ALLEX[®]64

Automated Nucleic Acid Extraction System



Instruction For Use

Thank you for purchaing the AllEx[®]64 Automated Nucleic Acid Extraction System. This user manual provides essential guidelines and precautions to ensure the effective and safe operation of the system. Please read it carefully before operation.

Initial Inspection

Please perform a thorough inspection of the instrument and all accessories when you first open the packaging. If you find any damage or if any components are missing, please get in touch with GeneAll Biotechnology or your local distributor for immediate assistance.

GENEALL BIOTECHNOLOGY CO., LTD

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1. Introduction

AllEx®64 provides compact and comprehensive solution for automated nucleic acid extraction for a variety of sample types. It combines the benefits of proven magnetic bead technology with the capability to rapidly extract 1~64 samples in a single run.



[Figure 1-1] Principle of Silica Coated Magnetic Beads Extraction



[Figure 1-2] Process of Silica Coated Magnetic Beads Extraction

1.1. Intended Use

AllEx[®]64 is designed to perform automated extraction of nucleic acids in molecular biology applications.

This system is intended to be used in conjunction with AIIEx[®] reagent kits that are recommended for use with AIIEx[®]64, as detailed in the kit manuals.

2. Precautions

Please read this manual carefully for the correct and safe operation of the system. Please be aware that any accidents arising from failure to comply with the instructions outlined in the official user manual will not be eligible for compensation.

2.1. General Precautions

- Before powering on the system, make sure that the correct voltage (200~240 VAC, 50/60 Hz, 5 A).
- Always use grounded power and power cords.
- The system is intended for nucleic acid extraction. Do not use this system for anything other than its designed purpose.
- Do not connect power with wet hands or operate the power switch. There is a risk of electric shock.
- This system can be used with potentially biohazardous materials. Use appropriate personal protective equipment (gloves, safety goggles, lab coat, etc.) for handling and perform sterilization with UV lamp after use.



2.2. Installation Precautions

- Locate on a sturdy, level surface.
- Choose a location that has good air circulation and is not exposed to direct sunlight.
- For proper ventilation, maintain a minimum 5 cm clearance on the sides and rear of the system. Inadequate ventilation can result in overheating, malfunctions, and potential fire hazards.
- Avoid installation near sources of water or damp locations. This can cause electrical shock, fire or system malfunction.
- Install it below 2,000 M above sea level.
- Avoid installation in a dusty environment. Excessive dust may cause malfunction or damage to the system.
- Avoid installation near heat sources. This can cause fire.
- Avoid installation near other electrically sensitive instruments.
- This equipment is designed to be the Pollution Degree of PD2.
- To avoid personal injury or damage to the system, do not lift the instrument alone when removing or replacing the system.

2.3. Maintenance Precautions

- Please follow the instructions in Section 8.
- Do not disassemble the equipment arbitrarily. It can cause malfunctions and serious injuries.
- Disassembly and/or modification of the system voids the warranty and may be refused service.

3. Product Specifications and Components

3.1. Product Specification

Model	AIIEx®64
Processing capacity	1~64 samples per run
Dimensions (mm)	420(W) × 599(D) × 440(H)
Weight	36.5 kg
Power Requirements	200~240 VAC, 50/60 Hz, 5 A
Operating temperature	15~30°C
Operating humidity	20~80% relative humidity, non-condensing
User interface	10.1" TFT LCD touch screen
Visualizing the progress/status of operation	Progress Bar (Top side), Status Circle (Front Side)
Decontamination	UV Lamp
Barcode	Internal Barcode Reader

[Figure 3-1] AllEx[®]64 Specification

3.2. Product Components



1 AllEx[®]64 system

1 220 V Power Cable forAllEx[®]64 system



1 Cassette 1 Single Cartridge Adaptor 2 Single Cartridge 2 Plate Cartridge





1 User Manual



8 Strip

[Figure 3-2] Components

3.3. Components Name



[Figure 3-3] Components name I



[Figure 3-4] Components name II

4. Product Installation

- 1. Clear and clean the area where the system will be installed.
- 2. Check for an appropriate power supply (outlet) in the vicinity.
- 3. Carefully unpack all of the components from the packaging.
- 4. Avoid attempting to lift the heavy main body alone to prevent injury of damage.
- 5. Remove the plastic wrap from the components.
- 6. Verify that all components are in good condition, without any visible damage or defects.
- 7. Place the AllEx[®]64 on a sturdy, level table that can sufficiently support the weight of the main body.
- 8. Connect the power cable to the rear of the system.
- 9. Turn on the system.
- 10. Wait for the system to completes the initialization process.
- 11. Once the system has completed initialization, confirm that the main menu is displayed on the screen.
- 12. Touch the cassette Loader forward.
- 13. Detach the Cassette from the Cassette Loader.
- 14. Touch the icon to move the Strip Loader forward.
- 15. Detach the Strip from the Strip Loader.
- 16. Touch the contract icon.
- 17. When the Protocol Selection screen appears, touch the ⊃ icon.
- 18. The installation of AllEx®64 is complete.

5. User Interface

5.1. Main Menu



[Figure 5-1] Main menu screen

The main menu contains interactive icons :

Cassette Loader Move Front	Move 'Cassette Loader' forward to open the door	*	Activate Setup screen
Cassette Loader Move Home	Move 'Cassette Loader' to home position in order to initiate nucleic acid extraction	Carsette Loader Stop	Stop 'Cassette Loader'
Cassette Loader Resume	Continue operating 'Cassette Loader'	Decontamination	Operate UV Lamp
Strip Loader	Operate 'Strip Loader'	Indoor Light	Turn on Indoor Light in Chamber



[Figure 5-2] Icons on main menu

5.2. Setup

GeneAll	Setup			/06	6 16:52		5	
• General	User Name			gene	all	<i>i</i>		
🖶 Protocol	Sample ID					No		
න History	Barcode Scan					No		
2	Protocol Selection				No			
Camera	Camera Enable	Yes			No			
• Calibration	Time Format	12h 24h						
Accumulated data	Decontamination time		14 min		value		2	+
	Decontamination Interval		5 min		value	-	2	+
C2 Software update	Ventilation Time		12 sec		value	-	2	+
🔦 Engineer Mode	Ventilation Interval		— 5 sec +			-	2	+

[Figure 5-3] Setup screen

6. Nucleic Acid Extraction

6.1. Kit Installation

- 1. Check the kit manual and follow the instructions.
- 2. If Cassette is inside the system, touch cassette from the Cassette Loader.
- 3. Place Cassette on the experiment bench.

- 4. Unpack the kit on the bench to take out the Cartridge. *Cartridges come in two types : Single Cartridge for 1 extraction and Plate Cartridge for 16 extractions, each capable of processing 1 or 16 samples.
- 5. Dispense the required amount of samples into the Lysis Lane (1st and 7th Lane) on the Cartridge following the instructions in the kit manual.
- 6. Push the Lock Switch towards the Unlock position.
- 7. For Single Cartridge, use Single Cartridge Adaptor.
- Load Cartridge with the samples from seat 1.
 When there are multiple cartridges, load the cartridges in the order of Seat 2, 3, and 4.





- 9. After loading the cartridge(s), push the Lock Switch towards the Lock position.
- 10. Bring the Cassette with Cartridge(s) loaded, along with the Strip(s) corresponding to the quantity of the Cassette(s) and sample(s) to the system.
- 11. Load the Cassette to the Cassette Loader with the FRONT of the Cassette facing forward until you hear a clicking sound.
- 12. Press on the corners of the Cassette to verify if they are installed correctly on the Cassette Loader.
- 13. Improperly installed Cassette may cause damage to the system during operation.

6.2. Sample Entry and Strip Installation

1. Touch icon to open sample ID screen.

GeneAll		Sample ID Input	2023/03/30	18:01
	Cartridge No. 1	Cartridge No. 2	Cartridge No. 3	Cartridge No. 4
	Well Sample ID	Well Sample ID	Well Sample ID	Well Sample ID
3				
[86868868][86868686]				
1				
	F1	F1	F1	F1
	G1	G1	G1	G1
Total No. of Samples to be		H1		
performed the extraction	87	87 B7	87	87
8 24 40 56			C7	C7
Save				
8 24 40	56	[Figure	6-2] Sample ID so	creen
16 32 48	64			

- 2. Select the appropriate number corresponding to the sample quantity.
 - * Select 8 for 1~8 samples, select 16 for 9~16 samples, select 24 for 17~24 samples, select 32 for 25~32 samples, select 40 for 33~40 samples, select 48 for 41~48 samples, select 56 for 49~56 samples, and select 64 for over 57 samples.



[Figure 6-3] The position of the cartridge(s) corresponding to the number of sample(s)

- 3. Touch _____ icon to save and touch \supset icon to return to Main Menu.
- 4. Touch icon to move the Strip Loader forward. The Strip Loading Guide will also

be displayed on the screen. Please ensure that you insert the strip in the correct position as indicated by the Strip Loading Guide.



[Figure 6-4] Loading position of Strip and Cartridge corresponding to the number of samples

- * Improperly loading Strips and Cartridges can not only lead to errors in the extraction efficiency but also potentially damage the equipment.
 - 5. The Strip Loader moves back to home position once icon is touched.



[Figure 6-5] Final confirmation of Strip loading

6. Please verify that the Strip is correctly loaded in the designated location, and then touch the contract location location to send the Strip Loader to its home position.

6.3. Protocol Run

- 1. Touch icon to the Cassette Loader move back to its home position.
- 2. Select a protocol and touch iokay icon to run the protocol.

GeneAll			Protoco	l Selecti	on	202	3/03/30	12:55	1
	Sample Volume	Lysis Temp	Lysis Time		Elution Temp.	Elution Time	Elution Volume	Running Time	
									_
									\land
									1/1
									_
									\sim
			~ (Okay					

[Figure 6-6] Protocol Selection

3. Check the running Protocol and the estimated end time.



[Figure 6-7] Protocol in Progress 1 Start Step



[Figure 6-8] Protocol in Progress 2 Last Step

GeneAll	Protocol in progress V-F-ly310-0.5	2023/03/31 l 11:42
	Extraction	
	Extraction is completed!	
	Continue	me

[Figure 6-9] Protocol in Progress 3 Step Completion

- 4. Touch control icon to move to the main menu screen.
- 5. Touch icon to Cassette Loader forward to open the door.
- 6. Touch icon to move the Strip Loader forward in order to separate the used strip

from the Loader, and then discard it.

- 7. Touch C: icon to move the Strip Looder to its home position.
- 8. Detach the Cassette from the Cassette Loader by lifting it up with your hands, and move it to the experiment bench.
- 9. Touch conto move Cassette Loader to its home position.
- 10. When Protocol Selection screen is shown, touch ⊃ icon to skip the Protocol Selection.

7. Supplementary Features

7.1. Decontamination

The AIIEx®64 contains a UV light that can help aid in Sterilization of the system. It is possible to specify the duration of the UV treatment and when UV light treatment of the system should be performed.

^{1.} Touch icon to open the Decontamination setting screen.



[Figure 7-1] UV-Sterilization

- 2. The initial setting for UV-Sterilization is 10 minutes, and it can be changed in the 'General' section of the icon.
- 3. Touch $\langle \rangle$ button to set the running time.
- 4. Touch <u>controut</u> icon to start Decontamination.
- 5. Once the decontamination is completed, touch icon to return to main menu.

7.2. Ventilation

1. Touch icon to open the Ventilation setting screen.



[Figure 7-2] Ventilation

[Continue]

- 2. Touch **< >** icon to set running time.
- 3. Touch <u>continue</u> icon to start Ventilation.
- 4. Once the ventilation is completed, touch

icon to return to main menu.

7.3. Indoor Light

- 1. Touch icon to turn on the Indoor Light in Chamber.
- 2. Touch icon to turn off the Indoor Light in Chamber.

7.4. Recovery

It is designed to resume the protocol from the last failed or interrupted run. The effectiveness and progress of the recovery process are entirely at the user's discretion.

- Check the interrupted Protocol and consider overall factors, like remaining reagents. Following a comprehensive assessment including run progress and the system status, if it is deemed that recovery is feasible, proceed with the Protocol Run by correctly positioning the Cartridge and Strip.
- 2. In the [Remarks] column, "ES" means Emergency Stop interrupted by the user, and "MS" indicates Missing Step, which is a malfunction related to motor or operation. Also, blank itself means interruption caused by power failure.
- 3. Con makes screen turned to Recovery mode when touched.

Gen	eAll	Recove	гу	2023/03/30	18:11	5	
	Protocol						
	V-F-ly310-0.5	2023-03-30	13:04:02				
	V-F-ly310-0.5	2023-03-30	17:26:20	Wash 2	09:47	MS	
					O Rec	covery	



4. After select the Protocol for Recovery, touch c recover the Protocol.

7.5. Emergency Stop

It can be used when there is a need to stop the progress based on the user's discretion during the operation.



[Figure 7-4] Protocol in progress

1. Touch • (MERGENCY STOP) icon to stop the operation.



[Figure 7-5] Emergency Stop

2. To cancel the Emergency stop and resume the Protocol, select the icon to continue its protocol.

- 3. Selecting the 🗙 icon to completely stop the operation will terminate the Protocol, and system will return to its initial state.
- 4. Following a comprehensive assessment including status of Cartrdige, Strip, sample and the system, if it is deemed that recovery is feasible, recover the Protocol through Recovery function.

7.6. User Setup

Touch 🔹	lcon
---------	------

GeneAll	Setup			2023/03	3/31	12:02		5
General	User Name			adm	in	é		
🖶 Protocol	Sample ID					No		
A History	Barcode Scan					No		
	Protocol Selection	Yes			No			
Camera	Camera Enable	Yes				No		
• Calibration	Time Format	me Format 12h 24h						
Accumulated data	Decontamination time		10 min		value		2 +	
	Decontamination Interval		5 min		value	-	2 +	
C Software update	Ventilation Time		10 sec		value	-	2 +	1
Engineer Mode	Ventilation Interval	— 5 sec +			value		2 +	

[Figure 7-6] General

7.6.1. General

- ① On/off of User Name registration
- ② On/Off of Sample ID function
- ③ On/Off of Barcode Scan function
- ④ On/Off of auto protocol selection
- S On/Off of Camera function

- 6 Option of Time Format
- $\ensuremath{\textcircled{O}}$ Set the initial decontamination time
- In the decontamination interval time
- Is Set the initial ventilation time
- \circledast Set the ventilation interval time

7.6.2. Protocol

The list of saved Protocol can be viewed.

G	eneAll	Setup					2023/03/31 12:11				5
0											
8	Protocol	Name AllEx Viral DNA	Volume 10	20	Temp 30	Time 40	Wash 50	Temp 60	Time 70	Volume 80	Time 1076
Ð	History	GDE-Fast	200			300			200	50	15m30
٥	Camera	V++-IY310-0.5	200		35	310		85	210	100	
¢											
٩											

[Figure 7-7] Protocol

7.6.3. History

The performed Protocols can be tracked.

c	GeneAll		Setup	2023/10	/27 10:25	5	
0							
8							
		Genomic-Standard	2023-10-05	13:54:25	14:03:41		
	Camera	RPM-TEST2	2023-10-05	14:54:29	14:55:43		Terminated
Ô		Genomic-Standard	2023-10-05	14:59:41	15:05:42		Terminated
		Genomic-Standard	2023-10-05	15:16:05	15:36:56		Finished
Ŷ	Calibration	Genomic-Standard	2023-10-05	15:51:40	16:12:31		Finished
	Accumulated data	Genomic-Standard	2023-10-12	09:21:22	09:29:09		Terminated
		Genomic-Standard	2023-10-12	09:29:56	09:50:47		Finished
(٢)							
ع							



7.6.4. Camera

The inside of the Chamber can be viewed by the Camera Viewfinder.



[Figure 7-9] Camera

7.6.5. Calibration

Calibration information can be checked and auto- calibration can be performed.





7.6.6. Accumulated Data

Accumulated information about the Device Shelf Life can be accessed.

GeneAll	Se	etup	2	023/04/06	17:06
 General 					
🗄 Protocol	Item		Accumulated	Last Reset	Last Value
	AllEx 64		8h 4m 0s		
o Camera	Indoor Light	U		2023/03/31 12:39:27	
 Calibration 	UV Lamp	J		2023/03/31 12:38:58	
Accumulated data	Heater	J		2023/03/31 12:39:04	1m 45s
 Software update 	Ventilation	J		2023/03/31 12:39:09	
Engineer Mode					

[Figure 7-11] Accumulated Data

7.6.7. Software Update

- Application
- ② Protocol

- ③ Temperature Conversion File
- ④ Calibration Data

GeneAll	Setup		2023/03/31	12:42	5
General					
🗄 Protocol					by
		2023/03/30 13:02:34	HeaterConversion_No Conversion.csv	admin	
	1. Prepare USB stick with update file	2023/03/30 13:02:34			
Camera	2. Insert USB into USB port	2023/03/30 13:02:34			
Calibration	3. Touch "Update" Button	2023/03/30 13:02:34			
		2023/03/30 12:55:33	HeaterConversion_No Conversion.csv		
Accumulated data		2023/03/30 12:55:33			
	Q Update				
Software update					
Engineer Mode					ion : 1.0)3 05:34



7.6.8. Engineer Mode

It can only be activated by authorized service engineers.



[Figure 7-13] Engineer Mode

8. Maintenance

8.1. Daily inspection

8.1.1. Before use

- 1. Clean any dirt from the Magnet Rod.
- 2. Check whether the Magnet Rod get damaged or broken.
- 3. Clean any dirt from Heating Block and Cassette.

8.1.2. After use

- 1. Wipe up any spills immediately. After each use, wipe off the Magnetic Rod, inside/ outside system using cloths dampened with 70% ethanol.
- 2. Operate the Decontamination for 10 minutes.
- 3. Clean any dirt from stuck in Door hinge.
- 4. Remove and discard the used Strip.
- 5. Move back the Cassette Loader to home position.
- 6. Turn off the power.

8.2. Regular inspection

8.3 Monthly

- 1. Check the operation status of the UV Lamp.
- 2. Check for damage and alignment of the Magnetic Rod.

8.4. Semi-annually

- 1. Check calibration.
- 2. Check alignment of Magnet Rod.

8.5. Troubleshooting Guide

Trouble	Troubleshooting		
No display after tuning on power	Reconnect Power Cable Check the fuse and replace		
The Cartridge cannot be equipped	Check for the position of Cartridge Remove any foreign substances from the Cassette Check for the defective of Cartridge		
The Strip is cannot be equipped	Check for the defective of Strip		
No UV light	Check the accumulated run time Replace UV Lamp		

[Figure 8-1] Troubleshooting

9. Quality Assurance

AllEx[®]64 is the product manufactured under strict quality control and inspection, and we would thoroughly fulfill our accountability for quality assurance in accordance with the relevant regulations.

9.1. Warranty period

- 1. System : One(1) year from the Invoice date.
- 2. Consumables : Three(3) months from the Invoice date.
- 3. Retention period of repair parts : Five(5) years from manufacturing date.

9.2. Warranty details

- 1. The product in failure under normal operation environment is subject to repair service for free within the warranty period.
- 2. The following case is not subject to the repair service for free.
 - Failure due to negligence, improper use, impact, or submergence
 - ② Disassembled or renovated product
 - ③ Failure due to natural disaster
 - ④ Product repaired by the unqualified
 - (5) Out of region covering a warranty
- 3. 1:1 exchange of product

The product which has been repaired more than three times by same problem is subject to exchange for same model.

9.3. Warranty condition

Only purchased product which has completed the registration as per procedure.

10. Registration Details

Product name	AllEx®64		
ltem	Automated Nucleic Acid Extraction System		
No. of Certificate	-		
Issue Date	April 1, 2023		
Revision Date	-		
Manufacturer	GeneAll Biotechnology Co., Ltd. D-1110, Hanam Techno Valley U1 Center, 947, Hanam-daero, Hanam-si, Gyeonggi-do, 12982, Republic of Korea		





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