

# GeneXpert<sup>®</sup> Infinity System Training on Xpertise 6.8

# Agenda:

- Infinity Overview
- Xpertise Software Features
- Infinity Files
- Infinity Workflow
- Viewing Test Results
- Data Management

- Brief LIS Overview
- Troubleshooting
- Shut Down Protocol
- Maintenance



# **Infinity Overview**

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# GeneXpert<sup>®</sup> Infinity Real-time PCR System

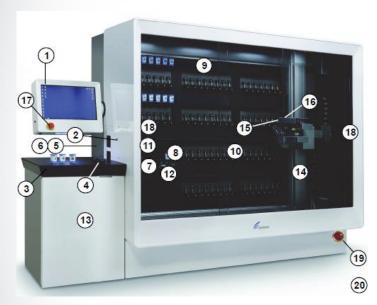


#### **System Components**

- GeneXpert Infinity
  - o Conveyor, Gantry, Accumulator
  - Modules
    - Thermal and Optical system
    - Precision Fluidics
- Extraction and Reaction Cartridges
- Reagents
  - Dry and wet Reagents
- Computer System
  - Software, barcode scanner, LIS interface and LINK connectivity



# **GeneXpert® Infinity Components**

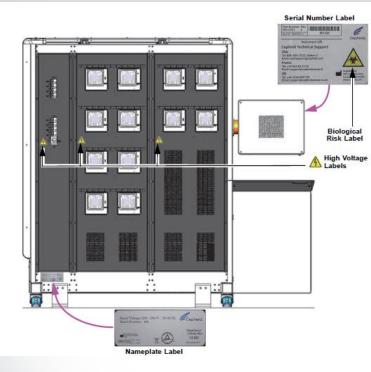


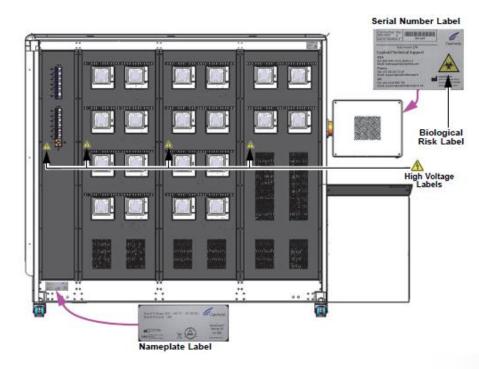
1 - Monitor with touch screen	13- Waste container (hidden)
2 - Kiosk barcode scanner	14 – Robotic Gantry System
3 - Keyboard (wireless)	15 - Gripper
4 – Mouse (wireless)	16 – Gantry Barcode Scanner
5 - Kiosk computer (in the main cabinet)	17 – Emergency STOP button
6 – Embedded Computer (in the main cabinet)	18 – Left and Right Door handles
7 - Conveyor	19 – UPS (hidden)
8 - Lobby	20 – AC Power Switch
9 – Accumulator Shelves	
10 – GeneXpert Modules	
11 – Shuttle	

12 – Waste disposal shelf



### **View from the back**





Infinity-80





### **Kiosk View**





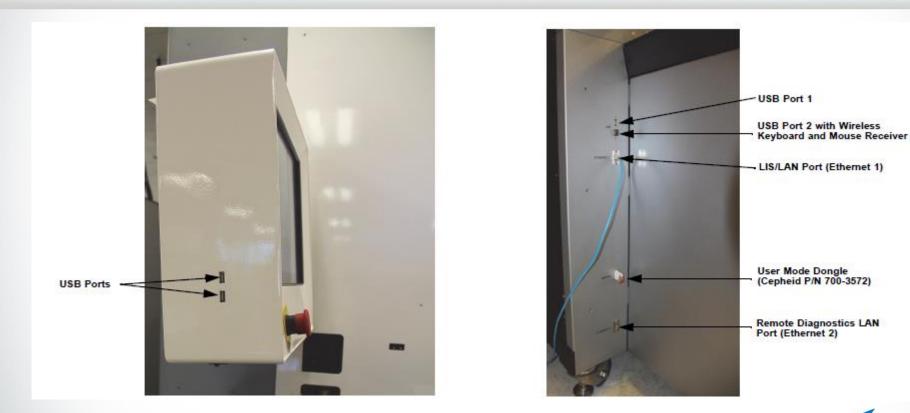
### Kiosk View - 2



Shuttle Loading Drawer (Open)



# **USB and Ethernet ports**





# **Kiosk Barcode Scanner**

- 1 Cartridge
- 2 Barcode reader (built in)



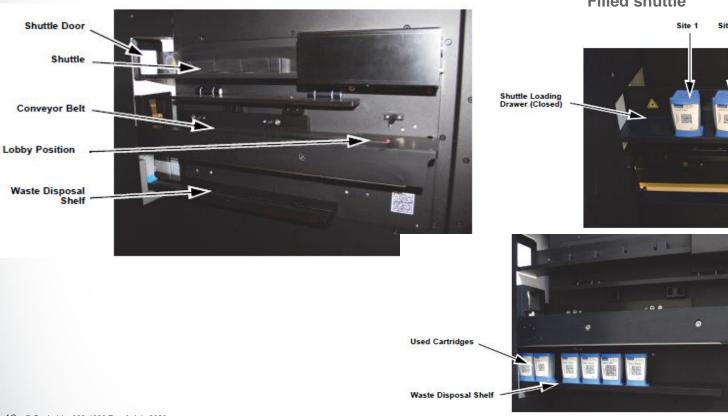


# **Waste Container**





# **Lobby View**



Filled shuttle

Cepheid.

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# Shuttle

#### **Function of the shuttle:**

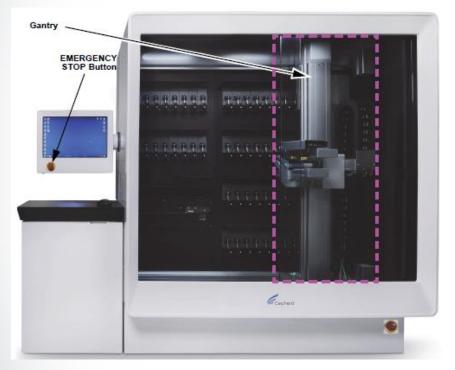
- Submit cartridges of STAT orders
- Remove retrieved or rejected cartridges

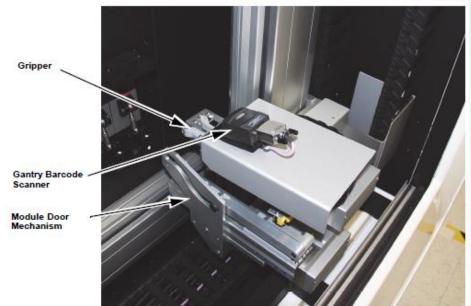


Shuttle Loading Drawer (Closed)



## **Robotic Gantry**



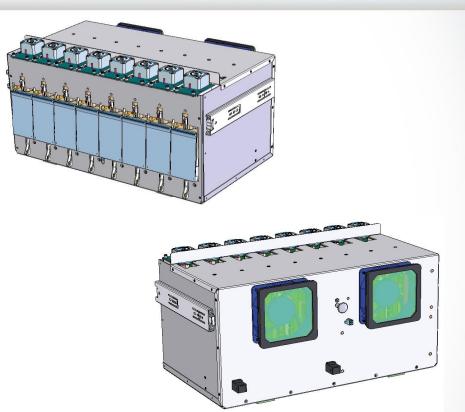


Robotic gantry consists of a gripper, a gantry barcode scanner and a module door mechanism



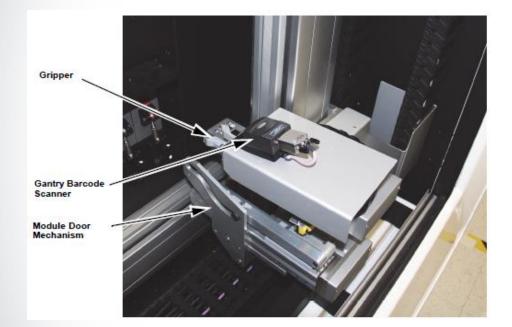
# **Modules – Eight-pack panel**

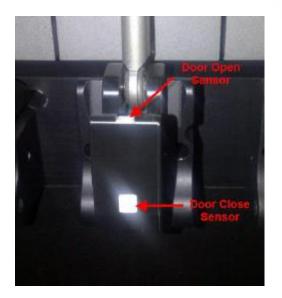






### **Door mechanism**

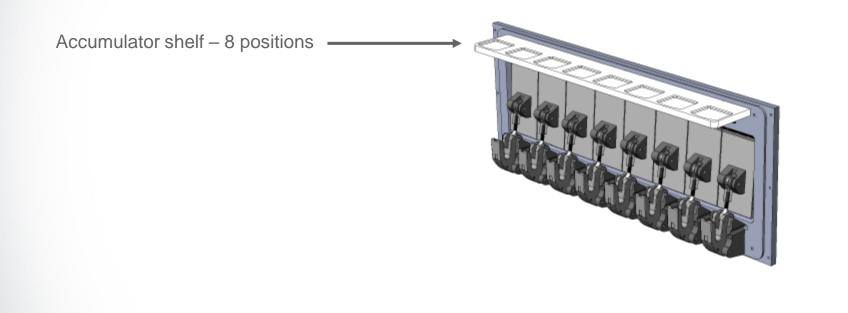




Reflecting squares that indicate whether door is open or closed

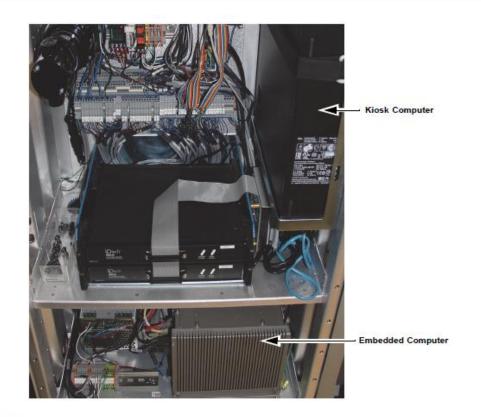


### Accumulator





# **Kiosk and Embedded Computer (in the main cabinet)**





# **Xpertise Software Features**

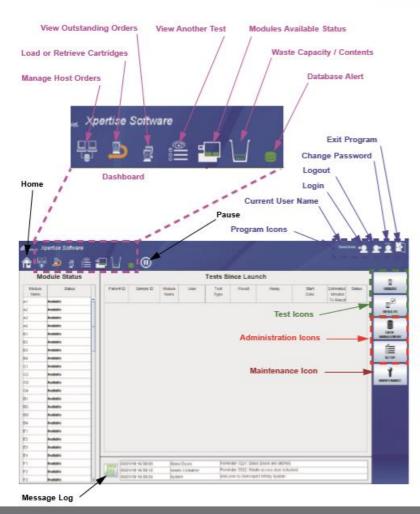


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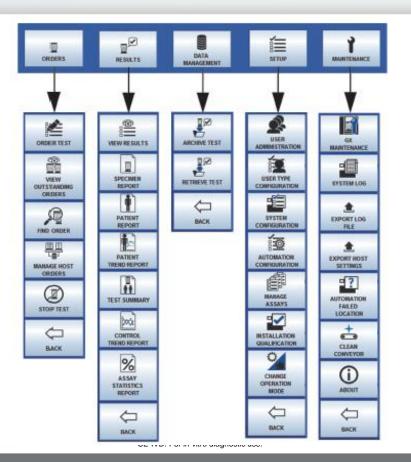
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# **Home Screen**



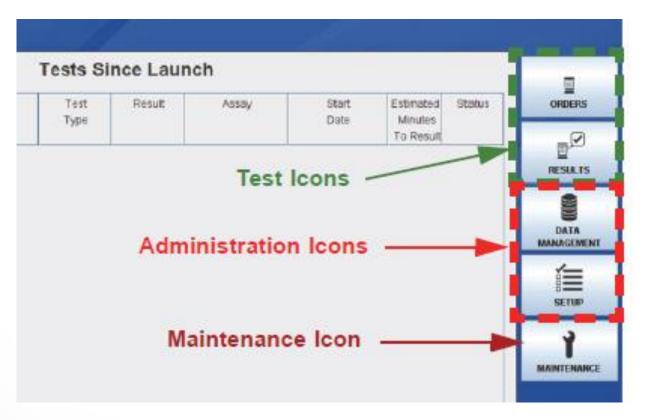


# Menu Panel Menu Map (Quick Finder)





# **Available workspaces**





# Message Log

- ····		0.000				
Mo	dule Status	T			Message Log	
Module	Status	Тур	pe Time	Subsystem	Message	
Name		. 0	08/04/11 17:31:53	System	Software Initialization Database Integrity Check started	100
A1	Available	0	08/04/11 17:31:53	System	Software Initialization Database Integrity Check completed	
A2	Available	. 🛆	08/04/11 17:33:30	Emergency Stop	Reminder 7202: Emergency Stop de-activated.	
A3	Available	. 🛆	08/04/11 17:33:30	Glass Doors	Reminder 7223: Glass Doors are closed.	
A4	Available	. 4	08/04/11 17:33:30	Glass Doors	Reminder 7223. Glass Doors are closed.	
81	Available		08/04/11 17:33:31	Waste Container	Reminder 7323. Waste access door is unlocked.	
82	Available		08/04/11 17:33:53	Glass Doors	Reminder 7221 Glass Doors are latched.	
B3	Available		08/04/11 17:33:56		Reminder 7322: Waste access door is locked.	
84	Available					
C1	Available	1 1 1 1 1 1 1 1 1				
C2	Available					
C3	Available					
C4	Available					
D1	Available					
D2	Available					
D3	Available					
D4	Available					
E1	Available					
E2	Available					
E3	Available					
E4	Available					
F1	Available		08/04/11 17:33:31	Waste Container	Reminder 7323 Waste access door is unlocked.	
		CITED 1	000411111.00.01	Traste Container		
F2	Available		08/04/11 17:33:53	Glass Doors	Reminder 7221: Glass Doors are latched	

#### Ability to print the Message Log as a PDF file for Troubleshooting



# **Verifying Proper Installation and Setup**

GeneXpert PC

03/05/19 17:18:13

GeneXpert® Infinity System Installation Qualification Report

This report provides documented evidence of the installation of this GeneXpert® Infinity System.

#### System Information



Software	Version	Status
Xpertise™ Software	6.8	Pass
Java Runtime Environment	1.8.0_131	Pass
GX_Utils.DLL	0.8.4.0	Pass
SQL Database	2012 (SP3) (KB3072779) - 11.0.6020	Pass
Database	gx_db 3.1.9.0	Pass
Operating System	Windows 7 6.1 Service Pack 1	Pass
CIT Plug-In	1	Pass

#### Instrument Information

Instrument S/N 805034							
Software	Version	Status					
Infinity Server	2172.004	Pass					
IOServer	1007	Pass					

Gateway Name	Gateway S/N	Gateway Firmware
A	712374	2.0.18
В	712375	2.0.18
ç	712378	2,0,18,



# **Infinity Scheduler**

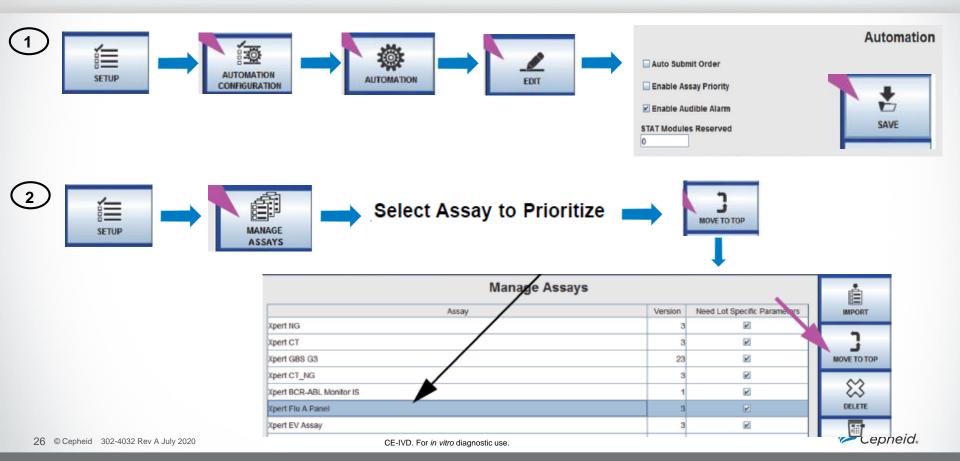
**Priorities:** 

- STAT\*: loads first, unless there is a cartridge that will expire
- Assay Stability: if there are 2 cartridges with similar expiration times, the one with the higher assay priority will go first
- Assay Priority: user defined in Manage Assays Menu





**Assay Priority** 



# **Monitoring Tests in Progress**

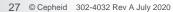
Sa

Module Status			Tests Since Launch										
Module Name	Status	Patient ID	Sample	Mod Name	User	Test Type	Result	Assay	Start Date	Estimated Minutes	Status		
A1	Available									To Result	-		
42	Available	738743170	738743170147	A4	Detail User	Specimen	NO RESULT	Xpert EV Assay	03/05/19 17:59:21	6	Running		
A3	Running	H73874317	SD0385762929.	A3	Detail User	Specimen	NO RESULT	Xpert EV Assay	03/05/19 17:59:31	3	Running		
A4	Running												
81	Available												
82	Available	111											



ample ID (U	se '_'as a single letter	wildcard, 9			nother Te	est			N	
(pert M 03051										TETTREBOLTS
Patient ID	Sample ID	Mod Name	User	Test Type	Result	Assay	Start Date	Estimated Minutes To Result	Status	FIND
jgfikdjägski	5489453874538	C1	Administratio	Specimen	NEGATIVE	Xpert SA Nasal Co.	03/04/1917 55:51		Done	, Le
D205145	Xpert M 03051	A1	Administratio.	Specimen	NO RESULT	Xpert MRSA Assa	03/04/19 16:23:45		Aborted	
	Xpert M 03051	D4	Administratio.	Specimen	NEGATIVE	Xpert MRSA_SA B	03/04/19 16 23:24		Done	CLOSE
	Xpert G 03051	D3	Administratio	Specimen	ERROR	Xpert GBS	03/05/19 16:22:59		Incomplete	
D205145	Xpert v 030518	01	Administratio	Specimen	NEGATIVE	Xpert vanA	03/04/1916:22:34		Done	
D205145	Xpert M 03051	B4	Administratio.	Specimen	NEGATIVE	Xpert MRSA Assa	03/05/19 16 22:08		Done	
	Xpert M 03051	C1	Administratio	Specimen	NEGATIVE	Xpert MRSA_SA B	03/05/19 16:21:23		Done	
D205145	Xpert M 03051	B3	Administratio.	Specimen	NEGATIVE	Xpert MRSA_SA B	03/05/19 16:19 02		Done	
	Xpert M 03051	C1	Administratio.	Specimen	NEGATIVE	Xpert MRSA Assa	03/05/19 16:17:38		Done	



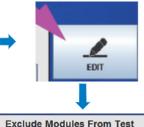


# **Exclude Modules From Test**









	Module Name	Status	Module S/N	Estimated Minutes To Result
	A1	Available	642969	
	A2	Available	642999	
	A3	Available	643030	
	A4	Available	642845	
M	B1	Available	643015	
(e)	B2	Available	642812	
	B3	Available	642706	
	B4	Available	643243	
	C1	Available	602699	
	C2	Available	612818	
	СЗ	Available	612666	
	C4	Available	612816	
×.	D1	Available	600323	
	D2	Available	612665	
	D3	Available	612004	
	D4	Available	620358	

Any modules that have been disabled will be highlighted in yellow in the module status section.

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CE-IVD. For in vitro diagnostic use.



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# **Cartridge Retention**



Ability to retain an individual cartridge while test is inprogress

						View Res	sults			
Patient	ID*	H0360002160	85			Pat	ient ID 2	P394857894943		
Sample	ID	SD304956854	904							
Ass	ay*	Xpert Flu							Version*	3
Test Result	•	Analyte Result	•	Detail	► A	mplification Curve	► Erro	s History	Support	-
Result Torrasulti Disclaimer										
Sample Type Other						Other Sample Ty	pe			
User										
Detail User						Retain Cartrid	lge After 1	est Completion		
Status										



CE-IVD. FOI III VILIO UIAGNOSIIC USE

# **Removal of retrieved cartridges**



	IIII Shuttle					Cartridge				
		Accumulator	Needs Attention	Cartridge Status	Priority	Sample	Assay	Order Time	Cartridge SN	
1		1	â	Rejected	Normal	127856789	Xpert C.diff-Epi	03/05/19 14:45	10015808	FILL SHUTTL
										MOVE TO SHUTTLE
										CLOSE



# **Infinity Files**

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# File types used by the Infinity

#### Assay Definition (.gxa)

- File contains the sample preparation command sequence, thermal cycling protocol and analysis settings.
- Assay definition must be imported into the system software prior to scanning the cartridge.

#### Lot Specific Parameter (.gxr)

If the assay requires LSP, it is embedded in the barcode of the cartridge.
 Barcode must be scanned for the software to recognize LSPs.

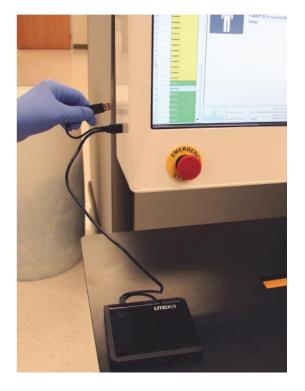
Run File (.gxx)

Archived files used for back up and send to Technical Support for review.



# **Connect the external DVD drive to the Infinity**

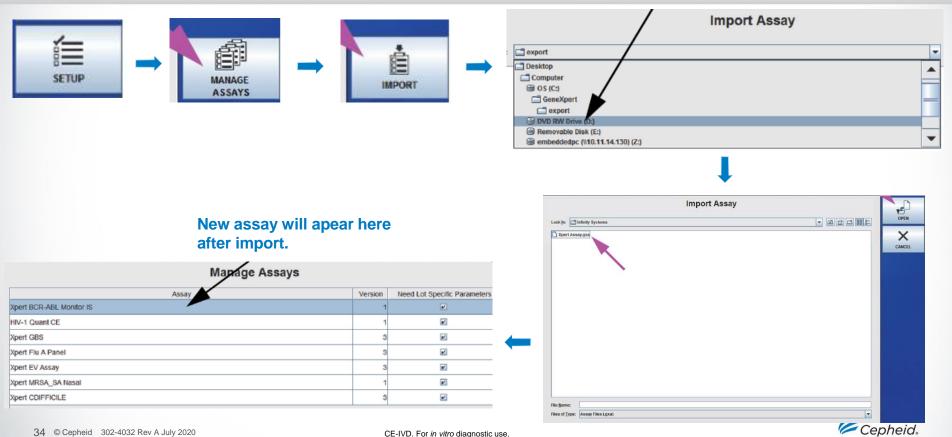








### Import ADFs



# **Infinity Workflow**



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# System Start Up



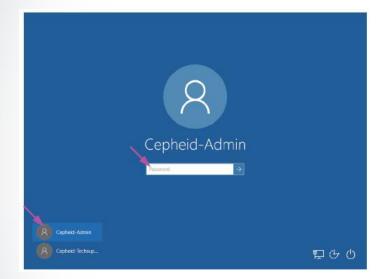
AC main power switch Turned to "on" Wait for 2 minutes (system will boot up), kiosk computer and embedded computer will start communication



After the waiting time (mandatory!), log in with your Windows password



# **Start-Up and Desktop icons**



Enter password, usually "cphd"



Xpertise Software (double click to start)



Cepheid Remote Diagnostics Access shortcut



GeneXpert Folder



GX support Database backup



Infinity shutdown protocol



## Log on to Xpertise software (optional)

Ccenna Xp	ertise Software						1	
	dule Status	,			Login			1
Module Name	Status							OK
								×
			User Name deta#1 Password					DUT
			03/05/19 17:55:42	System	GeneXpert® Infinity Xpertise Software, Software Initialization Database Integri		55:42	
			03/05/19 17:55:43	System	powware minanzaron Database integr	ny check compresed		

If admin users and basic users have been defined, log on by your user name and your password



## **Database Management Screen (optional)**

Economic Xpertise Software	Detari User
Module Status	Database Management
Module Status	YES
Name	Do you want to perform Database Management tasks?
	03/05/19 17:55:42 System GeneXpert® Infinity Xpertise Software, version 6.7, started 09/05/15 17:55:42
	03/05/19 17:55:43 System Boftware initialization Database Integrity Check completed
	03/05/19 17:57:08 System User [Detail User] login.

If not opted out in the system configuration, Database Management will be performed (appears at software start and software exit)



# **Test Archive Reminder (optional)**

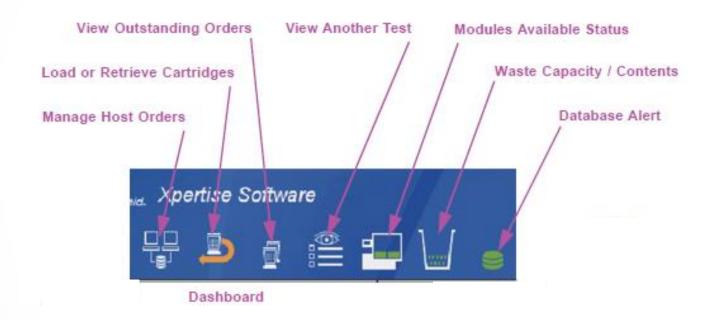
pertise Software		Detail User 👷 👷 🕱													
- 1 🖺 e															
dule Status	Test Archive Reminder														
Status		115													
odelen	?	×													
alable		ND													
alable	Archive is overdue. Do you want to archive now?													_	_
lable			Courses X0	ertise Software								De	1317 Unter •		
astie astie			A 110												
sbio			6 🐨	đ 🛍 🖕											
able			Mo	dule Status					Arch	ive Test	-				
lable															
ble ble			Module Name	Status	Cloak IC										
He I			A1.	Axalable	Purge S	elected Tests fro	m List After /	Inchiving (Re	commended N	Aonthly)					
ste			A2	Available	1	Patient ID	Gample	Mod	User	Result	Assay	Status	Error	Start	
			A3	Axellable	-	H3518272993.	ID UH489831	Name		NEGATIVE	Xpert CDIFF.	Dees	Status OK	Date 07/14/16 17	-
			A4 B1	Ausiable		H3518272903.	SD142231	C3	<none> Detail User</none>	NEGATIVE	Xpert CDIFF.		OK	07/14/16 17.	-
	03/05/19 17:59:16 Gantry Reminder 7263: Recovered gantry to saf	location.	82	Analativ		0.000	SD142231	AI	Detail User	ERROR		Aborted	Error	01/30/18 15	
	03/05/19 17:59:21 System Full Automation Operating Mode 03/05/19 17:59:21 System Welcome to Genexpert Infinity System		B3	Anaikabio		H0510900025.	HG656788	85	Detail User	HV-1 DETE.	-		OK	08/08/18 15.	-
	Concerto tratecti agreene		84	Analable		H3518903866.	FTS49558	K2	Detail User	HIV-1 DETE	HIV-1 Quant	Done	OK	08/08/18 15	
			C1	Axaitable		H3518903826.	HG656788	AZ	Administrati.	HV-1 DETE.	HIV-1 Quant.	Done	OK	08/05/18 14	
S	ame applies to the Test		C2	Analishie		H3518903886.	FT343557	AS	Administrati.	HV-1 DETE.	HIV-1 Quant.	Done	OK	08/08/18 14.	
Δ	Archive Reminder		C3	Axailable		H3518758826.	TT555698	83	Basic User	ERROR	HIV-1 Quant.		Error	09/16/18 14.	-
			C4	Assibile		H3518903826.	TG478589	82	Administrati .	HV-1 NOT	HV-1 Quant.	-	OK	09/16/18 14.	
			D1	Available	-	H3518903456.	CR538763	64	Administrali	MTB NOT D			OK	09/16/18 13	-
			02	Axailable	-	H3959038268	KW630967	B\$	Administrati.	MRSA NEG	Xpert SA Na.		OK	09/16/18 13.	-
			03	Analable		internet statement states	GH487365 SR543267	42	Administrati.	MRSA NEG	Xpert SA Na. Xpert SA Na.	-	OK	09/16/18 13.	-
			D4	Presson .		H3510907020.	DA1155637	82	Administrati	MRSA POSL	Noert SA Na	Done	OK	10/16/16 13.	¥
						SELECT ALL		SELECTALL		SELECT	DES	ILLECT		ECT NEW BOHNE	





A3 A4 B1 B2 B3 B4 C1 C2 C3 C3 C3 C4 D1 D2 D3 D4

## **Dashboard icons**





# **Additional Important Icons**



Shuttle is open





**Glass door is unlatched** 



Silence alarm

**Error is present** 



Analysis Mode



Replace waste container/ close waste Door



Manual Mode Operation



### **Available workflows**

**Two operation modes are possible:** 

- Automation Mode (Regular workflow)
- Manual Mode (useable if the automated system is not fully functional)



## **Order a test in Automation Mode**

	Order Test - Sample ID
	Scan or type in Sample ID
	Sample ID is successfully scanned when you hear the
ORDERS ORDER TEST	
ORDERS ORDER TEST	
	Patient D
	H736743170147
	Patient ID 2 HK44905720365
Detail User + 👥 👥 🗓 💽	Last Name First Name Name1 Patient
	Date of Birth Postal Code
	Gender Ethnicity SUBMIT
Order Test - Patient Information	
Scan or type in Patient ID	
Patient ID is successfully scanned when you hear the beep.	Order Test - Assay
END ORDER TEST	Scan Cartridge Barcode
	Cartridge barcode is successfully scanned when you hear
Patient ID 2 H049586720395	the beep.
Last Name First Name Name1 Patient	
Date of Birth Postal Code	
Gender Ethnicity	Patient ID
dione> T	H7387243170147
Ontional	S00365/632332
Optional	Patient ID 2 HG4956720305
	Last Name Pirat Name Name1 Name1 Piedent
	Date of Birth         Postal Code           1995/03/14         907/65
	Cender Ethnicity
	Fende While Priority
44 © Cepheid 302-4032 Rev A July 2020	CE-IVD. For <i>in vitro</i> diagnosuc use.

### **Order a test in Manual Mode**

ORDERS ORDER TEST	H203948050934 Patient ID is successfully scanned when you hear the beep.	B CALENDAR
	Patient ID 2 HG40596720395 Last Name Eist Name	

Order Test - Sample ID Scan or type in Sample ID SD948375028 Sample ID is successfully scanned when you hear the beep.	CONTINUE CLEAR ORDER	Order Test - Assay         Scan Cartridge Barcode         Cartridge barcode is successfully scanned when you hear the beep.         Patient ID         MO03040605034	MANUAL BARCORE ENTRY SELECTION CLEAR ORDER
Patient ID H203948050934 Patient ID 2	]	Sample ID SD046375026 Patient ID 2 H049866720395	
Patient ID 2 HG49686720395			

Cepheid.

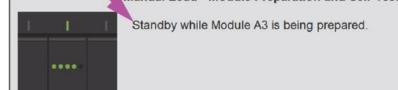
45 © Cepheid 302-4032 Rev A July 2020

# **Order a test in Manual Mode**

Patient ID H203948050934 Sample ID S0948375028 Patient ID 2		Select the module to run the test
HG49586720395 Last Name	CLEAR ORDER	
	Patient	

Press CONTINUE to proceed.







#### Manual Load - Load Cartridge

Load the cartridge in Module A3 with the flashing GREEN light, and close the module door.



#### Test Start Successful - Ready For Next Test

Successfully started the test.

Press ORDER NEXT TEST to order another test.

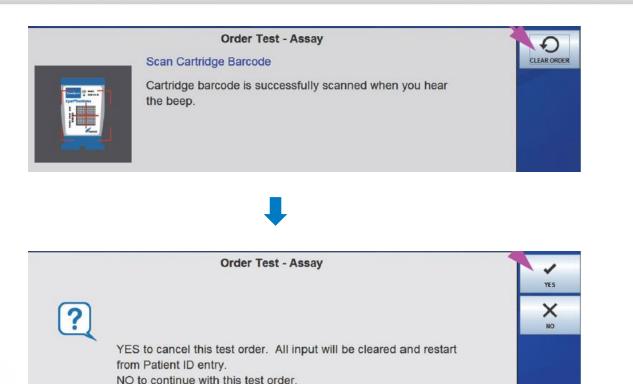
Press END ORDER TEST when you are done.



ORDER NEXT

TEST

## **Clear Test Orders – in Automation Mode**





## **Clear Test Orders – in Automation Mode**

#### Or (in case of outstanding orders):



	View Order	ş	
Patient ID			EL ORDER
H430596840405965			
Sample ID			
SD39485875			LOSE
Assay*		Version*	
Xpert CT_NG		3	
Reagent Lot ID'	Cartridge S/N*		
05821	427271437		
Expiration Date*	Priority		
07/19/19	Normal		
	View Outstanding Orders		/
			YES
0			×
?			NO
YES to can	cel this test order with sample ID [].		
	nue with this test order.		
CE-IVD. For in vitro diagnostic		Cepheid	1.

#### **Clear Test Orders – in Manual Mode**

/ 🔹 💷 🖉						
	Order	Test - Tes	st Information			
Patient ID						SUBMIT
H203948050934						300000
Sample ID						Ω
SD948375028						t)
Patient ID 2						CLEAR ORDER
HG49586720395						
Last Name				First Name		
Name1				Patient		
Date of Birth		Postal Code				
1995/03/13		98765				
Gender		Ethnicity				
Female		White				
Assay'					Version*	
Xpert CT_NG					3	
Reagent Lot ID'			Cartridge S/N*			
07105			443432184			
Expiration Date*			Priority			
2020/01/15			Normal			
Test Type						
Specimen		-				
Sample Type			Other Sample Type			
Other		-	ourer oumpre type			
		•				
Notes					1	
l						



# **Viewing Test Results**



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# **Viewing Test Results**

				View	Another	Test				
Patient ID	Sample ID	Mod Name	User	Test Type	Result	Assay •	Start Date	Estimated Minutes To Result		
H35185598	UJ690762	B3	Detail User	Specimen	FILHETERO.	Xpert FIL& FV Co	03/05/19 17:29:35		Done	CLOSE
H35189059	UJ787933	A3	Detail User	Specimen	FII NORMA	Xpert FII & FV Co	03/05/19 17:28:47		Done	ceose
H35188538	HN237945	A2	Detail User	Specimen	FII HOMOZ	Xpert Fil & FV Co	03/05/19 17:27:55		Done	
H29495860	SD43958674	B4	Detail User	Specimen	NEGATIVE	Xpert EV Assay	09/13/18 11:43:32		Done	
H35189038	SD4958104883	B3	Detail User	Specimen	NO RESULT	Xpert EV Assay	09/01/18 15:49:26		Stopped	
H73874492	HG3958203956	B2	Detall User	Specimen	NEGATIVE	Xpert EV Assay	09/01/18 12:52:35		Done	
H73474347	HD3049586721	B1	Basic User	Specimen	NEGATIVE	Xpert EV Assay	09/01/18 12:33:35		Done	
738743170	738743170147	A4	Detail User	Specimen	NEGATIVE	Xpert EV Assay	09/01/18 12:16:43		Done	
H73874317	SD038576292	A3	Detail User	Specimen	NEGATIVE	Xpert EV Assay	05/01/18 12:13:32		Done	
H35189055	RL439664	82	Detail User	Specimen	CT DETEC	Xpert CT_NG	06/15/18 17:15:06		Done	
H35189055	TZ637890	A4	Detail User	Negative C	CT NOT DE	Xpert CT_NG	06/03/18 17:41:03		Done	
H05688905	HA233987	A3	Detail User	Specimen	CT DETEC	Xpert CT_NG	06/03/18 17:39:54		Done	

#### Alternatively:





#### **Test Result View**

				,	lew	Results				
Patient ID*	H7387	4317014	7			Patient ID 2	HG495	8672039	5	
Sample ID	SD038	5762929	32							
Assay*	Xpert	EV Assay	у						Version* 3	
▶ Test Result ▶	Errors	► Su	upport							
Result										
NEGATIVE										
For SW demonstrati		-7.				Other Sample	Туре			
Other					-					
User										
Detail User										
Status										
Done										
Notes										
Notes										

#### View for Basic Users (3 tabs)

	View Results	1
Patient ID	P36754321	EDIT
Sample ID	\$34078	
Assay*	Xpert Fil & FV Version* 1	
		REPORT
Frest Result	Analyte Result > Detail > Amplification Curve > Errors > History > Support	j D
Result		UPLOAD     RESULT
FILNORMAL; EV NORMAL		()
L		PREVIOUS TEST
Disclaimer For In Vitro Diagnostic	- Use Only	
For in vitro Diagnostic	c use only.	
		NEXTTEST
Sample Type	Other Sample Type	
Other		
User		VIEW ANOTHER
Detail User		TEST
Status	Upload Status	
Done	Uploaded	CLOSE
		CLOSE
Notes		
		<b>T</b>

#### View for Admin Users (all tabs)

You can switch between previous and next test or choose from the list (view another test). Applies to all user types!



### **Result tabs – available for all user types**

	View Results					
Patient ID* D205145	Patient ID 2		EDIT			
Sample 🗽 Xpert M 03061						
Assay* Apert EV Assay	Versi	on' 3	REPORT			
Test Result Frrors Support						
A CONTRACT OF A			PREVIOUS TEST			
eagent Lot ID*	Assay Type					
0254	In Vitro Diagnostic					
artridge S/N*	Expiration Date		NEXT TEST			
508105378	12/21/25					
est Type						
pecimen	×.					
iority			TEST			
ormal						
art Time	End Time					
3/05/19 16:22:08	03/05/19 17 39 54		n in			
ror Status				View Results		
K						
W Version	Instrument S/N	Patient ID	H738743170147	Patient ID 2 HG49	586720395	
8	805034					
odule Name	Module S/N	Sample ID	SD038576292932			
3	643030	Atsay	Xpert EV Assay		Version*	3
		-				
		Test Result	Errors Support			
		#	Description	Detail		Time
				Error 5007: [SPC] probe check failed. Probe check		

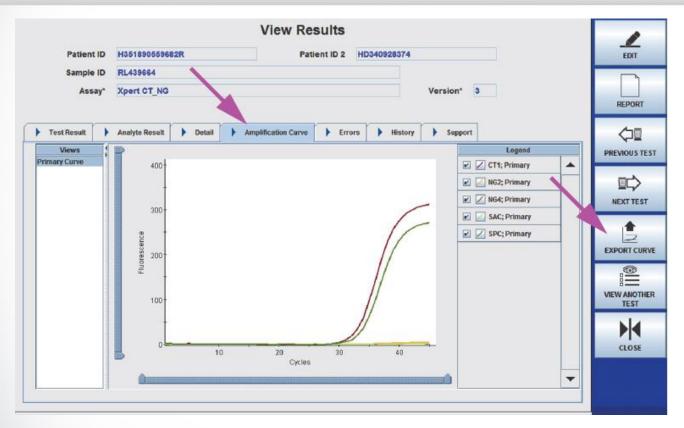
### **Result tabs –available only for admin users**

			View Re	sults							View Resu	ults		
Patient ID	H3518905596	32R	Pat	ient ID 2	HD340928374			Patient ID	H351890559682	R	Patien	nt ID 2 HD340928374		
Sample ID Issay'	RL439664 Xpert CT_NG					Version* 3			RL439664 Xpert CT <u>N</u> G				Version* 3	
Test Result	Analyte Result	• Detail	Amplification Curve	► Erro	rs History	> Support		F Test Result	Analyte Result	▶ Detail ▶ Am	plification Curve	Errors History	Support	
Analyte Name		Ct	EndP	L.	Analyte Re	esult	Probe Check Result	Analyte Name	Prb Chk 1	Prb Chik 2	Prb Chk 3	Probe Check Result	2nd Deriv Peak Height	Curv Fit
CT1	32.1		312		POS	PASS		CT1	239	280	239	PASS	0.0	PASS
NG2	0.0		4		NEG	PASS		NG2	220	273	220	PASS	0.0	NA
NG4	0.0		1		NEG	PASS		NG4	41	52	41	PASS	0.0	NA
SAC	0.0		1		NA	PASS		SAC	105	86	103	PASS	0.0	NA
SPC	33.6		271		NA	PASS		SPC	357	390	355	PASS	0.0	NA

			View Results					
Patient ID	H351890	559682R	Patient ID 2 HD34	0928374				
Sample ID	RL439664	4						
Assay*	Xpert CT	NG Version* 3						
Test Result			uplification Curve Frors		pport			
Field Nan	ne	WAS	IS	User	Time			
· · · · · · · · · · · · · · · · · · ·	ne							



# **Amplification Curve View (only admin users)**





# **Export Amplification Curve**

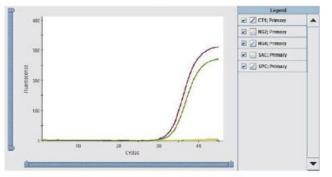


#### GeneXpert PC

Sample ID: Test Type: Assay Name: Assay Type: Assay Version: Reagent Lot ID: Status: Error Status: Notes: Order Time: Started At: Ended At: User: S/W Version: Graph Name:

#### Graph Report RL439664 Specimen Xpert CT NG In Vitro Diagnostic 3 05814 Done OK 03/05/19 17:14:14 03/05/19 17:15:06

03/05/19 18:43:13 Detail User 6.8 Primary Curve





03/05/19 18:59:50













#### Content of the Report File differs between Basic and Admin Users

	Patient ID	Sample	Mod Name	User	Test Type	Result	Assay 🔺	Status	Error Status	Start Date	
	H351827299	UH489831	C3	<none></none>	Specimen	NEGATIVE	Xpert CDIF	Done	OK	07/14/18 1	1.
	H351890559	RL439664	B2	Detail User	Specimen	CT DETE	Xpert CT	Done	OK	09/15/18 1	ŀ
	H351890559	TZ637890	A4	Detail User	Negative C.	CT NOT D	Xpert CT	Done	ок	03/21/19 1	
	H056889055	HA233987	A3	Detail User	Specimen	CT DETE	Xpert CT	Done	OK	03/21/19 1	
2	H351890550	HA245654	A1	Detail User	Specimen	CT NOT D	Xpert CT	Done	OK	03/21/18 1	
	H350395485	SD934854	B1	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	OK	05/13/18 1	
	H351890382	SD495810	B3	Detail User	Specimen	NO RESULT	Xpert EV A	Stopped	OK	05/01/18 1	
	H738744925	HG395820.	B2	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	OK	05/01/18 1	
	H734743470	HD304958	B1	Basic User	Specimen	NEGATIVE	Xpert EV A	Done	OK	05/01/18 1	
	738743170147	73874317	A4	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	OK	05/01/18 1	ŀ
	H738743170	SD038576.	A3	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	OK	05/01/18 1	
	H351855982	UJ690762	B3	Detail User	Specimen	FILHETER	Xpert FII &	Done	OK	09/15/18 1	
	H351890596	UJ787933	A3	Detail User	Specimen	FII NORMA	Xpert FII &	Done	OK	09/15/18 1	
	H351885382	HN237945	A2	Detail User	Specimen	FII HOMOZ	Xpert FII &	Done	OK	09/15/18 1	ľ
		Xpert F 01	A1	Detail User	Specimen	NEGATIVE	Xpert Flu A	Done	OK	01/30/19 1	
	H351890345	CR538763	B4	Administra	Specimen	MTB NOT	Xpert MTB	Done	OK	03/16/19 1	
	H351877782	GK563895	B1	Detail User	Specimen	ERROR	Xpert MTB	Aborted	Error	03/21/19 1	ŀ
	H356129382	TF277659	B4	Detail User	Specimen	MTB NOT	Xpert MTB	Done	OK	03/21/19 1	
	H395903826	KW630987	B3	Administra	Specimen	MRSA NE	Xpert SA N	Done	OK	03/21/19 1	ŀ

						Test Re	port					
2 Inc	clude	Amplification	Curve									
		Patient ID	Sample	Mod Name	User	Test Type	Result	Assay 🔺	Status	Error Status	Start	
1		HIV-IVD	HIV-Factor.	A6	Detail User	Positive Co.	HIV DETE	HIV-Factor	Done	ок	01/17/18 1	-
1		HIV-IVD	HIV-Factor.	A5	Detail User	Positive Co.	HIV DETE	HIV-Factor	Done	ок	01/17/18 1	
. 1		HIV-IVD	In Range	A1	Basic User	Positive Co.	HIV DETE	HIV-Factor	Done	ок	01/16/18 1	
1		HIV-IVD	HIV-Factor.	A1	Basic User	Positive Co.	HIV DETE	HIV-Factor	Done	ок	02/18/18 0	
1		HIV-IVD	HIV-Factor.	A5	Detail User	Positive Co.	HIV DETE	HIV-Factor	Done	ок	03/17/18 1	
		HIV-IVD	HIV-Factor.	. A1	Detail User	Positive Co	HIV DETE	HIV-Factor	Done	OK	07/17/18 1	
1		H11287489.	SD142231	A1	Detail User	Specimen	ERROR	Xpert BCR-	Aborted	Error	07/30/18 1	
		H11287489	SD142231	A1	Detail User	Specimen	NEGATIVE	Xpert CDIF	Done	OK	07/30/18 1	
1		H35182729.	UH489831	C3	Detail User	Specimen	NEGATIVE	Xpert CDIF	Done	ок	08/05/18 1	-
		H35189037.	HA245614	A1	Detail User	Specimen	ERROR	Xpert CDIF	Done	Error	08/29/18 1	
		H05688905.	HA233987	A3	Detail User	Specimen	CT DETEC.	Xpert CT	Done	ок	09/03/18 1	
	R	H35189055.	HA245654	A1	Detail User	Specimen	CT NOT D	Xpert CT	Done	ок	09/03/18 1	
1		H35189055	RL439664	B2	Detail User	Specimen	CT DETEC.	Xpert CT	Done	ок	09/15/18 1	
1		H35189055.	TZ637890	A4	Detail User	Negative C	CT NOT D	Xpert CT	Done	OK	02/15/19 1	
		738743170	73874317	A4	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	ок	03/05/19 1	
		H73474347	HD304958.	. B1	Basic User	Specimen	NEGATIVE	Xpert EV A	Done	ок	03/05/19 1	
1		H73874317	SD038576.	A3	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	ок	03/05/19 1	
1		H73874492	HG395820	B2	Detail User	Specimen	NEGATIVE	Xpert EV A	Done	ок	03/05/19 1	-

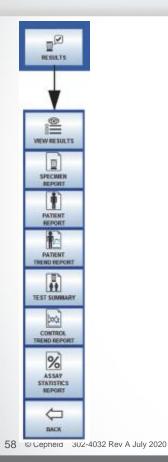
#### **Admin Users**



#### 57 © Cepheid 302-4032 Rev A July 2020

**Basic Users** 

## **Other Reports**



				GeneXpert PC		03/05/1
					Control	Trend Report
GeneXpert PC			03/05/19 17:54:33	- Selection Criteria -		
	Control T	rend Report		Date Range:	All	
	Control	rena Report		Assay:	HIV-1 Viral Load	1
				Assay Version:	1	
<ul> <li>Selection Criteria -</li> </ul>				Reagent Lot Number:	All	
Date Range:	All			Test Type(s):	Positive Control	
Assay:	Xpert-C. difficile	G2		LQL	96 (log 1.98) co	
Assay Version:	2			UQL	991 (log 3.00) c	opies/mL
Reagent Lot Number:	ÂII					
-		14			7 7.	atta) Faund
Test Type(s):	Negative Contro				- / Te	st(s) Found -
Analyte(s):	SPC, Toxin B			Trend Log Information		
Data Type:	Cycle Threshold	d, EndPt		Date Range:		01/01/16 - 07/01/18
				Number Tests Graphed	ŧ	6
				Number Tests Not Grap		1
	- 4 Test	(s) Found -			at have ERROR, INVALID, NO	RESULT or no quantitative value are exclude
				trend graph.		
Trend Log Information				Test Type:		Positive Control 1
Date Range:		01/20/19 - 01/28/19		Target:		200 (log 2.30) copies/mL
Number Tests Graphed:		4		Lower Limit:	GeneXpert PC	96 (log 1.98) copies/mL
Number Tests Not Graphed	d(*):	0		Upper Limit:	Genexpert PC	991 (log 3.00) copies/mL
Note(*): Tests with errors, a	borted, or stopped	with insufficient data are ex	cluded from the			
trend graph.				3.00	Upper Li	to to the second s
crend graph.				₽ 2.40 ·		
				- 2.40 5n	Target	
Test Type:		Negative Control 1		S 1.80		
Test Result:		Number of Test Results		5 1.80 4 3 3 5 5 0.60		
Number of Test Results For [Tox	inenic C diff	4		. 0.60		
NEGATIVE]:	ageine oluin	-		8 0.60		
				0.00		
				Jan-1	1-16 Jul-1-16 Jan-1-17	Jul-1-17 Jan-1-18 Jul-1-18
					Date	
				In LOL a	and UQL Bange 🔹 Out	of LQL and UQL Range
				- 112320	ana okenange 🔹 out	or Exe and outer range



# **Data Management**



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# **Data Management Tasks**

- Archiving/Retrieving Tests
  - Creating or retrieving a copy of the data
  - Automatic Archive available
- Database Backup/Restore
  - Create copy of all user profiles, system configuration, ADFs and data (available at start-up and at shutdown)
- Compact Database
  - Available at Start-up and Shutdown only
- Check Database Integrity
  - Integrity check is performed at launch
- External Remote DB Backup utility (to be found on the Windows Desktop)
  - Back up data with encrypted patient information



# **Brief LIS Overview**

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#### **Host Status**

Host



Host Status (white if not connected)





	ertise Software	<u>ا تە</u>		m			Detail oner	1 1 Ï I
_	dule Status	T		<u> </u>	Mar	nage Heat Orders		
Module	Status			Patient ID	Pater	ID 2 Patent Name	Sample ID Assay	Priority Host Order
None	Available	8	P1344320		H2138642	Name4, Patient	81234508 apent 088	Normal 03/05/191
	Arabate		P32141244		H324902344	Name4, Patient	812545322 Rpert Plu A .	. Normal 03/05/191
	Arabeble							
	Arabeble							
	Available							
	Available							
	Available							
	Available							
		INVEST	lowedload likelin	<ul> <li>Host guery is sential 05 2 sater(s) have been do Done completes al 050</li> </ul>	writeaded.	•		
				00/05/19 12:01:45	aysten	User (Denil User) login.		
				03/05/19 12:02:00	System	User [Detail Line] ingina		
				03/05/12 12:02:17	System	User [Detail User] login		



Host Test Order Table



K K N P K K

## **Enable Host Communication**

S S	ETUP			
Konne Xperitse Software		- COF	Module St	18 <b>9</b> 4.0
A1 Kesikila A2 Kesikila A3 Aesikila	Host ID	<b>H</b>	A1 Available A2 Available A3 Available	Lines Ceptres Line (Line (Line (Line ) yes have the Ceptres Line masterians solution for sample recomming)      Host D     Centry of hilling
A4         Available           D1         Available           D2         Available           D3         Available	Chatematic Next Query After Sample 10 Scatt		A4 Arabebe B1 Arabebe B2 Arabebe B2 Arabebe	Automatic Heat Guary After Sample (D Scan     Automatic Text Order Download
Dr Availation C1 Availation C2 Availation D5 Availation	RAuteente Result Lidead     Une internet Spectreet ID		C1 Avelable C2 Avelable C3 Avelable	SActoratio Result Lighted
C4 Avelatile D1 Avelatile D2 Avelatile	Protect		D4 Avelaste D1 Avelaste D2 Avelaste	Prolocal # H27 0 X87M
D4 Available	Communication Sattings O Server Server IP Address Port IP		Di Avelate Di Avelate	Conneutication Sattings  * Server Server Server (address







Cepheid recommends to always confirm that LIS uploaded results match GeneXpert results after any changes to the GeneXpert or host system, including, but not limited to, changes to the following:

- GeneXpert software version
- GeneXpert assay definition files and version
- GeneXpert host communication settings
- Host middleware software or configuration changes
- LIS software or configuration changes



# Troubleshooting

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#### **Pause Mode**



- The Pause mode should be used only when manually adjusting or removing a cartridge.
- Do not remove a cartridge without following the "remove cartridge" protocol!
- When Pause is activated:
  - Cartridge order processing STOPS
  - Cartridges in modules continue to RUN
  - Gantry at the end of its current move STOPS
  - Conveyor Belt STOPS
  - Glass doors UNLATCH
- When normal operation is resumed, all processing continues.



# **Emergency Stop Function**



*Emergency Stop should only be used for situations where immediate termination of moving parts is required to prevent user injury or instrument damage.* 

During emergency stop, the following actions occur:

- •All cartridge transfer functions are suspended.
- •All user interface features are suspended.
- •The cartridges in the modules will continue to run.

To resume from emergency stop, you must:

•Remove all cartridges from the Conveyor. They can be reprocessed.

•Do not move or add cartridges to other areas of the system under any circumstances.

Note: If stopped for too long, cartridges may expire.



# **Emergency Stop**



Press UNLATCH GLASS DOORS to open the Glass Doors to access the system. Warning: You must be trained to access the instrument.

If a cartridge is stuck or fallen, remove it from the system.

Remove all cartridges from the conveyor.

Do not move or add cartridges to other areas in the system under any circumstances. To resume normal operation, untwist the Emergency button.

Press RESUME to return to normal operation.



#### Emergency Stop

After completing your operation, untwist the Emergency button. Press RESUME to return to normal operation.

4

**Emergency Stop** 

Close all glass doors. And then press LATCH GLASS DOORS.



RESUME

-

UNLATCH GLASS DOORS

RESUME

2 Do not forget to untwist the Emergency Stop button by turning it clockwise!





# **Retrieving Cartridges from Accumulator**

**ONLY AVAILABLE IN AUTOMATION MODE!!!** 



Outstanding order needs attention icon (shown on dashboard)

Needs Attention	Cartridge Status	Priority	Patient ID	Sample ID	Assay	Location	Order Time	Estimated Minutes To Result	Minutes To Expire	VIEW ORDER
	Detected	Normal	123456789	127856789	Xpert C.diff-Epi	ACC 1	03/05/19 14:45		7	
	Ordered	STAT	123456778	123786789	Xpert C diff-Epi	Kiosk	03/05/19 14:58		180	CANCEL ORDER
										REMOVE OLD ORDERS

# **Retrieving cartridges from Accumulator**



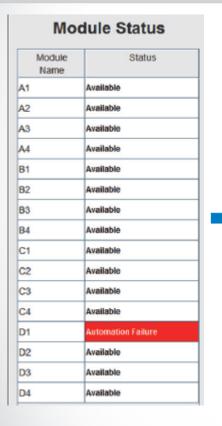
Augusta Needs Continue County County August	OPEN SHUTTI

				Cartridge	e I/O				
LEEE Shuttle		nulator						OPEN SHUTTLE	
Shuttle Site	Needs Attention	Cartridge Status	Priority	Sample ID	Assay	Order Time	Cartridge S/N	M	
1		Retained	Normal	127856789	Xpert C.diff-Epi	09/05/18 14:45	7508105376	CLOSE	

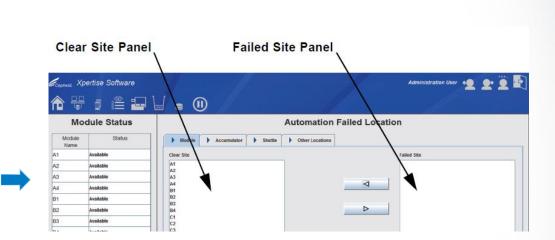


CLOSE

# **Clearing an Automation failed location**





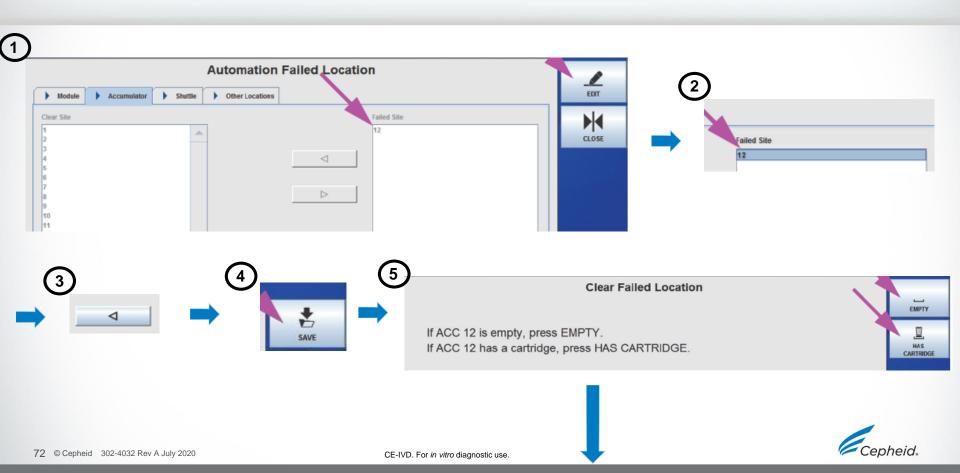


#### Check which location has a failed site:

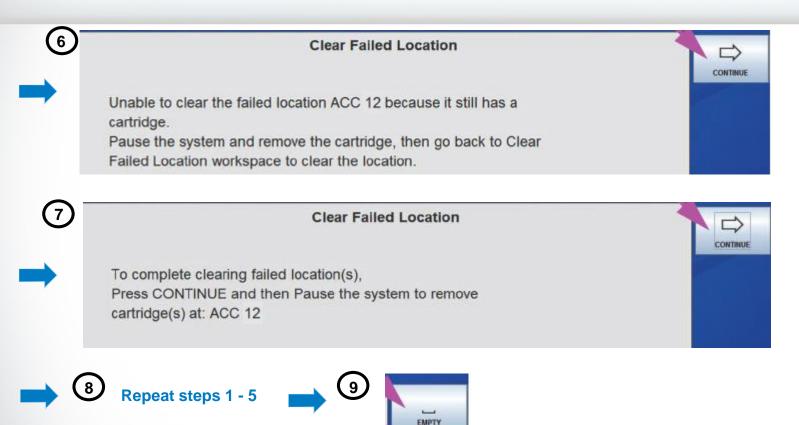
- Open failed location: accumulator, shuttle or lobby
- Closed failed location: module



# **Open failed location (accumulator, shuttle or lobby)**



# **Open failed location (accumulator, shuttle, lobby)**

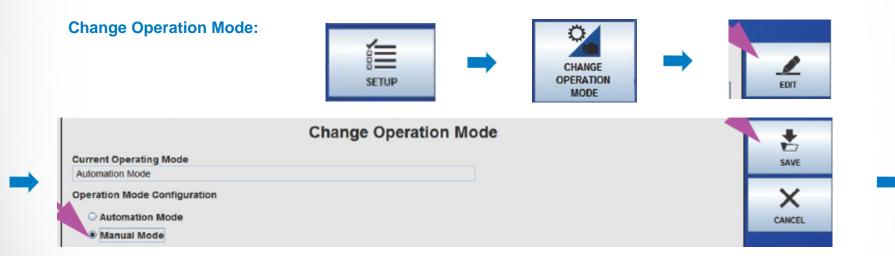




	Mo	odule Status				Automation	Failed Locatio	n	1	1	
	Module	Status	Module	Accumulator	Shuttle	Other Locations				EDIT	
	A1	Available	Clear Site					Failed Site		M	
	A2	Available	A1 A2					01		CLOSE	
	A3	Available	A3							00000	
	A4	Available	A4 B1				$\lhd$				
	B1	Available	82 83								
	B2	Available	B4 C1								
	B3	Available	C2								
	B4	Available	C3 C4								
	C1	Available	D2 D3								
	C2	Available	D4 E1								
	C3	Available	E2								
	C4	Available	E3 E4								
	D1	Automation Failure	F1 F2								
	D2	Available	F3								
	D3	Available	F4 G1			_					
	D4	Available	G2								
				C	ear F	ailed Lo	ocation				
mo Afte	dules er faile	ed locatio									
		n Mode.									Cepheid.
32 Rev A July	2020				CE-IV	<ol> <li>For in vitro dia</li> </ol>	agnostic use.				Cepheid.

### Closed failed location (module): change of Operation Mode

The system must be in Manual Mode to clear a failed module location!





			Leaving	Automa	ation Mode	- Remove Car	tridges		
ok	110,000,000,000,000,000,000,000,000,000	RTRIDGE	(S) REMO		nulator, Shu	ttle, Conveyor	and Modules a	and then	CARTRIDGE(S) REMOVED
	Shuttle	Needs Attention	Cartridge Status	Priority	Sample	Assay	Order Time	Cartridge S/N	

Any tests that are currently running in the GeneXpert modules will continue to run after the system switches to Manual mode. These cartridges will need to be removed manually from the GeneXpert modules after they have finished.

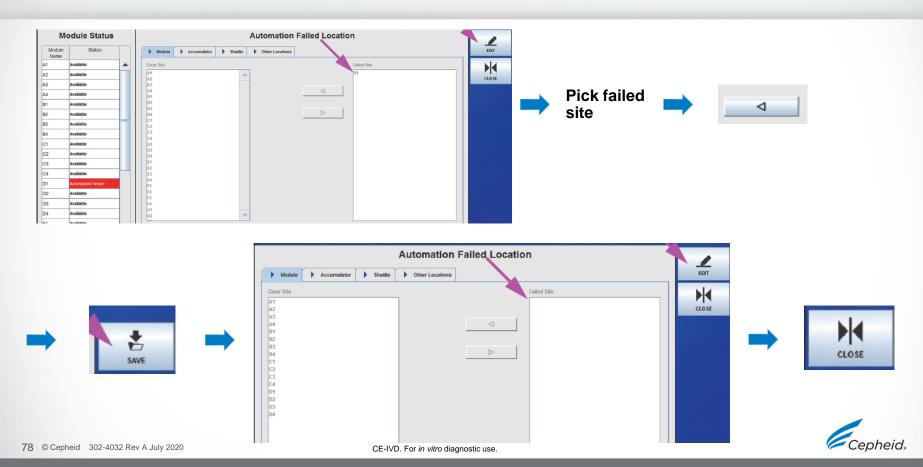
Any tests that have been ordered but have not yet started (outstanding orders) will be cancelled after the change to Manual mode. These tests can be ordered again in Manual mode or they can be ordered again in Automation mode if they have not expired. If there are outstanding tests that will be cancelled, the Leaving Automation Mode - Remove Cartridges workspace shown in Figure 5-95 will be modified to indicate that there are outstanding tests that will be cancelled.





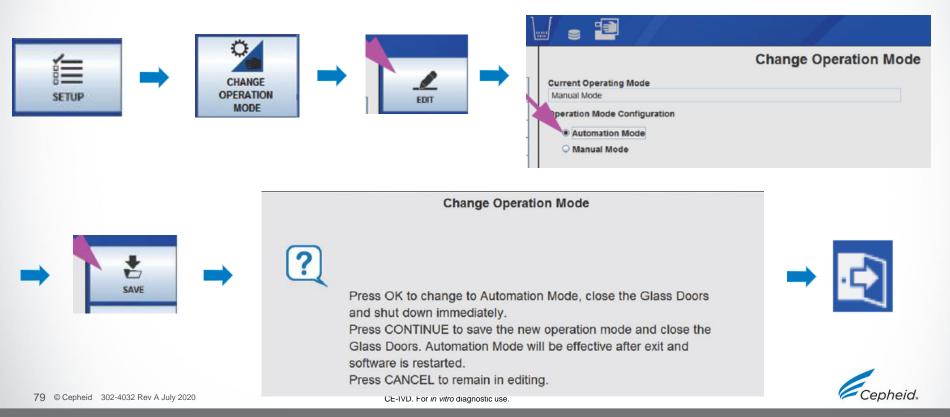






# **Change Operation Mode: Manual to Automation Mode**

### Check that all runs have finished and all modules are empty!



# **Shutdown Protocol**



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# **Infinity Shutdown Protocol**

Before you exit, ensure that there are no tests in process. There will be a warning if tests are still running!





Archiving and Database Management Reminders may appear. Follow the Instructions that appear.

X

Cancel





### Infinity shutdown v1009

You are about to shutdown the Infinity system.

Are you sure you want to do this?

#### Reminder:

Wait 2 minutes for the Infinity system to shut down before turning the AC power switch to the OFF position.

Wait another 2 minutes before turning the AC power switch back to the ON position.

The system may not boot up correctly if it is turned off and/or turned back on in less than 2 minutes.

OK

### Cepheid.

#### 81 © Cepheid 302-4032 Rev A July 2020

## Maintenance

-

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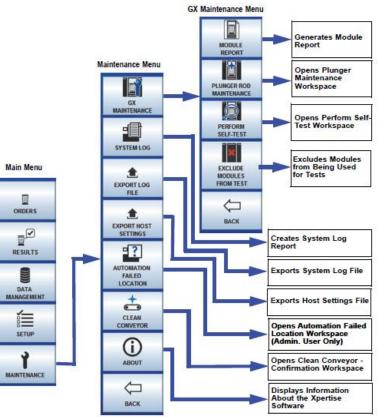
0

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### **GX Maintenance Menu**





CE-IVD. FOI IN VILLO DIAGNOSTIC USE.

### **Service and Maintenance**

-	1	le fi	nity S	-		una b						_					Qua	rter	ly M	ainte	enan	ice F	Perfo	orme	d:						
Name of Institution		Intir	iity s	sena		umo	er:												Jal N						- 7						-
Instructions: 1. Enter the name of your ins				. v					N																1					_	-
Date, and the current Mon 2. For each maintenance act initials (2 characters maxin 3. Save the file after entering	h an vity l num)	d Ye isteo in t	ear i 1 bel he b	n the low otto	e fiel cheo m ro	lds cktł w.	abov ne bo	e. ox(e	s) ur	nder	the	day	of tł	ne m	onth	h tha	it the	act	tivitie	25 W	ere	perfo									
Weekly Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	3
Clean kiosk table top, keyboard and monitor <sup>1</sup>																															
Quick Clean Conveyor belt <sup>1</sup>																															
Perform System Shutdown <sup>2</sup>																															
Monthly Maintenance										_												_									
Vacuum rear fan filters <sup>1</sup>																															
Archive / Purge Tests 2,3																															С
Quarterly Maintenance																															
Clean Kiosk Scanner																															Г
Clean Conveyor Belt 1																															
Clean Cartridge Bays and Plunger Rods <sup>1</sup>																															С
Clean Instrument Surfaces <sup>1</sup>																															
Replace or Clean Fan Filters <sup>1</sup>																															
Yearly Maintenance																															
Check Instrument Calibration <sup>4</sup>																															
As Necessary														-																	
Print System Log and Module Reports <sup>1</sup>																															С
Empty / Replace Waste Container 1																															
Back up Database <sup>2</sup>																															
Clean Instrument Surfaces <sup>1</sup>																															
Check keyboard and mouse battery. Replace as required. <sup>1</sup>																															E

1. Refer to Chapter 9 (Service and Maintenance) in the Operator Manual for detailed procedure. 3. Frequency of data management and data storage location can be determined by individual laboratory. 2. Refer to Chapter 5 (Operating Instruction) in the Operator Manual for detailed procedure. 4. Calibration check to be performed by Capitel Field Service Engineer or customer.

NOTE: These are minimum recommendations for cleaning. Your institution may require that maintenance be performed on a more frequent basis. Reference: GeneXpert Infinity Operator Manual (PN 302-0785, Rev. A)

Disinfect the Kiosk table top, Monitor, Mouse, Keyboard	Weekly
Clean the Rear Fan Filters	Monthly
Clean Instrument Surfaces	Quarterly
Disinfect the Cartridge Bay interior	Quarterly & on demand
Disinfect the Syringe Plunger Rod	Quarterly & on demand
Clean Conveyor Belt	Weekly (quick clean) & Quarterly (extensive)
Empty Waste Container	On demand
Check Instrument Calibration	Annually



## Materials needed for Maintenance (not provided)

- Bleach solution (0.5% final active chlorine concentration or a 1:10 dilution factor of a household chlorine bleach)
- 70% ethanol
- Deionized water
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection



### **Cleaning the Kiosk Table Top, Monitor, Mouse & Keyboard**

Materials required:

- Bleach solution (0.5% final active chlorine concentration or a 1:10 dilution factor of household chlorine bleach prepared within one day of use
- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)
- **Deionized** water
- Lint-free wipes or paper towels
- **Disposable gloves**
- Eye protection

Remove the mouse and all other items from the kiosk table top.

Thoroughly moisten a lint-free wipe or paper towel with the bleach solution.

Wipe the table top surface thoroughly with the lint-free wipe or paper towel. Use additional lint-free wipes or paper towels, as needed, to ensure adequate coverage, Allow the bleach solution to remain on the surface a minimum of two minutes.

Discard the used lint-free wipe according to your standard laboratory procedure.

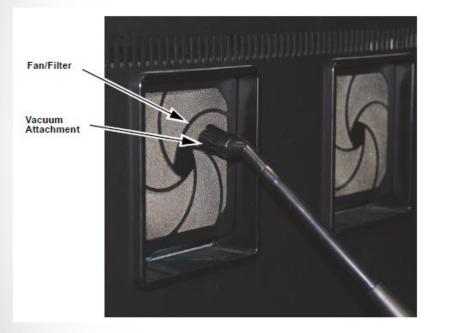
Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.

Wipe the table top, keyboard, mouse and monitor thoroughly with the lint-free wipe or paper towel. Use additional lint-free wipes or paper towels, as needed.

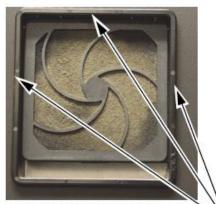
Discard the used lint-free wipes or paper towels according to your standard laboratory procedure.



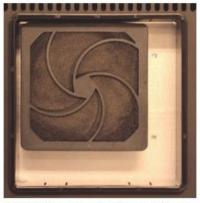
## **Cleaning of the Rear Fan Filters**



Eventually the Fan filters need to be replaced. For more information, please refer to the Operator Manual!



Fan Filter NOT to be Replaced by Customer



Fan Filter to be Replaced by Customer

Not Enough Space to Remove Filter



# **Clean the Instrument Surfaces (quarterly maintenance)**

Before you start, ensure that all test have finished and that no cartridges are left in the modules! The initiate The shutdown protocol!

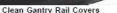
### Important

For the quarterly cleaning procedure, do not use a bleach solution. A bleach solution is to be used only in the event of a spill.

Materials required:

- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection







Clean Door Rail





## **Clean the Instrument Surfaces – in case of spill**



The GeneXpert Infinity system must be completely shut down when cleaning the instrument surfaces.

Important

Materials required:

- Bleach solution (0.5% final active chlorine concentration or a 1:10 dilution factor of household chlorine bleach prepared within one day of use
- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

Thoroughly moisten a lint-free wipe or paper towel with the bleach solution.

Wipe affected surfaces inside the instrument. Change lint-free wipes or paper towels frequently while wiping.

Allow the bleach solution to remain on the surfaces at least two minutes but no longer than five minutes.

Repeat Step 1 through Step 4 two more times for a total of three times.

Thoroughly moisten a lint-free wipe or paper towel with the 70% ethanol solution.

Wipe affected surfaces inside the instrument. Change lint-free wipes or paper towels frequently while wiping.

Discard the used lint-free wipe or paper towel according to your standard laboratory procedure.



# **Clean the Conveyor Belt (quick clean, weekly)**



Do not use alcohol or ethanol to clean the conveyor belt. Alcohol or ethanol can damage the conveyor belt material.

### Materials required for weekly quick clean:

- Deionized water
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

Thoroughly moisten a lint-free wipe or paper towel with deionized water.

Hold the lint-free wipe or paper towel tightly (to avoid it being pulled from your hand) against the exposed surface of the conveyor belt for two rotations of the belt (approximately two minutes).

Dry the belt using a new lint-free wipe or paper towel. Hold the lint-free wipe or paper towel tightly (to avoid it being pulled from your hand) against the exposed surface of the conveyor belt for two rotations of the belt (approximately two minutes).

### to remove particulate debris





# Clean the Conveyor Belt (quarterly or in case of spill)



Do not use alcohol or ethanol to clean the conveyor belt. Alcohol or ethanol can damage the conveyor belt material.

Materials required:

- Bleach solution (0.5% final active chlorine concentration or a 1:10 dilution factor of household chlorine bleach prepared within one day of use
- Deionized water
- Lint-free wipes or paper towels
- Disposable gloves
- Eye protection

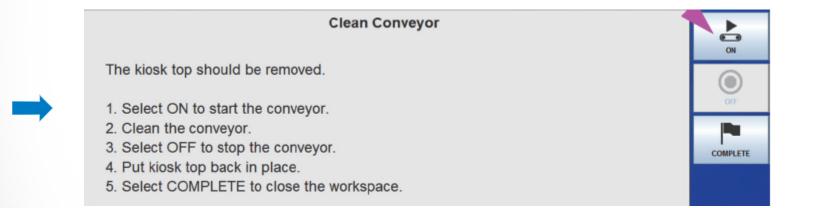


to clean and disinfect or in the event of spill



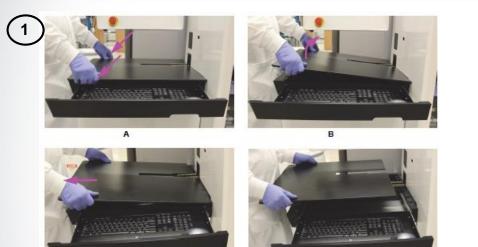
## Clean the Conveyor Belt (quarterly or in case of spill)



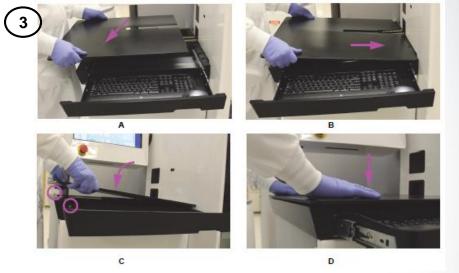




### **Clean the Conveyor Belt (quarterly or in case of spill)**



D



It is possible to pinch your fingers when installing the kiosk table top. To avoid pinching your fingers, perform the following steps exactly as instructed.

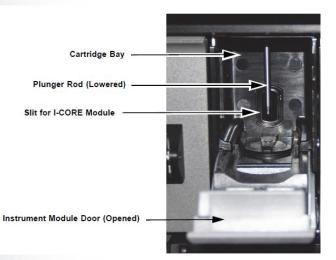


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# **Cleaning the Cartridge Bays & the Plunger Rods**

the modules before you start!



Prevent entrance of any liquid into the slit of the I-Core Module!

#### **Biological Risks**



Wear disposable gloves, eye protection and other personal protective equipment mandated by your institution's safety policies while performing this cleaning procedure. Wearing personal protective equipment prevents exposure to chemical and biologically hazardous materials.

Ensure that no tests are running and that no cartridges are left in

The materials required for this procedure are:

 A final concentration of 1:10 dilution of household chlorine bleach (used within 1 day of preparation)

Perform the bleach wipe-down three separate times on the interior surfaces of the cartridge bay, allowing the bleach to remain on the surfaces for two minutes after each wipe. After the final two minutes, remove the bleach residue by thoroughly wiping the cartridge bay and plunger rod with ethanol.

- 70% ethanol or denatured ethanol (70% ethanol containing 5% isopropanol and 5% methanol)
- Soft lint-free wipes

#### Caution

Important

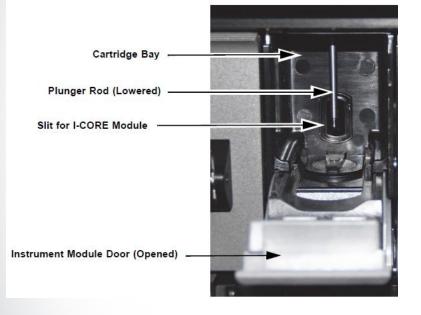


Do not use 70% isopropanol alcohol for cleaning the cartridge bay and plunger rod. Isopropanol alcohol can degrade plastics.

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### **GX Maintenance Workspace**

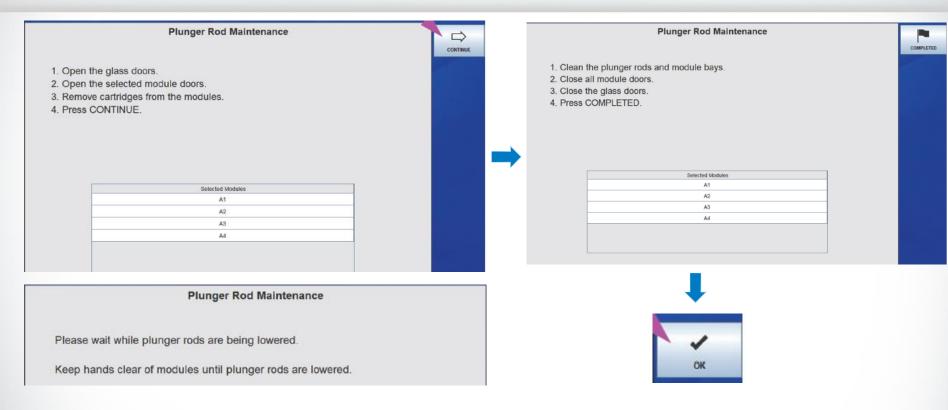




	Module Name	Status	Module S/N	Estimated Minutes To Result	Tests Since Last Cleaned	CLOS
	A1	Available	642969		54 🔺	
1	A2	Available	642999		48	
×	A3	Available	643030		44	
2	A4	Available	642845		48	
	B1	Available	643015		54	
	B2	Available	642812		52	
	B3	Available	642706		49	
	B4	Available	643243		49	
	C1	Available	602699		31	
	C2	Available	612818		101	
	C3	Available	612666		101	
	C4	Available	612816		100	
	D1	Available	600323		203	
	D2	Available	612665		97 🕳	

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### **GX Maintenance Workspace – cont'**





### **Empty Waste Container**



### Check waste container icon on dashboard! Click on icon and follow the instructions on the screen!

#### **Biological Risks**



Remove the waste container bag carefully to avoid puncturing of the bag by the cartridges. If the bag punctures, liquid from the cartridges may leak.



Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

Warning

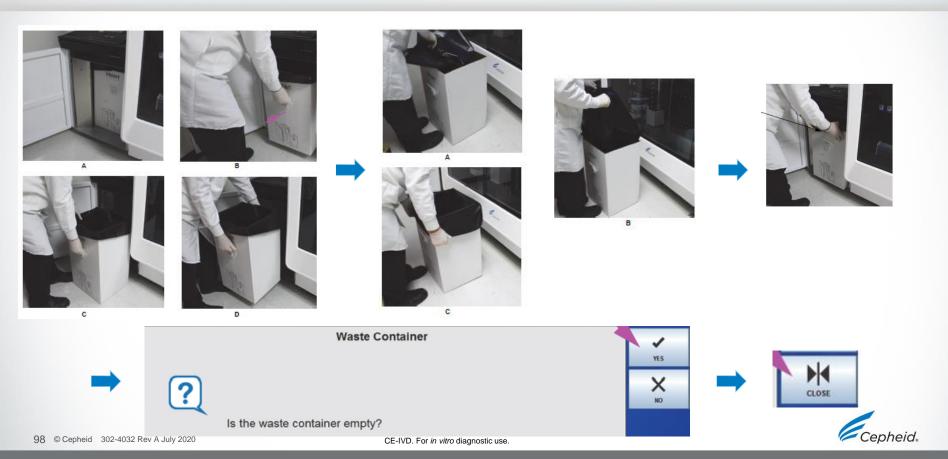


A bag filled with cartridges is very heavy (approximately 17 kg (38 lbs.)). Use proper lifting techniques when lifting the waste container and bags with cartridges.

Be careful not to damage the metal latch that protrudes from the door while removing the waste container. See Figure 9-46.



### **Empty Waste Container**



### Thank You.

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