

# Module 9: Troubleshooting

Slides adapted from Cepheid

# Contents of This Module

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- ▶ GeneXpert instrument problems
- ▶ Errors, invalid results, and no results
- ▶ Other testing issues
- ▶ Cepheid contact information

# Learning Objectives

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At the end of this module, you will be able to:

- ▶ Troubleshoot common GeneXpert instrument problems
- ▶ Explain causes and solutions to common error codes
- ▶ Address other common testing issues

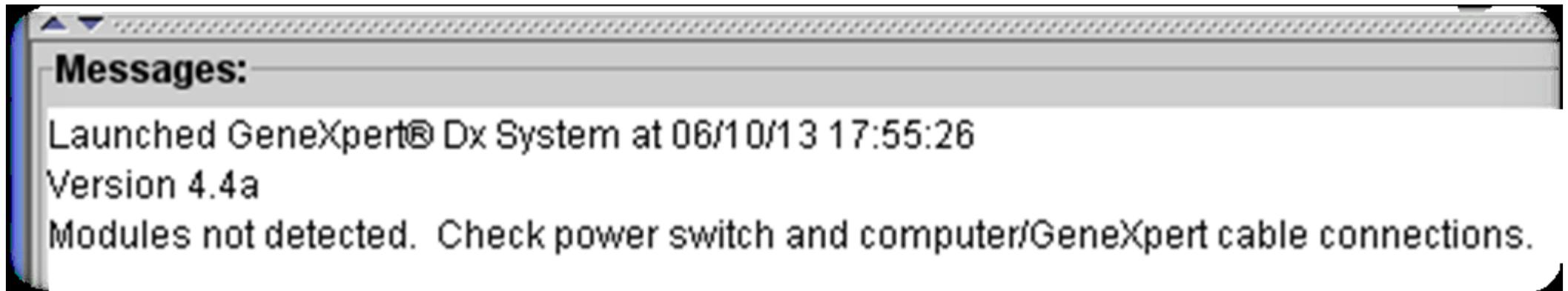
# GeneXpert Instrument: Problems that may be encountered

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- ▶ GeneXpert modules are not detected
- ▶ Barcode scanner is not working
- ▶ Red light on module is blinking
- ▶ Cartridge is stuck in GeneXpert

# GeneXpert Modules Not Detected (1)

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# GeneXpert Modules Not Detected (2)

Was GeneXpert machine switched on before the computer? ⇒

NO

Close GeneXpert Dx software ⇒  
shut down computer ⇒  
turn on GeneXpert ⇒  
turn on computer ⇒  
open GeneXpert Dx software ⇒

YES

Ethernet cable loose, not connected or damaged?

NO

YES

Replace the cable

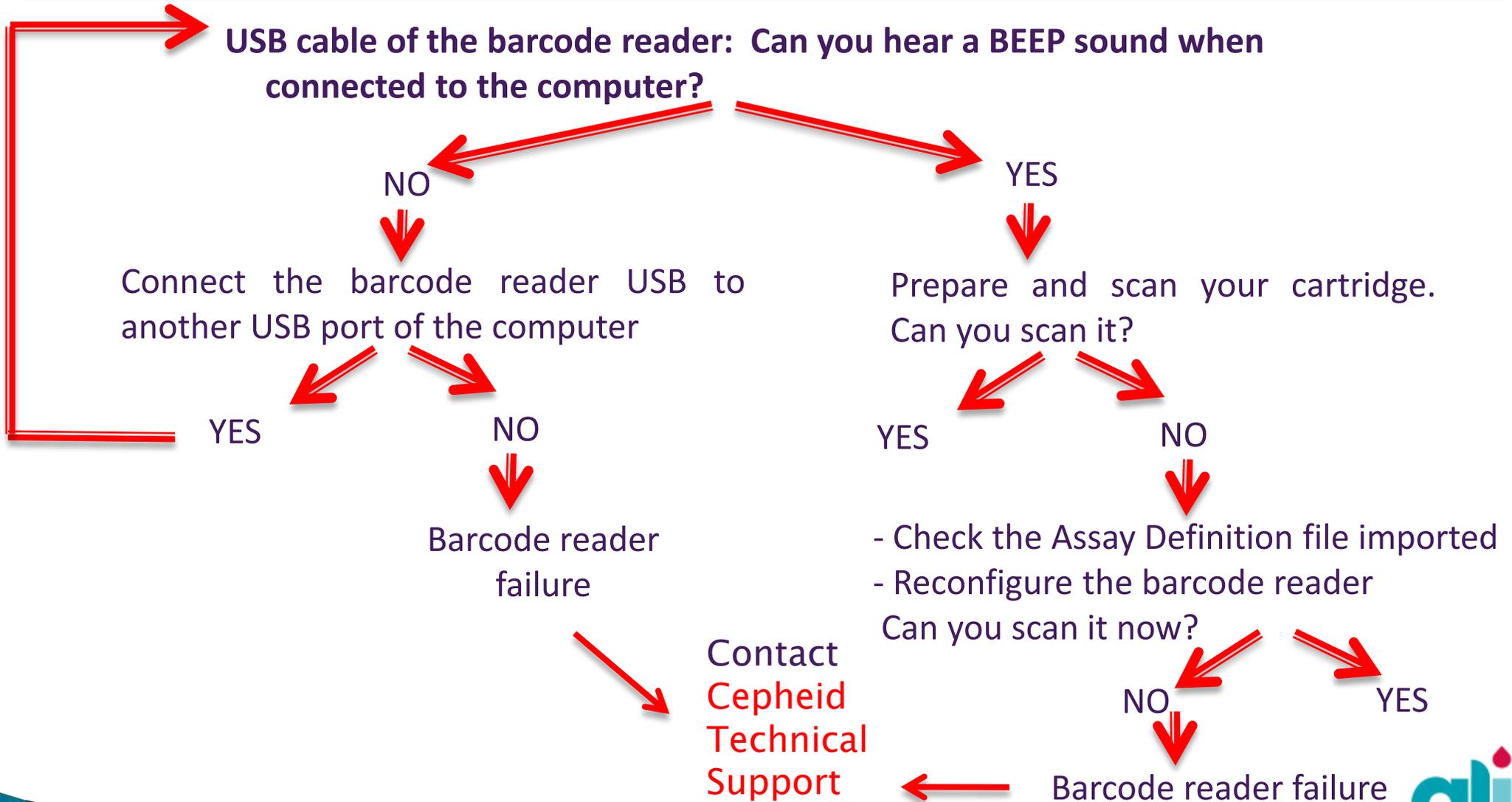
IP address issue

Bad Gateway board or Computer LAN Port

⇒ Contact **Cepheid Technical Support** to replace the computer or module

⇒ Contact **Cepheid Technical Support** reconfigure the IP address

# Barcode Scanner Error



# Barcode Scanner reconfiguration



**2D Barcode Scanner Configuration  
Procedure, Worksheet, and Purchasing Spec**

Scanner Serial Number: \_\_\_\_\_

Part number: 800-0207 Rev. \_\_\_\_\_

This worksheet is used to document the configuration of the bar code scanner (800-0207). The information for each section should be signed and dated as they are completed.

Document Number: 800-0207  
Rev: B  
Originator: B. Kutner  
Effective: 08/02/07  
p. 1 of 5

**Part 1: Configuration**

Step	Description	Initial	Date	Comments (if applicable use Log Sheet Part 5)
<b>PREPARATION AND SET-UP</b>				
1.	Printout this document- if any barcodes are smudged or lines have missing marks, reprint the document.			
2.	Locate Computer with Windows 2000 and USB Hub			
3.	<b>Set-up Scanner</b> <ul style="list-style-type: none"> <li>• Remove the barcode scanner from the box</li> <li>• Connect the black USB cable connector (looks like a telephone jack) with the scanner, you should hear a "click" when the connector is properly seated into the scanner.</li> <li>• Connect the other end of the USB connector the USB Hub/PC's USB connector-the computer will automatically detect and install drivers for the scanner. Once it has been recognized, the scanner will beep three times.</li> </ul>			
4.	<b>Configuration</b> <ul style="list-style-type: none"> <li>• Scan the following barcodes, in order, from top to bottom.</li> <li>At least 1 beep from the scanner after each successful scan- wait for green light to turn off or flash prior to the next scan.</li> </ul>			



**\*Set All Defaults**

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Scan Prefix  
(07h)

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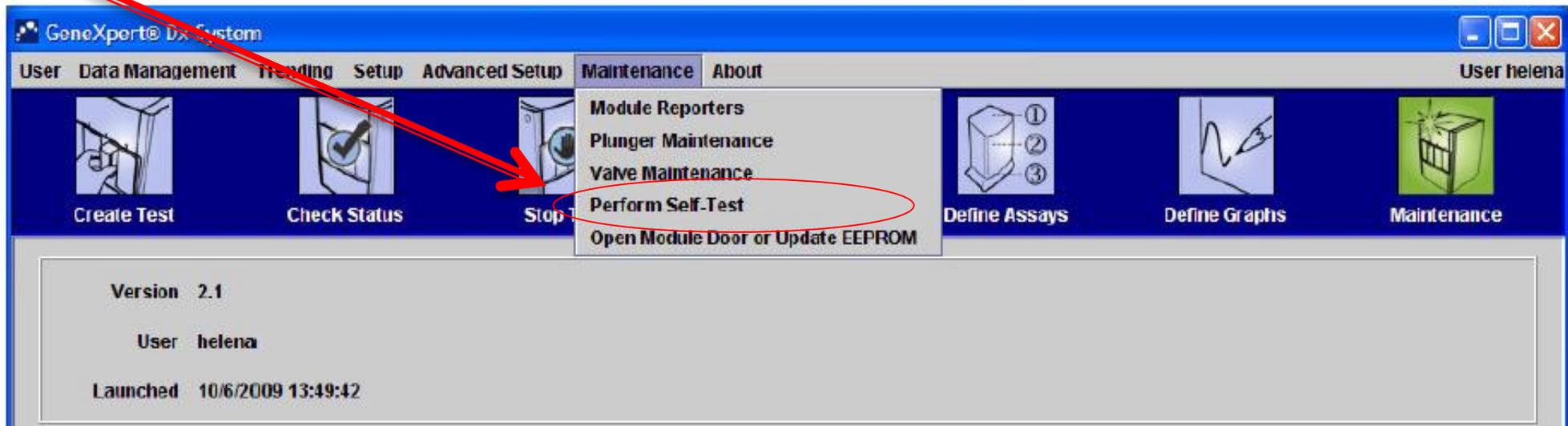


1



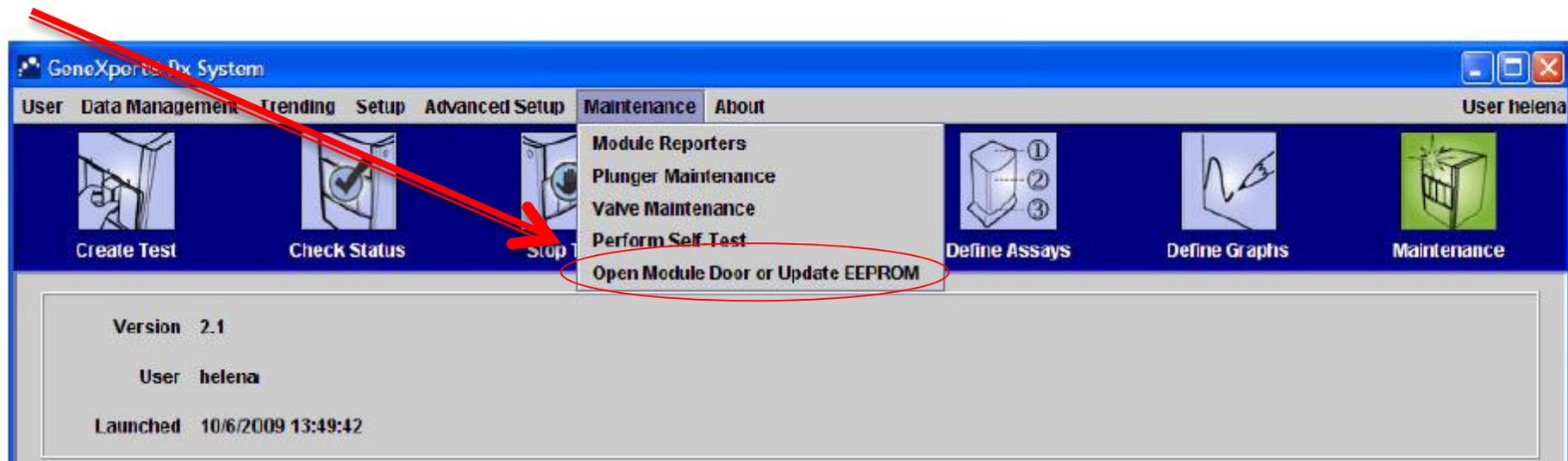
# Red Light on Module Blinking

- ▶ This indicates that the module may be failing
- ▶ In the GeneXpert Dx System window, click “Maintenance” on the menu bar and select “Perform Self-Test”
- ▶ If problem persists, contact **Cepheid Technical Support**



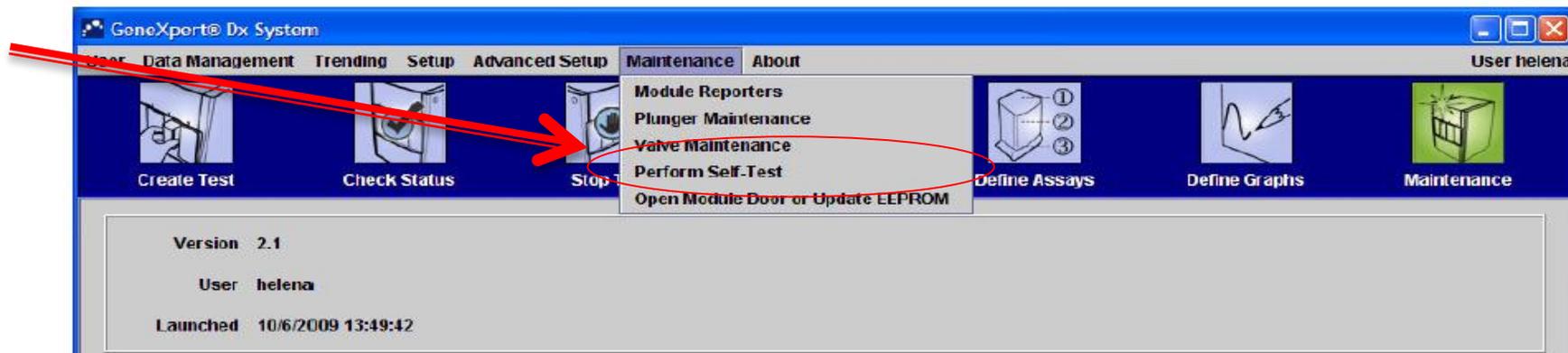
# Cartridge Stuck in GeneXpert (1)

- ▶ **Solution 1:** Verify that module door is not open
  - Gently try to open module door.
- ▶ **Solution 2:** In the GeneXpert Dx System window, click “Maintenance” on the menu bar and select “Open Module Door or Update EEPROM”



# Cartridge Stuck in GeneXpert (2)

- ▶ **Solution 3:** Close the software, and re-launch the software
  - When the software is re-launched, the module will reinitialize itself, by putting the valve and the syringe in correct position. This may help to open the door.
- ▶ **Solution 4:** Turn the system off and restart both GeneXpert instrument and software
- ▶ **Solution 5:** In the GeneXpert Dx System window, click “Maintenance” on the menu bar and select “Perform Self-Test”



# Cartridge Stuck in GeneXpert (3)

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- ▶ **Solution 6:** if none of previous solutions works, MANUALLY REMOVE cartridge.
  - **Caution:** This should only be performed by laboratory supervisor or other qualified individual.

**SEE NEXT SLIDES ON HOW TO REMOVE A STUCK CARTRIDGE**

# Manually removing a stuck cartridge:

## 1. Disconnect GeneXpert Instrument

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**Only for staff trained in GeneXpert, in consultation with "expert user", or laboratory supervisor, or other qualified individuals!**

1. Disconnect the instrument from electrical sources and the computer



### **CAUTION!!**

**There is a cartridge inside!**

Be careful not to turn the instrument upside down or the cartridge content could leak inside the instrument and damage the module (which will need to be replaced).

# Manually removing a stuck cartridge:

## 2. Open GeneXpert Instrument

**NOTE: ONLY FOR NEW INSTRUMENTS !!**



2.1: Remove all 3 screws from each foot underneath the GeneXpert machine



2.2: Remove all 4 screws from the back cover. If necessary, pliers can be used to remove back over by gripping the area indicated above. Avoid using the fan vent located below as this can damage the fan

# Manually removing a stuck cartridge: 2. Open GeneXpert Instrument (contd.)

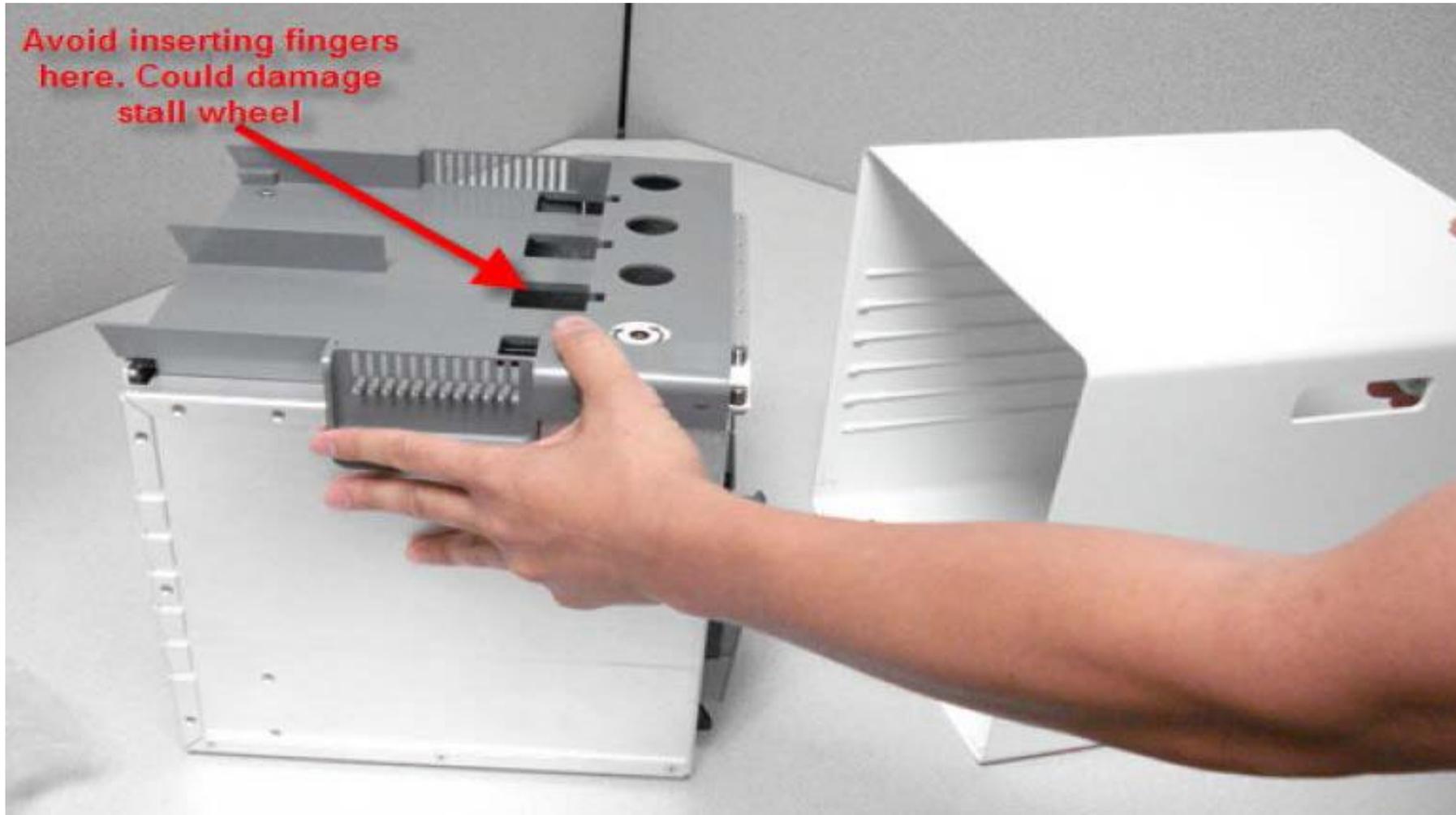


2.3: Carefully pull the device out of the outer casing while pushing on the doors of the device

**CAUTION: SHARP EDGES!** The corners indicated in the figure are sharp and can cause injury if care is not taken!



## Manually removing a stuck cartridge: 2. Open GeneXpert Instrument (contd.2)



# Manually removing a stuck cartridge:

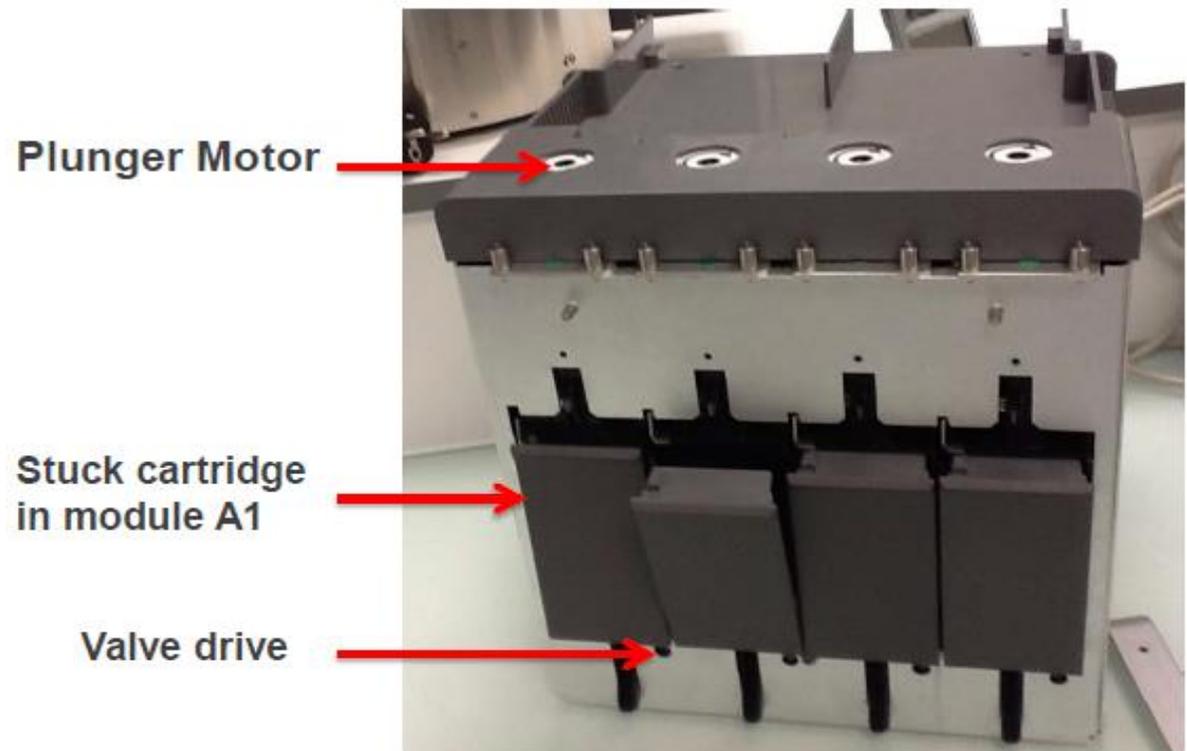
## 3. Manually Remove Stuck Cartridge

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3. At this stage, there are 2 options to remove the stuck cartridge:

Option 1: Move up the Plunger

Option 2: Turn valve in the correct position



# Manually removing a stuck cartridge:

## 3. Manually Remove Stuck Cartridge (contd.)

### Option 1: Move up the plunger

- A. Screw the plunger back to correct position by turning the screw in the “UP” direction.
- B. Try to open the door.



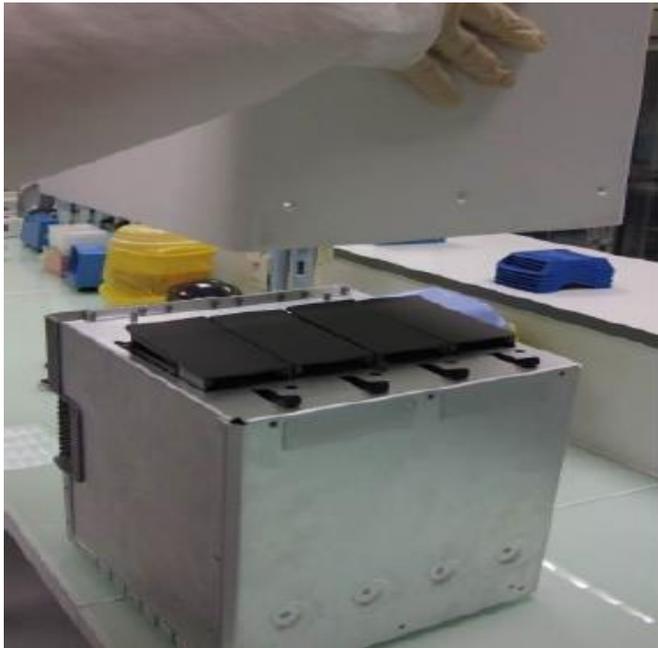
### Option 2: Turn valve in correct position

- A. Screw slowly in one direction while trying to open the door. Be aware that it may take a while.
- B. Eventually the valve will go back in correct positioning, the door will open and you will be able to remove the cartridge.

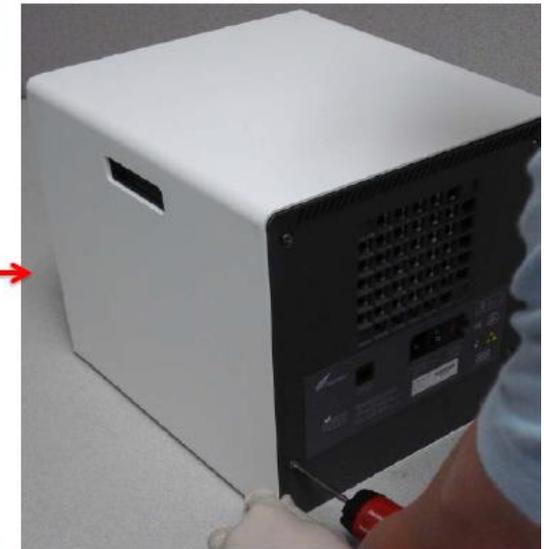


# Manually removing a stuck cartridge:

## 4. Reassemble GeneXpert Instrument



4.1. Place the instrument carefully on its back and lower the outer casing over



4.2. Place back the backside and screw back all 4 screws (not too tight!)



# Manually removing a stuck cartridge:

## 4. Reassemble GeneXpert instrument (contd.)

4.3. Screw back all 3 screws of each foot underneath the GeneXpert



After reassembly, if the doors become difficult to open or close, then the front feet have been screwed on too tightly.

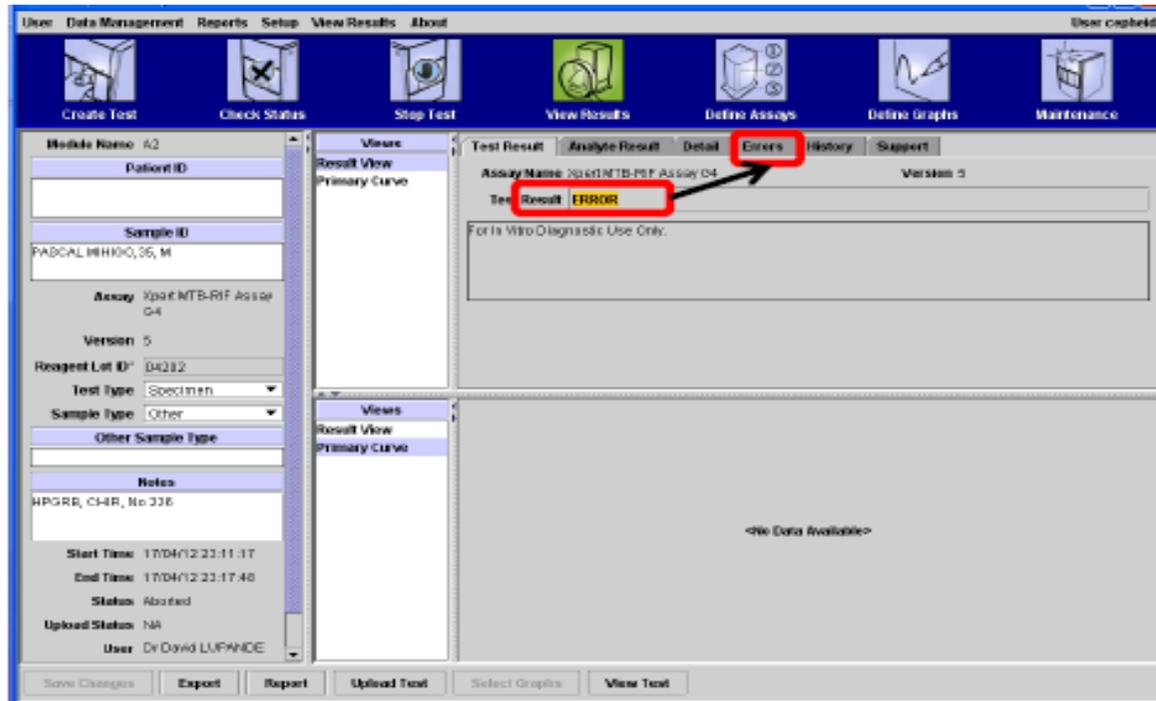
→ loosen the screws of the front feet until the door opens freely

# Error, Invalid, and No Result

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- ▶ Understanding error codes
- ▶ Common error codes
  - 5006/5007/5008**
  - 5011**
  - 2008**
  - 2127**
  - 2037**
  - 2014/3074/3075/1011**
- ▶ Invalid results
- ▶ No result

# Understanding Error Codes



## Cause(s)

Many different causes can lead to an ERROR result. Click on “Errors” to learn more about the issue.

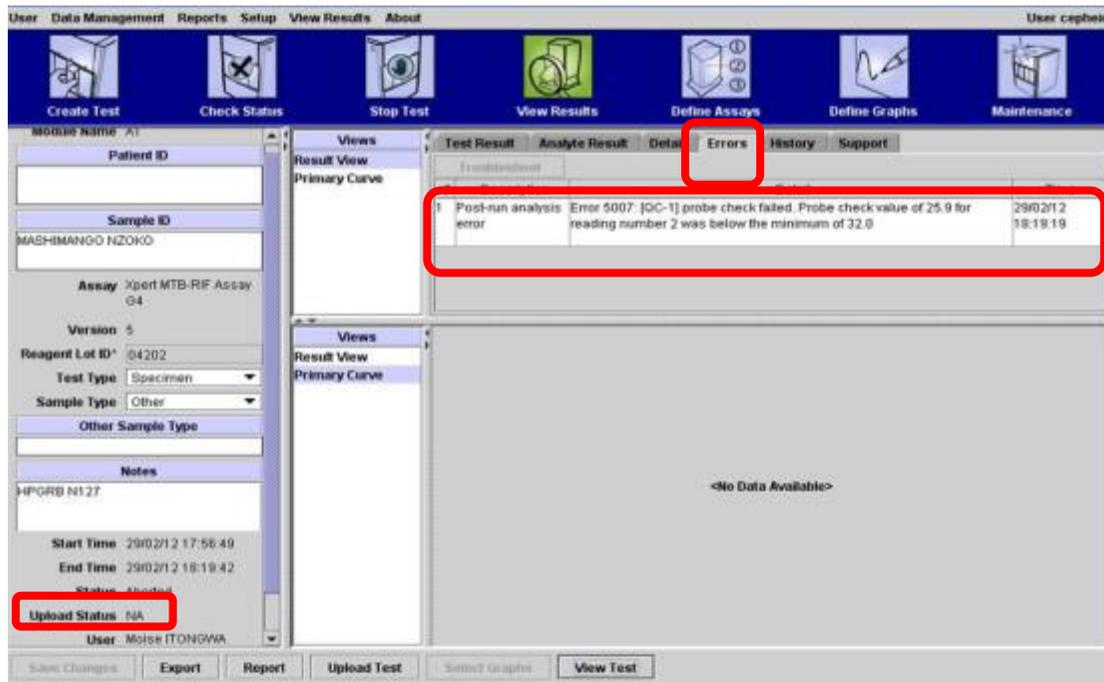
## Origin(s)

Most frequent issues are detailed in the following slides. They should be addressed by operators following the advice contained in this slide set.

## Solution(s)

To easily reduce an unexpectedly high error rate, it is essential that all operators identify errors and address them following the advice in the following slides.

# Error Code: 5006 / 5007 / 5008



## Cause

Probe Check Control failed and test was stopped before amplification.

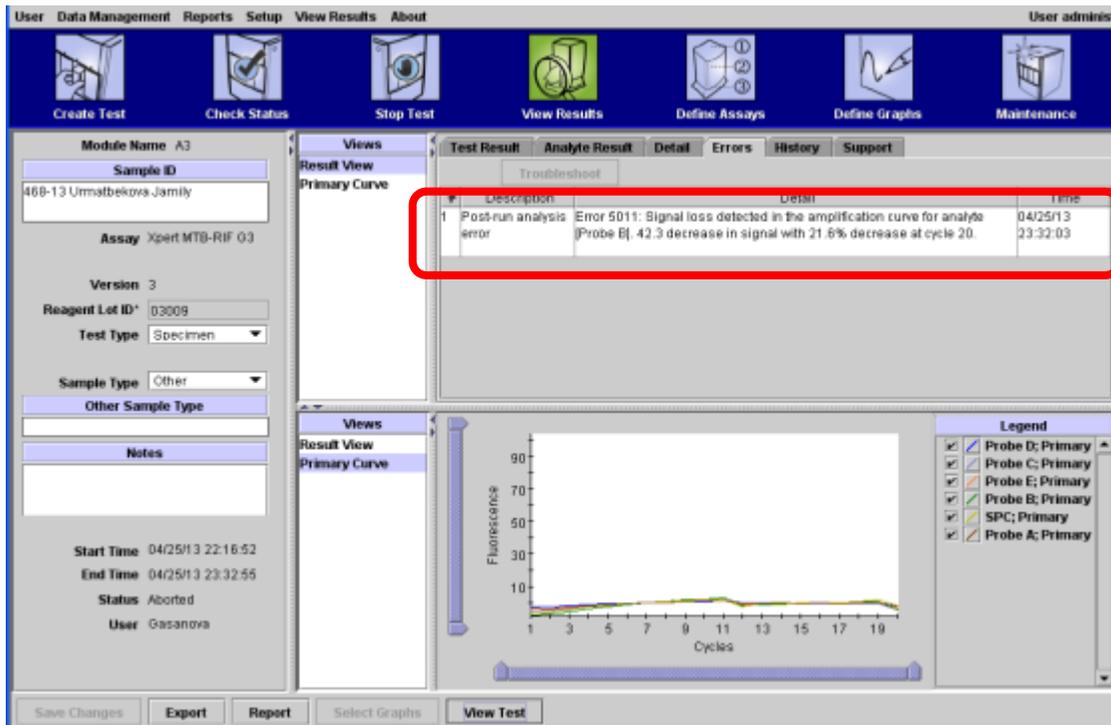
## Origin(s)

Sample too viscous and/or wrong sample volume added to cartridge; Cartridge reaction tube improperly filled, contains bubbles, or probe integrity issues detected.

## Solution(s)

After 15 (10+5) minutes of decontamination, if the sample is still too viscous do not load it into the cartridge. Wait up to 10 additional minutes until the sample is totally liquefied, then transfer it into the cartridge using a new disposable pipette. The transferred volume into the cartridge should be between 2 and 4 mL max.

# Error Code: 5011



## Cause

Signal loss detected in the amplification curve.

## Origin(s)

Loss of tube pressure because the cartridge tube is not airtight or cartridge valve is not working correctly.

## Solution(s)

Repeat the test using a new cartridge. If error persists, it can be module related; i.e., the module fluidics may not be working. Contact **Cepheid Technical Support**.

# Error Code: 2008

The screenshot displays the Xpert MTB/RIF software interface. The top menu bar includes 'Data Management', 'Reports', 'Setup', 'View Results', and 'About'. The user is identified as 'User cepheid'. The main window is divided into several sections. On the left, there are fields for 'Patient ID', 'Sample ID' (with value 'SCAL MIH100,35, M'), 'Assay' (Xpert MTB-RIF Assay G4), 'Version' (5), 'Reagent Lot ID' (04202), 'Test Type' (Specimen), and 'Sample Type' (Other). The 'Notes' section contains 'GRB, CHIR, No 228' and the 'Start Time' is '17/04/12 23:11:17'. The central area shows a 'Test Result' table with a red box highlighting an error entry:

#	Description	Detail	Time
1	Operation terminated	Error 2008: Syringe pressure reading of 120.0 PSI exceeds the protocol limit of 120.0 PSI	17/04/12 23:17:38

Below the table, the 'Views' section shows 'Result View' and 'Primary Curve' with the message '<No Data Available>'.

## Cause

Pressure exceeds the maximum pressure allowed.

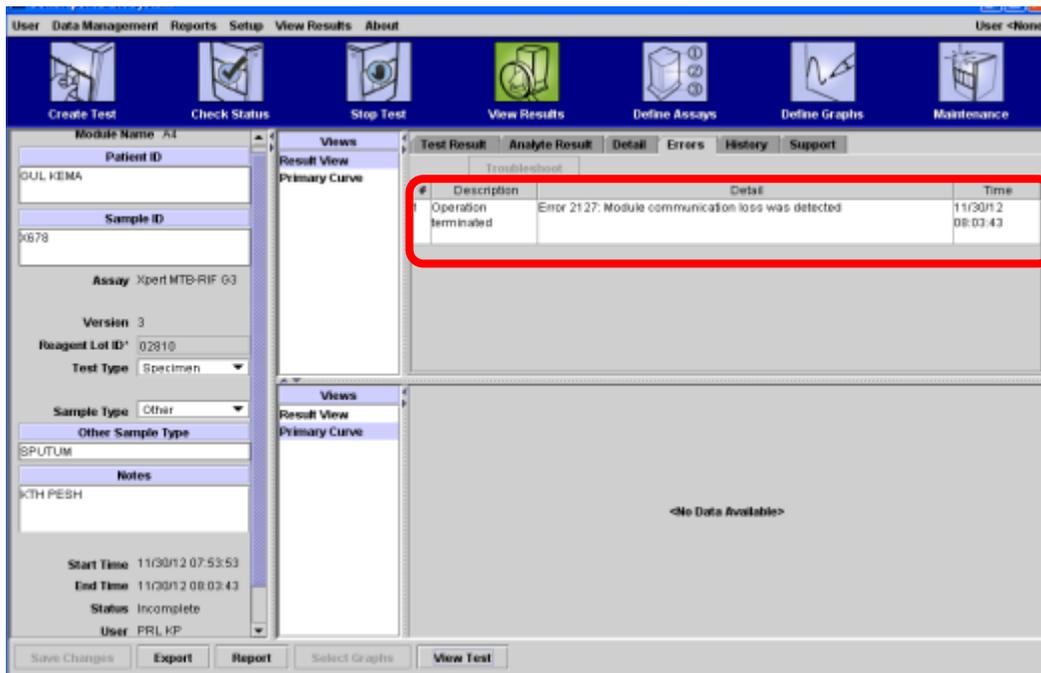
## Origin(s)

Sample is too viscous.

## Solution(s)

After 15 (10+5) minutes of decontamination, if the sample is still too viscous do not load it into the cartridge. Wait up to 10 additional minutes until the sample is totally liquefied, then transfer it into the cartridge using a new disposable pipette.

# Error Code: 2127



## Cause

Module communication loss was detected.

## Origin(s)

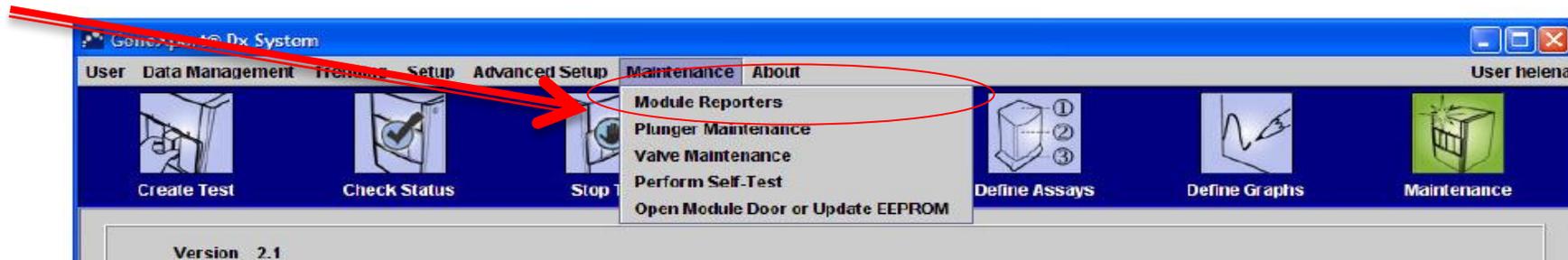
Power supply issue (main power or UPS fluctuations/failure).

## Solution(s):

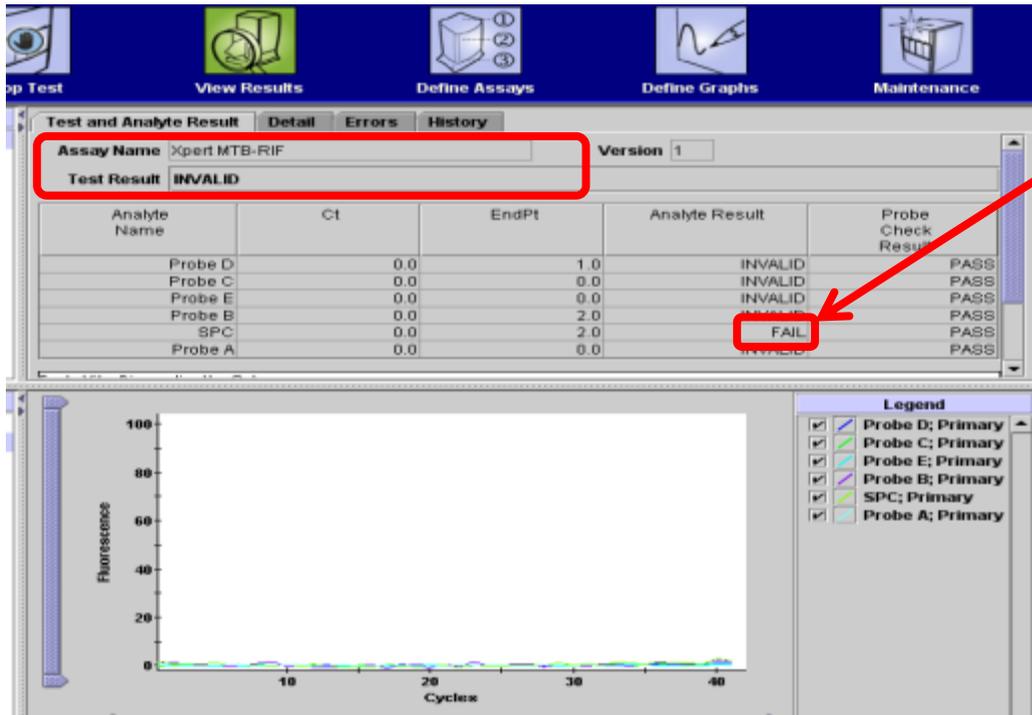
- Unplug and plug again the Ethernet cable between computer and instrument.
- Unplug and plug again the communication cable between gateway board and GeneXpert.
- Restart system and check temperature (should be below 30°C).
- Check the functioning of the UPS and install a surge protector.

# Other Error Codes

- ▶ **Error 2037:** Cartridge integrity testing
  - At the early beginning of a test, the GeneXpert checks the pressure inside the tube. If pressure is not correct, the software will stop the test because the cartridge is not airtight (quality issue). Do not use that cartridge.
- ▶ **Error 2014/ 3074/ 3075/ 1001:** temperature/heater failure
  - Causes: high temperature in module; heater component failure; broken fan; dust on filter near fan
  - Does this error affect only one module? Always the same?
    - In the GeneXpert Dx System window, click “Maintenance” on the menu bar and select “Module Reporters” to check module temperatures



# Invalid Result



## Cause

Sample Processing Control (SPC) failed.

## Origin(s)

PCR was inhibited due food particles or blood in the sample.

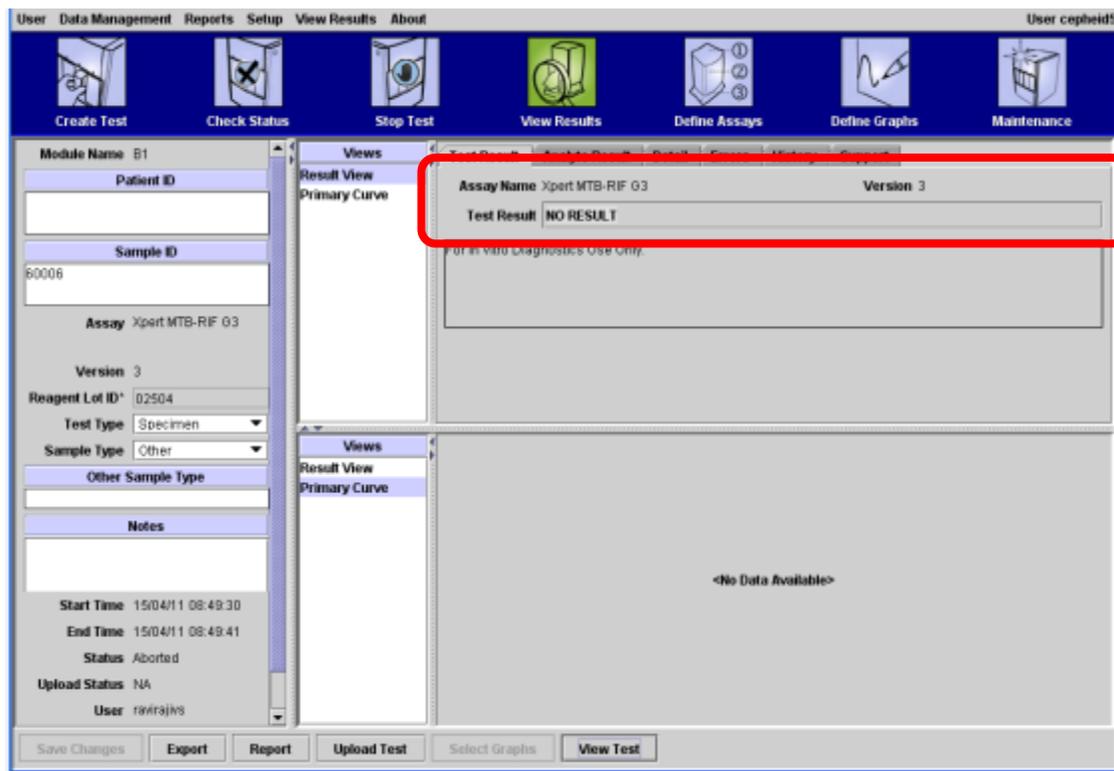
## Prevention

Before mixing with sample reagent (SR) for decontamination, check whether the sample contains food particles or blood. Allow food particles to settle to bottom of specimen before adding sample to cartridge.

## Solution(s)

Collect another specimen if necessary.

# No Result



## Cause

Test could not be completed and insufficient data were collected.

## Origin(s)

Software stops working before test is completed due to:

- Windows or software freeze
- Power failure
- STOP TEST function was activated (accidentally , or deliberately)

## Solution(s)

Secure the power supply, restart the machine and repeat test with new cartridge. Contact Cepheid if the problem persists.

# Monitoring of errors and invalid/no results

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- ▶ Rates of errors and invalid/no results should be monitored by module and by user
- ▶ Identifying the most frequent types of problems can help to troubleshoot since certain errors may be associated with a user's technique in sample processing, while others to mechanical problems with the instrument modules, or room temperature, etc.
- ▶ Recurring errors should be timely reported to Cepheid

# OTHER TESTING ISSUES: What To Do If (1)

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You have started a test and realize that you did not enter Sample ID number (eg. Lab register number)

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1. Go to “View Result” for this module at the end of run.
2. Remove cartridge from module.
3. Make sure that you copy ID number on cartridge in sample ID field on the left. Save change.

# OTHER TESTING ISSUES: What To Do If (2)

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You realize that one of the patient specimens does not contain enough volume (>1 mL is required)

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1. Volume should normally be ensured by the health care worker who collected the specimen.
2. It is important to check volume during specimen reception at lab.
3. Process if at least 1 mL and inform health care worker accordingly to ensure more than 1 mL obtained in future.
4. If less than 1 mL, request new specimen.

# OTHER TESTING ISSUES: What To Do If (3)

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You have added Sample Reagent (SR) to 8 sputum samples and started testing of 4 samples, but then realize that it will be lunch time when you could start the next run

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1. You can incubate sputum in SR for up to 5 hours before loading the cartridge at room temperature, or up to 12 hours if refrigerated at 2-8°C (Note: Once sample is added to cartridge, testing must start within 4 hours).
2. Avoid batching, if possible.
3. If you need to batch, respect the 5 hour maximum period.
4. In this case, tests can be started after lunch, since you will still be within the time limit.

# OTHER TESTING ISSUES: What To Do If (4)

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You dropped an inoculated cartridge while transporting it to GeneXpert

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1. Do not load cartridge into the instrument.
2. Follow spill procedures in biosafety guidelines.

To prevent dropping cartridges, be sure to wear dry gloves and use a trolley for transporting

*In case you have a spill: REFER TO MODULE 2 – Biosafety*

# OTHER TESTING ISSUES: What To Do If (5)

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The GeneXpert is moved and a cartridge is inside

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Big risk to damage the module. It is highly recommended to:

1. Notify Cepheid (contact Cepheid technical support)
- 2a. Before moving the system, unblock the stuck module and perform a full cleaning procedure.
- 2b. If the system was moved with a cartridge left inside, as soon as the system is relocated remove the cartridge, clean the module (regular cleaning procedure) and check if system works correctly
3. Monitor that module.

Best is to prevent: if a system is moved/relocated, check there is no cartridge in the module before moving the system.



# OTHER TESTING ISSUES: What To Do If (6)

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A run is aborted by GeneXpert

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1. Document on Xpert result form.
2. Repeat testing if at least 2 ml of SR/sputum mixture remain.
3. If insufficient volume remains, request for a new specimen.

# OTHER TESTING ISSUES: What To Do If (7)

## Sample Reagent dropped & splashed on hands, face or eyes

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Consult the Xpert MTB/RIF Material Safety Data Sheet (MSDS).

Eyes: Causes serious eye damage. Rinse cautiously with water for several minutes. Remove contact lenses if present and possible to do. Continue rinsing. Consult a physician.

Skin: Causes skin irritation. Wash with plenty of soap and water. Consult a physician.

Ingestion: May be harmful if swallowed. Rinse mouth with water. Consult a physician.

Inhalation: May cause drowsiness or dizziness. If breathing difficulty should occur, remove person to fresh air and consult a physician.



# Other Hardware, Software or Reagent Problems?

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- ▶ Look up error number in GeneXpert User Manual and perform corrective measures recommended.
- ▶ Contact your local supplier or Cepheid Technical Support.
- ▶ If possible, continue testing in other modules while solving any module-specific problem.

# When is module replacement needed?

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- ▶ If a hardware problem caused the module to break down
- ▶ If the software indicates that a module is not available
- ▶ If the software indicates another problem with the module
- ▶ Possibly if the error rate is increasing (this could indicate a hardware problem)

Contact the Cepheid Technical Support team: they will make the decision whether module replacement is needed or not

# Steps to prepare for module replacement (swap)

1. Provide to Cepheid:
  - Shipping address of site where module needs to be shipped
  - Contact person at the site
  - The address for sending the invoice

2. Prepay for module(s):

Price for modules swap is

- 900 USD for 1 module
- 1200 USD for 2 modules
- 1500 USD for 3 modules
- 1800 USD for 4 modules

Free if machine is  
under warranty

Shipment included to the nearest international airport  
Customs clearance not included

3. Receive module(s)
4. Disinfect old module(s): instrument surfaces, cartridge bay, plunger rod
5. Replace (swap) module(s) – *Contact Cepheid Technical Support for help if needed*

# Module replacement (swap)



Movie is available from FTP: <ftp://hbdc:Crasa7Uc@ftp.caplaser.net>  
(paste in Windows Explorer, not Internet Explorer)  
The FTP movies are large files so should be downloaded on to a CD before the training.



Module replacement can only be done by Cepheid local service provider or a trained expert

# Steps after replacing (swapping) modules

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6. Restart system and generate Installation Qualification Report (send to Cepheid)
7. Fill, sign and send to Cepheid the Clearance Certificate for module return
8. Cepheid sends you RMA number for tracking
9. Repack old module(s) in original box and label correctly:
  - Write RMA number on the box
  - Write address on the box: Cepheid Europe, Vira Solelh, 81470 Maurens Scopont, France
10. Send old module(s) back to Cepheid within 10 days after replacement

# Cepheid Assistance & Support

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- ▶ Cepheid HBDC Europe Training and Assistance
  - Phone: +33.5.63.82.53.60
  - Monday to Friday, 8 am – 6 pm GMT+1
- ▶ Cepheid Technical Support (Instrument Issues and Other Error Codes)
  - Europe:
    - Phone: +33.5.63.82.53.19
    - Email : [support@cepheideurope.com](mailto:support@cepheideurope.com)
    - Monday to Friday : 8 am - 6 pm GMT+1

Before asking for support, have the following items ready:

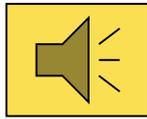
- GeneXpert serial number, Error code(s), description of incident, and (if possible) archived GXX file for last 3 months, and system log file



# Summary

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- ▶ Operational problems encountered may be related to incorrect user technique or may indicate a technical problem with modules, the barcode scanner, or cartridges
- ▶ Understanding the specific error codes and why you have received invalid results or no results may help identify the cause of the problem and find a solution for it
- ▶ Rates of errors and invalid/no results should be monitored by module and by user
- ▶ Cepheid Technical Support should be timely contacted whenever there are recurring problems



# Assessment

- ▶ List the most frequent operational problems that may occur while starting/performing a test
- ▶ Describe any of the main error codes and how they can be prevented
- ▶ Explain when you may get invalid results or no results
- ▶ Which is the maximum time you may incubate sputum in the sample reagent?
- ▶ What is the information you need prior to contacting Cepheid for technical assistance



## Acknowledgements

The Xpert MTB/RIF Training Package has been developed by a consortium of GLI partners, including FIND, KNCV, US CDC, USAID, TB CARE I and WHO, with funding from USAID.

The modules are based on materials originally developed by FIND, KNCV and Cepheid.

