**Post CBNAAT EQA -Site Visit Report**

The purpose of the post EQA visit is systematic assessment of lab practices to evaluate the potential cause of deviating results (if any) in CBNAAT EQA and initiate corrective actions

**Name of the CBNAAT Laboratory:**

**Address:**

**Reason for site visit**: -

**Date of visit:**

**During the visit, the team of assessors will discuss, observe and record various aspects of the lab and work practices as below**

* **Process and operating procedures**: handling of sample, processing of sample, loading of sample in cartridge, system login and test run, CBNAAT SOP/guidance document displayed and application, disinfecting work area before and after work. Foot operated bin with lid (containing 5% phenol), disposal of Cartridges, Disposal of sputum containers) as per guidelines
* **EQA sample receipt and handling**: condition of received PT samples, their storage before testing, when were samples processed, read the instructions carefully before processing PT samples, staff processing the samples, PT samples processed in the same batch with other clinical specimens or as a separate batch, separate tips or Pasteur pipettes used to dispense sample into the cartridge, etc.
* **Staff Competency & training**: staff trained by authorized technical person i.e. NRL/IRL/company technical person, interview staff to assess competency on various aspects such as CBNAAT SOP, Contamination control measures, Error codes (eg. 5006,5007,5017 etc and their reasons, Equipment maintenances practices such as Frequency of cleaning of fan filter, instrument surface, cleaning plunger, etc.)
* **Equipment:** Check all modules are functional and used at the time of EQA and assessment, is functional power backup available for 2 hours, what is the source -Solar/UPS/Generator (check the documents), is AC available and functional and CBNAAT machine working in ambient temperature 25-28ºC
* **Facility and work area**: is CBNAAT workbench dust free, storage of cartridges (Temperature, segregation from clinical samples), availability of separate designated area for sample processing, etc.
* **Recording & Reporting practices**: review the RNTCP lab register to assess the TOT, result completeness, review stock register for adequate availability of cartridges & adequate lab consumables for next two months, review records of last calibration check done and its status (pass or failed), review maintenance schedules of CBNAAT and log sheets being used and updated regularly, review temperature maintenance log sheets for the lab and storage place, calculate total no of errors occurred in last 6 months and Error types reported, Module wise frequency of Errors, Number of No Results reported, invalid results reported, review availability and completeness of monthly quality indicator data, etc.

*Though the above guidance is exhaustive, the assessors are suggested to feel free to review issues further to arrive at root cause analysis for issue identified and for preparing a plan for corrective action*

**Observation based on discussions, observations and review of records and reports:**

|  |
| --- |
|  |
|  |
|  |
|  |
|  |
|  |

**Recommendations for corrective and preventive action (with timelines and responsible person):**

|  |  |  |
| --- | --- | --- |
| Recommendations | Responsible person | Time lines  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Signature of Assessor Signature of Incharge / Seal

Name: Name:

/

Designation: Designation: