



# Xpert MTB/RIF test

## Laboratory monitoring & evaluation tool Xpert Installation Checklist

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This tool is intended to be used by staff/consultants undertaking laboratory monitoring and supervision visits on behalf of the National Tuberculosis Control Programme (NTLP) to install GeneXpert equipment for Xpert MTB/RIF test implementation according to country specific instructions. The Site Pre-assessment report should be reviewed prior to a site visit.

The Xpert Installation Checklist is used to ensure correct implementation of the Xpert MTB/RIF test. All sections must be filled with the assistance of appropriate supplementary documentation. Documents gathered must be copied to the GeneXpert focal person and the NTLP in a timely fashion.

Part 1: Contact details			
Date of installation			
Facility name/ Laboratory name		Contact details facility: Name, phone, email	
GeneXpert laboratory responsible		Contact details Laboratory: Name, phone, email	
Partner organization (if required)		Contact details Partner Organization Name, phone, email	
Part 2: Equipment details			
GeneXpert serial number		Computer details (type, windows)	
GeneXpert Software details		Printer details	
Has pre-site check been completed and filed with CTRL?	YES	NO	



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Part 3: Site Plan				
Support by partners ending on date			Comments:	
Support to include:	Cartridges (number)		Calibration	Technical support:
	Statistical support		Computer support	Printer/Ink/Paper
	Extended warranty		Other:	
Training of laboratory staff using agreed standardized training	YES	NO	Certificate provided	YES NO
Training of Clinical staff completed	YES	NO	Certificate provided	YES NO
Other training conducted	YES	NO	Details:	
Do Laboratory staff have computing skills	YES	NO	Level of proficiency (1 no skills, 5 programming skills)	1 2 3 4 5
Does laboratory have regular access to internet?	YES	NO	Who pays for internet access	
If no internet how will monthly stats be communicated to program?				
Comments:				



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### DOCUMENTATION

SOP's and protocols in place				Where are documents?	Person responsible to complete
National GeneXpert testing algorithm	YES	NO	NA		
Sample transport	YES	NO	NA		
Sputum collection	YES	NO	NA		
GeneXpert request form	YES	NO	NA		
Waste disposal	YES	NO	NA		
Rejection criteria and recording	YES	NO	NA		
Laboratory processing protocols	YES	NO	NA		
Results reporting	YES	NO	NA		
Patient tracing	YES	NO	NA		
Initiation on to therapy	YES	NO	NA		
Reporting of RIF resistance to NTP	YES	NO	NA		
Collection and transport of samples for culture	YES	NO	NA		
Room and fridge temperature monitoring monthly sheets	YES	NO	NA		
Error record monthly sheet	YES	NO	NA		
Back up of computer	YES	NO	NA		
Update of virus software	YES	NO	NA		



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SOP's and protocols in place				Where are documents?	Person responsible to complete
GeneXpert register book for laboratory	YES	NO	NA		
Monthly statistics	YES	NO	NA		
Stock ordering protocol	YES	NO	NA		
Calibration ordering protocol	YES	NO	NA		
Spill protocol and spill kit in place	YES	NO	NA		
Incidence record	YES	NO	NA		
Comments:					



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GENEXPERT SETUP				
Place the instrument on an appropriate surface	YES	NO	NA	See document "place the instrument on an appropriate surface"
Connect all the cables and UPS	YES	NO	NA	See document "connect all the cables and UPS"
Turn on the instrument	YES	NO	NA	Switch is at back of unit
Turn on the computer	YES	NO	NA	
Set up the local date and time on computer	YES	NO	NA	See document "Change time and date"
Start the software, check that the modules are "available"	YES	NO	NA	See document start program and module availability
Configure the GeneXpert software according to English US: System Configuration, Language	YES	NO	NA	See Document 5: GeneXpert_DX_regional_setting
Assign instrument letter	YES	NO	NA	Machine 1 =A, machine 2 = B etc; refer to document "Assign instrument letter"
Change GeneXpert name to <u>site name</u> A,B,C,D	YES	NO	NA	See document "Change GeneXpert name"
Import the MTB-RIF ADF (Assay Definition File)	YES	NO	NA	AS per document "How to import assay definition file" (also available on all MTB-RIF CD)
Set up yearly archive files in export folder	YES	NO	NA	See document set up yearly archive files in export folder
Create a user admin account for NTBP access	YES	NO	NA	See document "Create a User Admin Account"
Create a user admin account at least one onsite "super user"	YES	NO	NA	See document "Create a User Admin Account"



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GENEXPERT SETUP				
All other users to have a detail account and password	YES	NO	NA	See document "Create a User Admin Account"
Define system type configuration	YES	NO	NA	See document "Define system type configuration"
Set up system configuration	YES	NO	NA	See document "Set up configuration"
Run verification samples (1 per module)	YES	NO	NA	As per GLI instructions included with GeneXpert
Did all samples run as expected	YES	NO	NA	* Refer to GLI instructions
Save and print verification files (where possible)	YES	NO	NA	Print results if possible and attach to verification sheet. Archive and delete files, call file <u>GLI "site name" "date"</u> , see document "How to archive and delete GeneXpert files"
Print installation qualification (IQ)	YES	NO	NA	See document IQ report
Register GeneXpert with Cepheid	YES	NO	NA	See document IQ report
Register site with CDC EQA	YES	NO	NA	Site details, contact and email
Print error code chapter for laboratory reference	YES	NO	NA	Manual, Trouble shooting
Save PDF GeneXpert manual on desktop	YES	NO	NA	See document "Desktop Icons"
Save quick stats on desktop	YES	NO	NA	See document "Desktop Icons"
Save yearly stats files on desktop	YES	NO	NA	See document "Desktop Icons"
Where are tools kept	YES	NO	NA	
Where are GeneXpert and Microsoft CD's kept	YES	NO	NA	
Does site have rewritable CD's for back up?	YES	NO	NA	



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GENEXPERT SETUP	
If yes where are they stored	
Comments:	

To be filed with CTRL					
Verification runs	YES	NO	NA		
IQ report	YES	NO	NA		
Contact details	YES	NO	NA		
Agreement of partner support document	YES	NO	NA		
Comments:					
Is the machine fully operational and set to country specific standards	YES	NO	NA		
Comments:					



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Conclusions:

Recommendations:

Sign Partner representative		Sign installer	
Sign CTRL responsible			