

Training on Tuberculosis Drug and Susceptibility Testing (MGIT DST - Liquid Method)

Module 7: BACTEC MGIT 960 DST Quality Control

Date:

**By: Uganda Supranational Reference
Laboratory**

Content Outline

- Quality control organism
- Drug and organism preparation
- SIRE, 2nd line and PZA QC records.

Why QC reagents?

- ✦ BD thoroughly tests all BACTEC MGIT 960 DST products prior to release
- ✦ So why test at your facility?
 - ✦ Product may be mishandled during shipment
 - ✦ Antibiotic potency may decrease
 - ✦ Checks ability of laboratory to perform test
 - ✦ Reagent storage
 - ✦ Reagent preparation
 - ✦ Organism preparation

BACTEC™ MGIT™ 960 DST

User quality control

- ✦ New shipment or lot number of drug kits before use with patient isolates
- ✦ Weekly SIRE, 2nd line drugs and PZA DST QC
 - ✦ If validated, otherwise set up a QC DST set each time DSTs are inoculated
- ✦ QC organism:
 - M. tuberculosis* ATCC 27294 (H37Rv), OF, RS, KN, MA
 - ✦ SIRE drugs
 - ✦ PZA
 - ✦ 2nd line drugs.
- ✦ Drug concentrations tested should be the same as those used for routine testing
 - ✦ Two concentrations of INH used for patients; QC both concentrations

QC organisms

- Pure culture of *M. tuberculosis* ATCC 27294 (H37RV) or well-characterized pan-susceptible MTB strain
 - Colonies from solid media 14 days old
 - MGIT 960 tube 1-5 days after flagged positive by instrument
- Additional organisms may be tested to supplement BD QC recommendations
 - Laboratory dependent
 - May want to inoculate a known mono-resistant strain of MTB

Drug and organism preparation

- Care should be taken to ensure proper reconstitution of lyophilized drugs
 - Wrong drug concentration
 - Improper preparation significantly impacts results
- Proper dilution of organism for drug and growth control tube is critical
 - Suspension must be well mixed and homogeneous without clumps
 - Prepare QC organism suspension in the same way as patient isolate suspension

Inoculate SIRE and PZ DSTs

- Drugs
 - Rehydrate drugs with sterile water
 - Remove aliquots of prepared drugs from freezer
 - Check expiration dates
- Prepare inoculum and dilutions
 - Solid seeds
 - Liquid seeds

SIRE and PZA QC

- **Entry of tubes into MGIT 960**
 - Scan DST set carrier into the BACTEC MGIT 960 instrument
- **Interpretation of results**
 - Instrument will interpret results between 4-13 days
 - Results should read susceptible for all drugs
 - If proper results are not observed, repeat test

SIRE and PZA QC records

- Record lot numbers of MGIT 960 tubes, drugs and drug supplements
- Record QC results
- Maintain records for a minimum of two years

Assessment

1. Why QC reagents
2. How often do we perform QC
3. List the organisms used in QC

QC summary

- QC of DST is critical to ensure test is functioning properly
 - Should be performed on all new lots or new shipment of SIRE and PZA drugs
- QC organism suspension can be prepared from MGIT tube or solid media
- Organism suspension must be homogeneous, i.e. without clumps
- Sterile tubes and pipettes must be used
- Use calibrated pipettes to inoculate drugs to media tubes, not disposable transfer pipettes

References

- BACTEC[®] MGIT 960[™] System User's Manual. Becton Dickinson Company. 2004/06 Document number MA-0117. Revision E
- BACTEC[®] MGIT 960[™] System. Policy and procedure. October 1999. Revision A.
- Global Laboratory Initiative (GLI)

Acknowledgments

