

Standard Assay Development Phases

From concept to commerce



• Concept generation	Brief	Objective development	R&D Services
• Proof-of-principle	Phase 1	Concept development (wet)	
	Phase 2	Optimise concept	
• Feasibility	Phase 3	Test assay (dry)	
	Phase 4	Optimise assay	
• Optimisation	Phase 5	Test with real samples	
	Phase 6	Optimise real samples	
• Realisation	Phase 7	Document assay standards	
	Phase 8	Prototype production	
• Production	Phase 9	Technology transfer	
	Phase 10	Test batch production	
• Testing & Validation	Phase 11	Design and development	
• Trials		Product trials	Management Services
• Regulation		Regulatory approval	
• Manufacture*		Volume production	
• Commercialisation		Packaging, promotion, distribution, sales	

* manufacturing in-house or contracted out depending on volume size



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