Fit for Purpose Validation
Classification Matrix

The following are proposed guidelines listing general categories (Purpose) and corresponding Minimum Validation Requirements. The level of method validation used should be based on several factors including risk, application, industry standards or regulatory requirements. When choosing a method and desired outcome, also, consider other factors that contribute to the result including sample size, sampling plan, laboratory/technician proficiency and measurement uncertainty.

Purpose	Examples	Minimum Method Validation Requirements
Process Monitoring Product Monitoring	Raw Material Tests In-process Tests Indicator Test (Quality)	**SLV (Single Lab Validation) Methods:** Methods validated through single laboratory studies including inclusivity, exclusivity, ruggedness, stability and lot-to-lot variation. For qualitative methods, method performance is determined by LOD50 and compared to a reference method, if available. For quantitative methods, method performance is determined by LOD, LOQ, RSDr and linearity in comparison to a reference method.
Process Verification	Routine Sample Tests HACCP Verification Tests Supplier Verification Tests	**MLV (Mult-Lab Validation) Methods:** Methods have been validated by two or more laboratories. Inclusivity, exclusivity, ruggedness, stability and lot-to-lot variation studies are performed in one lab. Method performance studies (see SLV) are conducted in two or more labs following identical protocols using the same matrix/strain combinations.
Process Validation	New Process Validation Tests Equipment Validation Tests	**MLV (Mult-Lab Validation) Methods:** Methods have been validated by two or more laboratories. Inclusivity, exclusivity, ruggedness, stability and lot-to-lot variation studies are performed in one lab. Method performance studies (see SLV) are conducted in two or more labs following identical protocols using the same matrix/strain combinations.
Regulatory Screening, Commercial Screening	Finished Product Release Tests Routine/Scheduled Audit Tests Routine Import Tests	**HCV (Harmonized Collaborative Validation) Methods:** Methods that have been validated by full collaborative study. The collaborative study must report valid data for method performance (see SLV) using robust statistcs without removal of outliers, except for assignable causes. The HCV must be preceded by a succssful SLV or MLV.
Regulatory Confirmation Testing	"Official Samples" Tests in response to complaints or previous positives	**HCV (Harmonized Collaborative Validation) Methods:** Methods that have been validated by full collaborative study. The collaborative study must report valid data for method performance (see SLV) using robust statistcs without removal of outliers, except for assignable causes. The HCV must be preceded by a succssful SLV or MLV.
Forensic Testing	Lab Confirmation tests for BioTerrorism Agents	**HCV (Harmonized Collaborative Validation) Methods:** Methods that have been validated by full collaborative study. The collaborative study must report valid data for method performance (see SLV) using robust statistcs without removal of outliers, except for assignable causes. The HCV must be preceded by a succssful SLV or MLV.
Crisis Management	Emerging Pathogens	Use Best Available Method (dependent on critical time and risk) **SLV (Single Lab Validation) Methods**: Methods validated through single laboratory studies including inclusivity, exclusivity, ruggedness, stability and lot-to-lot variation. For qualitative methods, method performance is determined by LOD50 and compared to a reference method, if available. For quantitative methods, method performance is determined by LOD, LOQ, RSDr and linearity in comparison to a reference method
	Emerging Disease Outbreaks	**MLV (Mult-Lab Validation) Methods:** Methods have been validated by two or more laboratories. Inclusivity, exclusivity, ruggedness, stability and lot-to-lot variation studies are performed in one lab. Method performance studies (see SLV) are conducted in two or more labs following identical protocols using the same matrix/strain combinations.