Improving your experience with Xpert MTB/RIF

Cepheid HBDC, May 2012
Introduction

The Cepheid Xpert MTB/RIF test is considered by many as a revolution in the Diagnostics of Tuberculosis in providing a platform that is accurate, fast and easy to use directly from a patient’s Sputum sample.

While this technology is simple to implement, the quality of the final results ultimately depends on the quality of pre-analytic steps.

The following slides aim to provide a few simple recommendations aimed at highlighting some of the steps that, if not done correctly, frequently generate error messages that can be avoided by following the recommendation provided in this guide.

Focusing on those few specific points through this specific operators training, should drastically decrease the need for re-processing samples, and thereby the error rate.

Your Cepheid support team
“We are dedicated to providing you the best user experience using Cepheid solutions”
Sample Preparation: Key Points

The Xpert MTB/RIF assay is validated only on EXPECTORATED SPUTUM SAMPLES (or induced sputum)

• Sample collection:
  Rinse the patient’s mouth twice with clean water (avoid food or solid particles, blood presence, and pus containing sample), also avoid saliva
  Do not collect less than 1 mL of sputum per specimen

• Sample Storage:
  Do not leave the specimen at room temperature (18°C - 35°C) more than 3 days.
  Specimens are stable from 4 to 10 days at 4°C.
  Specimens should be held at 2–8 °C whenever possible, including during transport to the laboratory

• Precaution:
  Do not open the Xpert MTB/RIF cartridge lid before you are ready to add sample
  Do not use a cartridge that has a broken lid or PCR tube
  Do not hold the cartridge by the PCR tube
  Avoid forming bubbles while transferring the sample into the cartridge
  Do not use a cartridge that has been dropped or shaken after you have loaded the sample
INVALID

**Cause**
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
NO RESULT

Cause
Test could not be terminated and Insufficient data were collected

Origin(s)
Power failure
Or
STOP TEST function has been activated (accidentally or deliberately)

Note: In case of Laptop, which can run on its own batteries, Error - code 2127 - will appear (instead of NO RESULT) if the laptop is still working while power failure only affects the GeneXpert block.

Solution
Secure the power supply. This error is independent from the GeneXpert
ERRORS

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 advice contained in this document.

Solution(s)
To easily reduce an unexpectedly high Error rate, it is essential that all operators identify errors linked to sample preparation, and address them as indicated next slides.

All other issues should be reported to Cepheid technical support group.
ERROR 5006/5007

Cause
Probe Check control failed and test was stopped before amplification

Origin(s)
Sputum viscosity and/or wrong sample volume, or
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 further 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 to 2 and 4 mL max.
ERROR 2008

Cause
Pressure exceeds the maximum pressure allowed

Origin
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 further minutes until the sample is totally liquefied, then transfer it into the cartridge using a new disposable pipette.
Cepheid Assistance & Support

Following these recommendations should really help you to improve your process. Should you still face some of these situations please contact Cepheid for a review of your results and eventually for a refresher training on sampling.

• Contacts
  Cepheid HBDC Europe training & assistance: +33.5.63.82.53.60
  Monday to Friday : 8.00 am - 6.00 pm GMT+1

  Cepheid Technical hotlines: (Instrument Issues or Other error codes)
  Europe  Monday to Friday : 8.00 am - 6.00 pm GMT+1
    Tel.  +33.5.63.82.53.19
    Email: support@cepheideurope.com

  US  Monday to Friday : 6.00 am - 9.00 pm Pacific Time
    Tel.  888-838-3222, Option 2 /
    Email: 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.

* See slide 15
Probe Check

Principle
Prior to starting thermal cycling, multiple fluorescence readings are made at different temperatures, to evaluate the response of the chemicals contained in a cartridge. Results are automatically compared to pre-established factory settings in the software. A test is stopped if Probe Check is not PASSED.

Role
Probe check verifies
- Bead re-hydration
- PCR tube filling
- Probe integrity
- Dye and quencher stability

A failed PROBE CHECK can be linked to
- Sample viscosity and/or volume (low volume or sample not loaded)
- Cartridge integrity
Other Possible Error

**Error 5011: Signal loss of detection.**
Might happen if initial volume transferred to the cartridge is incorrect.
A bubble is created which goes into the PCR tube and affects the optical reading

To understand other ERROR codes, also refer to the Troubleshooting section, chapter 11 of the Operator manual (white and blue CD provided with the system)

Never hesitate to contact Cepheid for more information
MTB DETECTED VERY LOW, RIFF RESISTANCE INDETERMINATED

Cause
Because of a very low concentration of bacilli in your sample (Ct close to the end of the test) this is difficult to provide a result regarding RIFAMPICIN resistance.

Origin
This is a real result: MTB is detected with a Very Low concentration of TB bacilli in your sample: This is not an ERROR.

Solution
Collect a new sample from patient.
How to Archive a Run

Select the incriminated run(s)
Thank You