**Clinical-laboratory interface and the diagnostic cascade checklist**

The purpose of the checklist is to provide additional information on the clinical laboratory interface beyond what is already included in the assessment tool verification questions. The checklist is designed from the perspective of a laboratory-based interview. Similar questions should also be directed to collaborating clinicians to get a complete picture of the clinical-laboratory interface. Questions are to be answered with a ‘Yes’, ‘Partial’ or ‘No’, numbers, or text. Space is provided in a ‘Comments’ column to elaborate on the responses for each question. Where appropriate, enter N/A (not applicable).

For this checklist, the diagnostic cascade is divided into 5 stages: pre-pre-analytical (e.g., deciding which test to order), pre-analytical (e.g., sample collection and transportation), analytical (e.g., testing), post-analytical (e.g., results review and reporting), post-post analytical (e.g., results interpretation and use for patient care and public health). Each stage except the analytic stage is assessed in this checklist.

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| Laboratory facility | Clinical facility |
| |  |  | | --- | --- | | Name of laboratory |  | | Location of site (City/town, District, State) |  | | Laboratory Level | \_\_ National Intermediate (supervisory) \_\_ Peripheral | | TB tests performed at this site  (check all that apply) | \_\_\_ Collect Specimens \_\_\_ AFB Smear-microscopy  \_\_\_ Xpert MTB/RIF \_\_\_ LPA  \_\_\_ Culture \_\_\_ DST |   Persons interviewed   |  |  | | --- | --- | | Name | Position | |  |  | |  |  | |  |  | | |  |  | | --- | --- | | Name of facility |  | | Location of site (City/town, District, State) |  |  |  |  |  | | --- | --- | --- | | Type of facility (circle one) | Type of service and TB model of care (circle one which apply) | | | 1. HIV, TB hospital. 2. Central hospital 3. Regional hospital 4. District hospital 5. Primary health facility 6. Others……………. | 1. Centralized TB unit 2. Decentralized TB unit 3. Satellite TB unit 4. DOT centre 5. In-patient | 6. Outpatient  7. Ambulatory  8. One-stop-shop strategy  9. Others………. |   Persons interviewed   |  |  | | --- | --- | | Name | Position | |  |  | |  |  | |

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| --- | --- | --- | --- | --- |
| Audience  CO: Clinical Officer  LO: Lab Officer | Question | Answer | Comments | |
| Pre-pre-analytical stage | | | |
| CO | Are the national guidelines for evaluating patients and using X-ray findings followed by all clinicians? | Y / P/ N | Clinicians/DTO 1.4.3, 4.1.3 | |
| CO | Are health care workers involved in the TB diagnostic cascade provided with standardized sensitization content (e.g., brochures, training materials, customer handbook)? | Y / P/ N | Lab/Clinicians/DTO | |
| CO | Is there national guides and actions to be taken for TB patients with HIV positive test | Y / P/ N |  | |
| CO | Have clinicians and other health care providers been provided training on the TB diagnostic algorithm, available TB diagnostic tests and the importance of referring specimens for testing? | Y / P/ N | Lab/Clinicians/DTO 4.1.4 | |
| CO | Are there trainings for clinicians or medical officers on changes made to laboratory policies (i.e., changes on algorithms)? | Y / P/ N | Lab/Clinicians/DTO 4.1.4 | |
| CO/LO | Are tests ordered according to the TB diagnostic algorithm, national policy and patient factors? | Y / P/ N | Lab/Clinicians/DTO 4.1.5 | |
| CO | Is there a sample transportation SOP known by all clinicians or staffs who collect specimens in this facility? | Y / P/ N |  | |
| CO | Who is responsible for patients to be timely linked TB laboratory test site | Y / P/ N |  | |
| CO | Describe the procedures used to ensure efficient linkage of persons with presumptive TB to TB laboratory testing |  | | |
|  | Pre-analytical stage | | | |
| LO/CO | Are the following standardized documents and forms available and readily accessible to all clinical and laboratory staff?   * Laboratory or customer handbook | Y / N | Lab/Clinicians/DTO 4.1.4 | |
|  | * Test requisition SOP and form | Y / N |  | |
|  | * Sample collection, packaging and transport SOP | Y / N |  | |
|  | * Sample rejection SOP | Y / N |  | |
|  | Are NTP-approved presumptive TB registers available and used and are entries up-to-date and complete? |  | Clinicians | |
| LO/CO | Is training provided to all health care providers on how to request tests and complete the test requisition form? | Y / P/ N | Lab/Clinicians/DTO | |
| CO | Clinical officers have been trained on gastric lavage and/or sputum induction for pediatric sample collection? | Y / P/ N | comments | |
| CO | Does the facility have material and equipment for gastric lavage and sputum induction? | Y/P/ N | comments | |
| LO/CO | Are the staff aware of the sample requirements for testing for each of the laboratory methods (smear, culture, LPA, Xpert MTB/RIF testing, etc.)? | Y / P/ N | Clinicians/DTO |  |
| LO/CO | Does the testing site or collection site ensure patients are instructed in good sputum collection technique? | Y / P/ N | Lab/Clinicians/ | |
| LO/CO | Are specimen containers correctly labelled and accompanying request forms completely and accurately filled? | Y / P/ N | Lab/Clinicians/ | |
| LO/CO | Are all laboratorians, health care workers, clinicians, and transport personnel trained in the procedures for safely collecting, labelling, packaging, handling and transporting TB specimens? | Y / P/ N | Lab/Clinicians/DTO 3.2.1 | |
| LO/CO | Are systems in place for referring samples from collection sites to the testing laboratory? If yes: | Y / P/ N | Lab/Clinicians/DTO 3.2.4 | |
|  | * Are appropriate containers and materials for packing and transport available and used? | Y / P/ N |  | |
|  | * Are specimens properly stored prior to transport? | Y / P/ N |  | |
|  | * Do transport conditions comply with international recommendations? * Are specimen transport logs or registers available and used and are entries up-to-date and complete? | Y / P/ N | Lab/clinicians | |
|  | * How often and by what means are specimens transported? |  | | |
| LO | Are SOPs for sample receipt and accessioning available and used in the laboratory? | Y / P/ N | Lab | |
| LO | Are NTP-approved laboratory registers available and used and are entries up-to-date and complete? | Y / P/ N | Lab | |
| LO/CO | Are there clear policies and procedures for sample rejection? | Y / P/ N | Lab/clinicians | |
|  |  |  |  | |
| LO | Does the testing site have a log in which it records the number of samples rejected, and the reason for the rejection? | Y / P/ N | Lab | |
| LO/CO | Describe the procedures that are in place to inform clinicians promptly of the rejection of a specimen and to request another specimen? | Lab/Clinicians | | |
|  | Post-analytical stage | | | |
| LO/CO | Are the test result reporting SOP and forms available and readily accessible to all clinical and laboratory staff? | Y / P/ N | Lab/clinicians | |
| LO/CO | Do the standardized reporting forms include information on reporting codes and interpretation of results? | Y / P/ N | Lab/clinicians 8.2.1 | |
| LO/CO | How are results transmitted to clinicians?  (e.g., by phone, mail, email, SMS, digitally, etc.) | Lab/clinicians | | |
| LO/CO | Is there an electronic system (e.g., LIMS) supporting the reporting of diagnostic data to clinicians for patient management? | Lab/clinicians 8.2.2 | | |
| LO/CO | Are test results reported within 24 hours of result generation or as per national guidelines? | Y / P/ N | Lab | |
| LO/CO | What procedures are in place for informing clinicians of test delays, unusual results or critical results (e.g., detection of drug-resistant TB)? | Lab/clinicians | | |
|  | Post-post-analytical stage | | | |
| LO/CO | Does the testing site sensitize clinicians on the interpretation of test results? | Y / P/ N | Lab/clinicians | |
| CO | Describe any challenges in the use of diagnostic test results for patient care decisions (e.g., reluctance to act on a rapid molecular test result) | clinicians | | |
| CO | Describe the procedures used to ensure efficient linkage of persons diagnosed with TB and DR-TB to appropriate care and treatment, such as reporting TB patients to TB or DRTB treatment focal person | Lab/clinicians/DTO 3.3.2 | | |
| LO/CO | Do clinical and laboratory staffs meet (at least quarterly) to troubleshoot gaps in laboratory-clinical communications and linkages and aspects of the diagnostic cascade such as application of testing algorithms, specimen referral, result interpretation and reporting? If yes, how often do they meet? | Y / P/ N | Lab/clinicians 3.3.3 | |