Troubleshooting

Cepheid HBDC training
2013

Cepheid®
A better way.

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")*

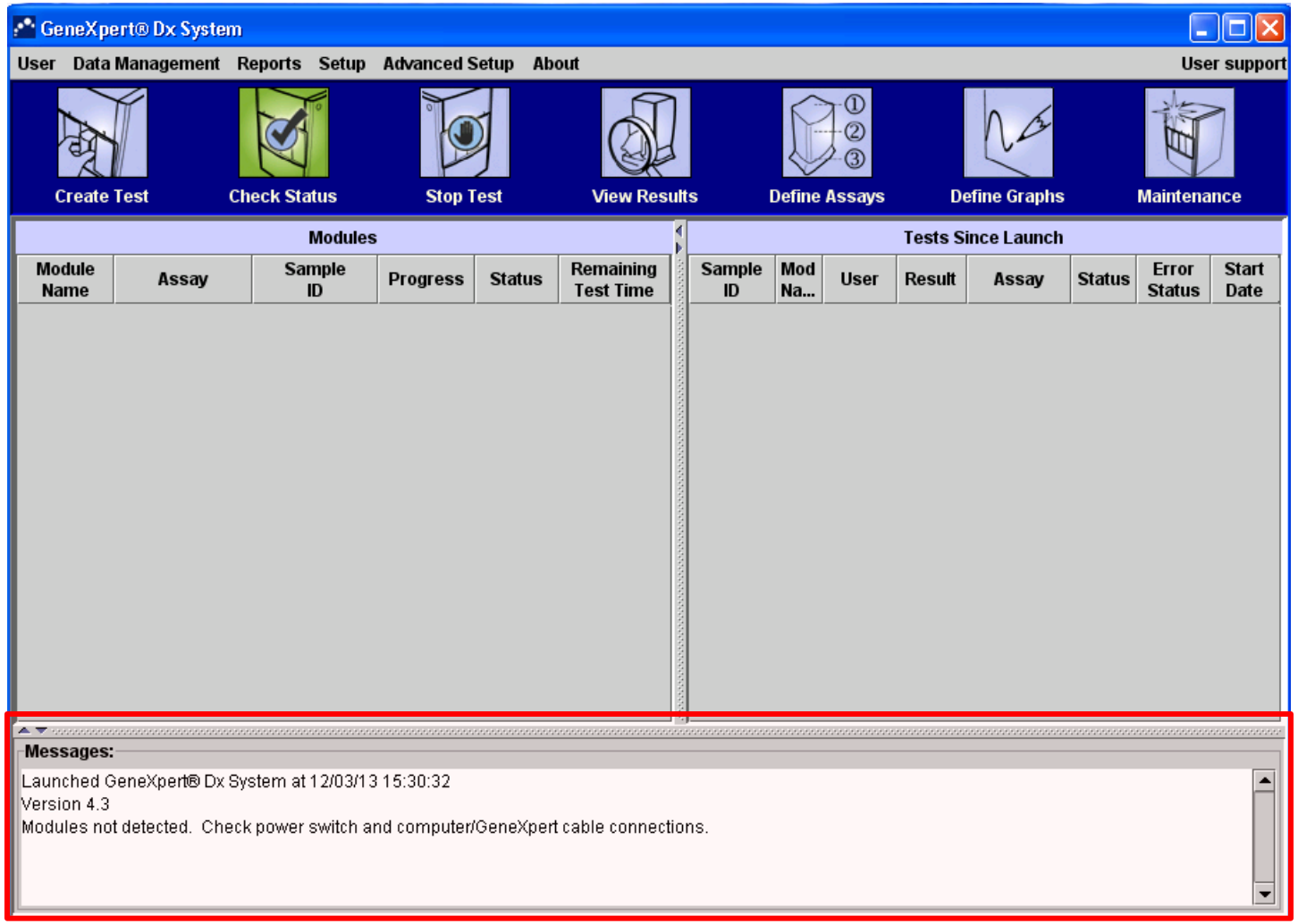
2. Look for the error code in the GeneXpert user manual and follow the recommended corrective actions.

3. If the problem remains, contact your local service provider (if applicable) or Cepheid assistance

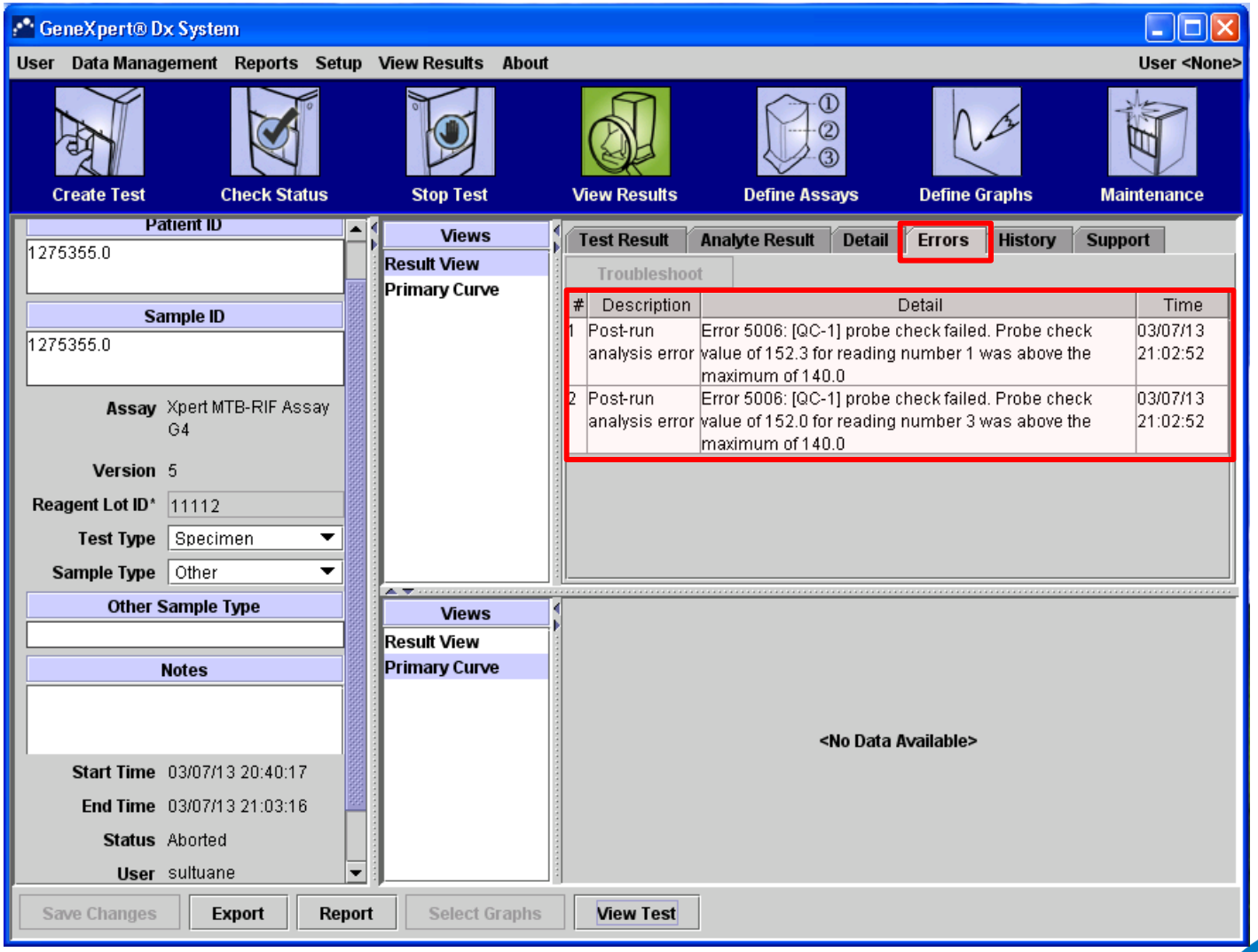
Service	Telephone	Email address
Technical hotline (Europe based)- Instrument errors	+33.5.63.82.53.19	support@cepheideurope.com
Technical hotline (U.S.A based)- Instrument errors	888-838-3222, Option 2	techsupport@cepheid.com

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?



Where to find Error messages?



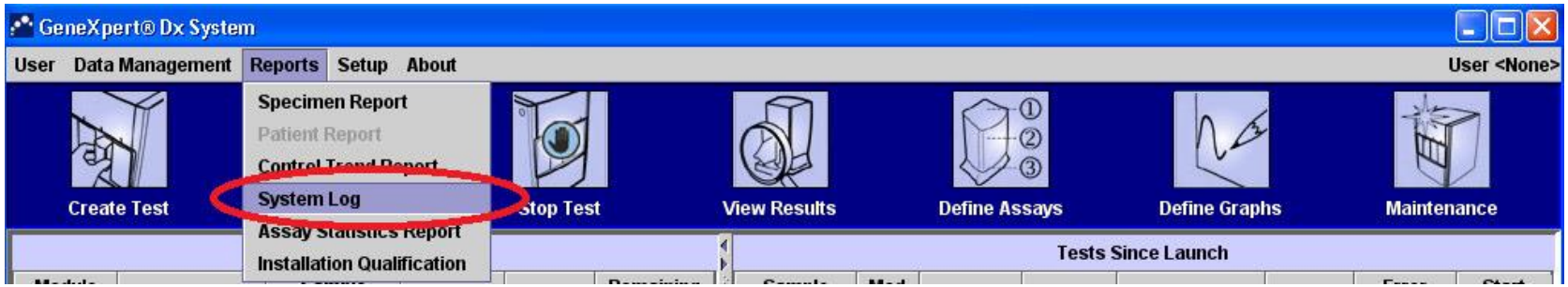
Troubleshooting section in Operator Manual

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.

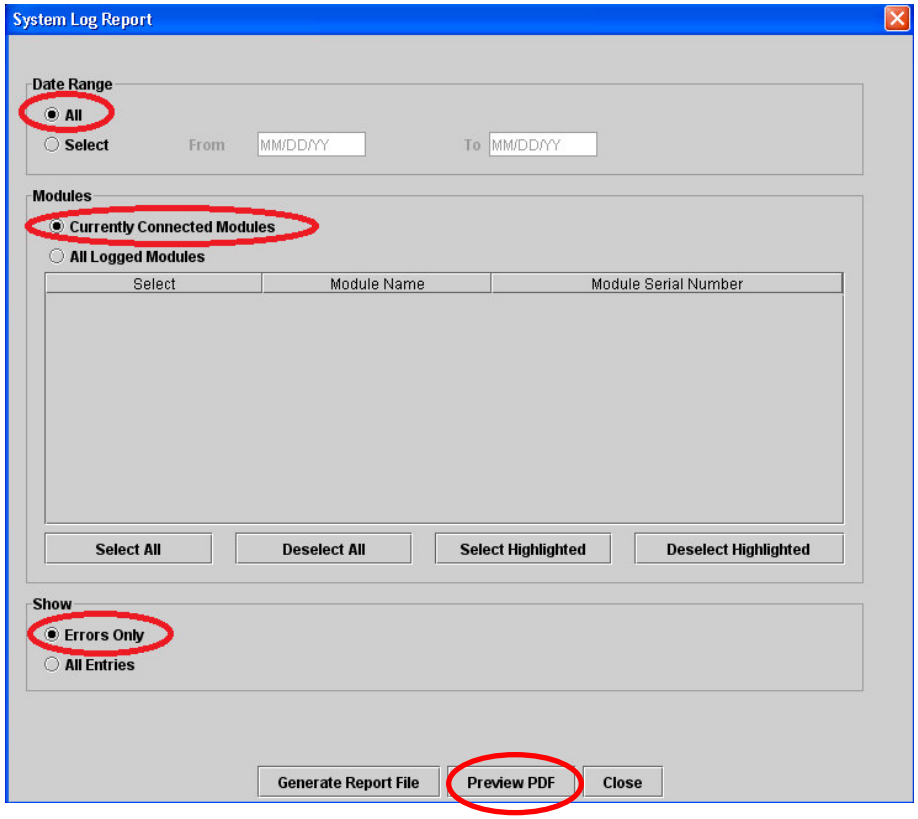
How to obtain System Log Report

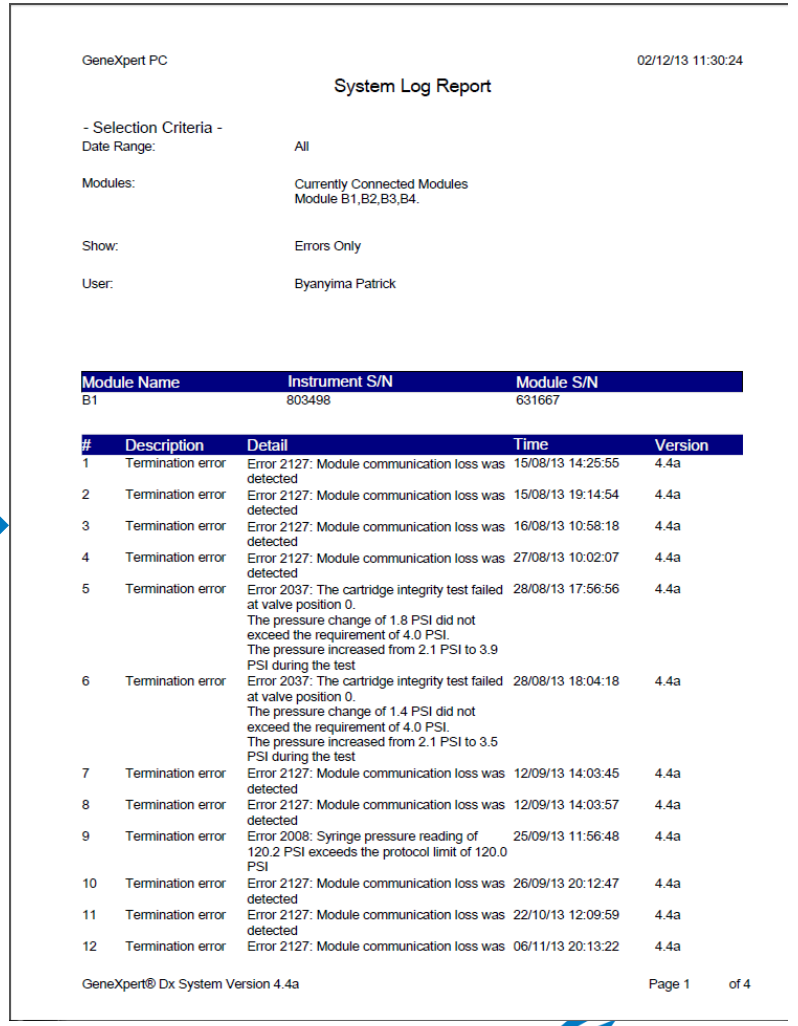
- Switch ON the GeneXpert
- Open the GeneXpert Software
- Click on « Report » then select « System Log »



- 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





GeneXpert PC 02/12/13 11:30:24

System Log Report

- Selection Criteria -

Date Range: All

Modules: Currently Connected Modules
Module B1,B2,B3,B4.

Show: Errors Only

User: Byanyima Patrick

Module Name	Instrument S/N	Module S/N
B1	803498	631667

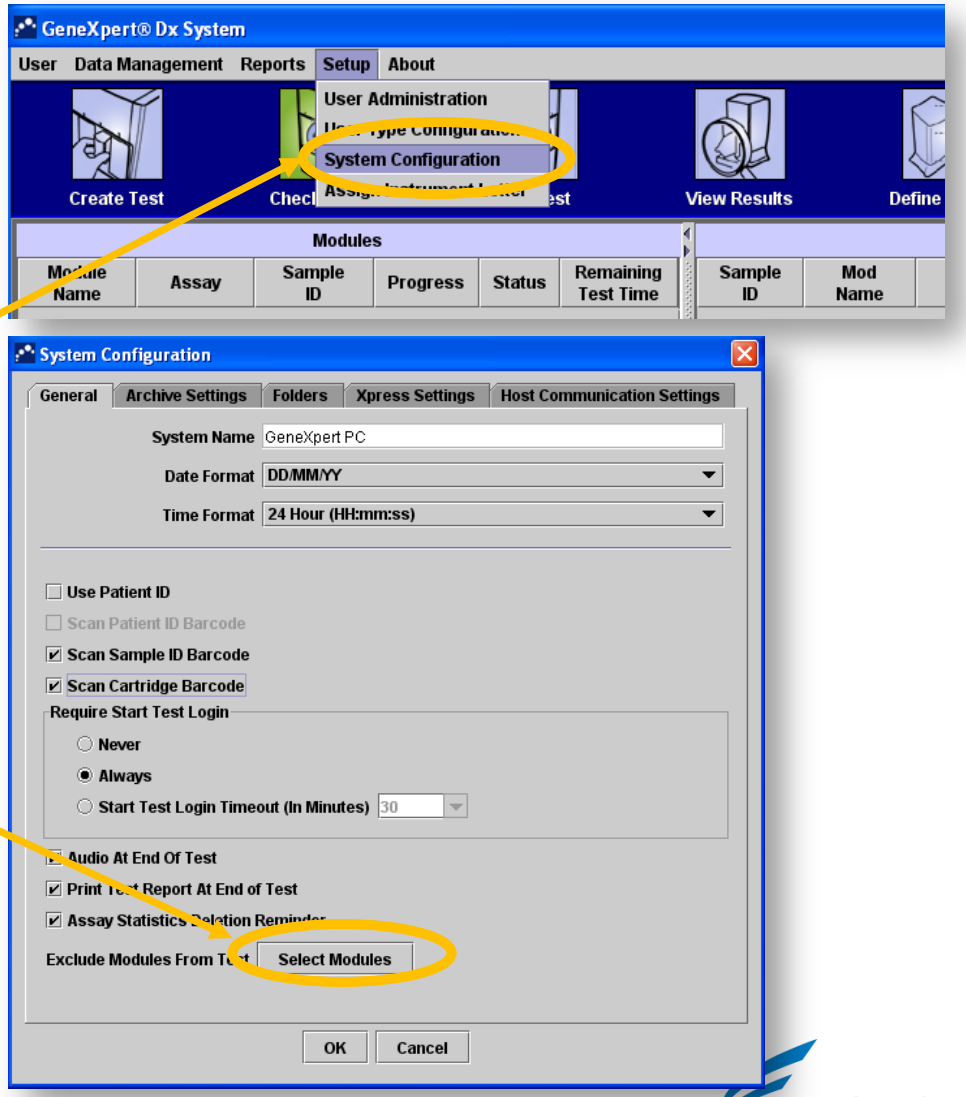
#	Description	Detail	Time	Version
1	Termination error	Error 2127: Module communication loss was detected	15/08/13 14:25:55	4.4a
2	Termination error	Error 2127: Module communication loss was detected	15/08/13 19:14:54	4.4a
3	Termination error	Error 2127: Module communication loss was detected	16/08/13 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
11	Termination error	Error 2127: Module communication loss was detected	22/10/13 12:09:59	4.4a
12	Termination error	Error 2127: Module communication loss was	06/11/13 20:13:22	4.4a

GeneXpert® Dx System Version 4.4a Page 1 of 4

How to Exclude Module(s) from Tests

1 Click on ‘’Setup”, then “System configuration”

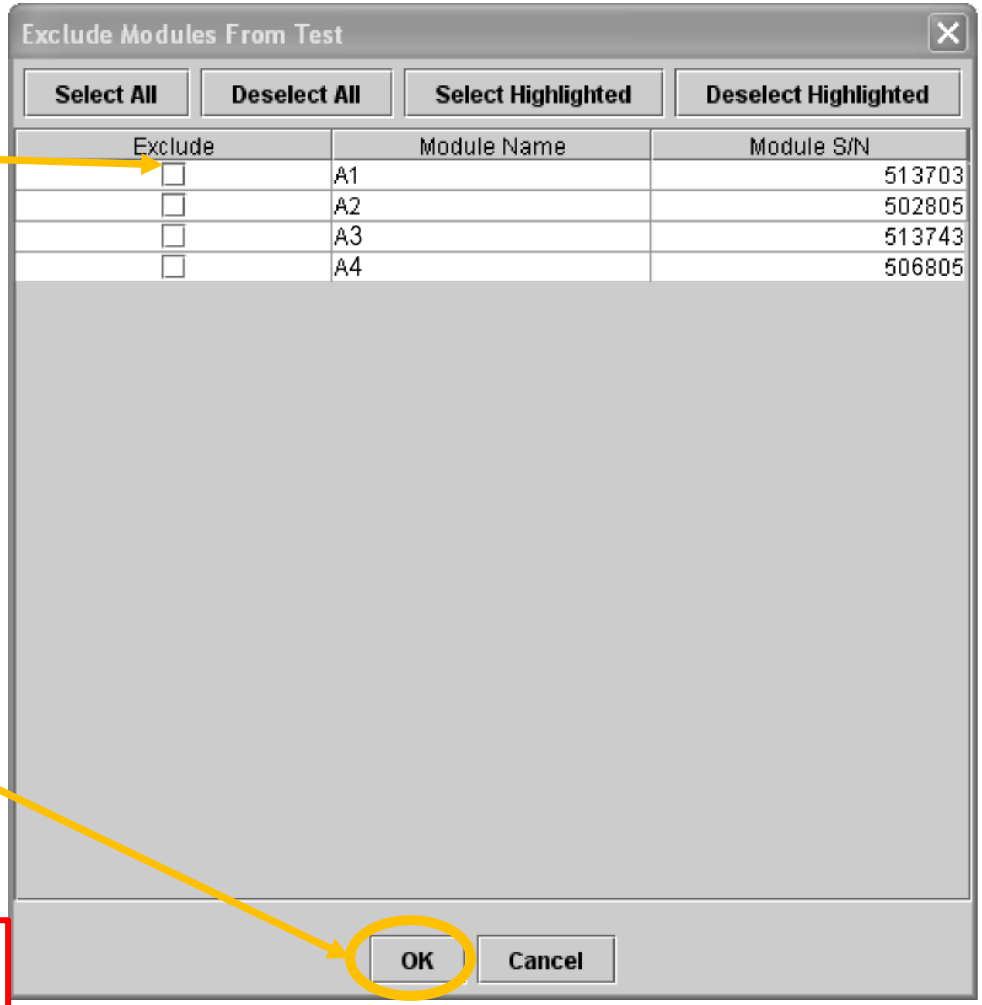
2 Click on the button « Select Modules »



How to Exclude Module(s) from Tests

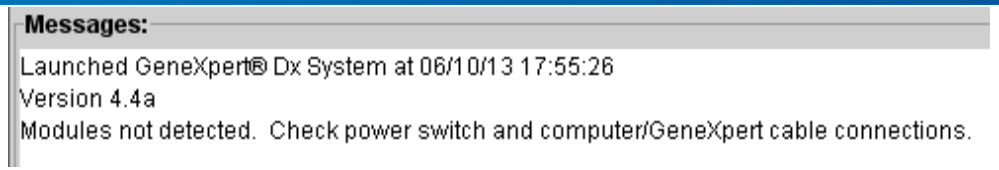
3 **Select the module(s) to exclude by checking the box**

4 **Click on « OK »**



!!! Excluded module(s) will not be usable anymore. Once the situation is back to normal, the module(s) must be removed from this list.

Modules not detected



GeneXpert switched on before Computer?

Modules available in software? → Check Status

YES → Run a test

NO

Check Ethernet cable: Loose? or damaged?

YES

Replug or Replace Ethernet cable

Run a test

NO

1- Right Ethernet port selected (On desktop)?

2- IP address setting lost ?
IP address needs to be re-configured: *Contact Technical support*

3- Problem with LAN Port Computer or GX ?

- Test the Computer LAN port with a printer to see if it works or not
- *Contact Technical support*

4- Problem with Gateway board or Modules?

Module or Motherboard needs to be replaced:
Contact Technical support

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^{0}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)*

Stuck Cartridge

A cartridge is stuck inside a GeneXpert module

Causes:

- Module mechanical malfunction during the test
- Electrical failure

Solutions:

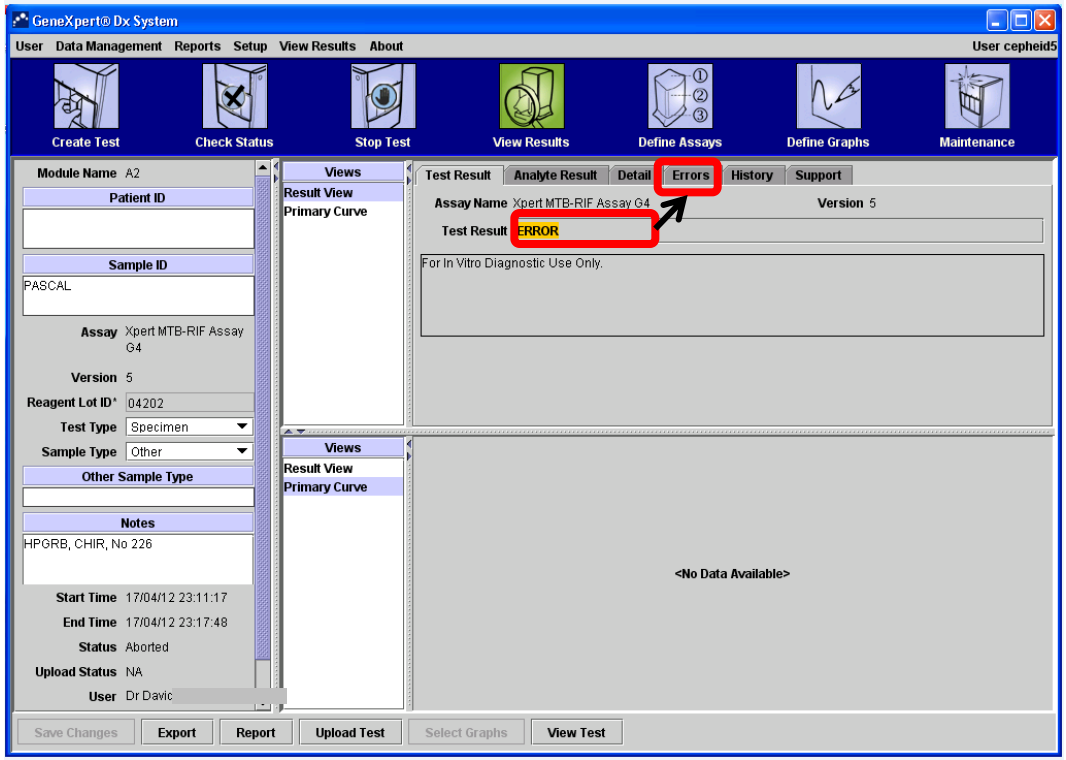
1 – try to remove the cartridge from the software

- 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

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



Cause

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

Origin(s)

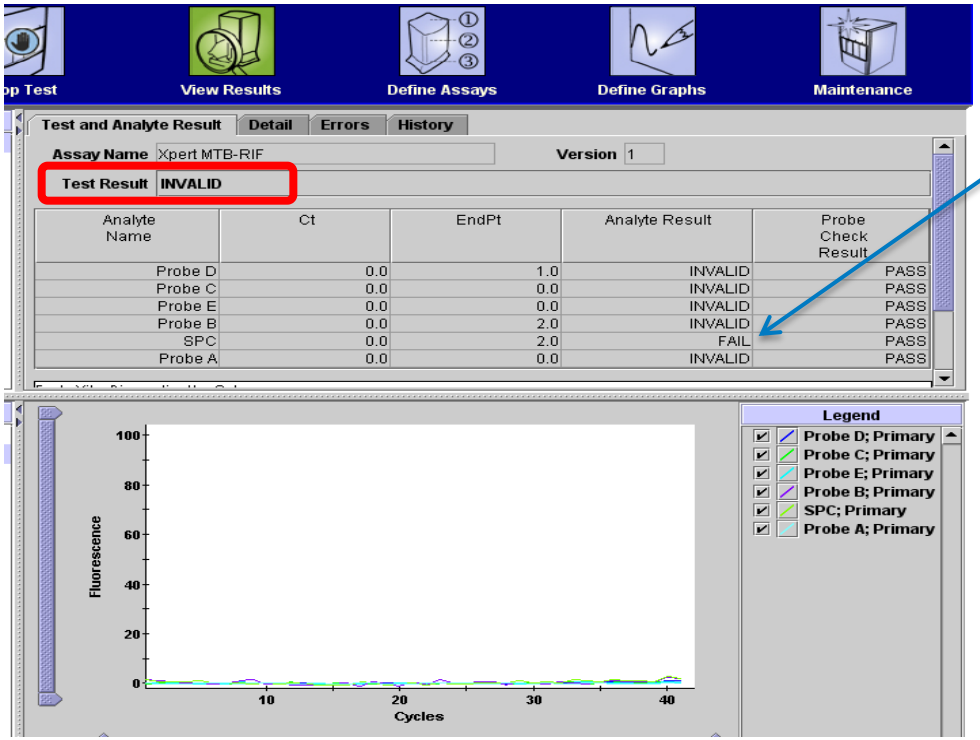
Most frequent issues, linked to sampling, are detailed in the next slides. They should be addressed by operators following the advices contained in this document

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**



Problem

SPC (Internal Control) failed

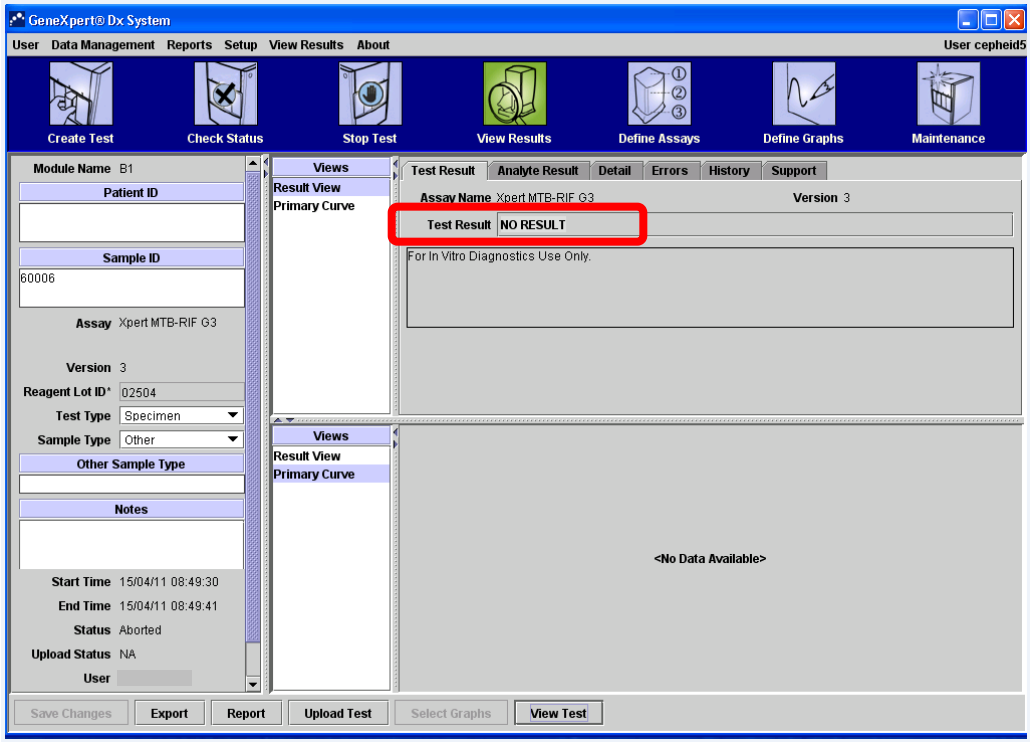
Origin

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**



Problem

Test could not be terminated and Insufficient data were collected

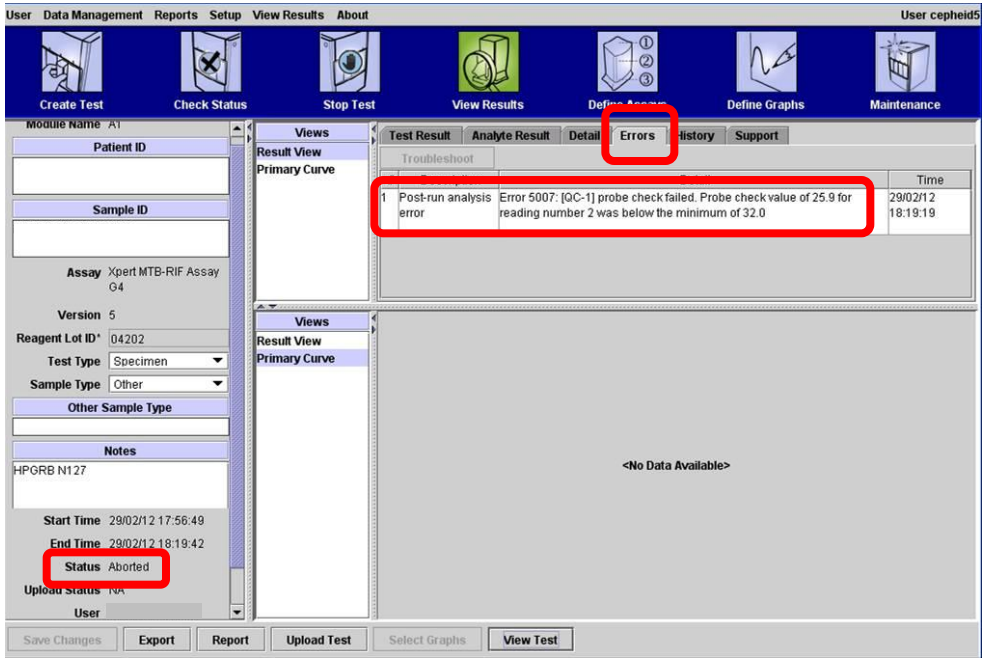
Origin(s)

- 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



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)

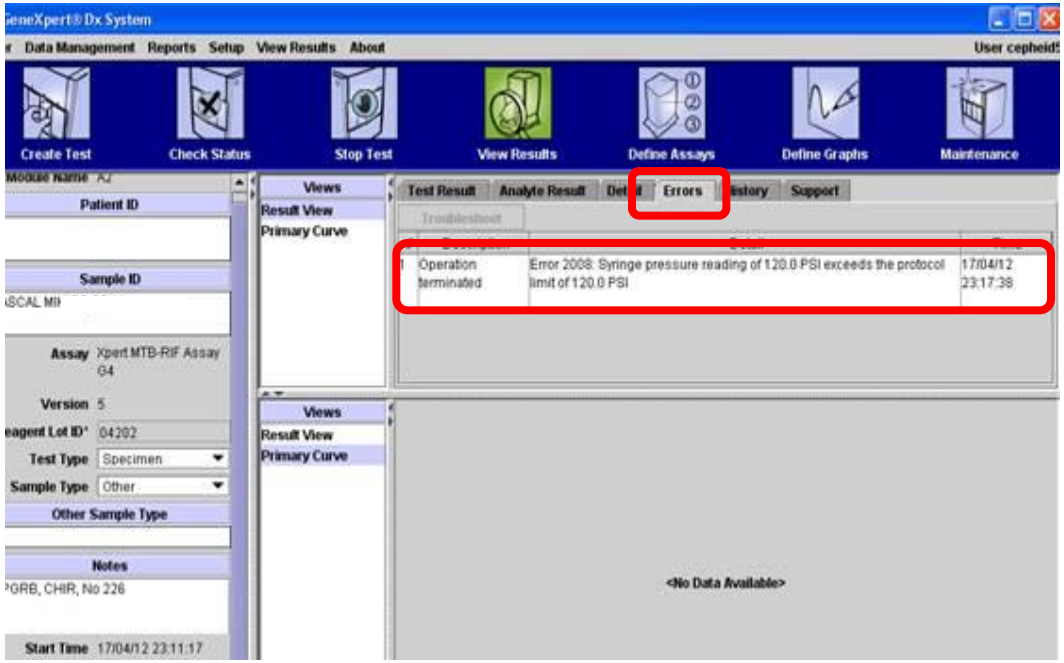
Solution(s)

- 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 do not load it into the cartridge. 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



Problem

Pressure reading exceeds the maximum (2008)

Origin

- Filter of cartridge is clogged (due to too viscous sample or particles)
- Pressure sensor failed

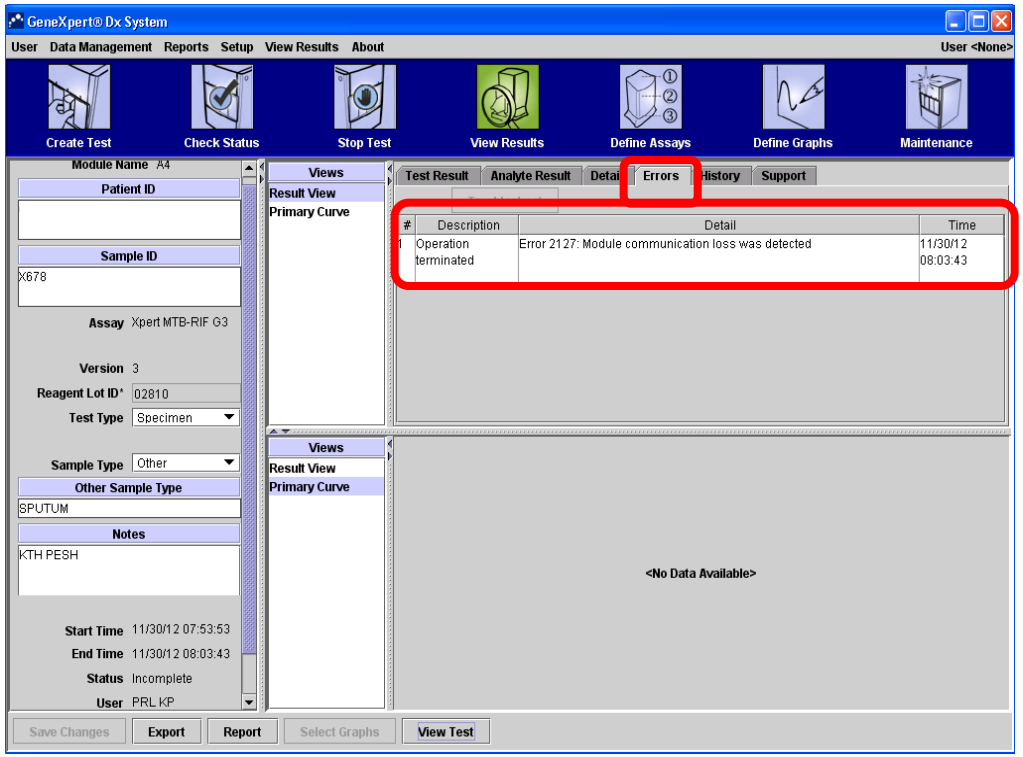
Solution(s)

- 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 do not load it into the cartridge. Wait up to 10 more minutes.

- Make sure sample does not contain any solid particles
- Use a new cartridge and add only Sample Reagent, if problem persists it's likely a module problem: contact Cepheid

Error Messages:
Module communication loss was detected: 2127



Problem

Communication is lost between modules and software

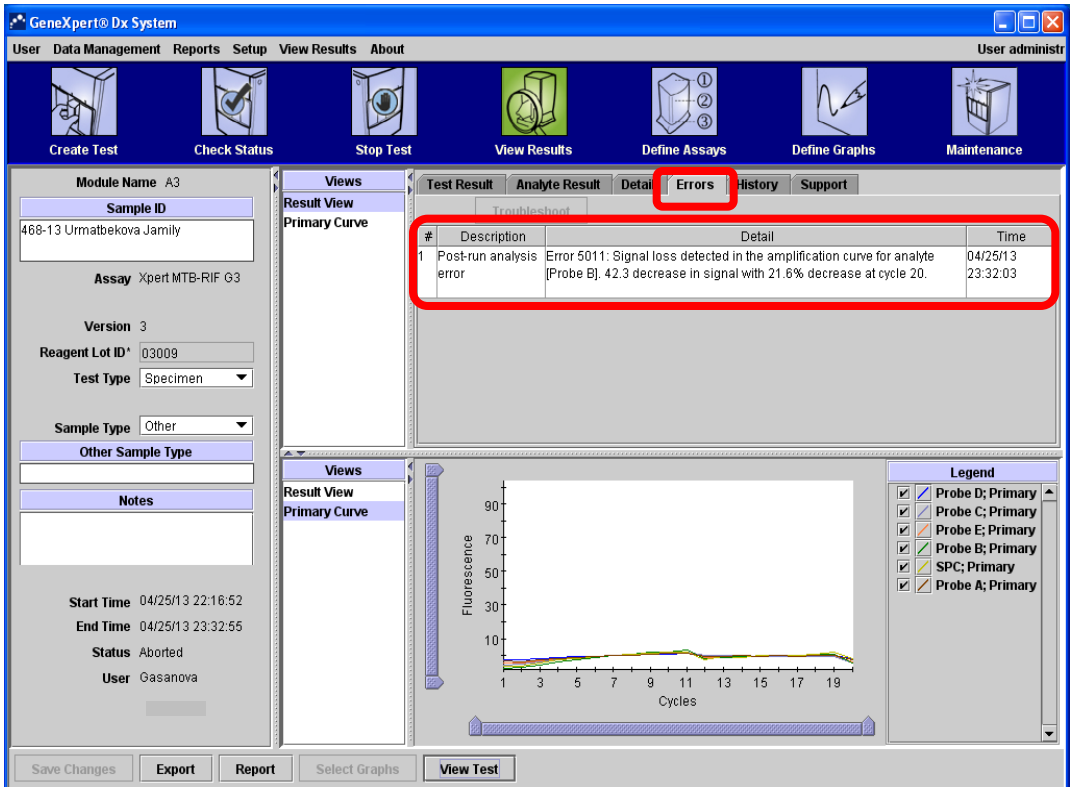
Origin

- 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



Cause

Signal loss detected in the amplification curve.

Origin

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.

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