# Quality assurance - frequently asked questions

## *1. Why do we need quality assurance?*

Through monitoring and, where necessary, the prompting of corrective action QA ensures that MODS testing is optimally performed according to rigorous criteria. This means that patients and TB control programme and laboratory staff can be confident that the MODS test results that are delivered are accurate and timely.

## *2. What is the purpose of MODS quality assurance?*

Any test, however good, can give misleading or incorrect results if it is performed improperly or not according to the standard operating procedure (SOP) - this also applies to MODS.

Thus the purpose of the QA outlined in "Quality assurance plan for MODS" is to ensure that any variation from the SOP that might affect the reliability of the MODS results is detected and rectified.

## *3. What specific points does MODS QA aims to address?*

For MODS to deliver the highest standard in culture detection and rapid DST it is necessary to assure the quality of: the sputum samples received, the sputum decontamination procedure, the culture methodology, the drug susceptibility testing (DST) methodology and the results reporting mechanism.

- We want to know that good quality samples are transported safely, with all necessary accompanying information and arrive in a timely fashion and in good condition.
- We want to know that the sputum sample decontamination procedures are neither so fierce that all mycobacteria are killed nor so mild that most cultures suffer bacterial or fungal overgrowth.
- We want to know that the MODS culture media is optimally supporting growth of TB to ensure that we are not failing to detect cases (sensitivity).
- We want to know that the positive cultures we encounter are indeed true positive cultures and not due to cross-contamination (specificity).
- We want to know that the concentrations of isoniazid and rifampicin in the MODS media are accurately distinguishing between drug resistant and drug-susceptible TB by inhibiting growth of susceptible strains and failing to inhibit growth of resistant strains.
- We want to know that the benefit of rapid testing in the laboratory is being translated into rapid reporting and thus early availability of MODS results in health clinics for patient care

For each element there are specific indicators which are measured and monitored; if performance falls outside pre-determined limits of acceptability then corrective action is needed [see "Quality assurance plan for MODS"].