

Troubleshooting

Cepheid HBDC training 2013



Troubleshooting Approach

- 1. In case of problem, look for an error message on the screen (pop-up windows, message box at the bottom of the screen or in the "Error" tab in the menu "View Results")
- 2. Look for the error code in the GeneXpert user manual and follow the recommended corrective actions.
- 3. If the problem remains, contact your local service provider (if applicable) or Cepheid assistance

Service	Telephone	Email address
Technical hotline (Europe based)- Instrument errors	+33.5.63.82.53.19	support@cepheideurope.com
Technical hotline (U.S.A based)- Instrument errors	888-838-3222, Option 2	techsupport@cepheid.com

4. Continue to use other modules in the meantime (if possible) and exclude faulty

module(s) from tests (see slides 8 & 9)



Where to find Error messages?

		Reports Setup	Advanced		our	1		Ŕ	0		0 12		Use	r supp
Create	est	Check Status	Stop T	J	View Res			Define	+@ 2-3 Assays	De	fine Graphs		Maintena	
croater		Modules						Denne	noouyo		nce Launch			
Module Name	Assay	Sample ID	Progress	Status	Remaining Test Time		Sample ID	Mod Na	User	Result	Assay	Status	Error Status	Start Date
						ana								
						and a state of the								
						and a state of the								
						and a state of the								
						and the second								
						anananan.								
						and a state								
essages:- unched Gi	eneXpert® Dx	System at 12/03/11	3 15:30:32											
rsion 4.3		eck power switch a		'GeneXper	t cable connec	tions	S.							



Where to find Error messages?

GeneXpert® Dx System		
er Data Management Reports Setup	View Results About	User <n< th=""></n<>
Create Test Check Status	Stop Test	View Results Define Assays Define Graphs Maintenance
Patient ID	Views	Test Result Analyte Result Detail Errors History Support
275355.0	Result View	Troubleshoot
	Primary Curve	# Description Detail Time
Sample ID		Post-run Error 5006: [QC-1] probe check failed. Probe check 03/07/13
275355.0		analysis error value of 152.3 for reading number 1 was above the 21:02:52
		maximum of 140.0 2 Post-run Error 5006: [QC-1] probe check failed. Probe check 03/07/13
Assay Xpert MTB-RIF Assay G4		analysis error value of 152.0 for reading number 3 was above the 21:02:52
		maximum of 140.0
Version 5		
Reagent Lot ID* 11112		
Test Type Specimen 💌		
Sample Type Other 🗾		·
Other Sample Type	Views	4
	Result View	
Notes	Primary Curve	
Start Time 03/07/13 20:40:17 End Time 03/07/13 21:03:16 Status Aborted User sultuane		<no available="" data=""></no>
Save Changes Export Repor	t Select Graphs	View Test
onfidential.		

Troubleshooting section in Operator Manual

Chapter 9.13 in current Operator Manual

Error code	Error message	Possible causes	Solution
5007	X probe check failed. Probe check value of n for reading number m was below the minimum of p. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	 One or more of the following might have caused the error: An incorrect amount of reagent was inserted into the cartridge. The reagent is bad. Fluid transfer failed. The sample was processed incorrectly in the cartridge. 	 Check the following: Reagents are added to the cartridge correctly. Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.
5008	X probe check failed. Probe check delta value n between reading number m and reading number p was below the minimum of q. (x is the analyte name, n, m, and p are values that the software displays. The values can vary.)	 One or more of the following might have caused the error: An incorrect amount of reagent was inserted into the cartridge. The reagent is bad. Fluid transfer failed. 	 Check the following: Reagents are added to the cartridge correctly. Cartridges were stored correctly. Rerun the test using fresh cartridges. If the error recurs, call Cepheid Technical Support.



How to obtain System Log Report

- Switch ON the GeneXpert
- Open the GeneXpert Software
- Click on « Report » then select « System Log »



- On the new windows that opens, select:
 - Date range: « All »
 - Modules: « Currently Connected Modules »
 - Show: Errors only »
 - Click on « Preview PDF »
 - Save the file and send it to Cepheid Tech Support: support@cepheideurope.com



How to obtain System Log Report

ystem Log Report			
Dat <u>e R</u> ange			
O Select From	MM/DD/YY	To MM/DD/YY	
Modules			
Currently Connected Mo	odules		
O All Logged Modules			
Select	Module Name	Mod	ule Serial Number
Select All	Deselect All	Select Highlighted	Deselect Highlighted
Select All	Descrettin	ocicet inginighted	Deselect Highlighted
Select All		Select highlighted	Deselect Highlighted
Show		Select Ingingited	Deselect Highlighted
Show Errors Only			Deserect Highlighted
Show			Deserect nigninginea
Show Errors Only			
Show Errors Only			
Show Errors Only			
Show Errors Only	Generate Report File	Preview PDF Clo	

Gen	eXpert PC	Sustana Law Banant		02/12/13 11:30:
		System Log Report		
_	election Criteria -			
Date	e Range:	All		
Mod	ules:	Currently Connected Modules Module B1,B2,B3,B4.		
Show	w:	Errors Only		
User	c.	Byanyima Patrick		
Mod	dule Name	Instrument S/N	Module S/N	
B1		803498	631667	
Ħ	Description	Detail	Time	Version
1	Termination error	Error 2127: Module communication loss was detected		4.4a
2	Termination error	Error 2127: Module communication loss was detected	15/08/13 19:14:54	4.4a
3	Termination error	Error 2127: Module communication loss was detected	16/08/13 10:58:18	4.4a
4	Termination error	Error 2127: Module communication loss was detected	27/08/13 10:02:07	4.4a
5	Termination error	Error 2037: The cartridge integrity test failed at valve position 0. The pressure change of 1.8 PSI did not exceed the requirement of 4.0 PSI. The pressure increased from 2.1 PSI to 3.9 PSI during the test	28/08/13 17:56:56	4.4a
6	Termination error	Error 2037: The cartridge integrity test failed at valve position 0. The pressure change of 1.4 PSI did not exceed the requirement of 4.0 PSI. The pressure increased from 2.1 PSI to 3.5 PSI during the test	28/08/13 18:04:18	4.4a
7	Termination error	Error 2127: Module communication loss was detected	12/09/13 14:03:45	4.4a
8	Termination error	Error 2127: Module communication loss was detected	12/09/13 14:03:57	4.4a
9	Termination error	Error 2008: Syringe pressure reading of 120.2 PSI exceeds the protocol limit of 120.0 PSI	25/09/13 11:56:48	4.4a
10	Termination error	Error 2127: Module communication loss was detected	26/09/13 20:12:47	4.4a
	Termination error	Error 2127: Module communication loss was detected	22/10/13 12:09:59	4.4a
11			06/11/13 20:13:22	4.4a



How to Exclude Module(s) from Tests



How to Exclude Module(s) from Tests



Modules not detected



Temperature issues

Error codes: 1001, 1002, 2014, 4009 etc.

Causes:

- A heater component in a module is malfunctioning
- Ambient temperature is not within acceptable range
- Fan failure (broken or filter is dirty)

Solutions:

- Does this error affect only one module? Always the same?
- Check the internal temperature of the modules (in the Maintenance menu)
- Check room temperature (must be 15 to 30°C)
- Check the fan functionality (exhaust at rear of the instrument)
- Check the filters are clean
- Check clearance around the system (must be 10-15 cm on all sides)



11 © Cepheid – Confidential.

Stuck Cartridge

A cartridge is stuck inside a GeneXpert module

Causes:

- Module mechanical malfunction during the test
- **Electrical failure**

Solutions:

1 – try to remove the cartridge from the software

- In the GeneXpert Dx window, click "Maintenance" button
- On the Maintenance menu, click "Open Module Door" -
- Select the module. Click "Open Door" to open the module door. -
- If the door does not open, restart the system and repeat the above steps.

2 – Manual removal of the cartridge

© Cepheid - Confidential.

12

If above steps did not solve the issue, contact Cepheid in order to be guided on how to remove module manually (detailed procedure and online support will be provided)



Error Messages

🌁 GeneXpert® Dx System					
User Data Management Reports Setup	View Results About				User cepheid5
Create Test Check Status	Stop Test	View Results	0 2 3 Define Assays	Define Graphs	Maintenance
Module Name A2	Views	Test Result Analyte Result	Detail Errors Histo	ory Support	
Patient ID	Result View	Assay Name Xpert MTB-RIF Ass	av G4	Version 5	
	Primary Curve	Test Result ERROR			
Sample ID PASCAL		For In Vitro Diagnostic Use Only.			
TABOAL					
Assay Xpert MTB-RIF Assay					
G4					
Version 5					
Reagent Lot ID* 04202					
Test Type Specimen 💌	A.7				
Sample Type Other 🔍	Views Result View				
Other Sample Type	Primary Curve				
Notes					
HPGRB, CHIR, No 226					
			<no avai<="" data="" td=""><td>able></td><td></td></no>	able>	
Start Time 17/04/12 23:11:17					
End Time 17/04/12 23:17:48					
Status Aborted					
Upload Status NA					
User Dr David					
Save Changes Export Report		Select Graphs View Test]		

<u>Cause</u>

Many different causes can lead to an ERROR result. Click on Errors to know more about the specific issue

Origin(s)

Most frequent issues, linked to sampling, are detailed in the next slides. They should be addressed by operators following the advices contained in this document

All other issues should be reported to Cepheid technical support group

Solution(s)

To easily reduce an unexpectedly high Error rate, it is essential that all operators identify errors linked to sample preparation



Results with Errors: **INVALID**

est and Anaț	te Result		ne Assays story	Define Graphs	Maintenance
Assay Name	Xpert MTB-R	IF	Ve	rsion 1	
Test Result	INVALID				
Analyt Name		Ct	EndPt	Analyte Result	Probe Check Result
	Probe D	0.0	1.0	INVALID	PASS
	Probe C	0.0	0.0	INVALID	PASS
	Probe E Probe B	0.0	0.0	INVALID INVALID	PASS PASS
	SPC	0.0	2.0	FAIL	PASS
	Probe A	0.0	0.0	INVALID	PASS
100- - 80- - - - - - - - - - - - - - - -					Probe D; Primary Probe C; Primary Probe C; Primary Probe B; Primary Probe B; Primary Probe A; Primary Probe A; Primary

Problem SPC (Internal Control) failed

<u>Origin</u>

PCR was inhibited due to inhibitors (pus, food particles, ...)

Solution

Before mixing with Cepheid sample reagent (SR) for decontamination, check that sample does not contain food particles, pus ...

Collect a new sample when necessary



Results with Errors: **NO RESULT**

A GeneXpert® Dx System					
User Data Management Reports Setup	View Results About				User cepheid5
Create Test Check Status	Stop Test	View Results	Define Assays	Define Graphs	Maintenance
Module Name B1	Views	Test Result Analyte Result	Detail Errors Histo	ory Support	
Patient ID	Result View	Assay Name Xpert MTB-RIF G3		Version 3	
	Primary Curve	Test Result NO RESULT			
Sample ID		For In Vitro Diagnostics Use Only.			
60006					
Assay Xpert MTB-RIF G3					
Version 3					
Reagent Lot ID* 02504					
Test Type Specimen					
Sample Type Other 🗸	Views				
Other Sample Type	Result View Primary Curve				
	Primary Curve				
Notes					
Start Time 15/04/11 08:49:30			<no avail<="" data="" td=""><td>able></td><td></td></no>	able>	
End Time 15/04/11 08:49:41					
Status Aborted					
Upload Status NA					
User					
Save Changes Export Report	Upload Test	Select Graphs]		

Problem

Test could not be terminated and Insufficient data were collected

Origin(s)

- Power failure during test
- "Stop Test" function was used. (accidentally or deliberately)
- Computer freeze or crash during test

Solution

Secure the power supply. Use "Stop Test" only when it's necessary Do not open other applications on the computer during tests



Error Messages: Probe check failed: 5006/5007

User Data Management Reports Setu	View Results About		User cepheid5
Create Test Check Statu	is Stop Test	View Results Define Graphs	Maintenance
	Views		
Patient ID	Result View	Test Result Analyte Result Detail Errors History Support	
	Primary Curve	Troubleshoot	
			Time
Sample ID		1 Post-run analysis Error 5007: [QC-1] probe check failed. Probe check value of 25.9 for error reading number 2 was below the minimum of 32.0	29/02/12 18:19:19
		endi induling humber 2 was below the minimum of 52.0	10.10.10
Assay Xpert MTB-RIF Assay			
G4			
Version 5	A.T		
Reagent Lot ID* 04202	Views		
	Result View Primary Curve		
Test Type Specimen 💌	Primary Curve		
Sample Type Other			
Other Sample Type			
Notes			
HPGRB N127		<no available="" data=""></no>	
Start Time 29/02/12 17:56:49			
End Time 29/02/12 18:19:42			
Status Aborted			
Uploau Status INA			
User			
Save Changes Export Repo	ort Upload Test	Select Graphs View Test	

Problem

Probe Check control failed and test was stopped before amplification

Origin(s)

- Incorrect processing of sample (viscosity)
- Incorrect sample volume
- Improper fluid transfer (bubbles)
- Incorrect storage of cartridges (Probe integrity issues detected)

Solution(s)

- Make sure the sample is totally liquefied before transferring to the cartridges:

→ If after 15 minutes of incubation with Sample Reagent, sample is still too viscous <u>do not load it into the</u> <u>cartridge</u>. Wait up to 10 more minutes.

- Add from 2 to 4 mL of the preparation in the cartridges
- Avoid making bubbles
- Store the kits between 2 to 28° C





Error Messages: Abnormal Pressure detected: 2008

e Data Management Reports Setup Create Test Check Statur Module name A/ Patient ID	Stop Tes		Problem Pressure reading exceeds the maximum (2008)
Sample ID SCAL MI Assay Xpert MTB-RIF Assay G4 Version 5 eagent Lot ID* 04202 Test Type Sociemen • Sample Type Other •	Views Result View Primary Curve	Coperation Error 2008: Syringe pressure reading of 120.8 PSI exceeds the protocol 17/04/12 23:17:38	Origin - Filter of cartridge is clogged (due to too viscous sample or particles) - Pressure sensor failed
Other Sample Type Notes PGRB, CHIR, No 226 Start Time 17/04/12 23:11:17		<no available="" data=""></no>	

Solution(s)

- Make sure the sample is totally liquefied before transferring to the cartridges:

 \rightarrow if after 15 minutes of incubation with Sample Reagent, sample is still too viscous <u>do not load it into the cartridge</u>. Wait up to 10 more minutes.

- Make sure <u>sample does not contain any solid particles</u>
- Use a new cartridge and add only Sample Reagent, if problem persists it's likely a module problem: contact Cepheid
 17 © Cepheid Confidential.

Error Messages: Module communication loss was detected: 2127

📑 Ge	neXpert® Dx \$	System				\mathbf{X}
User	Data Manager	nent Report	ts Setup	View Results About	User <nor< th=""><th>ie></th></nor<>	ie>
	A A		N			
	Create Test Module Na		eck Status	Stop Test	View Results Define Assays Define Graphs Maintenance	
	Patie		_	Views	Test Result Analyte Result Detai Errors History Support	
	Paue	ant ID		Result View Primary Curve		
				Primary Curve	# Description Detail Time	
	Sam	ple ID			Operation Error 2127: Module communication loss was detected 11/30/12 terminated 08:03:43	
X678					106.03.43	J -
	Assay	Xpert MTB-R	NF G3			Ш.
	Version	3				
R	eagent Lot ID*	02810				Ш.,
	Test Type	Specimen	-			
				Views		
	Sample Type	Other	-	Result View		
	Other Sar	nple Type		Primary Curve		
SPU	TUM					
	No	tes				
ктн	PESH				<no available="" data=""></no>	
		11/30/12 07:				
		11/30/12 08:	:03:43			
		Incomplete				
<u> </u>	User	PRL KP	-	I		
Sa	ve Changes	Export	Repor	Select Graphs	View Test	
1						

Problem

Communication is lost between modules and software

<u>Origin</u>

- Ethernet connection between PC and GX is bad
- Power supply issue (main power or UPS fluctuations)
- Bad connection points between Gateway Board and modules
- Room temperature is too high

Solution(s)

- Unplug and replug Ethernet cable between PC and instrument, restart the system
- Unplug and replug the communication cable between gateway board and GeneXpert. Restart system.
- Secure Power supply and use adapted UPS/Surge protector
- Check Room temperature (should be below 39°C)





Error Messages: Signal loss detected in the amplification curve: 5011

🚰 GeneXpert® Dx System					
User Data Management Reports Setup	View Results About				User administr
Create Test Check Status	Stop Test	View Results	0 2 3 Define Assays	Define Graphs	Maintenance
Module Name A3	Views	Test Result Analyte Result	Detai Errors History	Support	
Sample ID	Result View	Troubleshoot			
468-13 Urmatbekova Jamily	Primary Curve	# Description	Detail		Time
		1 Post-run analysis Error 5011:		olification curve fo	
Assay Xpert MTB-RIF G3		error [Probe B]. 42	2.3 decrease in signal with 21.6	6% decrease at cy	rcle 20. 23:32:03
Version 3					
Reagent Lot ID* 03009					
Test Type Specimen 💌					
Sample Type Other 💌					
Other Sample Type					
	Views				Legend
Notes	Result View	90			🗹 🖊 Probe D; Primary 🔺
	Primary Curve	-			Probe C; Primary Probe E; Primary
		g 70-			✓ / Probe B; Primary
		8 50-			🗹 🖊 SPC; Primary
Start Time 04/25/13 22:16:52					🗹 🖊 Probe A; Primary
End Time 04/25/13 23:32:55		≓ ³⁰ †			
Status Aborted		10-	_		
				++++	
User Gasanova		应 1 3 5 î	7 9 11 13 15	17 19	
		A	Cycles		
					•
Save Changes Export Report Select Graphs View Test					

Cause

Signal loss detected in the amplification curve.

<u>Origin</u>

Loss of tube pressure because the cartridge tube is not airtight, or cartridge valve is not working right

Solution(s)

- Make sure there is no bubbles in the reaction tube
- Use a new cartridge. If error repeats, this can be module related: modules fluidics are not working well. Contact Cepheid support team.



Cepheid Assistance & Support

If you need help or have a question about GeneXpert please contact us

Service	Telephone	Email address
Training Center (Europe)	+33.5.63.82.5(386)/(378)/(360)	training@cepheidhbdc.com
Technical hotline (Europe based)- Instrument errors	+33.5.63.82.53.19	support@cepheideurope.com
Technical hotline (U.S.A based)- Instrument errors	888-838-3222, Option 2	techsupport@cepheid.com

When Contacting Cepheid, please prepare: The Serial number of the GeneXpert, the recorded error messages, the description of the incident and when possible the archived runs concerned

Information of the system	
Serial number of your GeneXpert (at the back side, near the power button)	
Computer Service Express Service Tag Number	
Installation date of the system	/ /





Thank You.

Visit us at www.cepheidcares.com

