

Laboratory and RDT Documentation List

Documentation which would support facility assessment and scoring. This list should be provided to the facilities prior to the visit to enable them to locate and make the documents available.

These are examples, the facility may name or structure their facility in numerous ways and it is understood that the necessary information may be in differently named documents, separately or as a whole. Sites which are only performing RDT's may not have laboratory specific documents, but facility and general documents can be provided as evidence.

Documents can be soft or hard copy and maybe named or organised in a manner other than as below.

Documentation list			
Document	Checklist Section	Available	Comments
Quality manual	Management review		
Safety manual	Management review		
Request and reporting form	Management review		
SOP's covering technical and management areas	Management review		
All cholera SOP's for lab testing	Management review		
Record review of quality and technical records	Management review		
Staff policy	Workforce / HR		
Duty roster	Workforce / HR		
Emergency/ contingency planning	Workforce / HR		
Laboratory meeting minutes	Workforce / HR		
Staff training records	Workforce / HR		
Staff competency records	Workforce / HR		
Temperature monitoring log sheets from fridges, freezers, incubators, rooms, water baths	Facilities		
Hazardous waste disposal logs	Safety		
Biosafety training curriculum and staff attendance history	Safety		
Equipment policy	Equipment		
Equipment records	Equipment		
Verification records	Equipment		
Equipment manuals	Equipment		
Maintenance records	Equipment		

Documentation list			
Document	Checklist Section	Available in Lab	Comments
Service records	Equipment		
Inventory policy	Inventory		
Stock cards/ inventory log	Inventory		
Temperature monitoring log sheets	Inventory		
Product disposal log	Inventory		
SOP for sample collection	Testing pre-analytical		
Information for patients	Testing pre-analytical		
Test request forms	Testing pre-analytical		
Sample referral procedures	Testing pre-analytical		
Referral logs	Testing pre-analytical		
Results return log/ records	Testing pre-analytical		
Register/ list /map of sites that refer samples	Testing pre-analytical		
Register/ list /map of sites samples are referred to	Testing pre-analytical		
All cholera SOPs for lab testing	Testing analytical		
Quality control logs for all cholera tests and media	Testing analytical		
EQA participation scheme and results	Testing analytical		
Procedure and/or process for reporting and release of results	Testing post-analytical		
Test results form	Testing post-analytical		
Reports/alerts of <i>Vibrio cholerae</i> to notification bodies	Testing post-analytical		