



INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

Reference Materials for Genetic Testing

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INNOGENETICS

Molecular Genetic Testing Products

Polymorphic genes / Different (rare) mutations

Test Principle

Sample/DNA extraction

PCR

Hybridization/detection

Transplantation

- LiPA HLA-A
- LiPA HLA-B
- LiPA HLA-C
- LiPA HLA-DRB
- LiPA HLA-DQB
- LiPA HLA-DPB
- LiPA HLA-DQA

Cystic Fibrosis

- LiPA CFTR36
- LiPA CFTR Italian



Development of Diagnostic Tests

- Assurance of safety and effectiveness
 - Quality and validity: analytical performance
 - Accuracy (right answer), precision (right every time)
- Time to market

↙ Accessibility of appropriate and verified reference material



Analytical Performance

- Hybridization
 - secondary structures
 - concentration
 - heterozygous/homozygousSynthetic samples, (Real samples)

- PCR
 - whole genome
 - concentration, purity
 - matrix, inhibitorsReal samples, (Synthetic samples)



Reference Material: Wish List

- Samples (in decreasing order of needs)
 - Real samples
 - Cell lines
 - DNA
- (Synthetic) matrices
- Databank
 - IEC/IRB approval
 - Informed consent (as many genes as possible)
 - Well-characterized samples
 - Accessible

