

Quality assurance - frequently asked questions

1. Why do we need quality assurance?

Through monitoring and (when necessary) corrective action, QA ensures that MODS testing is optimally performed according to rigorous criteria. If QA procedures are adhered to, patients and TB programme and laboratory staff can be confident that the MODS test results that are delivered are accurate and timely.

The MODS assay performed without QA is not MODS.

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 problems leading to inaccurate and unreliable results, including variation from the SOP, are 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
- the results **reporting** mechanism.

- Good quality samples should be transported safely, with adequate clinical request details; and should arrive in a timely fashion and in good condition.
- Sputum sample decontamination procedures should be neither so harsh that all mycobacteria are killed nor so mild that bacterial/fungal overgrowth is common.
- MODS culture media should optimally support growth of TB to minimise the possibility of failure to detect cases (sensitivity).
- Quality control measures ensure confidence that positive cultures encountered are really true positive cultures and not due to cross-contamination (specificity).
- The activity of isoniazid and rifampicin in the MODS media should accurately distinguish between drug resistant and drug-susceptible TB by inhibiting growth of susceptible strains and failing to inhibit growth of resistant strains.
- The benefit of rapid laboratory testing should be 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"].