

Assay Requirements Checklist



This template summarises key assay development information and requirements. We appreciate that projects have different demands and degrees of flexibility, but listing any known requirements, considerations and characteristics helps to focus the assay development process.

Assay Name	
Target(s) Substance targeted for detection	
Accuracy Specificity/sensitivity or tolerance targets	
Limit(s) of Detection Lowest/highest/range of detection required	
Device Format Preferred format of the finished product (if known)	
Reagents Preferred reagents to be used (if known)	
Reagent Characteristics Particle size, antibody pl etc.	
Sample (e.g. blood, saliva, urine, foodstuff, water etc.)	
Result Required Qual/Quant, Semi-Qual/Quant	
Reader Visual, Machine-read, Other	
Speed Time to result	
Target Unit Cost	
Manufacturing scale	
Target End-user	
Intended Tester (e.g. professional/end-user)	
Operating Environment (Temp. RH)	
Other Considerations/Requirements	

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