

Instructions for analytical verification and validation of immunohistochemical tests

Belgian recommendations for laboratories of anatomic pathology

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Challenges

1. Despite existence of **guidelines** on validation of immunohistochemical (IHC) biomarker assays specific details regarding its application in individual laboratories of anatomic pathology are lacking.
2. The **European IVDR** categorizes tests into CE-IVD tests and Laboratory developed tests (LDT) but does not contain a definition on modifications of CE-IVD tests resulting in LDTs and lacks information on how to demonstrate its clinical and analytical performance.

Improving quality



1. Help laboratories

- Improving
- Harmonizing
- Standardising
- Enhance compliancy to IVDR
- Increase het range of validated IHC tests
- Reduce cost and workload

2. Increase overall quality

- Increase accuracy of IHC testing
- Reduce inter laboratory variation

Step-by-step instructions for each type of test and its purpose

