THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on Proficiency Testing Scheme GeneXpert DTS

Module 13 : Data collection and analysis

Venue

Facilitators Name

Date

Introduction

Data analysis is a critical part in PT provision where performance of the participating laboratories is determined and also through this major PT indicators are measured and easily monitored.

Objectives

By the end of this module participants should be

- Able to understand the relevant information collected from participants
- Able to perform a data analysis for PT results
- Generate participant result reports
- Describe the data analysis process

Module outline

- Steps in data analysis
  - data collection
  - Compilation
  - Data cleaning
  - Addition of comments
  - Addition of formulas
  - Mail merge
  - Break the PDF pages

Participation in the genexpert PT scheme

Two (2) rounds per year

- Feb
- August

Stages at which data is analyzed in the genexpert Pt Scheme

- To use as an assigned value
- Finding a consensus
- Assessing participants' results
- Assessing the efficacy of the PT scheme
- homogeneity and stability testing of the distributed test material

When is data collected

- After sending the PT panels a deadline for submitting results is determined which is 44 days .
- From the above date the data submitted is both
  - quantitative
  - qualitative

Measurand in the genexpert Pt scheme

The measurand is targeted nucleic acid sequences in the TB genome

- NB: The Xpert MTB/Rif –Ultra test is a cartridge-based fully automated NAAT (nucleic acid amplification test) for TB case detection and rifampicin resistance.

Results are interpreted as

- MTB detected or MTB not detected
- Rifampicin resistance detected or Rifampicin resistance not detected.

How is the measurand determined

- The measurand is determined from WHO guidelines and product inserts of the manufacturer of the technology.

Type of data collected (Qualitative)

Collected using feed back result reports (genexpert result reporting form) with the following information,

- Name of testing facility,
- Laboratory code,
- Laboratory contact person i.e email/phone number

Type of data collected (Qualitative)

To confirm receipt of the panel at the facility

- Date panel received
- Date panel tested

Ascertain the functional of the instrument in use

- Machine/Module serial number
- Date of instrument last calibration
- Date instrument last calibrated

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory
Timely Accurate Diagonostics for a TB-Free Africa

Type of data collected (Qualitative)

Availability and quality of testing supplies

- Expiry date of the cartridge being used to test the panels
- Date each individual panel is tested

Type of data collected (Qualitative)

Details of the panel

- results of each panel
- Ct values of the tested panel MTB

  RIF/Ultra

Ct values are used to ascertain correct testing of the panels

THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Equipment used data collection

- Computers
- Software's that is user friendly with the personnel

Note;

- the computers should be well serviced and software's up to date
- Personnel should be trained with competence

Data compilation

- Compile in controlled excel spread sheets
- Institutional developed software's

Data cleaning

- The compiled data is cleaning by one
- ensuring that all the date entered is uniform
- The results entered in the same format
- The date also entered in a similar format
- The CT values are entered in the same format

Addition of comments

All the parameters are analyze and any out of the anomaly should be addressed in the following scenarios

- Used of expired cartridges
- Machine Calibration due
- Testing and panel receipt dates missed
- CT values not provided
- Reporting incorrect results
- Reporting errors with no error corresponding error codes

Considerations of a panel for analysis

There should be ≥ 80% consensus with the participants for each panel (expected score)

≥80% of the participants score proceed with analysis

< 80% of the participants score

- Proceed to do a root cause analysis and document findings
- PT item is not included in the analysis

Addition of formulas

- The formulas are added depending on the expected results.
- This informs the scoring process

Mail merge

- When using the excel sheets the information can be populated into individual word documents .
- The a should be reviewed against the initial results submitted by the facility to ensure the information was properly transcribed
- The reports with incorrect information should be corrected.
- The mail merge documents can be separated into individual documents using a pd software and

Back –up of the computers and soft ware

- Backup process and system recovery plan in cases of shutdowns
- Maintain records at al times

Methods used to analyze results

The methods used should be able to

- Enable data entry
- Data transfer
- Statistical analysis
- Facilitate result / feedback reporting

Out put of data analysis

- Summary statistics
- Performance statistics

How to deal with result wrongly reported

- Ie miscalculations
- Transporsitios
- errors

Managememt of PT panels that donot give appropriate results in th scenarios of

In the following scenarios Pt items are removed/ disregarded for analysis

- inhomogeneity
- Instability
- Damage
- contamination

Assessment

1. What measurands are considered for the genexpert PT skin?
2. Outline the steps undertaken in analyzing genexpert PT results
3. Under what circumstances is apt panels excluded from analysis?

Summary

The measurand for Genexpert based on the MTB detection and rifampicin resistance results

Data analysis involves data collection, c addition of comments scoring

Pt items are removed/ disregarded for analysis, when there is inhomogeneity, Instability, Damage, contamination

REFERENCES

- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials — General and statistical principles for certification*
- Guide 34, ISO Guide 35 and ISO 13528 (homogeneity and stability)
- ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement* (GUM:1995)
- ISO/IEC 17011:2004, *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*
- ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

Acknowledgments