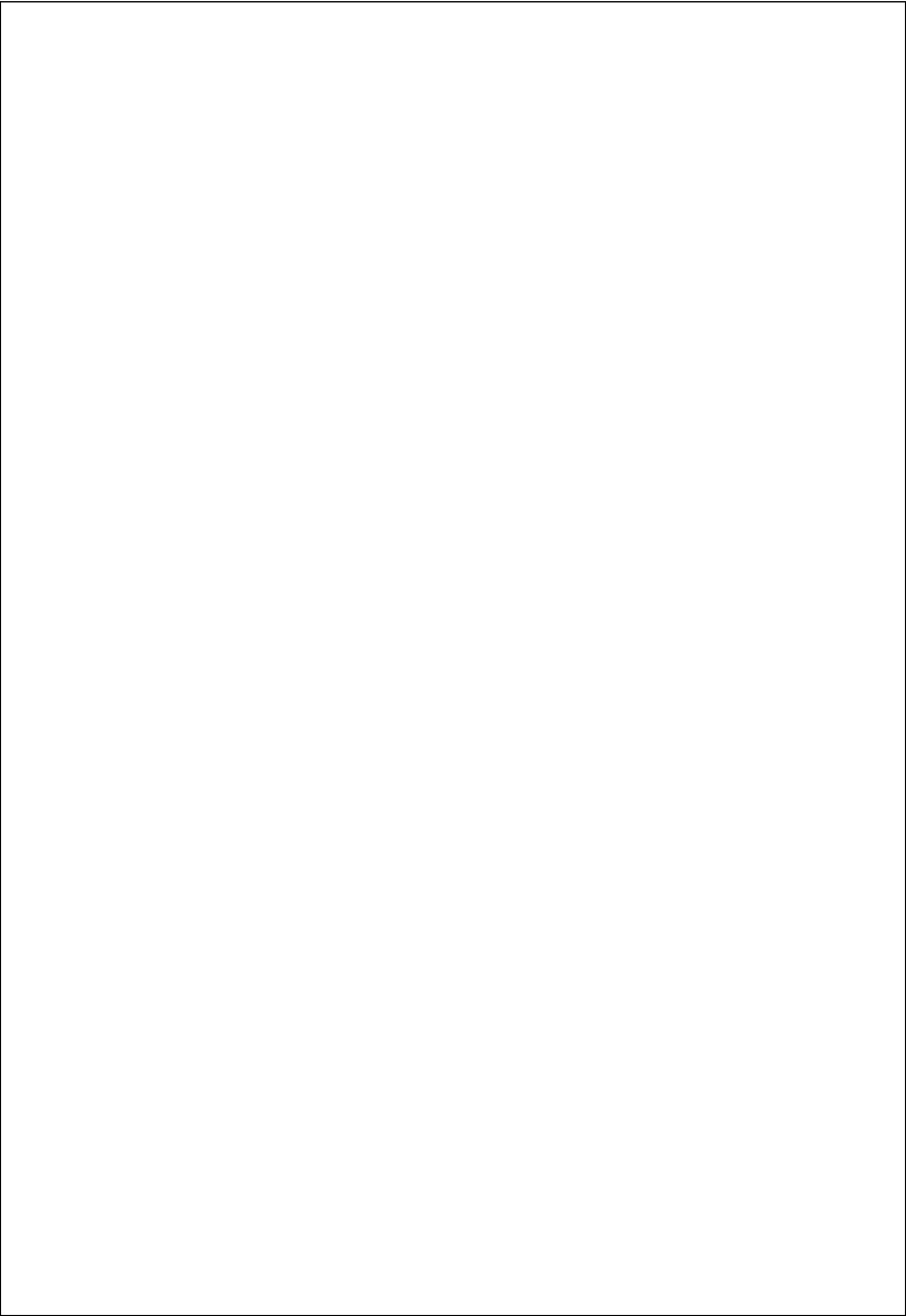
# Instruction Manual

Automated Nucleic Acid Purification System

## ***AmpliX<sup>®</sup> 12***



Cat # 8084



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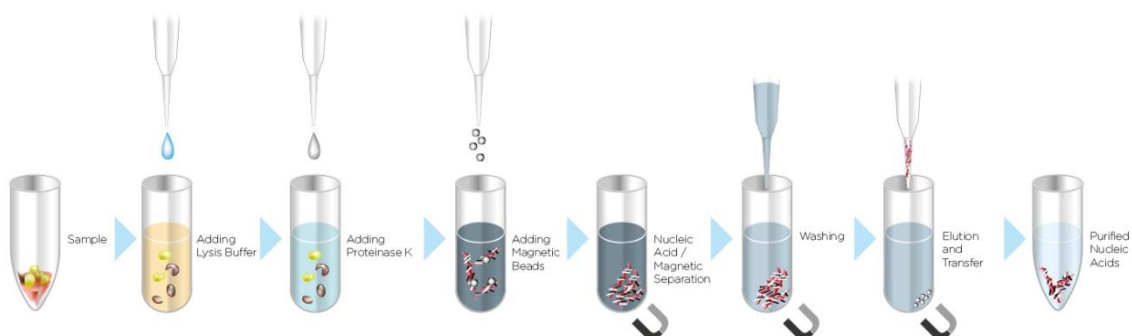
# INTRODUCTION

Thank you for purchase of the AmpliX 12 system which is a fully automated, standalone robot that can purify nucleic acids within 30-45 minutes. With advanced magnetic bead separation technology, it enables you to have high quality extraction results. Moreover, the most user-friendly interface makes users free from troublesome parameter settings and maintenance.

This guide contains important information regarding the safe use of the AmpliX 12 system. Please read this manual carefully before you start to run the system at the first time, especially for Safety Information.

If there is any question about how to install or operate it, please contact our certified distributors / agents or email to our technical support center ( [biomol@alldiag.com](mailto:biomol@alldiag.com) ).

## AmpliX Magnetic Bead Purification Process



# SAFFETY INFORMATION

The meanings of safety precaution marks are as follows:

## **WARNING:**

“WARNING” indicates a dangerous condition that may lead to death or serious injury.



## **BIOHAZARD:**

This symbol is used to indicate that certain precautions must be taken when working with potentially infectious material.



## **CAUTION:**

This symbol is used to indicate that non-compliance with instructions or procedures may lead to physical injury or even death or could cause damage to the instrument.

## **Important:**

“Important” shows the important notes for usage, as well as prohibited actions.

## **Note:**

“Note” indicates the notes, procedures that should be obeyed and supplementary information for use.



## **HOT SURFACE:**

This symbol is used to label potentially hot instrument surfaces.

For your safety and that of others, follow the guidelines provided in the following pages concerning the use of the AmpliX 12 system.

## **About Instrument**

### **WARNING:**

- Ignoring the following notations may lead to fire or electric shock.
  - In countries other than Taiwan, US and Canada, use a power cable that meets your country's standard, or contact your local distributor.
  - Do not use the AmpliX 12 system with voltage other than the voltage specified on the device.
  - Do not use the AmpliX 12 system with a damaged power plug or a loose socket.
  - If there is dust on the prongs of the power plug or on the plug socket, remove it with a dry cloth.
  - When you disconnect the plug from the outlet, be sure to hold the power plug itself. Do not pull the power cable.
  - For maintenance, disconnect the power plug from the outlet.
  - Do not touch the power plug when you hear the crash of thunder.
- Do not pour any liquid on the AmpliX 12 system.
- Do not place any objects containing liquid on the AmpliX 12 system. Doing so may cause a device failure, fire, or electric shock.
- In the event the device overheats, starts to smoke or smells strange, immediately unplug the power cable.



### **CAUTION:**

- Never attempt to remodel the AmpliX 12 system without the manufacturer's permission. Doing so may cause fire or electric shock.
- Do not place or drop objects on the AmpliX 12 system. Also refrain from bumping or knocking it, as doing so may cause a failure or malfunction of the AmpliX 12 system.
- If any liquid materials are left inside the device, wipe it up a soft paper tissue, etc. Otherwise, the AmpliX 12 system may be damaged.

- Repairs to the AmpliX 12 system should only be performed by such agencies as are specifically authorized by ALL.DIAG.
- Only original the ALL.DIAG replacement parts should be used.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

## **About Reagent Kits**



### **CAUTION:**

- When handling any of the kits, refer to the respective handbook.
- Reagents in each kit should be handled by observing the safety information and precautions regarding the kit.
- Extraction should be performed in an appropriate laboratory or workplace.

### **Note:**

The kits are not supplied with the AmpliX 12 system. Select the desired kit(s) and order it (them) separately.

## **About Samples**



### **BIOHAZARD:**

- Always wear appropriate gloves, a mask, and safety goggles etc. when handling any infectious samples.

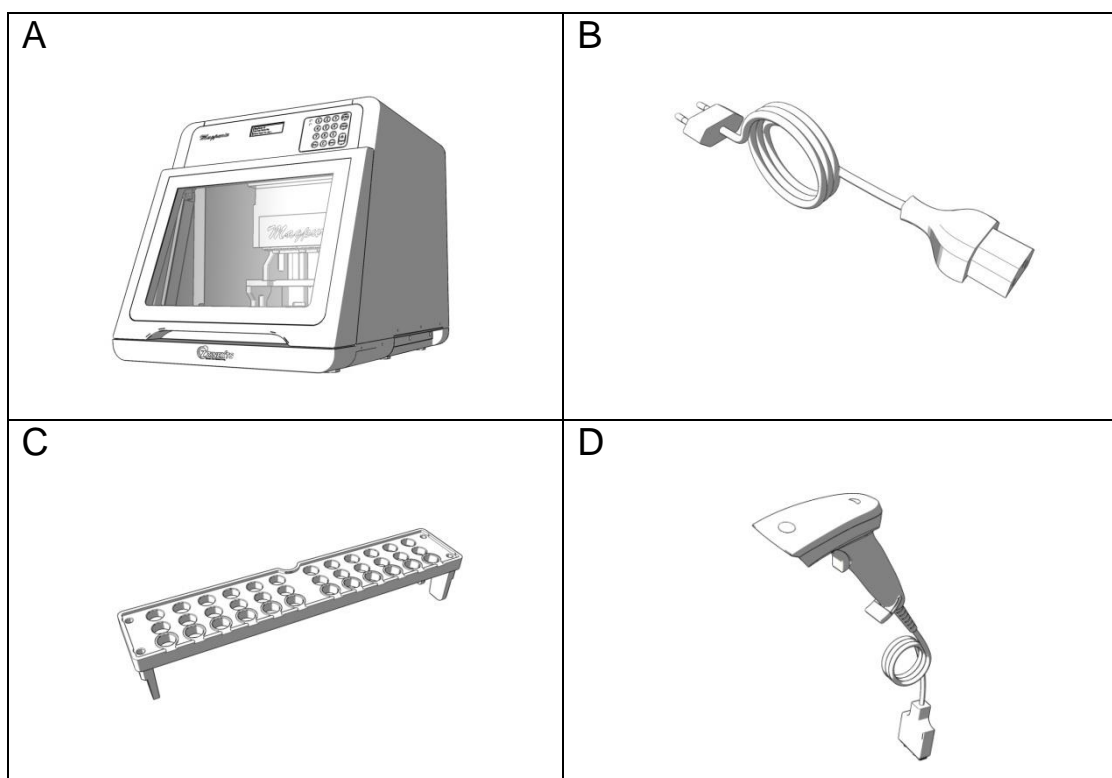
## **About Infectious Wastes**

- When handling or disposing of infectious materials, follow the laboratory guideline or the law regarding infectious waste to perform proper incineration, fusion, sterilization, and/or disinfection.
- When you use a third party to dispose of it, outsource this work an operator licensed to handle medical waste subject to special control, and give them the manifest of the medical waste at the same time.

# 1 Installation

## 1.1 Composition of the AmpliX 12 system

Check that the following are included in the package. Contact your local representative if you notice any missing part(s).



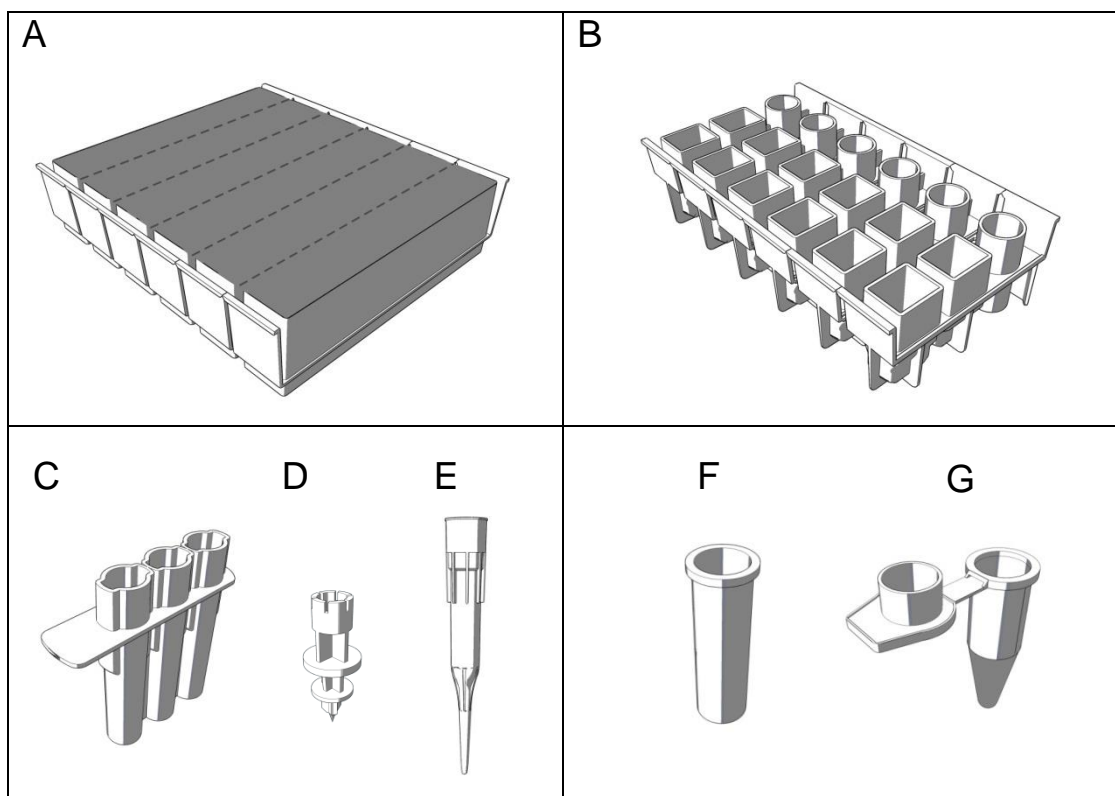
	Q'ty
A. AmpliX 12 Instrument	1
B. Power Cord	1
C. Sample Tube Rack	1
D. Barcode Reader	1

Please make all the components are free from damages as soon as you get the system. If any damage found, please contact your local representative for the instant support.

### Note:

ALL.DIAG's global warranty does not cover the damages from the transportation or improper operation.

## 1.2 Contents of Reagent Kits



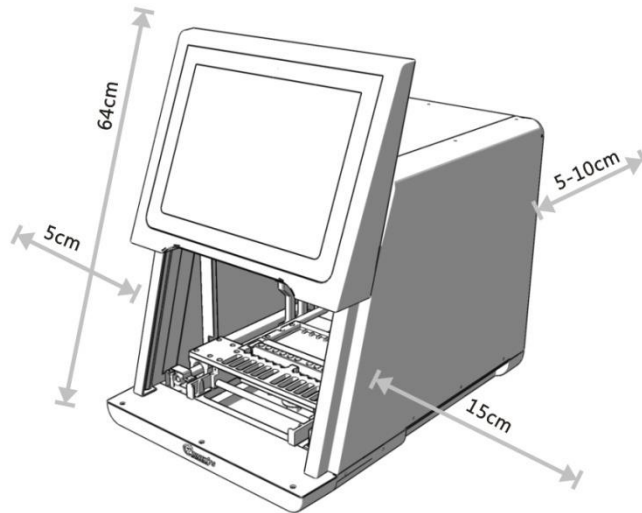
- A. Reagent Cartridge(s)
- B. Reaction Chamber(s)
- C. Tip Holder
- D. Piercing
- E. Filtered tip
- F. Sample tube
- G. Elute tube

### Note:

- Reagent kits are separated purchase. Please contact your local agents or representatives to get further info.
- The contents of reagent kits will be various. Refer to the handbook of kits enclosed in reagent box for details.

### 1.3 Operating Environment / Condition

Use the AmpliX 12 system in a location that meets the following conditions:



- The space for the allocation of the AmpliX 12 system must be remained 5-10 cm from instrument to side walls.
- A location where power can be provided.
- A location where the temperature is 10 to 40°C, and humidity is 30 to 80%RH (non condensing)
- A location that is flat and stable, with no vibration
- A location away from direct sunlight (Block the sunlight by closing curtains or blinds as necessary.)
- A location which is well-ventilated and not dusty
- A location where the temperature does not go up and down suddenly (Warming a cold room suddenly or moving the AmpliX 12 system from a room with low temperature to a warm room may cause condensation inside the device, resulting in abnormal extraction.)
- A location where the temperature and humidity are kept within the specified range (far from water taps, water heaters, humidifiers, air-conditioners and heaters)
- A location far from objects which generate strong magnetic fields (motors, transformers, TV, audio speakers, magnets, etc.) (Bringing the AmpliX 12 system close to any type of magnetic field may cause a malfunction.)

**Warning:**

Do not use the AmpliX 12 system to a location where it is wet or can be splashed with water. It may cause a device failure, fire, or electric shock.

When relocating the AmpliX 12 system, disconnect the plug from the outlet first. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.

**Caution:**

Do not use the AmpliX 12 system in an unstable place such as a slanted surface or a place subject to vibrations. It may cause injury or device failure.

Do not use the AmpliX 12 system in direct sunlight or close to a heating device. It may shorten the life of the AmpliX 12 system, or cause a trouble.

**Operating Conditions**

Items		Conditions
Temperature (°C)	During operation	10 – 40
	During down time	0 – 55
Humidity (RH)	During operation	30 – 80
	During down time	10 – 80
Max. wet bulb temperature (°C)	During operation	29 (non condensing)
	During down time	29 (non condensing)
Temperature gradient (°C/hr)		12 or less (non condensing)
Humidity gradient (RH/day)		30 or less (non condensing)
Altitude, operating (m)		1600 or less

## 1.4 Unpack the AmpliX 12 system

- (1) Open the packing box and take out the instrument and related accessories.

### **Important:**

The AmpliX 12 system has a weight of more than 45kgs. It should be lift and moved by two persons.

Hold the moving handler of the instrument from two sides to move it out from the box.



- Do not hold the plastic outer covering.
- Do not hold the front panel.
- Do not hold the door.



### **Caution:**

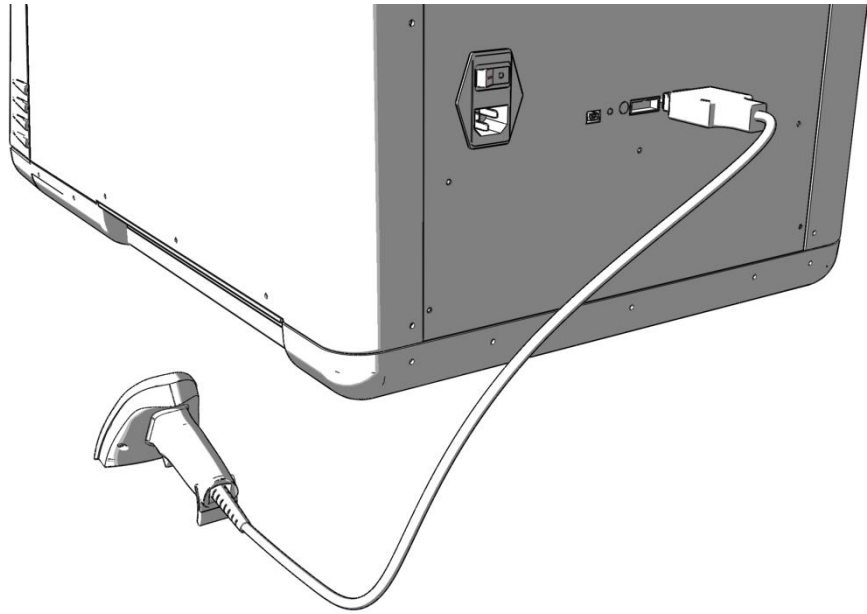
Improper handling of the movement of the AmpliX 12 system will lead to instrument damages.

For correct and safe use of the AmpliX 12, install it in a location that is close to electrical outlet and has enough space for installation and operation of the mains switch.

### **Important:**

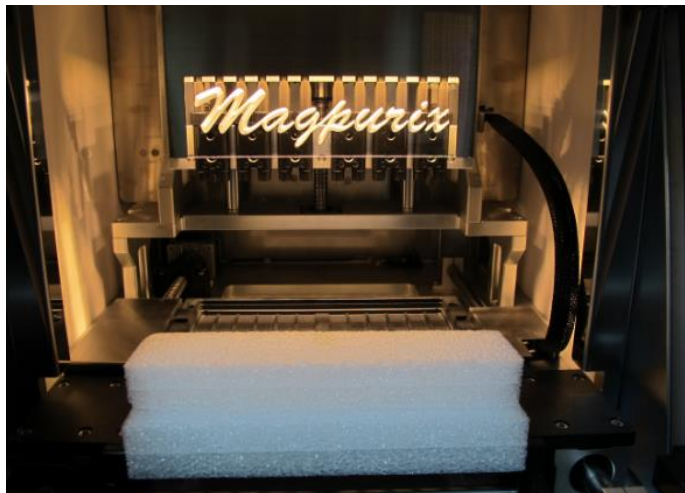
Keep the shipping box and stuffing materials. They will be needed again when transporting the AmpliX 12 system.

(2) Connect Barcode Reader with the Instrument.



(3) How to remove the fixing stuff inside the instrument following the steps below,

- i. Plug in the power cord to the instrument and connect to electric outlet
- ii. Turn the power switch on.
- iii. Press “START” button. The piston module will going up, and you can release the fixing stuff.

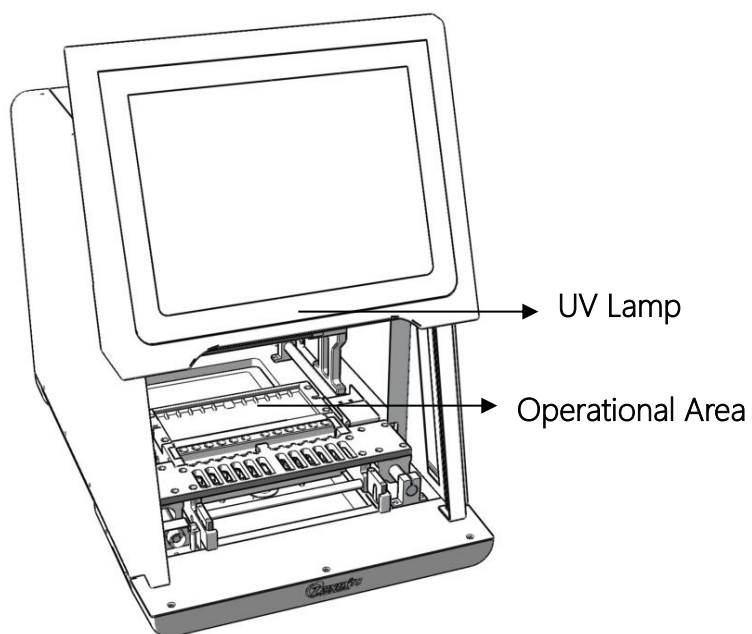


## 1.5 Overall View

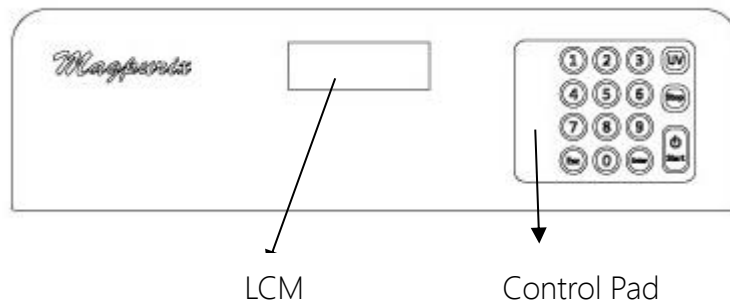
### ■ Front view with Sliding Door closed



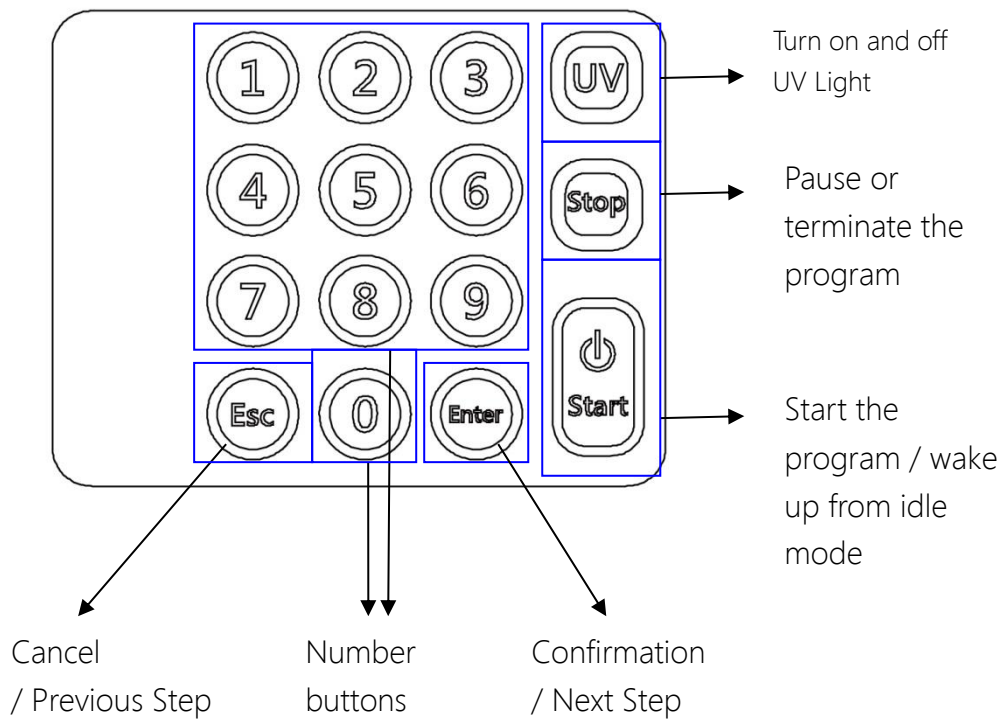
### ■ Front view with Sliding Door opened



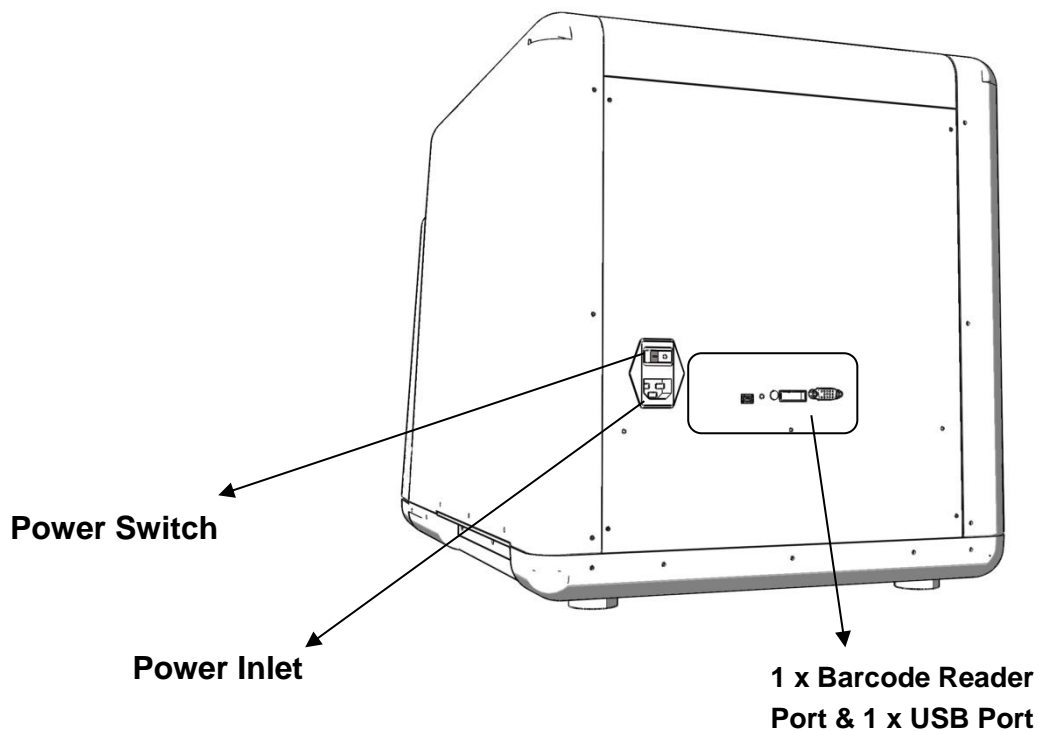
## ■ LCM Panel and Control Pad



- LCM displays information of operation instruction guide and program process status.
- Control pad is used for selection of functions and input of program and test codes.



## Back View



## 2 Getting Started



### **Biohazard:**

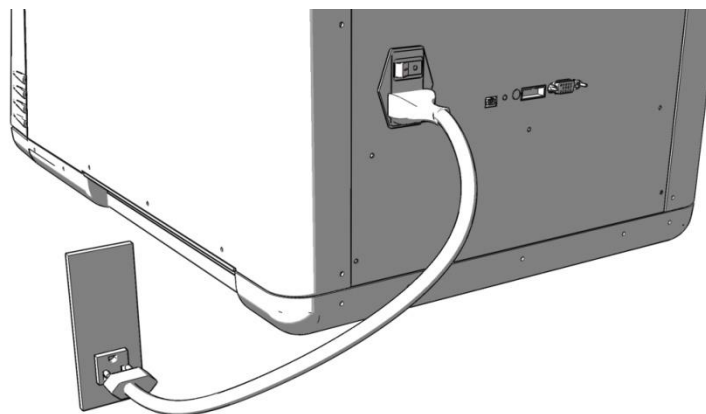
Always wear appropriate gloves, a mask, and safety goggles during any biohazardous operations in extraction process. Even when touching the device after any operation with a biohazard risk, wear appropriate gloves and a mask since the device may be contaminated.

### **Important:**

Before starting extraction, put on appropriate gloves, a mask, and safety goggles if required by the operation. In the operation from preparing samples to extraction completion, be careful not to contaminate the samples with sweat, saliva, etc.

## 2.1 Turning on the power

- (1) Make sure that the power cable are connected securely to the AmpliX 12 system.
- (2) Connect the plug of the power cable to the outlet.



## 2.2 Preparation

The following preparations are required for extraction operation.

■ Items to be prepared

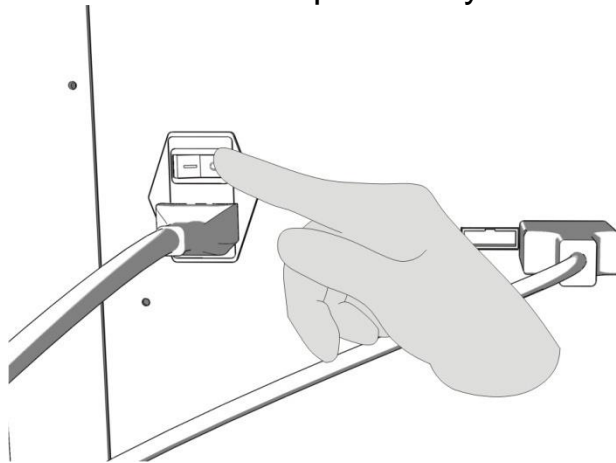
- Gloves
- Mask
- Safety Goggles
- Reagent Cartridge\*
- Reaction Chamber\*
- Tip Holder\*
- Pestle (Option)\*
- Filtered tip\*
- Sample tube\*
- Elute tube\*
- Piercing Pin

- For the preparation of samples, refer to the handbook of each kit.

\*: Provided with the Reagent Kits.

## 2.3 Extraction

- (1) Turn the power switch on and waiting for the LCM screen turn on and shows “AmpliX 12 System Stand-By”.



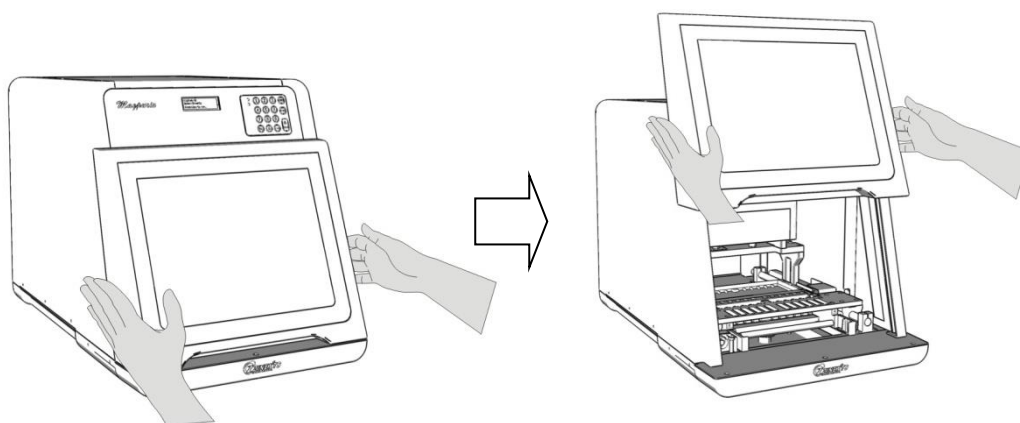
- (2) Press the “Start” button

(The system will process self-testing, and then go to steady mode)

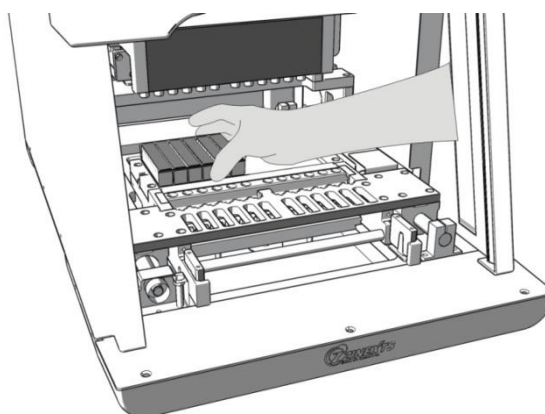
**Note:**

The system will block main functions before the completion of self-testing process.

- (3) Open the sliding door and remove the sample rack from the instrument.



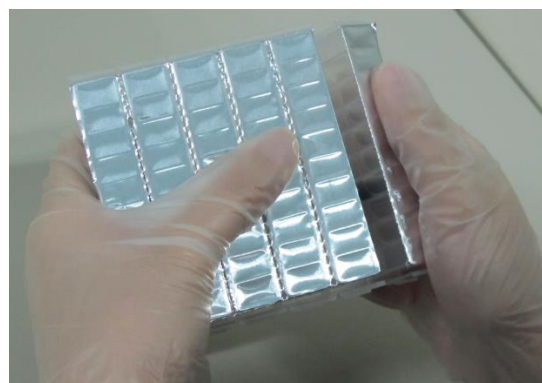
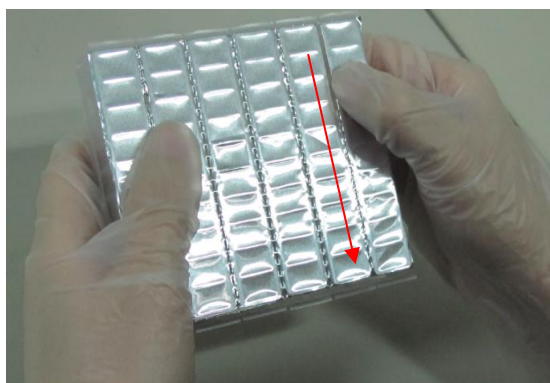
- (4) Load Reagent Cartridges, and all plastics disposables (Reaction Chamber, Tip Holder, Piercing Pin, Filtered Tip and Pestle (optionally supplied with some kit types))

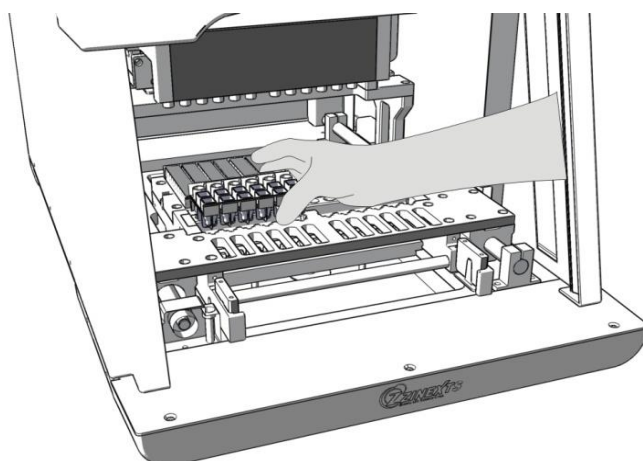


**Insert the cartridges**

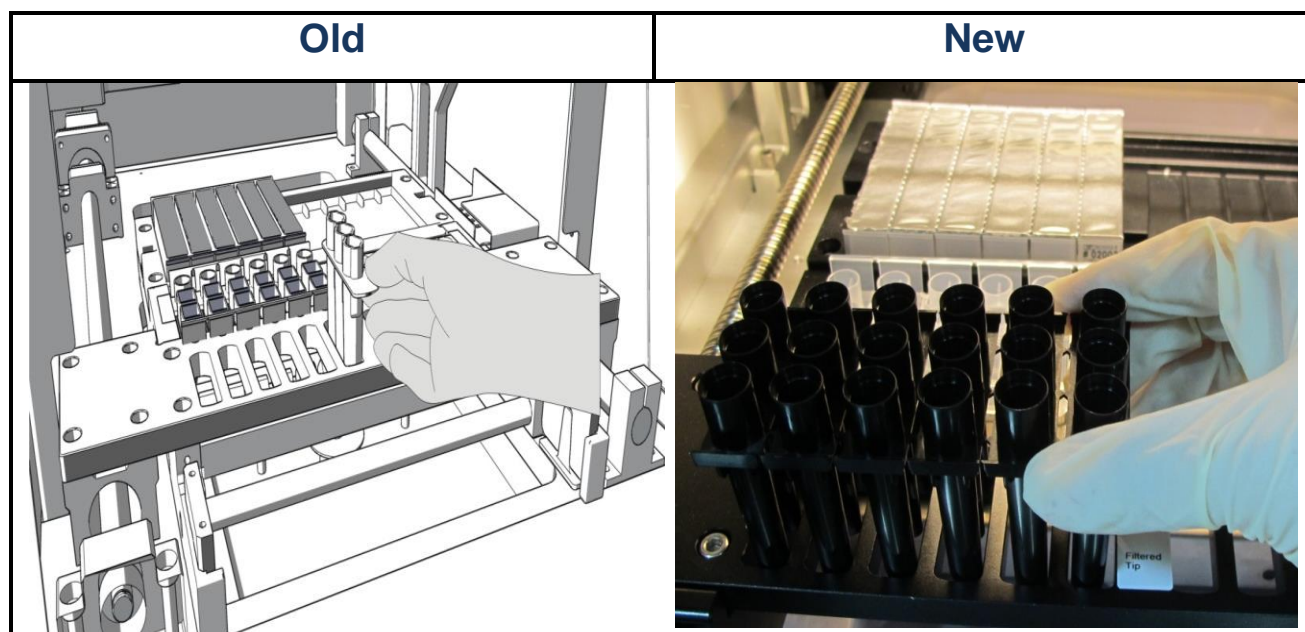
### ■ How to pull apart reagent cartridges

- Slash open the dotted line with nail and snap it with a little bit force.

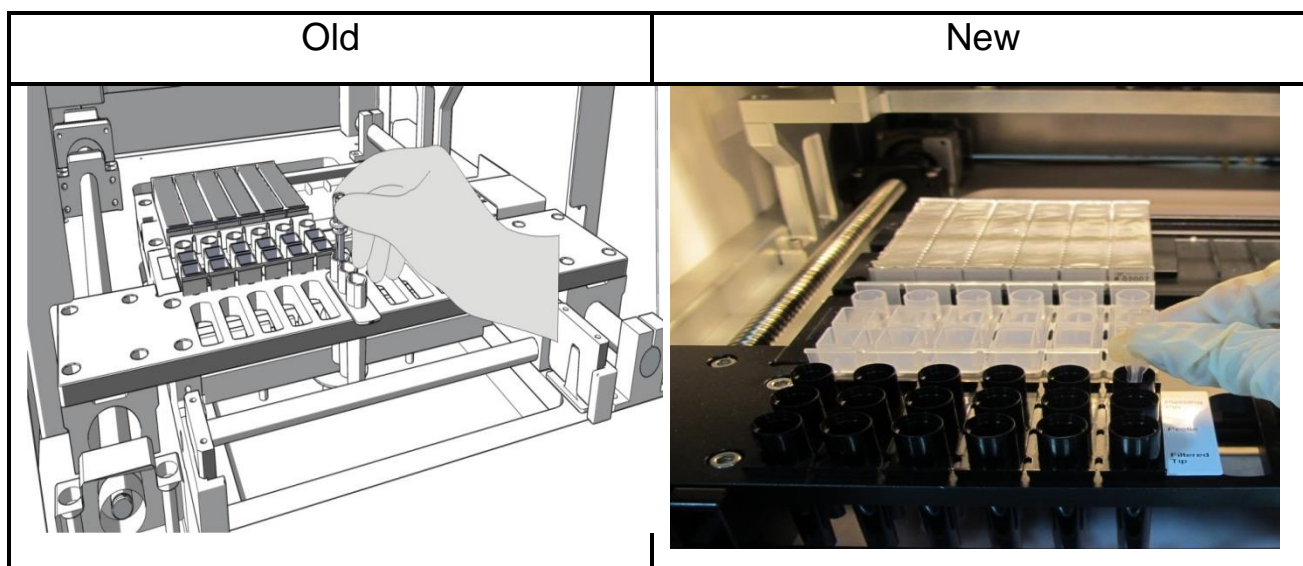




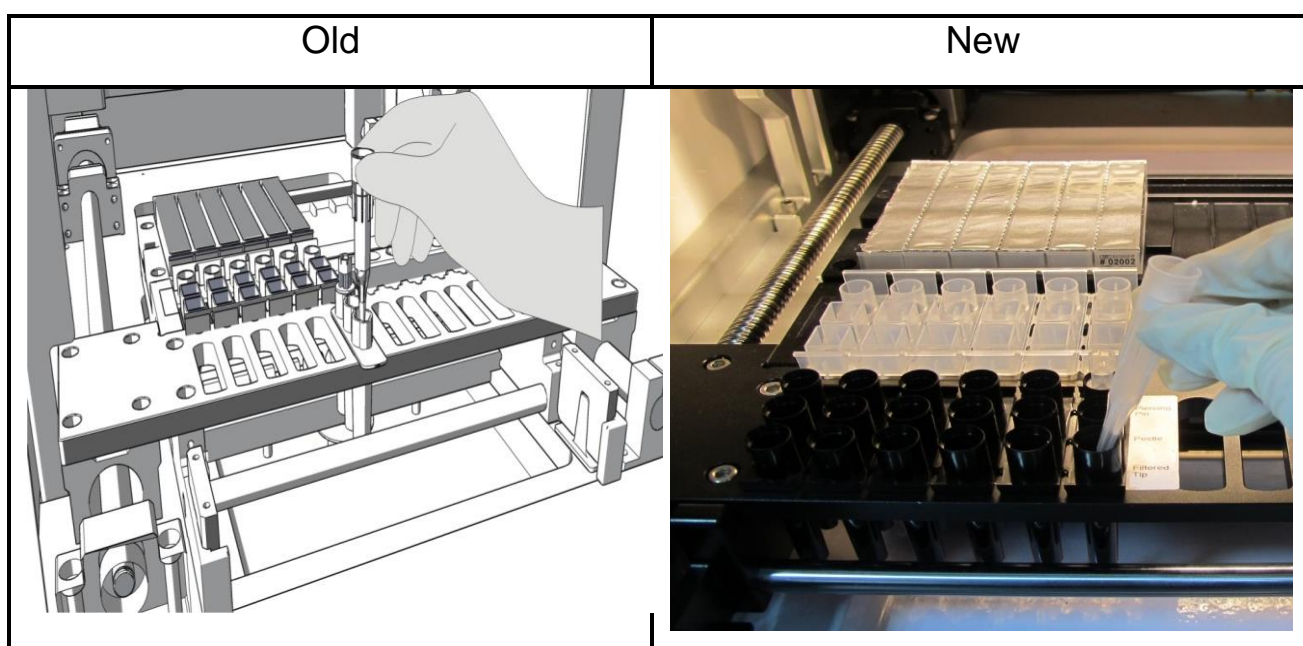
**Insert Reaction Chambers**



**Insert Tip Holder**



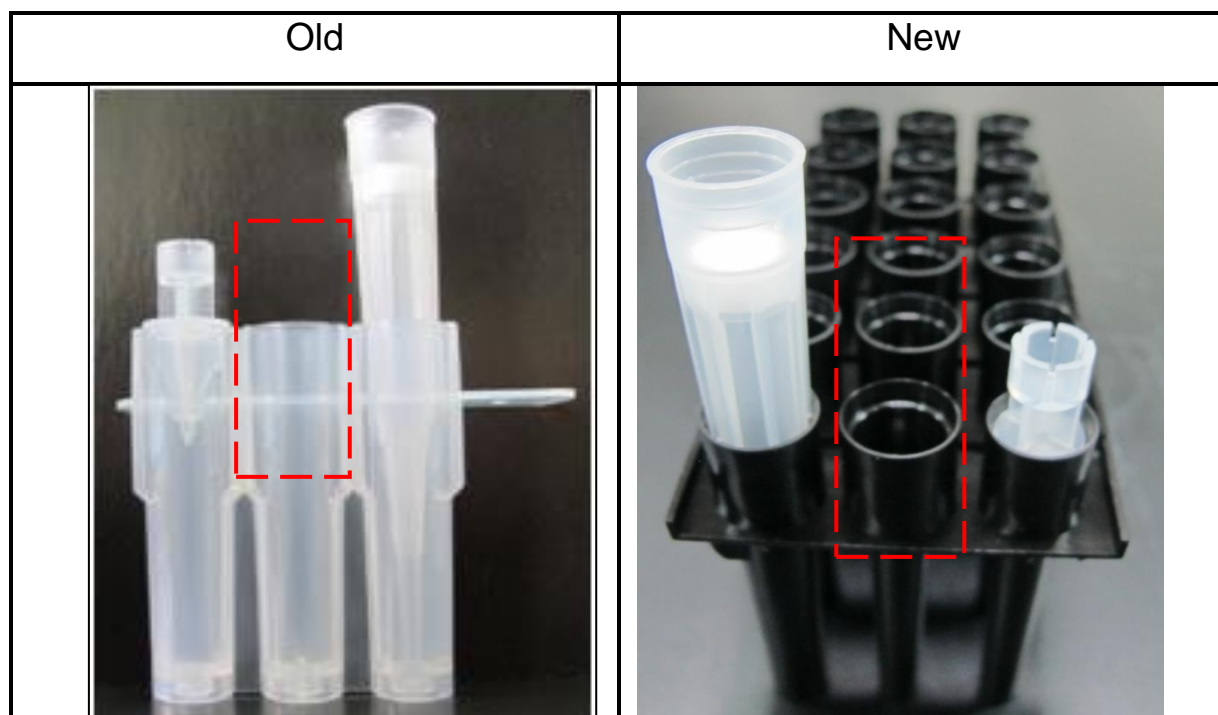
### Insert Piercing Pins



### Insert Filtered Tips

**Note:**

1. The positions of piercing pin and filtered tip; the 2<sup>nd</sup> row should be **“EMPTY”**.

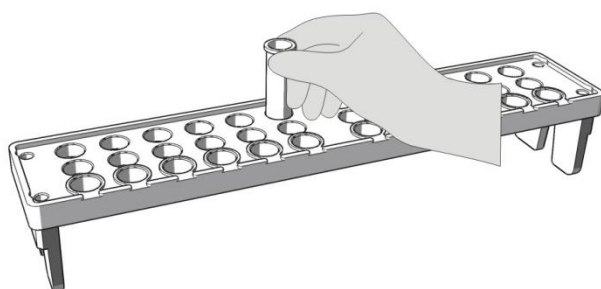


2. Load one Reagent Cartridge and one set of plastic disposable per sample.

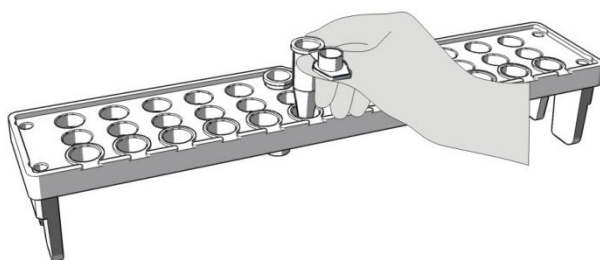
**Important:**

- Set Cartridges in the order of the number from left to right.
- Make sure that Cartridges are inserted in to the Cartridge Tray tightly.
- You can load 1-12 cartridges on the tray depending on the number of samples that you wish to process.

(5) Load Sample Tube and Elute Tube to Sample Rack on the bench

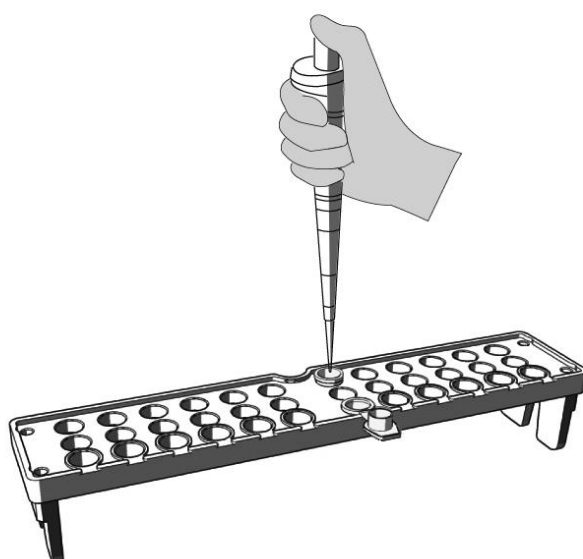


**Insert Sample Tube on to Sample Rack**



### **Insert Elute Tube on to Sample Rack**

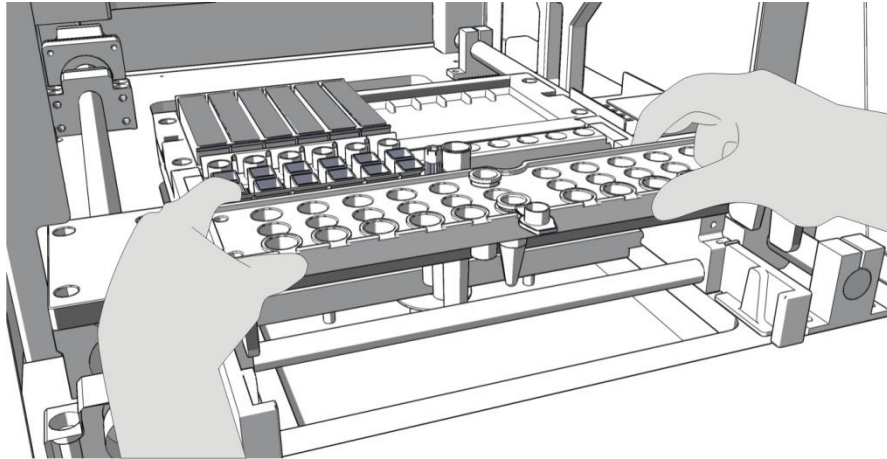
(6) Load the sample(s) to Sample Tube



### **Note:**

- Pretreatments are essential for some sample types before loading to Sample Tube. Please refer to the handbook of reagent kits for details.
- Make sure the caps of Elute Tube are open as the figure shown above.

(7) Place Sample Rack on the instrument platform



**Note:**

- Use two hands to handle the Sample Tray.
- Make sure the Sample Tray be placed correctly in the instrument

(8) Close the Sliding Door

(9) Scan the protocol barcodes to select purification protocol, sample volume and elute volume



**Note:**

- There is one protocol barcode paper enclosed in the reagent kit box.
- Protocol's name, sample volume and elution volume will be shown on LCD screen after protocol barcode is scanned.

(10) Follow the instructions displayed on LCM screen to double check the operating steps being completed before program running.

- (11) Push “Enter” to confirm. Instrument will start to run the protocol program automatically until whole processes are completed.

**Note:**

- It takes from 30 to 45 minutes to complete the extraction according to reagent types.

- (12) At the end of the run, the instrument beeps briefly and the LCM shows “Protocol Completed”

- (13) Open the instrument door

- (14) Remove the elute tubes containing the purified nucleic acid

**Note:** Store the purified nucleic acids at 4°C for short-term storage or store at -70°C for long-term storage

- (15) Discard the used cartridges, all plastic consumables into biohazard waste. Do not reuse the cartridges

- (16) If you’re not using the instrument, place the Sample Rack back to workplace, close the instrument door and push “Start” button for 2 seconds to get into “sleeping mode”.

And for longer time not using the instrument turn the power switch off.

## **2.4 After Extraction Operation**

- (1) Take out the Elute Tubes (The extraction yields in them)

**Note:**

- i. You can apply quality checking or do downstream study or storage them as what you expect.

- (2) Remove the Cartridges and plastic disposables from the instrument and then dispose of them.

### 3 Cleaning & Maintaining the AmpliX 12 system

Two types of maintenance are performed on the AmpliX 12 system Instrument as listed in the table. For details on each type of maintenance, see below:

Maintenance Type	Performed by	Schedule
Routine		
(17) Cleaning of Sample Tray		
(18) Cleaning of instrument body (outside)	User	After each use
(19) Cleaning of instrument body (inside)	User	Bi-weekly
Preventive	Service Engineer	Annually

- Clean the Sample Tray with mild detergent and rinse with deionized water. Allow the parts to dry before use. Clean and disinfect the platform surface by wiping with deionized water followed by 70% ethanol.
- Clean the instrument body by removing dust gently with a dry, soft cloth. If the outside of the AmpliX 12 system is heavily soiled, or if any samples that may cause infection are adhered to the outside of the AmpliX 12 system, wipe with a soft paper tissue, soaked with 0.5% sodium hypochlorite solution or ethanol.

### 4 Troubleshooting

Problem	Cause	Solution
<b>Instrument Problems</b>		
No power (the LCD Screen remains blank when the power is turned on)	AC power cord is not connected	Check AC power cord connections at both ends. Or Use the correct cords.
LCD Screen turns on when the power is on but the self-testing program does not run	Forget to remove the packing stuff from instrument	Turn off the instrument and remove the packing stuff.
	Technical problem	Contact your local representative or agent
Protocol stops after an initial start	Cartridge(s), Plastic wares (Reaction Chamber, Tip Holder, Filtered Tip Pestle, Sample Tube, Elute Tube) incorrectly loaded on the AmpliX 12 system	Turn off the power and then turn it on again to stop the program. The system will move back to initial state. Re-load them according to the instructions shown in this manual.  Note: you could not resume the protocol after stop and you may lose your samples.
	Problem with motion sensors	Turn off the power and remove all samples and plastic wares. Contact your local representatives
Bubbles formed during extraction	Missed adding sample or sample volume is lower than the recommended volume	Be sure to add the sample to tubes prior to starting the protocol. To ensure proper mixing of reagents in the tip and prevent bubble formation during mixing, make sure the sample volume is at least the recommended volume listed in the handbook supplied with the AmpliX Reagent Kits.
Presence of buffer in the Cartridge Tray	Motor movements may not be smooth, incorrect placement of plastic wares, or leakage from tips	Perform preventive maintenance annually to ensure proper motor movements.
Leakage from Filtered Tips or uneven liquid handling between Filtered Tips	Air leakage on the Filtered Tip	Swap the air-leaked Tip with new one
<b>Blockage of tips and pipetting failure</b>	<b>Too much starting material or excess DNA in sample</b>	<b>1. Decrease the amount of starting material. Use the recommended amount of starting material as listed in the Reagent Kit manual</b>

	causing clumps or aggregates	(Handbook). 2. Suggest using blood kit 1200 instead of blood kit 200 (if testing sample is blood)
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DNA Quality Problems		
Problem	Cause	Solution
Low DNA yield	Incomplete lysis	Decrease the amount of starting material used.
		Be sure to add Proteinase K during lysis, if included in the protocol.
		Make sure that the sample is completely immersed in the Lysis Buffer.
	Poor quality of starting material	Be sure to process sample immediately after collection or store the sample at appropriate temperature. The yield and the quality of DNA isolated depend on the starting material.
	Insufficient amount of magnetic beads added	During shipping, some magnetic bead solution may adhere to the sealing foil of the cartridge. To collect any bead solution from the foil, tap the cartridge to deposit the bead solution at the bottom of the well.
	Clogged Tips resulting in DNA loss	Ensure that the lysate does not contain any particulate material that can clog the tip sprout. If needed, centrifuge the sample prior to the AmpliX purification.
No DNA recovered	Magnetic beads stored or handled improperly	Store cartridge containing the beads at room temperature.
		Do not freeze the cartridge as the beads may be irreparably damaged.
		Make sure that the beads are in solution at all times and do not dry. Dried beads are non-functional.
Elute containing DNA is discolored	Magnetic beads present in the elute	Remove any magnetic beads using a magnetic separator or centrifuge the sample in a micro-centrifuge for 1 minute at maximum speed.
	DNA contaminated with heme	Minimize the amount of blood or blood-stained sample used ( $\leq 20 \mu\text{l}$ blood spot for forensics sample).
DNA is sheared or degraded	Bubbles formed during mixing steps	To prevent bubble formation during mixing, make sure the sample volume is at least the recommended volume listed in the manual supplied with Reagent Kits.
	Purified DNA repeatedly frozen and thawed	Aliquot purified DNA and store at 4°C (short-term) or -20°C (long-term). Avoid repeated freezing and thawing.
	DNA contaminated with	Maintain a sterile environment while working (i.e. wear

	DNases	gloves and use Dnase-free reagents).
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## 5 Specifications

<b>Model</b>	AmpliX 12
<b>Instrument Type:</b>	Benchtop automated nucleic acid extractor
<b>Sample Processing:</b>	1 to 12 samples per batch
<b>Sample Volume Handling:</b>	100 – 1200uL
<b>Processing Time:</b>	See purification kit manual for details
<b>Heat Block Temperature:</b>	60°C to 70°C (assuming the room temperature of ~25°C)
<b>Protocol Input:</b>	Barcode Reader
<b>Built-in Features:</b>	LCD Display Screen
<b>Instrument Dimensions:</b>	47 cm W x 68 cm D x 51 cm H
<b>Weight:</b>	43 kg
<b>Input Power:</b>	AC 100-240 V, 240 VA, 50/60 Hz
<b>Operating Temperature:</b>	10-40°C
<b>Operating Humidity:</b>	30-80%
<b>Fuse:</b>	F3A 250V
<b>Temperatures allowed during transportation/ storage/ packaging:</b>	-25°C to +70°C

### CE

LV directive (73/23/EEC)

EMC directive (89/336/EEC)

### EMC

EN61326-1

### Safety

EN60101-1, EN60101-2

# APPENDIX

## (20) Replacement/Optional Parts

Item	Q'ty	Parts No.
Barcode Reader	1	A01001
Power Cord	1	A01002
Sample Rack	1	A01003
Filttered Tip	38	A02001
Piercing Pin	38	A02004
Sample Tube	38	A02002
Elute Tube	38	A02003

## (21) Product Guarantees

- i. The guaranty period shall be one year from the delivery of the product.
- ii. Any part which fails to function properly under normal use, provided that all warnings and cautions in this manual are observed, during the guarantee period will be repaired by ALL.DIAG free of charge.
- iii. If the problem is due to the causes listed below, some charge may be applied for the repair even within the guarantee period.
  - Any failures due to improper use or that are affected by other devices except for those approved by the ALL.DIAG.
  - Any malfunctions or damages during transportation or due to dropping of the product by a user.

## **(22) About Services**

Before you ask for device repairs, refer to “4 Troubleshooting” to check the problems. If the problems cannot be solved, contact your local representative, or the relative customer support.

## **(23) Notes for Transporting / Shipping the AmpliX 12 system**

When transporting/shipping the AmpliX 12 system to a new location, perform the following tasks:

### **Warning:**

- Before carrying the AmpliX 12 system, disconnect the plug from the outlet. If the power cable is damaged, this may cause a device failure, fire, injury, or electric shock.
- When transporting/shipping the AmpliX 12 system, be sure to perform the following tasks:  
  
Remove all attached parts (Sample Rack, Barcode Reader) from the AmpliX 12 system.
- After completing the above tasks, pack the AmpliX 12 system in its original shipping box or some other equivalent box.

## (24) Instrument fixing stuff before Transport

(1) Press the button "0"



(2) Press the button "3"



(3) Press the button "5"



(4) Open the sliding Door

(5) Putting the Fixture on the Position of Tip Holder



(6) Close the sliding Door

(7) Press Enter button



(8) Finish

