

The new OIE principles and methods for validation of diagnostic tests

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Diagnosis ~ Validation ~ Epidemiology



Specificity

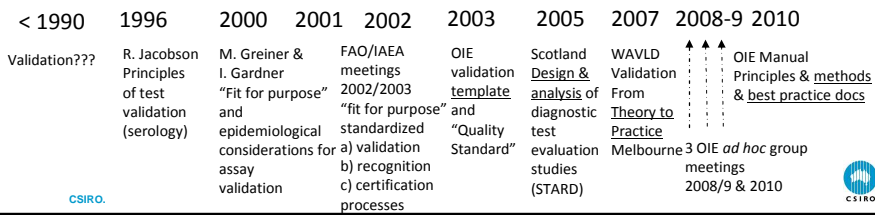
Sensitivity

Precision

Repeatability

Reproducibility

Accuracy



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Strategy presented at WAVLD 2007, Melbourne....

Workshop on Assay Validation: "From theory to practice"



WAVLD Pre-symposium Workshop

Assay validation: "From theory to practice"

Crown Promenade Hotel, Melbourne
Sunday 11 Nov 2007
9.00am – 5.00pm



www.wavld2007.com

- The "One-Set-of-Validation-Principles" concept is applicable to all types of diagnostic assays (Ab-Ag, NAD, TSE, etc.)

- One set of Validation **Criteria** is applicable to all assay types (what has to be done?)

- we need a **unified Validation Chapter**

- we need **Best Practice documents** or **annexes**, which describe the processes how to inform validation criteria for each assay type (how to do it?)

- we need a **unified template**, which would be accompanied by **Unique Guidelines** for each assay type

- OIE endorsed this proposal and supported its development through an **ad hoc group for test validation**



Essential changes in the new approach to international test validation

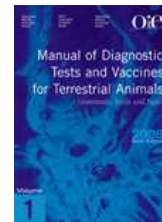
1) One chapter on test validation, which includes Nucleic Acid Detection Tests (NADs).
Before there were two chapters, e.g. one with a focus on serological tests and one for NADs.

2) The chapter includes principles and methods for test validation

3) The chapter has 7 annexes as best practice documents:
(The first 3 focus on the development and optimization of diagnostic tests)

- 3.1) Development and optimization of antibody detection assays (Ab)
- 3.2) Development and optimization of antigen detection tests (Ag)
- 3.3) Development and optimization of nucleic acid detection tests (NAD)

- 3.4) Statistical approaches to test validation including (Latent Class Models)
- 3.5) Method comparability (Equivalence testing)
- 3.6) Measurement Uncertainty (MU)
- 3.7) Selection and use of reference panels



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Essential changes in the new approach to international test validation (cont.)

4) Guidelines for the use of the OIE validation template

5) “Provisional recognition”

Example: Assays developed and used in emergency or outbreak situations.
To be assessed: ASe, ASp, repeatability and an estimate for reproducibility

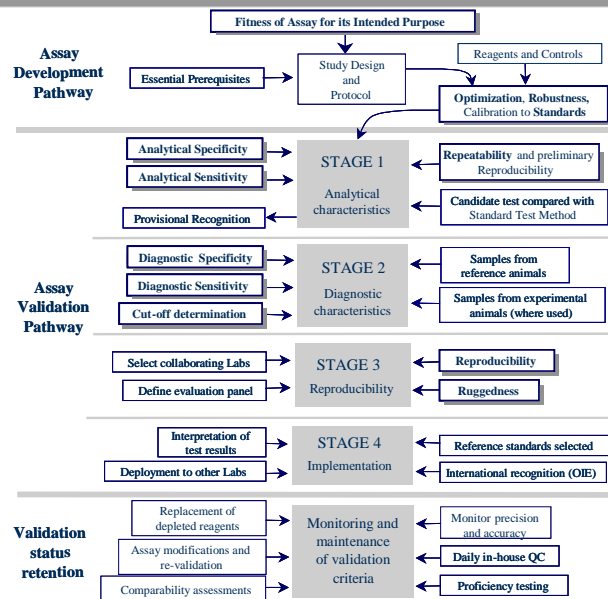
6) “Adjunct tests or procedures”

Example: VNT to type an isolated virus or molecular sequencing to confirm a real time PCR result.
To be assessed: ASe and ASp.

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OIE test development and validation pathway



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12 criteria that must be addressed in the development and validation of diagnostic tests

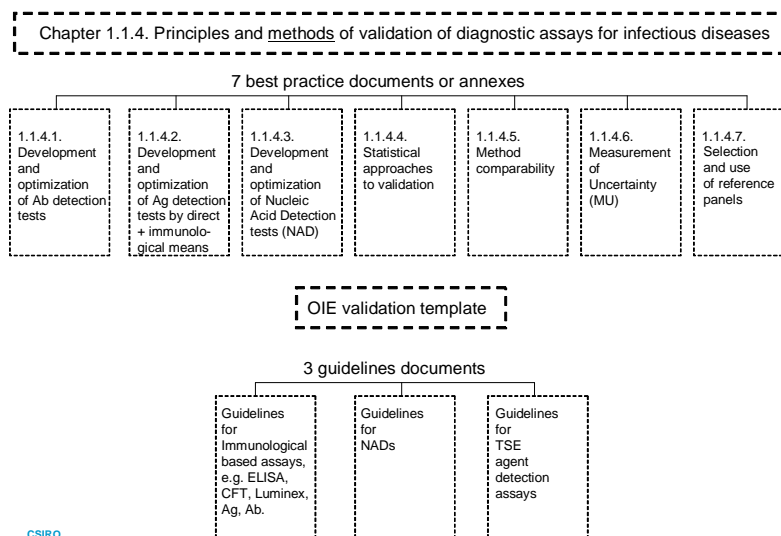
- 1) Fitness for intended purpose(s)
- 2) Optimisation
- 3) Standardisation
- 4) Robustness
- 5) Repeatability
- 6) Analytical sensitivity
- 7) Analytical specificity
- 8) Thresholds (cut-offs)
- 9) Diagnostic sensitivity
- 10) Diagnostic specificity
- 11) Reproducibility
- 12) Ruggedness

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The new proposed OIE validation process

OIE validation navigation flowchart



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Conclusions

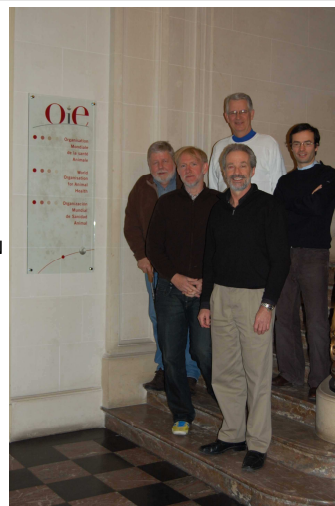
- We have come a long way toward a strong science based assay development and validation model.
- Validation is a process that determines the fitness of an assay, which has been properly developed, optimised and standardised, for an intended purpose. Validation includes estimates of the analytical and diagnostic performance characteristics of a test.
- We are close to implementing detailed processes that will harmonize validation efforts and drive assay validation science toward excellence.
- FAO/IAEA/OIE held a consultants meeting in Vienna, 6-9 September 2010 to develop a roadmap for the implementation of modern OIE principles and methods for diagnostic test validation.

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Thank you for your attention!



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