



Xpert MTB/RIF test

Laboratory monitoring & evaluation tool
Xpert Pre-handover Checklist

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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 organisation		Contact details partner Organisation Name, phone, email	
Part 2: Equipment details			
GeneXpert serial number(s)		Number of modules	
Laptop/Desktop		Brand of computer	
Windows version		Antivirus version	
GeneXpert Software version		Printer details	
UPS details		Battery/stabiliser details	
Comments:			



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Part 3: Site plan			
Support by partners ending on date		Comments:	
Hospital or NTLP to take over (please mark as appropriate)	Cartridge supply (Average no. per month)	Calibration	Technical support:
	Statistical support	Computer support	Printer/Ink/Paper
	Other:		
At handover date estimate remaining cartridges and expiry		Any other outstanding issues?	
Have all GeneXpert passed calibration in the last month?	YES	NO	
Attach report; If no explain, and detail what follow up action is being undertaken			
Has error rate over last 3 months been below 5%	YES	NO	Attach report; If no explain
Has total unsuccessful test rate been below 10%?	YES	NO	Attach report; If no explain
Has Cepheid examined last 3 month system log and .gxx files?	YES	NO	Attach report; If no explain
To the best of your knowledge and using all available tools is the GeneXpert machine in full working order as of hand over date?	YES	NO	
Is this machine still under original warranty	YES	NO	Date of warranty end
Has any extended warranty been purchased	YES	NO	Date of warranty end



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Was this site previously following NTLP testing algorithm?	YES	NO	If no which algorithm was used
Was this site previously supplying monthly indicators to the NTLP?	YES	NO	If no, what was agreement and can staff produce monthly statistics?
Are there any additional training needs to ensure a smooth handover?	YES	NO	Detail:
Have all staff performing testing completed and passed a certified training program for Xpert MTB/RIF testing	YES	NO	If no detail:
Have clinical staff completed sensitisation about MTB/RIF testing	YES	NO	If no detail:
Are standard NTLP procedures, SOPs, registers and other documents in place	YES	NO	If no detail:
Additional comments:			



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Part 4: Other documents to be supplied at handover				
Certification document	YES	NO	NA	Supplied with machine
Verification documents	YES	NO	NA	*to be decided how many and what is required
System log and last 3 months .gxx files	YES	NO	NA	As per document, how to generate a system log report and How to archive and delete runs
New IQ reports	YES	NO	NA	As per document how to generate an IQ report
Copy of last 6 months maintenance records	YES	NO	NA	Copied from laboratory records, if any missing please explain below
Copy of staff training certificates for Xpert MTB/RIF	YES	NO	NA	Copied from laboratory records, if any missing please explain below
Evidence of clinical sensitisation	YES	NO	NA	Certificates, training schedule, meeting minutes
Provide a letter explaining handover to be sent to Cepheid as evidence of change of owner	YES	NO	NA	As per document
Comments:				



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Part 5: Completion of GeneXpert Handover	
Partner signs to declare handover of GeneXpert instrument in full working condition and has no further role apart from that documented above	
NTP CTRL signs to confirm receipt of GeneXpert machine in full working condition and takes responsibility for full site support, including reagent supply, calibration and technical support	
Comments	
Disputes:	
Further actions:	
Final handover date:	