**CBNAAT Supervisory Checklist**

Name of the CBNAAT Laboratory:

Address:

Contact Person:

Nodal person for maintenance:

|  |  |  |
| --- | --- | --- |
| **S. No** | **Checklist** | **Response** |
| **Infrastructure** |
|  | Total Number of CBNAAT machines |  |
|  | Total number of modules |  |
|  | Separate area for sample receipt |  |
|  | Is sputum transport mechanism in place? |  |
|  | Number of days between specimen collection and result reported (Lab Culture and DST register Annex-IV) for last quarter | Average: Range: |
|  | Number of days between specimen receipt and result reported (Lab Culture and DST register Annex-IV) for last quarter  | Average: Range: |
|  | Number of days between specimen tested and result reported (Lab Culture and DST register Annex-IV) for last quarter  | Average: Range: |
|  | Is Power backup available for 2 hours? Please mention Solar/UPS/online |  |
|  | Is AC available and in working condition? |  |
|  | Is thermometer/temperature gauge available? |  |
|  | Availability of refrigerator/cold storage for cartridges, consumables |  |
|  | Are temperature logs maintained for both the lab and for refrigerator/cold storage? |  |
|  | Is a dedicated desktop available with CBNAAT machine? |  |
|  | Is anti-virus updated? |  |
|  | Is internet connectivity available? |  |
|  | Are lab consumables for CBNAAT available for next two months?  |  |
|  | Is CBNAAT lab utilized to its full capacity (Approx 12 tests per working day for a 4 module machine)? |  |
|  | Are theft prevention measures in place?  |  |
| **External Quality Assurance and Calibration** |
|  | Were all CBNAAT machines validated using GLI Xpert MTB/RIF validation panel before testing patient samples |  |
|  | Date of last calibration (annual or 2,000 tests/module whichever is sooner) |  |
| **Inventory** |
|  | Total number of cartridges received since inception |  |
|  | Total number of cartridges used till last reporting quarter  |  |
|  | Current stock of cartridges with their date of expiry |  |
|  | How many cartridges expired?  |  |
|  | Is FEFO principle being followed? |  |
|  | Average lead time between request for new cartridges and receipt of requested cartridges for last reporting quarter |  |
| **Manpower and Training** |
|  | Number of lab personnel trained in CBNAAT |  |
|  | Quality of training |  |
| **Standard Operating Procedures** |
|  | Is CBNAAT SOP/guidance document displayed and followed? |  |
|  | Quality of sputum received in last quarter  | .......% M .......% S.......% B |
|  | Is sample adequately liquefied? What is the average time for liquefaction of sputum sample. |  |
|  | How many samples were rejected due to presence of blood, food particles, and leakages before the test is run? |  |
|  | Volume of liquefied sample added to the cartridge before the test is run  |  |
| **Maintenance** |
|  | Is the CBNAAT workbench dust free? |  |
|  | Frequency of cleaning of fan filter |  |
|  | Frequency of cleaning of instrument surface |  |
|  | Frequency of cleaning of plunger |  |
|  | Any issues with use of GeneXpert software? If yes, please specify the reason and how it was resolved |  |
|  | Frequency of data backup |  |
| **Usage and Downtime** |
|  | Average number of tests done per module per day |  |
|  | Number of modules replaced since inception |  |
|  | Is a log book being maintained for recording the downtime of modules? |  |
|  | Average time taken for module replacement  |  |
|  | Was module replacement done by authorized personnel? |  |
| **Outcomes (Last Quarter)** |
|  | Total number of TB suspects tested |  |
|  | Total number of tests with MTB+/Rif- |  |
|  | Total number of tests with MTB+/Rif-HIV+ |  |
|  | Total number of tests with MTB+/Rif-Paediatric cases TB  |  |
|  | Total number of MTB+/Rif+ detected  |  |
|  | Total number of MTB+/Rif+ HIV+ detected  |  |
|  | Total number of MTB+/Rif+ paediatric cases detected  |  |
|  | Total number put on first line treatment (Cat I, Cat II) |  |
|  | Average time to initiate first line treatment from diagnosis  |  |
|  | Total number put on second line treatment |  |
|  | Average time to initiate second line treatment from diagnosis  |  |
|  | Number of tests with MTB+/Rif Indeterminate  |  |
|  | Number of MTB+/Rif Indeterminate Retested |  |
|  | Number of MTB+ from Rif Indeterminate Retested. Was any additional sample collected? |  |
|  | Number of MTB not detected (MTB-)  |  |
|  | Number of tests with Invalid results |  |
|  | Number of Invalids retested |  |
|  | Number of MTB+ from Invalids retested, was any additional sample collected? |  |
|  | Number of tests with “No results” |  |
|  | Number of “No results” retested |  |
|  | Number of tests with “other Errors” |  |
|  | Number of Errors retested |  |
|  | List the type of errors reported along with their frequency |  |
| **Recording and Reporting** |
|  | Are PMDT C&DST register maintained? |  |
|  | Are CBNAAT laboratory indicator maintained? |  |
|  | Is CBNAAT usage register available? |  |
|  | Name of laboratory for confirmatory DST |  |
|  | Are records maintained by the laboratory re-confirming the results? |  |
|  | Number of sample send for confirmation of Rifampicin resistance by CBNAAT (both new and MDR-TB suspects) to laboratory |  |
|  | Number of results received |  |
|  | Number of results awaited |  |
|  | Discordance between the CB-NAAT results and Solid/Liquid DST results |  |
|  | Concordance between the CB-NAAT results and Solid/Liquid DST results |  |
|  | Discordance between the CB-NAAT results and LPA results |  |
|  | Concordance between the CB-NAAT results and LPA results |  |
|  | Total number of referrals from Private Providers |  |
|  | Are reports sent to Districts/IRL/NRL/CTD? |  |
|  | Are Nikshay entries done? |  |
| **Waste Management** |
|  | Foot operated bin with lid (containing 5% phenol) (Disposal of Cartridges, Disposal of sputum containers)  |  |
|  | Is Bio-medical waste management in place/deep burial pit/segregation? |  |
| **Supervisory Visits** |
|  | Number of visits by IRL/NRL |  |
|  | Name of the contact person to resolve technical issues |  |