

FACILITY SUPERVISION CHECKLIST - GeneXpert MTB/RIF

Date:

Laboratory/Hospital:

Location: City/Town/ District:

Laboratory Manager and contact:

Name of partner organization provided GeneXpert support:

Name of supervisor/assessor:

The tool is intended to be used by staff/consultants (implementer's) undertaking laboratory monitoring and supervision visits on behalf of the Bangladesh NTP to assess Xpert MTB/RIF test implementation. On-site supervisory visits form a critical part of the quality assurance programme associated with Xpert MTB/RIF implementation, and will be conducted at pre-determined time intervals as agreed by the NTP. Comprehensive site visit assessment will be conducted as an initial assessment of site competency after installation, and annually thereafter.

Documents available in laboratory	Check	Comments
Xpert/ Laboratory register		
Xpert/ Laboratory SOPs		
Xpert/ Service & Maintenance SOP		
Xpert/ Operator proficiency testing and competency assessment		
National diagnostic algorithms present and posted		
Xpert Troubleshooting problem documented		
Laboratory bench job aids (posted)		

General information on GeneXpert operation in the laboratory	
Date of start of GeneXpert operation	
Total number of Xpert performed per month/quarter/year	

	YES	NO	ACTION UNDERTAKEN / COMMENTS
GeneXpert placement			
Is there adequate space for the GeneXpert machine, and computer			
Is machine placed in a clean and dust-free area? (or covered when note in use)			
Is A/C available in room and functional? (or RT monitored)			
Is machine placed opposite/away from the A/C unit?			
Is the machine placed away from direct sunlight or heating source?			
Does the machine space at the back side to exhaust for proper cooling (>5cm)?			

Electricity			
Does the machine have regular-uninterrupted power?			
All tests were run without abortion due to power cut-offs?			
Is UPS available and operational?			
Safety			
Is sputum preparation performed in a well-ventilated area			
Is personal protection (gloves, lab coats, and N95 mask) used during sputum preparation?			
Are sputum cups or Falcon tube used with a screw cap to avoid spilling of the sample during shaking process?			
Sputum collection			
Is sputum collection done at a designated sputum collection area or booth away from other patients or staff?			
Is there a sample transportation mechanism in place to send samples to the Xpert lab?			
Are sputum samples used of good quality? What % is saliva?			
What is done if the sputum quality is not good? (describe)			
Storage			
Are the cartridges kits stored at the appropriate temperature, 2-28°C/ 2-8 °C			
Is the temperature recorded in the cartridge storage area daily?			
Did any cartridges kits expire this year?			
Are expired cartridges Kits discarded?			
Are stock cards or inventory records available and up-to-date?			
Was any cartridge stock-out recorded? If so, when/how long?			
Waste management			
How are used Xpert cartridges disposed? (explain)			
Is infectious waste discarded following the national guidelines?			
Staffing/human resources			
Are adequate numbers of staff trained on Xpert testing? (#)			
When was the last training performed and by who? (describe)			
Did routine Xpert operation start immediately after training? (note delay if any)			
Average number of Xpert tests performed per month			
Documentation (Xpert)			
Is the test included in the national lab register?			
Is the lab register filled correctly and completely? (Lab number, patient info, referral clinic, date of tests, Xpert result, smears)			
Are Xpert testing request available?			
Are the request forms correctly filled?			
Are Xpert results reported back to clinic within 1/4 days? (record average TAT)			
Is there an electronic data system available/regular data entry?			

Machine operation			
Number of unsuccessful tests to this date?			
Is the rate of invalid/error/no test results below 5%? (Xpert)			
Are error numbers recorded in lab register? (Xpert)			
Which types of errors occur most frequent? (Xpert)			

Xpert tests done in last 3 months:

Period:	All tests
Total suspects tested with Xpert	
Successful test results:	
Xpert MTB positive RIF detected	
Xpert MTB positive RIF not detected	
Xpert MTB pos. RIF indeterminate	
Xpert MTB negative	
Unsuccessful test results:	
error	
invalid	
no result	