METHOD EVALUATION FOR QUALITATIVE METHODS

Validation (*for* non-standard methods) / Verification (*for* standard methods) process

1. Write protocol.
2. Determine acceptance criteria
3. Select experiments to be run
4. Collect experimental data and record on relevant templates
5. Use statistical tools on the data to estimate size of analytical errors
6. Compare the observed errors with the defined allowable error
7. Judge the acceptability of observed performance characteristics
8. Write report

Resources for qualitative validation and verification of clinical laboratory tests

1. CLSI guidelines:
   EP12: User protocol for evaluation of Qualitative Test Performance
   M52: Verification of commercial Microbial identification and antimicrobial susceptibility testing systems
   M22: QC for commercially prepared microbiological culture media
   M50: QC for commercial microbial identification systems
2. CUMITECH 31A Verification and validation of procedures in the Clinical Microbiology Laboratory – Richard B Clark et al American Society for Microbiology
3. Psmile is a patient safety monitoring in International Laboratories based in John Hopkins University in Baltimore. Navigate to resources page. *www.**psmile**.org*
4. https://www.westgard.com/validating-qualitative-tests.htm
5. Statistical software: EP evaluator- Dr DG Rhoades/ https://analyse-it.com
6. Training webinars: https://www.pathlms.com/asm/courses/3372
7. Accreditation bodies *e.g* SANAS, KENAS, SADCAS *etc.*
8. Guidelines on validation and quality assurance in microbiological testing. TG 28-02.SANAS. Access at www.sanas.co.za
9. Technical guidance for the validation of methods used by chemical laboratories in the food. Water and related industries. TG 07-01. SANAS. Access at www.sanas.co.za (includes guidelines for what assessors are looking for in method validation)

Practical considerations in planning and conducting validation and verification studies.

Extent of testing for validation/verification should be based on risk.

For cost saving and efficiency, more extensive verification may be done at the NRL (e.g. 50-60 samples, equal number of positive and negative samples) and a more limited verification study done at individual labs.

However, rerification must be done at individual labs, though sample size could be reduced (e.g. 10-20 samples, 50% positive, 50% negative). Labs may

Countries should develop a national generic protocol for method validation/verification which includes general considerations (for qualitative and quantitative methods), which can then be adapted for test-specific protocols.

For semi-quantitative tests, a mix of samples should be selected that will give results at test thresholds.

Example of NHLS (conforming to SANAS requirements) – for verification of standard qualitative methods, typically conducts accuracy and reproducibility studies. Accuracy, as described above. Reproducibility testing usually comprises 3 samples tested over 5 days (total 15 tests).

For methods introduced into labs without verification and in routine use, labs may conduct a retrospective verification by analysis of historic EQA data. The protocol and acceptance criteria for this retrospective evaluation must be pre-defined and documented, and a formal verification report prepared.

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