Xpert MTB/RIF test

Clinical site monitoring & evaluation tool
Comprehensive site visit assessment

This tool is intended to be used by staff/consultants undertaking clinical site monitoring and supervision visits of behalf of the National Tuberculosis Control Programme to assess GeneXpert Xpert MTB/RIF test implementation. On-site supervisory visits will form part of the quality assurance programme associated with GeneXpert Xpert MTB/RIF test implementation, and will be conducted quarterly or at pre-determined time intervals as agreed by the National Tuberculosis Control Programme. Ad hoc supervisory visits may also be required.

Review the instructions for assessors (page 2) before completing this assessment.

Name of Assessor(s)	
Title & organization of Assessor	
Name of clinical site being assessed	
Location of clinical site being assessed (City/Town, District and Country)	
Contact person at clinical site	
Name and location of laboratory performing Xpert MTB/RIF, if not on-site	
Date of assessment visit	

Instructions for assessors

- The Clinical site monitoring & evaluation tool (Comprehensive site visit assessment) is to be used for assessing all clinical sites offering TB services.
- This assessment is divided into four sections:
    - Section A: Clinical site information
    - Section B: Clinical site information (Xpert MTB/RIF test sites only)
    - Section C: Clinical site assessment checklist
    - Section D: Non-conformances & corrective actions
- Note: All questions in this Clinical site monitoring & evaluation tool (Comprehensive site visit assessment) are compulsory.
- The assessor will compile a report, which is shared with the National Tuberculosis Control Programme after the visit.
- The report will list the non-conformances (Section D) and make recommendations regards corrective actions.
- Assessors are requested to review on-site records to verify the answers provided the staff at the clinical facility. If possible, assessors should arrange to observe the collection of sputum samples.

Section A

In this section, the assessor is required to collect general information regards the clinical site being assessed. This section is best completed with help from the clinical site manager (or a senior member of staff). Answers must be completed in the space provided. Any additional (pertinent) information should also be collected and included in the site assessment report.

Section B

In this section, the assessor is required to collect additional information regards procedures associated with the GeneXpert Xpert MTB/RIF test implementation. This section is best completed with help from the clinical site manager (or a senior member of staff). Answers must be completed in the space provided. Any additional (pertinent) information should also be collected and included in the site assessment report.

Section C

In this section, the assessor is required to assess GeneXpert Xpert MTB/RIF test implementation at the site in three categories. The assessor must select ‘Yes’, ‘Partial’ or ‘No’ based on the assessor’s interpretation of the sites verbal response to the question. Mandatory comments must be included in the final column for any questions to which the answer “Partial” or “No” is given.

Section D

In this section, the assessor must collate all questions for which the answer was ‘Partial’ or ‘No’ (i.e. non-conformances), and make recommendations for corrective actions. The assessor must also indicate whether follow-up of the non-conformance is required at the next laboratory assessment.

Section A: Clinical site information

What health services are offered at this health care facility? (a) HIV Screening (b) Antenatal Services (c) Chronic Disease Management (d) TB Screening (e) Other	
Is this facility a (select one): (a) Satellite health care facility (b) Primary health care facility (c) Referral health care facility	
Does the site use a TB Suspect Register? If yes, how many different TB Suspect Registers are used, and where are located?	
How many sputum samples are collected per suspects and for which diagnostic tests?	
Are sputum samples collected by: (a) Clinical staff (b) Laboratory staff (c) Clinical & Laboratory staff	
Is a separate waiting area utilized for TB suspects?	
Which referral laboratory is utilized by the clinical facility? What is the distance to the referral laboratory?	
Are samples for culture and drug susceptibility testing sent directly to the Reference Laboratory, or first to the local laboratory, and then the Reference Laboratory?	
Is there facility for MDR-TB care and treatment on-site? If not, where is the nearest center located?	
Are all MDR-TB cases treated at the MDR-TB Unit? Do any MDR-TB cases receive MDR-TB treatment in the community?	

Section B: Clinical site information (Xpert MTB/RIF test sites only)

Does this site perform Xpert MTB/RIF on-site?	
If 'No', how frequently are sputum samples for Xpert MTB/RIF testing transported to the laboratory or to another site for testing (e.g. daily, every other day etc.)?	
Are there satellite sites referring samples for Xpert testing to this facility?	
If so, how many satellite sites refer to this facility for Xpert testing?	
Is there a sample transportation mechanism in place to send samples from this site to the Xpert testing laboratory?	
If you receive a positive Xpert MTB/RIF test result, is your site able to initiate treatment?	

Section C: Clinical site assessment checklist

1. Documentation

A. TB Suspect & Laboratory Register

		Yes	Partial	No	Comment
1	Does the clinical site have a TB Suspect Register at the clinical site?				
2	Is the TB Suspect Register completed correctly?				
3	Are all Xpert MTB/RIF results correctly recorded in the Laboratory Register?				
4	Are all Xpert MTB/RIF results correctly transferred to the TB Suspect Register?				
5	Are all Xpert MTB/RIF positive results entered in the District TB Register?				
6	If Xpert MTB/RIF positive, is the TB District number entered in the Laboratory Register?				
7	Are DST results properly recorded in the TB suspect register?				
8	Is there a TB Treatment register either at the site or at the district office in which confirmed TB cases are recorded?				

B. Diagnostic Algorithm

		Yes	Partial	No	Comment
1	Is the approved NTP laboratory request form (smear and Xpert) available and in use at the facility?				
2	Does the clinical site have a copy of the current national algorithm?				
3	Did clinical site staff receive training in the algorithm?				
4	Do the clinical staff understand the algorithm?				
5	Do clinical staff follow the diagnostic algorithm for requesting Xpert MTB/RIF testing?				

		Yes	Partial	No	Comment
6	Does the clinical site request additional testing is required by the national algorithm?				

C. Xpert MTB/RIF test requests & results

		Yes	Partial	No	Comment
1	Are specimen containers and request forms of specimens submitted for Xpert testing adequately labeled / completed?				
2	Are sputum samples for Xpert MTB/RIF testing tracked properly using a logbook or tracking form?				
3	Are any quality indicators for Xpert MTB/RIF recorded by the site E.g. a) Number of samples tested				
	b) Number of positive Xpert MTB/RIF results				
	c) Number of rifampicin resistant samples				

D. Follow-up & referral

		Yes	Partial	No	Comment
1	Does the clinical site have a system for following-up newly diagnosed TB patients not yet on treatment?				
2	Are sputum samples referred for culture and drug susceptibility testing tracked properly using a logbook or tracking form?				
3	Is there a sample transportation mechanism in place to send samples to culture and DST laboratory?				
4	Does the clinical site have a record of patients referred to the MDR-TB Unit (i.e. transferred out)?				

2. Sample collection & transport

		Yes	Partial	No	Comment
1	Are the staff aware of the sample requirements for Xpert MTB/RIF testing?				
2	Have the staff been trained in sample collection procedures?				
3	Are the TB suspects given proper instructions on how to produce good quality sputum?				
4	Do the staff check sputum samples for quality and quantity before submitting to the laboratory or another site?				
5	Does the clinical site request the patient to produce another sputum if the sputum quality or quantity is not good?				
6	Are sputum samples collected outside or in an appropriately ventilated area away from other people?				
7	Are sputum specimens stored prior to be transported to the laboratory or another site? If so, under what conditions?				
8	Are specimens packaged appropriately according to local and or international regulations before being transported to the laboratory or another site?				
9	Are specimens transported to the laboratory or another site within acceptable timeframes (7 days)?				

3. Safety

		Yes	Partial	No	Comment
1	Are the clinical staff trained in biosafety, and are good infection control measures in place in the clinic and patient waiting areas?				
2	Is adequate personal protective equipment (PPE) available to clinical staff and patients?				
3	Are the TB suspects provided with respiratory masks on arrival at the clinical site? And/or does triage of coughing patients occur with segregation of waiting areas for coughers?				
4	Are the drivers/couriers and cleaners working in the clinical site trained in biosafety practices relevant to their job tasks?				

Section D: Non-conformity & corrective actions

Non-conformity	Recommended corrective action	Follow-up required

Signature of assessor: _____

Date: _____

Signature of recipient of report: _____

Designation (e.g. Site Manager, Clinician): _____

Date: _____