

Assay Validation

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What is the purpose of assay validation ?

- To confirm published reports and observations
- To show comparability with existing techniques
- To ensure accuracy within the laboratory system
- To ensure accuracy with an automated laboratory system
- To prove clinical value of the results generated

To have a documented the reasons for accepting the assay



Factors which determine a good diagnostic technique

- Sensitivity
- Specificity
- Ease of use/ expertise required
 - Robustness
- Equipment needed
 - Turnaround time
 - Cost
- Diagnostic value



Why select a “new assay”

Prepare a list of assay requirements (User Specification)

- CE marked assay
- Detection of a new marker
- Determine specification for the new assay: IgM
- Duration of assay
- Can it be automated ?
- Ease of use
- Incorporation of reagent addition monitors ?



How do you source information on a “new” test

Research literature

- PROMED/ Internet
- Blue book reports
- Working groups/consensus statements
- “Best practice” protocols
- Comparisons reported by commercial companies????



You have identified the assay. What is the next step ?

Convene an evaluation team

One individual will become lead evaluator and prepare the final report



How is the test evaluated ?

Prepare a panel of well characterised samples
- based upon sequential samples, alternative assay results

Usually on approximately 200 samples

Try to obtain evaluation kit FOC from company



How is the evaluation panel configured ?

Positive archive samples

Negative archive samples

Difficult samples - recent infection

Potential false positives

- Pregnant women
- Poor samples
- RF samples

Commercially available samples- BBI



Evaluation of a “novel assay”

A “novel” assay is a test with far superior sensitivity to those currently available

- Chlamydia PCR

Panel configuration as before using results of the “old generation test”

Potential problem - New assay POS, old assay NEG
- False Pos, more sensitive ?



Previous results and detailed clinical information are required to determine the accuracy of the assay

Performance of the evaluation

-What to look for ?

Sensitivity

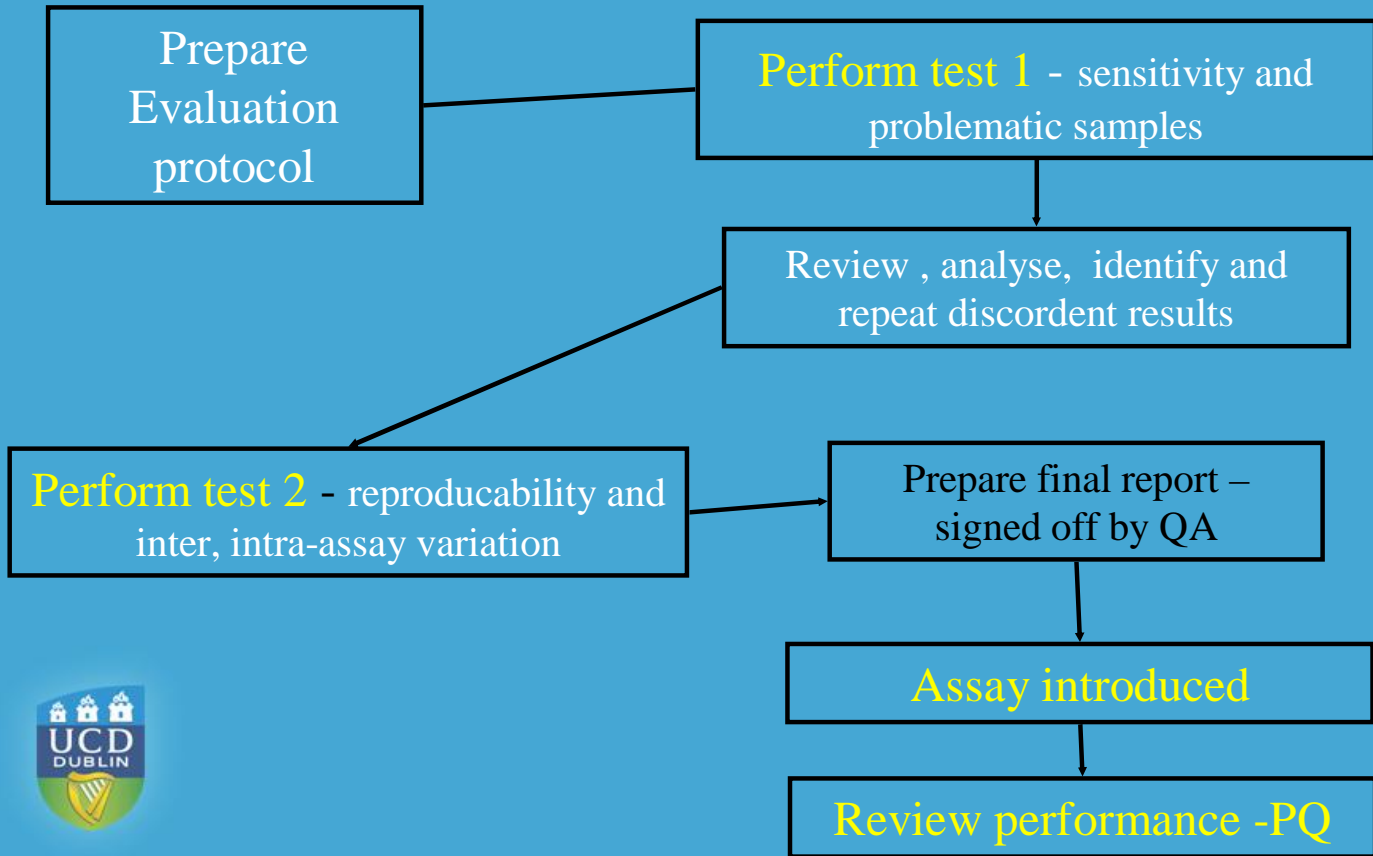
Specificity

Inter-assay variation

Intra-assay variation



Performing the evaluation



Validating an updated assay

Manufacturer modification - don't trust their data

Does the modification impact on the accuracy of the assay

No

Assay does not require validation

YES

Ask company for FOC kit and perform evaluation-



Validating an updated assay

Prove comparability with previous technique

1. 50% of plate - routine samples recently tested
2. Use remaining assay to investigate truncated panel

Introduce updated assay

Evaluate the result and
prepare short report

Amend SOP



Validated assay and automation – A happy relationship ?

CE marked validated assay

Do NOT assume that the assay can be put on an automated platform even though the equipment has been validated – CE issues

Validation is parallel with “manual procedure” – extensive panel

Review data – write report and sign off that assay with that equipment only

Review performance -PQ



Assay Validation- Summary

- Creates confidence that the validated assay performs well in your laboratory
- Become aware of the limitations of the assay
- Review performance of the assay in the laboratory
- Review the clinical impact of the assay
- Introduce assay on an automated platform only after validation



Assay Validation

Thank-you for your attention

Any Questions ?



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