Xpert MTB/RIF test

**Laboratory monitoring & evaluation tool
Xpert Pre-installation Checklist**

Laboratory monitoring & evaluation tool Xpert Installation Checklist

Part 1: Laboratory profile		
Date of Assessment/Audit		
Name(s) and Affiliation(s) of Assessor(s)		
Laboratory contact name (s)	Phone/email	
Laboratory Name	Region	
District	Town	
Postal Address		
Laboratory Telephone	Fax	Email
Head of Laboratory	Telephone (Head of Lab)	Personal?
		Work?
Regional or District coordinator	Contact details	
Funding partners involved with Lab	Main aims	
Main access to site (road, air…)	Nearest MSD supply warehouse	
Is the laboratory taking part in SLAMTA or other accreditation?	No of stars/level	

Laboratory Level (check those that apply)				Laboratory Affiliation (check those that apply)			
	National		Regional / Provincial		Public		Academic
	Zonal		District		Private		NGO/Religious Institution

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Laboratory Staffing Summary				
Profession	*Number of Full Time Equivalents*	*Adequate for facility operations?*		
Laboratory scientist		Yes	No	Insufficient Data
Laboratory Technicians		Yes	No	Insufficient Data
Laboratory Technologist		Yes	No	Insufficient Data
Cleaner/ laboratory attendant Data Clerk		Yes No Insufficient Data *Has the cleaner(s) been trained in safe waste handling?* Yes No		
Driver for sample transportation		Yes No Insufficient Data *Is the driver(s) dedicated for only laboratory?* Yes No *Has the driver(s) been trained in biosafety?* Yes No		
Does the laboratory have dedicated staff in the following areas		Yes	No	Insufficient Data
Quality manager		Yes	No	Insufficient Data
Safety officer		Yes	No	Insufficient Data
Stock manager / store person		Yes	No	Insufficient Data
Other:		Yes	No	Insufficient Data
		Yes	No	Insufficient Data
Briefly describe the laboratory network in the region/district, how many TB diagnostic centers and treatment centers? Are there other labs with GeneXpert in the region?				

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Part 2: Laboratory Physical Infrastructure	
Checklist Question	YES/NO
1. Does the laboratory have a lockable door and secure windows?	
Comment	
2. Does the Laboratory have enough space including bench space to install GeneXpert and its related ancillary equipment	
Comment	
3. Does the laboratory have stable power supply? – count the plug sockets available	
Comment	
4. Does the laboratory have backup generators or solar power? Are they started manually? Is there sufficient fuel? How long does it take to start the alternate power supply	
Comment	
5. Does the laboratory have enough appropriate chairs and benches for testing and at reception (liquid impermeable and chemical resistant?	
Comment	
6. Does the laboratory have sufficient storage space for all consumables in temperature controlled environment (2-30°C)?	
Comment	
7. Does the laboratory have adequate waste disposal for infections materials? Describe below	
Comment	

Part 3: Laboratory Environment	
Checklist Question	YES/NO
8. Does the laboratory have a means of controlling temperature between 2-30°C e.g. air circulation, thermometers, refrigerators? What is the normal temperature?	
Comment	
9. Review laboratory workflow and determined appropriate location for GeneXpert, computers, printers and scanners	
Comment	
10. Does the Laboratory have enough wash basins with soap dispensers?	
Comment	
11. Does the laboratory have other large, electronic and or computer based equipment?	
Comment	
12. Does the laboratory have enough regular supply of PPE (gloves, masks, goggles)?	
Comment	
13. Does the laboratory have refrigerator for storing sputum samples?	
Comment	

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Part 4: Laboratory Human Resources	
14. Does the Laboratory need additional personnel to implement GeneXpert? Specify type and number?	
Comment	
15. Do laboratory staff have adequate computer skills for GeneXpert and reporting needs?	
Comment	
16. Is someone responsible for computer maintenance, virus scanner updates etc.?	
Comment	
17. Do the laboratory staff need additional training? Specify type of training.	
Comment	

Part 5: Supply chain	
18. Describe the current supply chain	
Comment	
19. Is the supply chain adequate?	
Comment	
20. How long is the average lead time from ordering to receiving stock?	
Comment	

Part 6: Clinic/hospital readiness	
21. Has the National TB algorithm for Xpert MTB/RIF testing been introduced to clinicians?	
Comment	
22. Is there an established sample transportation system from other sites to the laboratory (Describe the current system, its adequacy, efficiency and coverage)?	
Comment	
23. Is a sample referral system in place for additional testing for TB samples at referral laboratories (transportation of samples and results, schedules, triple packaging materials)?	
Comment	
24. Is there any additional training needs for clinical staff?	
Comment	
25. Are TB patients initiated at this site and how long does it take to initiate TB treatment?	
Comment	
26. Have any MDR cases previously been identified at this site and how are they handled?	
Comment	

Part 7: Current TB Diagnostics methods	
27. Does the laboratory current have another TB diagnostic method in use? If yes please specify methods.	
Comment	
28. If the answer is YES above, indicate average monthly tests done including positivity rates	
Comment	
29. If the answer is YES to 19, are there staff dedicated to that method only? Are these the same staff who will use the GeneXpert?	
Comment	
30. How are results currently returned to clinician?	
Comment	
31. Which laboratory statistics are reported to the TB program and how?	
Comment	

Part 8: Management Involvement **(This maybe clinic, hospital, NTB, Ministry of Health etc.)**	
32. Is management aware of the implementation of GeneXpert at this laboratory?	
Comment	
33. During the assessment, did the assessors meet with management to discuss the implementation of the GeneXpert and the expectations from laboratory and management (this could take place before or after the assessments)?	
Comment	

Overall rating (Tick appropriate box and give reasons in the general comments section)							
Not ready		Ready- no work		Ready- but minor changes		Ready but- major changes	
General Comments							