GLOBAL TASK FORCE ON CHOLERA CONTROL

LABORATORY ASSESSMENT ATTENDANCE LIST

Complete during all management and laboratory meetings and continue to complete when meeting any new staff during the site assessment.

1. Complete the names and affiliations of all auditors evaluating the laboratory. Fill in which checklist sections they completed.
2. Complete the names and details of all staff involved with the visits. This includes regional/unit mangers, all hospital managers, clinical, laboratory and auxiliary staff such as cleaners, waste managers, sample transporters spoken to during the assessment.
3. Contact/email is only needed for people who will be sent the final report.
4. Next to each name, note the checklist sections someone has provided information for, this provides an evidence chain so if something is disputed later, it is known who provided and who completed the sections.
5. Status is one of 4 categories –
    a. **A - Assessor** (part of the assessment team),
    b. **M - Management** (Epi, response, regional, unit staff who are not based within the visited facility),
    c. **H - Hospital** (Anyone at the facility who is not employed as laboratory staff),
    d. **L - Laboratory** (Anyone employed specifically to perform testing, or working within the laboratory)

Please consider printing double sided to reduce waste and help our environment.

Title/First Name	Last Name	Affiliation / Position	Contact, email	Section(s)	Status

Title/First Name	Last Name	Affiliation / Position	Contact, email	Section(s)	Status

GLOBAL TASK FORCE ON CHOLERA CONTROL

LABORATORY DOCUMENTATION LIST

To be completed during facility visit.

This is only determining if the site has a document – Yes/No, it is not judging the quality of a document although that can be noted in the comments.

Document	Checklist Section	Available in Lab	Comment
Quality manual	Management review		
Safety manual	Safety		
Patient results form	Management review		
SOPs covering technical and management areas	Management review		
All cholera SOPs 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		
Competency records	Workforce / HR		
Temperature monitoring log sheets from refrigerators, freezers, incubators, rooms, water baths	Facilities		
Hazardous waste disposal	Safety		
Biosafety training curriculum and staff attendance	Safety		
Equipment policy	Equipment		
Equipment records	Equipment		
Verification records	Equipment		
Equipment manuals	Equipment		
Maintenance records	Equipment		
Service records	Equipment		
Inventory policy	Inventory		
Stock cards/Log book	Inventory		

Document	Checklist Section	Available in Lab	Comment
Temperature monitoring log sheets	Inventory		
Product disposal log	Inventory		
Process / procedure SOP for sample collection	Testing Pre-analytical		
Information for patients/clients	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 of sites that refer samples	Testing Pre-analytical		
Register/ list of sites samples are referred to	Testing Pre-analytical		
Quality control logs for all cholera tests and media logs	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		
Archived results	Testing Post-analytical		
Reports/alerts of Vibrio cholerae to notification bodies	Testing Post-analytical		
Reports/alerts of other relevant diseases of interest to notification bodies	Testing Post-analytical		

Additional comments:

GLOBAL TASK FORCE ON CHOLERA CONTROL

LABORATORY EQUIPMENT LIST

Complete during the facility visit. Available Yes/No must always be completed

Equipment information

Available: Is equipment readily available in the working area – Yes/No?
 # No: Quantity of each equipment available for cholera testing.
Functional: Is the equipment in working order Yes/No?
Monitored: Is the functionality of equipment regularly checked (e.g. temperature / calibrated) Yes/No?
Maintained: Is the equipment regularly maintained according to the manufacturer's recommendations (e.g. cleaning) Yes/No?
Serviced: Is the equipment regularly serviced by a qualified service technician Yes/No? (Review equipment logbook.)

Are the following equipment available?	Available	# No	Functional	Monitored	Maintained	Serviced	Comments
Thermometers							
Timer							
Incinerator / burn pit							
Loops for streaking							
Water distiller							
Bunsen burner or micro-incinerator							
Balance / scale							
pH meter							
Microscope							
Refrigerator (2-8°C)							

Are the following equipment available?	Available	# No	Functional	Monitored	Maintained	Serviced	Comments
Freezer (-20˚C)							
Freezer (-80˚C)							
Water bath							
Incubator (aerobic)							
Autoclave							
Antibiotic disk dispenser				[redacted]			
Ruler or calliper with millimetre markings		[redacted]					
Turbidity meter							
Laminar flow or PCR hood							
Molecular platforms for amplification *(PCR, LAMP etc)*							
Molecular platforms, sequencing							
Molecular extraction, automated							
Computer and data backup - bioinformatics							
Biosafety cabinet or other clean workstation							
Semi-automated/ automated microbial identification or susceptibility testing systems							
Computer, general lab results							
Printer							
Other equipment (specify):							

How does the laboratory obtain media for bacterial culture?	Media	Comment - describe the types of media prepared/ purchased
Media is ever prepared on-site (non-commercial)		
Media is ever prepared off-site (non-commercial)		
Ready-made media is procured from a media supplier (commercial)		
Comments:		

GLOBAL TASK FORCE ON CHOLERA CONTROL

LABORATORY TESTING INFORMATION

To be completed during the facility visit.

Testing information

Where tests are performed at this facility (Yes) there are additional questions to be answered below. For example: Site may collect samples and send to other facilities, in this case performed by laboratory = No; send tests to other facilities = Yes.

Which cholera testing methods are performed by the facility:				**Sufficient resources to do X tests per day?:**			
Method type	**Performed by laboratory**	**Accept tests from other facilities (referred in)**	**Send tests to other facilities (referred out)**	**10**	**25**	**40**	**If insufficient resources, what is the main limitation**
Enrichment in alkaline peptone water (APW).							
Rapid test for *Vibrio cholerae* O1 with/without O139.							

Method type	Performed by laboratory	Accept tests from other facilities (referred in)	Send tests to other facilities (referred out)	10	25	40	If insufficient resources, what is the main limitation
Isolation of potential cholera bacteria from stool using media selective for VC such as TCBS.							
Culture on non-selective media.							
Does laboratory perform *Vibrio cholerae* identification? If yes continue to detail all tests used.							
Oxidase test.							
Identification of *Vibrio cholerae* and serogroup by agglutination (01 and/or 0139)							
Identification of *Vibrio cholerae* serotype by agglutination (Inaba and/or Ogawa)							
Identification of *Vibrio cholerae* by automated of semi-automated methods (biochemical, immunological, MALDI-TOF etc).							
Gram stain or other microscopy.							
String test.							
Api tests.							
Biochemical tests.							
Antimicrobial susceptibility testing (AST).							

Method type	Performed by laboratory	Accept tests from other facilities (referred in)	Send tests to other facilities (referred out)	10	25	40	If insufficient resources, what is the main limitation
Molecular methods; (rapid molecular tests, PCR, LAMP etc).							
Sequencing methods.							
Any in-house developed procedures for isolation and/or identification cholera.							
Other testing:							

Additional testing questions to be asked based on tests performed:	
Name and brand of cholera testing RDT used?	
Specify oxidase method used?	
Specify agglutination serotype?	
Specify biochemical tests used?	
Describe which equipment and methods are used for Vc identification by semi/automated methods?	
Which antibiotics are used?	
Describe the molecular equipment, method and Vc DNA targets used in the testing?	
Which sequencing equipment, methods and targets are used?	
Describe which tests were developed in house?	
Other testing:	

LABORATORY TESTING INFORMATION

To be completed during the facility visit.
Sample information
For each testing method, indicate Yes or No for each listed sample type based on whether it is collected and accepted by the laboratory for that specific test.

Sample information										
Sample types accepted for testing:	**Fresh stool**	**Stool swab in CB**	**Stool swab in APW**	**Rectal swab**	**Rectal swab in CB**	**Rectal swab in APW**	**Stool on dry filter paper**	**Stool on wet filter paper**	**Isolates**	**Other sample types?**
Which sample types are used or referred for RDT testing										
which sample types are used or referred for culture/ID/AST?										
which sample types are used or referred for Molecular?										
which sample types are used or referred for sequencing?										

Controls and standard information				
Controls	**Yes /No**	**If Yes describe what is used**	**Frequency used**	**Comments**
Controls are available for media sterility and selectivity/differentiation				
Controls are available for RDT				
Controls are available for microscopy methods (if performed for *Vc*)				
Controls are available for *Vc* identification methods				
Controls are available for all agglutination methods				
Controls are available for AST				
Controls are available for molecular methods				
Controls are available for chemistry methods *(glucose etc.)*				
Comments:				

Which AST interpretation standard (and version) does the laboratory use (check all that apply)?

Standard	Yes /No	If Yes, which version is available and used?
Clinical & Laboratory Standards Institute (CLSI) (https://www.clsi.org)		
European Committee on Antimicrobial Susceptibility Testing (EUCAST) (www.eucast.org/)		
Other - please specify		
Comments:		

Cholera cases

	VC Rapid tests		Samples cultured for VC		Molecular tests for VC	
	So far this year	Last year	So far this year	Last year	So far this year	Last year
Tests requested and performed						
Positive for *Vibrio cholerae*						
No growth / invalids						

GLOBAL TASK FORCE ON
CHOLERA CONTROL

Management Documentation

#	Question	Answer	Comments	Notes for assessor
M.1	**Laboratory legal entity** Does the laboratory have the legal recognition from the country with an agreed mandate and terms of reference to perform it's roles?			A legal entity has formal documentation and recognition from the government that they are entitled to perform the tests and roles which they do.
M.2	**Budget for cholera activities** Is there adequate budget assigned to all laboratory cholera activities?			Budget can be assigned from cholera program, facility budget, from customer payment, research activities, NGO support or other.
	'- Is there an adequate budget assigned for consumable and reagent purchase related to cholera response?			Budget may only be controlled at national level for major items such as bulk reagents, staff salaries and training, but the laboratory/facility should have some assigned budget to compliment activities. This budget should be forecast and planned with the laboratory/facility management, tracked and accounts kept.
	'- Is there an adequate budget assigned for staff and staff training related to cholera response?			
	'- Is there an adequate budget assigned for facility maintenance and equipment purchase/maintenance related to cholera response?			
	'- Is there an adequate budget assigned for cholera surveillance?			
M.3	**Laboratory cholera plan** Is there an available and adequate laboratory strategic plan for cholera diagnostic and surveillance?			Review the plan and confirm it conforms to the national cholera plan, and provides adequate information for the lab to implement all relevant activities to support cholera testing.
M.4	**Minimum package of services** Does the laboratory provide the minimum package of services according to the facility levels aligned with the National cholera plan.			Peripheral - RDTs and referral District - Isolation and referral Regional - Culture, identification, AST National - Culture, identification, AST, molecular, Sequencing or referral for sequencing.
M.5	**Laboratory contingency plan** Does the laboratory have a contingency plan which includes policy and procedures to ensure that there are no interruption to services due to the following: - Utility failures - power, water and/or internet. - HR shortages, when staff are sick, on leave or unable to reach the faculty due to local conflict or environmental disruption such as flooding. - Equipment failure, this includes auxiliary equipment such as autoclaves, incinerators, refrigerators and freezers. - Sample transport failures, Cars are out of service, lack of drivers or changes to schedules etc. - Reagent failures, out of stock, out of date or batches failing verification QC at any time during use. - Local conflict based on local risk - Natural disasters - flooding, earthquakes based on the local risk			A contingency plan covers all eventualities which could impact services at the laboratory. The laboratory should conduct a risk analysis specific for their setting to determine what are the potential causes of disruption, both within and external to the laboratory Contingency plan should be clearly documented and appropriate to avoid long delays or being unable to perform and report accurate results.
M.6	**Laboratory quality system** Is there a current quality manual or equivalent, that details all aspects of the laboratory management system policies and objectives which has been communicated and understood by all personnel? - Description of the quality management system and the structure of its documentation - References policy and procedures for both managerial and technical activities covering all aspects of laboratory operations - Description of the roles and responsibilities of the laboratory manager, quality manager, safety officer and other key personnel - An organisational plan is available and shows all current positions their relationships - Evidence that this quality manual/ equivalent was communicated to internal and external persons.			A document must be available that summarizes the laboratory's quality management system, which includes policies that address all areas of the laboratory service and identifies the goals and objectives of the quality system. Documents can be paper based or electronic, or a combination or both, but must meet the requirements.

Workforce				
#	Question	Answer	Comments	Notes for assessor
HR.1	**Staff levels** Is the staff sufficient to cover daily microbiology/cholera activities.			Based on "General Lab information section, is the staff sufficient to cover all roles for collection, referral packaging, transport, testing, results return, reporting to cholera program.
HR.2	**HR planning**			Organogram must include:
HR.3	**Cholera testing services** Has the laboratory provided uninterrupted testing services for cholera, with no disruptions due to HR shortages in the 6 months?			Interruption to testing is any test which could not be delivered due to staff shortages, it maybe a delay due to short term absence, a single test if the person who can do that test is absent, it doesn't have to be the shut down of the entire laboratory.
HR.4	**Documentation of staff training and competency policy and procedures** How the laboratory will: - perform staff orientation to the laboratory or department, - conduct initial and refresher training, - provide a continuous education program, - identify required training relevant to job title and responsibilities, - keep record of training, - evaluate the effectiveness of training, - assess the competence of personnel to perform all tasks, - establish competency criteria, - schedule of retraining based on competency outcomes, - keep records of competency for all staff.			The entire staff training program should be documented. This could be the laboratory plan, or a higher national schedule of training that staff are enrolled in. Policy should include how records will be maintained. Which training is mandatory at for each job role the system for monitoring and recording competency, including timeframe and clear pass/fail criteria. Competence can be demonstrated through examinations, direct observation, modification of EQA program, review of IQC etc. competence must be performed on a defined schedule with all staff demonstrating competence on all laboratory activities within last 2 years.
HR.5	**Management training** Is there a training program for specialised laboratory roles in place, with documented evidence of completion and competence for the following positions.			This is not assessing the suitability of the training, only that the program has one in place and all staff, in these rolls are enrolled or have completed it with certification, refreshers continuous education. This should be different to the training technicians undertake. If nobody fills this role, mark as "No"
	Laboratory manager.			Laboratory manager can also mean, responsible, director or other title, who does the role of manager.
	Inventory/store manager.			The store manager training should include specific laboratory knowledge, such as chemical safety, storage temperatures etc. Otherwise score partial.
	Quality officer.			This could be part of a separate unit, but if they are responsible for the quality in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Safety officer.			This could be part of a separate unit, but if they are responsible for the safety in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Technical training			
HR.6	**Patient identification, samples collection and transportation.**			"Na" if samples not collected on site. To be asked to persons responsible for collection and persons responsible for packaging of samples for shipment, this may be separate people. The laboratory may also be responsible for sample shipment without sample collection.
	- Patient identification based on country algorithm.			Staff have been trained on the cholera testing algorithms and know the difference between the 2 scenario, looking for the first case and outbreak response.
	- Completion of request forms.			Staff should be able to demonstrate correct document filling.
	- Storage of sample prior to shipment pick up.			Samples should know correct temperature and times of storage of relevant sample types.
	- Sample packaging for transportation.			Staff should be able to describe or demonstrate triple packaging methods, paperwork should be separated from samples.
HR.7	**Cholera RDTs,** Specific to the brand in use at the time of visit.			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera RDT currently in use in the laboratory.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Correct use of APW.			"NA" if APW is not used for RDT testing method.
	- Interpretation of cholera RDTs, including appropriate reading of QC line.			Staff must state they read the control line before reporting the test result and understand next steps if control line is not present.
	- Correct reporting of RDT results.			Reporting must be clear that the RDT was positive, but not report as if VC is confirmed.
	- Competence of the use of available RDTs.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination. All staff performing RDT should have evidence of passing.

HR.8	**Isolation of bacteria from stool culture.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for stool culture.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Media preparation and quality assurance.			
	- Correct use of APW.			
	- Interpretation of stool culture.			
	- IQC use and interpretation for media and culture growth.			
	- Correct reporting of isolation, results.			
	- Competence of isolation bacteria from stool.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
HR.9	**Identification of bacteria from stool culture.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for all methods in use in the laboratory for the identification of VC from culture.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of tests used for identification of VC from culture.			
	- IQC use and interpretation for all identification methods in use.			
	- Competence on all tests used for the identification of Vibrio cholerae.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of identification results.			
HR.10	**AST testing of cholera isolates.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera AST.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of cholera AST with reference to appropriate current standards.			Staff should have access to and understand r appropriate reference standard when interpreting results.
	- IQC use and interpretation for AST.			
	- Competence on AST methods.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of AST results.			
HR.11	**Molecular methods,** this includes, rapid molecular tests, PCR, qPCR and other NAAT tests for identification of cholera sp. or Vibrio cholera identification, but not sequencing methods.			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera molecular methods, this should cover, extraction, master mix, amplification methods.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of molecular method.			Staff should understand what the primer targets are in relation to cholera identification, serotype and toxigenicity.
	- IQC use and interpretation for all molecular methods in			Internal controls, extract action controls, amplification controls etc
	- Competence on all molecular tests used for the identification of VC.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of molecular results.			Results are reported correctly e.g. Vibrio cholera only reported when primers used allow identification, not only genus level detection.
HR.12	**Sequencing methods.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera sequencing methods.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Bioinformatic pipelines in use.			
	- Interpretation of sequencing results.			Staff should also have been trained on the interpretation of results where they are returning results from external reference laboratories.
	- IQC use and interpretation for all sequencing methods in use.			Library, amplification, contamination, bioinformatic controls.
	- Competence on all sequencing methods used.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of sequencing results.			

Facilities				
#	Question	Answer	Comments	Notes for assessor
F.1	**Patient care areas** Are patient care and testing areas of the laboratory distinctly separate from one another?			Patient care areas (e.g. waiting room, collection areas should be distinctly separate from the testing areas of the laboratory. For biosafety reasons, microbiology and molecular testing should be segregated in a separate room(s) from general laboratory testing with access limited to authorised persons.
F.2	**Laboratory structure** Are all laboratory structures suitable for working? - Cleanable smooth floors. - Roofs do not leak. - Smooth cleanable walls. - No evidence of damage to electrical sockets. - Adequate drainage for sinks, autoclaves etc. - No mould or other growths. - Adequate functional lighting. - Adequate ventilation, air-conditioning, windows. - Adequate security, lockable doors and windows.			Laboratory should be free of damage and provide a safe working environment for testing. If more than 5 are not adequate, or any immediate risk to safety, then score as "No", if all are good score "Yes", all else score "Partial".
F.3	**Laboratory facilities** Is the laboratory area for cholera testing adequate in size and is layout of the laboratory and organized the space so that workstations are positioned to reduce risk, ensure optimal workflow, and prioritize occupational health?			Documentation could be in the form of a floor plan, results from internal audits and risk assessment. The assessor should visually asses the space and workflow and consider if all spaces are sufficient size, well organised, and makes sense in terms of workflow locations.
F.4	**Work environment** Is the physical work environment appropriate for testing?			Environment includes all areas associated for testing, i.e. reception, storage, testing area and data entry areas.
	- Maintained in a functional and reliable condition (e.g., housekeeping and maintenance, etc.) free of clutter and dust?			Clean, no areas have piles of stock or old equipment. Cupboards and draws are clean and organised etc.
	- Are wires and cables properly installed and protected from hazardous factors and from traffic?			"NA" if there are no equipment or computers with cables.
	- Is there a functioning back-up power supply and are there records of maintenance and equipment supported by uninterrupted power source systems?			Automatic generator with adequate fuel Solar power or other back ups which automatically start. "NA" if no testing requires cold sample/reagent storage or use of equipment , including computers/internet, that requires to be plugged in.
	- Is all equipment placed appropriately, i.e., away from water hazards, not in direct sunlight, out of busy areas?			"NA" if no testing requires cold sample/reagent storage or use of equipment , including computers/internet, that requires to be plugged in.
	- Are appropriate provisions made for adequate water supply, including deionized water or distilled water, if needed?			Partial is water is not available onsite but there is a system to access distilled water quickly and easily, such as within the facility.
	- Is clerical work performed in a designated clean area, separate from testing areas?			In small facilities or those conducting RDT this can be a designated clean area, or section of a bench as long as no testing, samples or infected products ever cross into the clean area. Testing forms returned to requester should not be in testing areas to record results. Computers used for testing should not be used for results printing etc.
	- Is safety signage posted and enforced, including “No eating, No smoking, and No drinking”?			All signs clearly posted in appropriate locations and all of them are followed, i.e. if no phones is posted staff should not be observed with their phones in that area.

F.5	**Cholera testing services** Has the laboratory provided uninterrupted services with no downtime due to power failure, water outages or other structural reason?			Interruption to testing is any test which could not be delivered due to a failure in general services such as water or power., it maybe a delay due to short term absence, a single test if the equipment cannot be powered, it doesn't have to be the shut down of the entire laboratory.
F.6	**Laboratory access** Is the laboratory/microbiology section properly secured from unauthorized access with appropriate systems and signage?			For culture and PCR this includes secured from couriers, clinical staff or other departments due to the risk levels.
F.7	**Laboratory storage areas** Is there adequate storage space under the appropriate conditions and properly labelled for the following? - Samples. - Equipment. - Reagents and consumables. - Documents and records. - Patient samples and materials used in examination processes, stored separately. - Hazardous materials and biological waste appropriate to the classification in context of any statutory or regulatory requirements. - Personnel items, food, and drinks in staff areas.			There should be effective separation to prevent contamination of reagents, samples or documentation.
F.8	**Monitoring and recording environmental conditions** Have acceptable ranges for temperatures been defined and environmental conditions monitored and recorded daily?			A document must be available with written ranges for each temperature equipment, i.e. fridges between 4-8°C or 6 ± 2°C All temperature dependant equipment and rooms should be monitored at least daily.
	- Room temperatures.			Including ALL storage areas and all areas involved with testing, e.g., server rooms.
	- Freezers (-20 and -80C).			"NA" if no samples or reagents require storage.
	- Refrigerators.			"NA" if no samples or reagents require storage.
	- Incubators.			"NA" if not present.
	- Water baths.			"NA" if not present.
F.9	**Review of environmental conditions** Is there evidence of documentation for action taken in response to unacceptable conditions?			If not all conditions are monitored then F.9 can not score higher than "Partial". Evidence of action should include immediate action to fix the immediate problem, and preventative action, to prevent reoccurrence.

Safety				
#	Question	Answer	Comments	Notes for assessor
S.1	**Laboratory safety manual** Does the laboratory have an approved safety manual?			Safety manual is accessible, and up to date at the laboratory. "Partial" if a manual is available but has not been reviewed and updated in more than 2 years
S.2	**Laboratory safety manual** Is the laboratory safety manual complete and accessible, communicated to all staff, up to date include guidelines on the following topics? - Safety policy. - Biosafety and biosecurity hazards, where appropriate. - Risk assessment and mitigation. - Biological hazards. - Hazardous waste disposal. - Chemical safety. - Vaccination for at least HepA for Stool handling. - Post-exposure prophylaxis - access to preventative vaccines and follow up health checks. - Fire prevention. - Electrical safety.			If no safety manual S1 then = "No" If manual is out of date S1 = "Partial" If manual doesn't cover all areas required for level of testing = "Partial" Ask to review the safety manual or procedures, ensure appropriate measures are in place for testing level such as instructions for: - BSC II (where appropriate) - PPE - Risk is described and mitigated - Monitoring of staff health.
S.3	**Biosafety training** Are - Laboratory staff, - Drivers/couriers, - Cleaners, trained in biosafety practices based on the safety manual, policy and procedures of the laboratory?			Yes if all, and documented, Partial if only some or no documentation but evidence of training program, No if none, No training program.
S.4	**Personnel protective equipment** Is personal protective equipment easily accessible at the workstation and utilized appropriately and consistently?			Management is responsible for providing appropriate personal protective equipment (gloves, lab coats, eye protection, etc.) in useable condition. Laboratory personnel must always utilize personal protective equipment while in the laboratory. Protective clothing should not be worn outside designated working areas.
S.5	**Safety equipment** Is standard safety equipment available, in use and maintained correctly in the laboratory?			
	- Biosafety cabinet(s).			"NA" if no BSC, BSC certification must be in date.
	- Hand-washing station.			Must be functional and stocked with soap.
	- Eye washing station.			Must be functional, in date and easily available.
	- Spill kit(s).			Must be complete, with instructions.
	- First aid kit(s).			Must be complete and items in date.
	- Fire extinguishers.			Must be maintained, in date and good pressure.
S.6	**Waste disposal separation** Is sufficient waste disposal available, separated into infectious and non-infectious waste, And sharps are handled and disposed of safely in a designated sharps containers?			Evaluate waste inside the laboratory and if appropriate collection areas.
S.7	**Waste disposal, sterilisation** Are all infectious waste autoclaved at appropriate temperatures and times, all infectious waste is incinerated after sterilisation in appropriate incinerators?			Autoclave waste cycle: 121°C at 15 psi for 30 minutes. Autoclave is cleaned after cycle and before sterilisation of any clean materials. Waste should be burnt into powder in a dedicated brick or automated hospital incinerators not in open burn pits. Visit the incineration area and confirm it is appropriately set up.

Equipment

#	Question	Answer	Comments	Notes for assessor
E.1	**Minimum cholera equipment** Does the laboratory have the minimum required equipment for the performance of cholera testing activities?			Based on the technical information section is the equipment sufficient for the laboratory to undertake the minimum cholera testing package as defined for this level of facility? If the minimum package of tests is not implemented, continue to review equipment based on the minimum package.
E.2	**Cholera testing services** Has the laboratory provided uninterrupted testing services for cholera in alignment with the minimum testing services offered at this level of the network, with no disruptions due to equipment failure in the last year?			Interruption to testing is any test which could not be delivered out of the minimum package of testing for this level of laboratory due to any missing equipment, equipment failure, power failure or internet failure, it maybe a delay due to short term outage/repair, a single test if the equipment to perform that test is absent, it doesn't have to be the shut down of the entire laboratory. Includes internet/LIMS systems, if results can not be returned within TAT. Laboratory must be able to perform the tests as per network position, if any test is missing due to missing/ broken equipment = "No" If more than 50% of tests have been disrupted in previous 6 months = "No" "Partial" if less than 50% have been disrupted, for minimal amount of time. "NA" if lab performs only RDT and has no equipment or LIS to fail.
E.3	**Laboratory equipment policy and procedures** How the laboratory will: - select equipment - purchase equipment - manage equipment - maintain equipment records - capture the minimum information on equipment label - manage defective equipment - define the equipment maintenance frequency - record the maintenance - manage obsolete equipment - track and verify completion of repairs?			Review the equipment management SOP that informs staff how equipment is managed to ensure all points are included in the procedure. If the laboratory does not select equipment there should be a description on where equipment comes from, how they review for suitability and accept/reject equipment based on suitability.
E.4	**Training, competency and authorization of equipment users** Is all equipment operated by trained, competent and authorized personnel?			If there is no training and competency program = No Authorisation can be found in SOPs, job descriptions or other similar, without documentation can only score partial.
E.5	**Equipment records** Is current equipment information available for all equipment in the laboratory including: - location of equipment - preventative maintenance checklists - maintenance, service and calibration schedule - repair records			Are records available and complete? There should be a list of all equipment with the equipment information as well as the equipment history- this may be called the "book of life" which contains installation, verification, service, maintenance, training and other records.
E.6	**Equipment manual** Are the manufacturer's operator manuals readily available to testing personnel and available in the language understood by personnel?			Ask to review several manuals for relevant equipment, e.g. Autoclave, refrigerators, molecular equipment, pipettes, microscope etc. see how long it takes to be found confirm they are in a language staff can understand.
E.7	**Equipment installation** Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked?			Review the manual for sleeted equipment and confirm it is installed correctly, this could include being out of direct sunlight, adequate ventilation, away from water, connected to UPS, correct computer and printing equipment etc.
E.8	**Equipment verification and documentation** Is all equipment checked to be functioning correctly after installation, servicing and repair before use?			Verification, checks the instrument works as expected, meets manufacturer claims, e.g. holds the correct temperature, measures the correct volume, measures the correct wavelengths etc. Lab can demonstrate this with equipment records.
E.9	**Equipment preventive maintenance** Routine user preventive maintenance is performed on **all** equipment according to manufacturer's minimum requirements?			Preventative maintenance is all routine cleaning and repair to be done by the laboratory as per the equipment manual. check charts match what is specified in the manual, confirm activity is performed and recorded with no unaccounted gaps based on the schedule in the manual includes pipettes and microscope.
E.10	**Equipment service maintenance** Is equipment routinely serviced according to a schedule as per the minimum manufacturer's recommendations by approved internal or external service providers and is this information documented in appropriate logs?			Service maintenance is performed by qualified engineers, on the schedule as per the equipment manual. Confirm activity is performed and recorded with no unaccounted gaps based on the manual, includes pipettes and microscope. Facilities might have service agreements with companies to maintain equipment, this must remain in compliance with manufacturer.
E.11	**Broken equipment** All equipment is functional, if not it is clearly labelled as out of use?			If there is no equipment currently out of service the laboratory should have a policy on how they would manage this situation to ensure broken equipment is not used for testing.

Inventory				
#	Question	Answer	Comments	Notes for assessor
I.1	**Access to cholera materials** Does the laboratory have all materials and reagents necessary for the performance of cholera testing activities based on an approved reagent list?			Includes all reagents and consumables used to manage the minimum cholera testing package the laboratory is tasked to perform, from collection to waste disposal and results reporting etc. If the laboratory does not perform the minimum test package based on the facility level, then score this as a "No" If country doesn't have an approved reagent list = "partial"
I.2	**Cholera testing services** Has the laboratory provided uninterrupted cholera testing services, with no disruptions due to stock-outs in the last year?			Interruption to testing is any test which could not be delivered out of the minimum package of testing for this level of laboratory due to any missing reagents, expired stock or damaged reagents. This can be a single test, such as one antibiotic, it doesn't have to be the shut down all testing. Laboratory must be able to perform the tests as per network position, if any test is unable to be provided = "No" If more than 50% of tests have been disrupted in previous 6 months = "No" "Partial" if less than 50% have been disrupted, for minimal amount of time.
I.3	**Purchasing and inventory control of cholera equipment, reagents, and consumables** Has the laboratory defined a procedure and/or process that addresses, the following? - Requisition, ordering and receipt of stock items - Establishment of acceptance and rejection criteria for stock items - Acceptance testing - Storage of stock items - Management of inventory - Monitoring and handling of expired items.			Defines how the laboratory ensures quality reagents are purchased or received into the facility. If laboratory does not make purchasing choices they still must have a procedure to order stock, check they receive what is ordered in good condition. Is there a procedure/SOP which covers all of these items? All need to be "Yes" to answer "Yes", If some items are in place answer "Partial". If all "No", then answer "No".
I.4	**Inventory records** Do laboratory records contain the minimum criteria for accurate monitoring of inventory? - Identity of the reagent or consumable - Batch code or lot number - Manufacturer or supplier name and contact information - Received date, expiration date, date of entry into service and date material was taken out of service, where applicable - Manufacturer's instruction/package insert - Records of inspection of reagents and consumables when received for expiration or damage.			Review the stock system, cards or electronically to ensure all criteria can be captured. All = "Yes" more than 50% = "Partial" Less than 50% = "No"
I.5	**Laboratory inventory system** Does the laboratory continually monitor stock in the laboratory through routine stock counts, and update when items are put into use so that the inventory log is complete for all cholera testing materials? - Are inventory records complete and accurate with minimum and maximum stock levels denoted and monitored? - Is the consumption rate of all reagents and consumables monitored? - Are inventory/stock counts routinely performed?			Check the current inventory records against the The laboratory inventory system should reliably inform personnel of the minimum amount of stock to be kept to avoid interruptions of service due to stockouts and the maximum amount to be kept by the laboratory to prevent expiry of reagents.

I.6	**Storage area - reagents** Are storage areas where reagents and consumables are stored set up and monitored appropriately? - Is the storage area well organized and free of clutter to prevent damage and deterioration? - Are there designated places for all inventory items for easy access - Is adequate cold storage available? - Is the temperature of the room monitored routinely? - Is storage in direct sunlight avoided? - Is the storage area adequately ventilated? - Is the storage area clean and free of dust and pests? - Are storage areas access controlled?			Storage areas include the lab store, pharmacy, hospital as well as local storage in microbiology or other areas where laboratory reagents are stored. Reagents should be separated from samples or isolates. Includes the storage of media and regents made at the facility
I.7	**Inventory use** Is First-Expiration-First-Out practiced?			FEFO - shortest expiration dates are used first.
I.8	**Product expiration** Are all cholera reagents/test kits in stock and /or in use currently within the manufacturer-assigned expiration or within stability?			Includes locally produced media, controls etc. Within stability refers to products which stability is based on the opening date as well as expiration date, e.g. within 30 days of opening.
I.9	**Storage area - samples, isolates, DNA etc.** Are storage areas where cholera samples, and materials derived from patient materials are stored set up and monitored appropriately? - Is the storage area well organized and free of clutter to prevent damage and deterioration? - Is adequate cold storage available? - Is the temperature monitored routinely? - Is storage in direct sunlight avoided? - Are storage areas access controlled?			Reagents should be separated from samples or isolates. Includes storage of materials in refrigerators and freezers.
I.10	**Material Biobanking** Are all stored materials derived from patient samples stored and inventoried appropriately?			Includes: - Isolates - DNA - Amplicons "Na" if Laboratory does not store any of the above. Check fridges and freezer storage to make sure this is true. Records should allow tracing back to original patient samples. Laboratory should have a detailed inventory of all stored materials.

	Testing Pre-analytical			
#	Question	Answer	Comments	Notes for assessor
TP.1	**Client information** Has the laboratory defined a procedure and/or process which has been communicated to all sites collecting samples? .			This is often found in a client handbook or information distributed to clinical staff or patients. The laboratory receiving samples is responsible for supporting collection staff providing instructions and feedback.
	- Location(s) of the laboratory, operating hours, and contact information.			
	- Instructions for pre-collection activities.			e.g. before antibiotic therapy has been initiated.
	- Procedures for requesting and collection of patient samples.			
	- Instructions for collection activities (including sample types, volume, etc.).			Meeting minimum requirements: https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Preparation and storage conditions and timings prior to dispatch to the laboratory.			Meeting minimum requirements based on the sample type. https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Transportation requirements, triple packaging, temperature etc.			Meeting minimum requirements based on the sample type. https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Scope of laboratory activities and time for expected laboratory results.			Which tests are performed, which are sent for referral and where.
	- Time limits and special handling of patient samples.			Meeting minimum requirements: https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Patient sample acceptance and rejection criteria.			All criteria relevant to samples and tests must be documented i.e. '- incorrect sample type/volume for test - sample leakage or contamination - incorrect sample conservation - missing documentation - antibiotics - Extended storage, or out of temperature range.
TP.2	**Sample collection** Does the laboratory, or local facility collect samples correctly and/or is there evidence that laboratory reviews samples and provides feedback to collection sites?			"Na" is sample collection staff can't be addressed.
	- Verification of the identity of the patient from whom a primary sample is collected.			"Na" if samples are collected off-site. If samples collected locally and in doubt of correct procedures try to ask collection staff, or visit clinical collection area.
	- Previous test results are recorded on the request form correctly.			RDT results performed are recorded, "Na" if RDTs are not available to requester.
	- Collection of primary samples, with descriptions of the primary sample containers and any necessary additives.			"Na" if samples are collected off-site. Documented on the request form and/or reception log and/or testing department records.
	- Labelling of primary samples in a manner that provides an unequivocal link with the patient from whom they Are collected - must match the request form.			Patient name alone is not sufficient.
	- Stabilization and proper storage conditions before collected samples are delivered to the laboratory.			"Na" if done off-site and unable to check, e.g. Temperature, out of direct sunlight, drying filter papers etc No if obviously delivered in poor condition.
	- Safe disposal of materials used in the sample collection process.			"Na" if done off-site and unable to check.
TP.3	**Test request** Does the laboratory use the national test request form and adequately collect information needed for examination performance?			The request form should at minimum have space to record all the below, Can not be Yes if a field is not available Review the cholera test request form, and check several examples for completeness of the fields.
	- Are all test requests accompanied by national approved test requisition?			
	- Does the request include patient identifiers, including gender, date of birth, location of patient and unique identifier?			
	- Name, initials/signature of authorized requester is recorded?			
	- Type of sample and examination requested?			
	- Clinically relevant information?			Such as antibiotic start, suspected cholera case etc.

	- Date of sample collection (may include time where appropriate)?			
	- Date and time of sample receipt?			To be completed by the reception.
TP.4	**Test request algorithm** Is testing available, requested and performed appropriately, in-line with national guidance?			Confirm the laboratory has a copy of the national guidelines for test requests and that tests are ordered inline with the guidelines. This includes not doing requested tests if outside of protocol.
TP.5	**Referral facilities** Is there a list of facilities which send samples/isolates for testing to this facility. The list should include contact details for results return? (referral in).			"Na" if no samples referred from other sites to this facility.
TP.6	**Referral feedback** Is there a protocol available detailing how feedback on samples, such as rejections or requests for further information are communicated to the requester?			"Na" if no samples referred from other sites to this facility.
TP.7	**Sample reception** Does the laboratory implement the sample receipt procedures and are there records of implementation of the following:			
	- Unique patient identifier is assigned on arrival to reception?			Assigned by the laboratory or information system, this ID should not repeat each month, e.g. using numbers 1,2,3.
	- Are received samples evaluated according to acceptance and rejection criteria?			Review acceptance/rejection logs - record main reasons for rejection, or improper samples which arrive to the laboratory.
	- is there evidence of feedback to requesters when criteria are not met?			Check call logs, results reported etc.
	- Are time and data recorded for sample reception as appropriate?			Time is relevant to specific samples, date may be sufficient for other sample types.
	- Are samples logged appropriately upon receipt in the laboratory?			Must include date of receipt, time of receipt, and name of receiving personnel. Details in laboratory match the request form.
	- Are samples delivered to the correct workstations as per the laboratory processes?			Do samples go directly to microbiology/ testing area without delay so testing can be performed within time restrictions.
TP.8	**Procedure for referral laboratories** Has the laboratory defined a procedure and/or process for sample/isolate referral? (referral out).			"Na" if no samples referred.
TP.9	**Sample/ isolate referral** Is there a list of referral laboratories with contact details available? (referral out).			"Na" if no samples referred.
TP.10	**Sample/ isolate referral tracking** Are referred samples/isolates tracked properly using a logbook, tracking form or electronically from shipment to results return so that TAT can be calculated? (referral out).			"Na" if no samples referred.
TP.11	**Transportation** Are samples which are sent to an external laboratory from this lab packaged correctly following national guidelines? (referral out).			"Na" if lab does not refer any samples, and does not receive any samples.
	- Samples transport SOP is available, complete and evidence of staff training?			Confirm the SOP has all needed information and staff are trained on referral methods.
	- Request forms/shipping list is provided, packed inside the main package, but separate from samples to avoid contamination?			Confirm lab has a copy of the regulations, if no samples are being sent/received at time of audit ask open ended questions to determine if the guidelines are implemented.
	- Are previous results of tests provided, such as RDT			
	- Are samples collected and transported within acceptable timeframe and temperature intervals?			Shipment at ambient temperature, timeframe bads on sample type and testing - Review transport logs, sample collection times, lab receipt times to confirm.
	- The name of the organism is **not** written on outside of packaging.			
	- When specimens are transported internationally, is the packaging and transportation in full compliance with international (e.g., IATA) regulations?			Reference laboratories only, else "Na".

Analytical Cholera Testing

#	Question	Answer	Comments	Notes for assessor
TA.1	**RDT test kits** Does laboratory use approved or validated VC RDTs for testing?			Approve RDTs include --> Crystal VC O1/O139, SD Bioline O1/O139 If other tests, then ask for validation and verification results and acceptance (this may need to be confirmed with cholera program).
TA.2	**RDT testing** Are current VC RDTs being performed correctly with adequate controls?			Fill all as Na if facility does not perform RDT's
	- Does laboratory have a timer available for performance of VC RDTs.			
	- Does laboratory perform RDTs with samples types as recommended by the manufacturer?			Sample types only: Fresh stool, Stool or rectal swab in APW, NOT direct rectal swab or using Cary Blair
	- Does laboratory have appropriate temperature monitoring of samples and reagents used for VC RDT testing?			This includes room temperatures, storage area temperatures, samples should not be stored in a fridge, in direct sunlight or other condition which could impact results.
	- Where pre-incubation in APW is carried out, is the incubation time (4-6 hrs) and temperature (37°C) correctly observed?			Fill as Na if facility does not use APW for RDT testing.
	- Does laboratory have an SOP for VC RDT testing, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the VC RDT test performed, and specific to the laboratory it is performed in?			The SOP should refer to laboratory specific requirements such as the RDT brand in use with correct timings.
	- Does laboratory perform new batch verification on current RDTs.			At least 1 test compared to old batch when opening a new kit.
	- Does the laboratory record the acceptance of VC RDT control line before reporting patient results? .			
TA.3	**Media preparation** Does the laboratory prepare media and/ or biochemical reagents for growth and identification correctly? .			If laboratory buys media premade appropriate controls must still be documented (B.19) Media = plates, slants, liquid, broth, transport or other growth methods. Biochemical reagents include oxidase, stains locally made.
	- Does laboratory have an SOP for media and reagent preparation, storage and QA, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the VC media preparation, and specific to the laboratory it is performed in?			SOP should include recipes, instructions to calculate based on volume, cooking instructions, how to perform QA, links to record sheets, storage conditions etc.
	Are controls always used, recorded and monitored when making media and reagents for sterility and correct biochemical properties?			QA should be done with characterised control strains. Must include appropriate biochemical reactions - TCBS, colour change due to sucrose fermentation by vibrio, Vibrio chrome - *Vibrio cholerae* strong growth/purple, *Vibrio parahaemolyticus* - strong growth/ blue-green colour. No growth of *E.coli* when plated on selective media etc.
	Are records kept showing: - Adherence to the recipe - Ph adjustment - Autoclave date - QA results - Expiration date - Storage conditions - Disposal of expired media .			This can be in a media log book, or individual sheets per batch of reagents as long as information is captured and can be traced back to test results.
	Are materials stored at the correct temperature for the correct length of time?			As per the manufacturer instructions.
	Are media plates poured correctly? - Uniform depth - Level .			Check plates available in the laboratory at time of visit. Also confirm no old plates are still available for testing.

TA.4	**Bacterial isolation** Does the laboratory currently perform bacterial culture and isolation correctly with adequate controls?			Fill all as Na if facility does not perform bacterial isolation. Bacterial isolation includes all steps required to isolate a pure culture of bacteria for further identification.
	- Does laboratory have an SOP for culture methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the culture methods performed and specific to the laboratory it is performed in?			Describes all methods, from media preparation, sample examination, enrichment, culture, subculture, controls, results reporting colony appearance etc.
	- Does laboratory perform couture from the correct sample types?			Stool or rectal swabs in carry Blair or APW, wet filter paper, Not dry filter paper.
	- Where pre-incubation in APW is carried out, is the incubation time (4-6 hrs) and temperature (37°C) correctly observed?			Fill as Na if facility does not use APW for RDT testing.
	- Does laboratory use appropriate media for culture of bacteria from stool samples? (Non-selective and selective for vibrio).			selective media = TCBS, Vibrio chrome or TTGA non-selective = MH, BHI, TSA etc.
	- Does laboratory have access to ATCC strains (or documented, well characterised strains), and appropriate storage methods to maintain them?			Including storage, and SOPs for regular subculture and maintenance of strains. Strains to be stored at least at -20°C.
	- Does the laboratory incubate cultures for correct time period (18-24 hrs) at the correct temperature (37°C)?			
TA.5	**Bacterial identification** Does laboratory perform identification of VC tests using adequate identification methods and controls?			Fill all as Na if facility does not perform bacterial identification. Bacterial identification includes all steps post pure culture, all biochemical and serological methods to confirm Vc
	- Does laboratory have an SOP for all identification methods performed, which is readily available in the testing area and in a language all testing staff understand?			SOP should describe appearance of suspected cholera isolates and decision tree for identification.
	- Are the testing methods described in the SOP accurate for the identification methods performed and specific to the laboratory it is performed in?			Are the method SOPs correct for the tests performed in the laboratory, with appropriate controls, and materials.
	- Does laboratory select appropriate strains for identification based on initial growth indicators?			"Na" for automated or semi-automated identification where ID is automatically performed from original samples.
	- Are appropriate positive and negative controls always used, recorded and monitored for all identification methods such as microscopy, API, agglutination, automated, MALDI-TOF systems etc.?			Look for evidence of controls - e.g. Positive and negative oxidase and gram stains, calibration standards and database control for MALDI-TOF etc.
TA.6	**Phenotypic bacterial identification - Species** Does laboratory use sufficient testing to accurately determine the vibrio species before reporting as *vibrio cholerae O1 or O139?*			Does the lab do isolate on selective media and do appropriate controls and perform agglutination following accurate methods?
TA.7	**Phenotypic bacterial identification - Serotype** Does laboratory use sufficient testing to accurately determine the VC serotype (Inaba or Ogawa).			Does the lab do appropriate controls and perform agglutination tests for Inaba/Ogawa following accurate methods?

TA.8	**Phenotypic AST testing** Does the laboratory currently perform bacterial AST correctly with adequate controls?			Initial > Erythromycin (EM), *S. Aureus* Initial > Pefloxacin (PEF), *E.coli* Initial > Tetracycline (TE), *E.coli* Confirm > Azithromycin (AZ) S. Aureus Confirm > Ciprofloxacin *E.coli* Confirm > Doxycycline *E.coli* Additional antibiotics must also be appropriately controlled
	- Does laboratory have an SOP for AST methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the identification methods performed and specific to the laboratory it is performed in?			SOP should describe correct preparation of pure isolates, suspension of colonies, controls and use of antibiotics.
	- Does laboratory use fresh, clearly defined isolates for AST testing?			"Na" for automated or semi-automated identification where AST is automatically performed from original samples.
	- Does laboratory use turbidity or other method to correctly inoculate AST cultures?			"Na" for automated or semi-automated identification where AST is automatically performed from original samples.
	- Does the laboratory have adequate antibiotics available, which are stored appropriately and dispensed using a dispenser or good ascetic techniques?			Lab must have all antibiotics they list as testing in stock, in date, stored correctly both before and after opening. Tweezers, burner or dispenser available to score "Yes"
	- Does the laboratory follow GTFCC guidelines, conducting initial testing with at least Erythromycin, Pefloxacin and Tetracycline?			Initial > Erythromycin (EM), (15 mg) Initial > Pefloxacin (PEF), (5 µg) Initial > Tetracycline (TE), (30 µg).
	- Does the laboratory follow GTFCC guidelines, conducting confirmatory testing with Azithromycin, Ciprofloxacin, Doxycycline?			Confirm > Azithromycin(AZ) - MIC measurement for AZ and CIP is not required for case management but is recommended for epidemiological surveillance of the strains Confirm > Ciprofloxacin (CIP) - If resistant to Na, the isolate should be tested for susceptibility to CIP by MIC measurement Confirm > Doxycycline (DO - if TE resistant, doxycycline must be tested individually by MIC measurement.).
	- Does the laboratory incubate cultures for correct time period (18-24hrs) at the correct temperature (37°C)*?			*or other appropriate times and temperatures if using automated methods.
	- Does laboratory have appropriate ATCC strains for controls in AST?			*well characterised strains can also be used, with good documentation. Without documentation = partial.
	- Are control strains run with every batch of AST testing?			
	- Does the laboratory have appropriate standards for AST interpretation, with access to newest standards?			Both Eucast and CLSI must be referenced
	- Does laboratory have access to measuring devices for AST results recording?			Ruler with mm, Automated equipment etc.

TA.9	**Molecular testing** Does the laboratory currently perform molecular methods for cholera species and/or subtype identification correctly with adequate controls?			This could be any rapid or conventional molecular method used to amplify and identify Vibrio, VC and or subtypes.
	- Does laboratory have an SOP for molecular methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the molecular methods performed and specific to the laboratory it is performed in?			SOP should describe correct preparation of samples, extraction, master mix - primers used, recipe etc., PCR method (number of cycles, temperature), Controls and methods used to interpret including any cut off values.
	- Does the laboratory have adequate space and separation to perform extraction, reagent preparation and amplification in a manner which minimalizes contamination?			For conventional PCR 3 rooms are required with no backflow. For rapid molecular tests, refer to instructions.
	- Are extraction and amplification controls included in every batch of tests, are control results reviewed prior to test result release?			"Na" if rapid molecular tests contain internal processing controls.
	- Does laboratory have adequate storage for isolates, and nucleic acids before and after testing, which includes a detailed archive of stored samples?			storage at least at -20˚C. Lab must be able to quickly find the location of any requested stored sample through a documentation system.
TA.10	**Genotypic bacterial identification - Species** Do molecular tests have targets to specifically detect VC before reporting as cholera?			Appropriate targets: ompW hlyA 16S rRNa.
TA.11	**Genotypic Bacterial identification - Serotype** Do molecular tests have targets to accurately determine the vibrio cholerae serotype before reporting serotype?			wbe gene for O1 and the wbf gene for O139, .
TA.12	**Genotypic Bacterial identification - Toxigenicity** Do molecular tests have targets to accurately determine toxigenic vibrio cholerae before reporting as toxigenic?			Appropriate targets: ctxA; ctxB; tcpA; rstR; rtxC.
TA.13	**Sequencing testing** Does the laboratory currently perform NGS correctly with adequate controls and have sufficient bioinformatic materials available?			Includes any sequencing methodology.
	- Does laboratory have an SOP for sequencing methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Have the sequencing and the bioinformatic methods been validated and approved for use by the laboratory, cholera program and/or regulatory body?			
	- Are the testing methods described in the SOP accurate for the sequencing methods performed and specific to the laboratory it is performed in?			
	- Does the laboratory have adequate space and separation to perform library preparation and sequencing which minimalizes contamination?			separated rooms, with no backflow.
	- Are libraries quality checked prior to sequencing?			
	- Are sequencing controls available, implemented and reviewed prior to results interpretation?			
	- Are appropriate bioinformatic pipelines available and followed?			

TA.14	Quality control and quality assurance Does the laboratory document and plan all quality assurance procedures, and they are sufficient to control all cholera tests performed by the laboratory. How the laboratory will: - use IQC and EQA (Interlaboratory comparison) - define the frequency of processing IQC - define the acceptable ranges - valuate and monitor laboratory performance using EQA and IQC data - troubleshoot unacceptable EQA and IQC.			Review process SOPs for internal control instructions to determine IQC and frequency. EQA is any external program, international, National or interlaboratory comparisons IQC are all controls the laboratory runs during testing e.g. media sterility, RDT control lines, ATCC strains used for AST, positive controls for agglutination etc.
TA.15	**Corrective actions** Is corrective action taken and documented when quality control results fall outside the acceptable range and reviews identify nonconformities in a timely manner?			If quality control is not in place for all methods, TA.15 can only score as "Partial". RDT controls include verification using a previous positive when opening new kits. Corrective actions include, repeating tests, remaking media, opening new kits, informing clinical staff etc Documentation could be as non-conformity reports, corrective actions, meeting minutes, letters to clinical staff etc.
TA.16	**Monitoring** Are quality control results monitored and reviewed to assess the performance of the method and/or identify errors over time for quantitative tests?			The laboratory should have evidence of periodic review looking for trends or repetitive failures as well as the actions taken. This goes beyond immediate action of repeating a test, or remaking media and should be done at least yearly.
TA.17	**Participation in external quality assessment (EQA)** Does the laboratory participate in EQA or alternatives for any microbiology tests?			This is applicable even if country does not yet have a scheme, "Yes" they are currently enrolled, "No" they are not.
TA.18	**If yes,** last 3 EQA schemes results have been reviewed and action taken to improve.			If TA.17 = "No", then score as "No" "Partial" if action was taken but was incorrect or unmonitored, and did not resolve the issue. Actions can include, review of results released since previous EQA pass event, recall of results, investigation to the cause, retraining of staff etc.

Post-Analytical Cholera Testing.

#	Question	Answer	Comments	Notes for assessor
TPA.1	**Procedure and/or process for reporting and release of cholera results** Has the national surveillance and reporting policy been communicated and implemented to testing facilities?			Review the policy and procedure documentation for results release, this could be an individual policy or within the testing SOP, ensure they align with country and cholera minimal requirements.
	- Defining report formats and frequency based on the current outbreak status.			Policy or procedures documenting how cholera results will be reported, Including if It is electronic or paper based, fields and how to complete.
	- Reviewing of patient results authorization.			Who is authorised to review, finalise test results, and is there evidence that this is done, at least 2 people, the person doing the test, and a second person should ensure results are accurate.
	- Communication of alert, urgent and critical patient results (confirmed case 24hr).			Confirmed positives results are reported to relevant surveillance program as soon as possible.
	- Release of results and reports by authorized persons.			Who is authorised to release results, is there a final check that the correct result is sent to the correct places.
	- Reporting of results performed by a referral laboratory.			How results from a referral lab will be reported, this would document if results are directly returned by the testing lab.
	- Deadlines for reporting.			How long are results retained for does it match the policy and are they archived correctly? Ask staff for results within the archive period to confirm.
TPA.2	**Cholera test result reporting system** Are results for all tests completed unambiguously, clearly marked to show which result, from which test type?			Review the results reports and track the result back through the test log books to sample receipt confirming correct results are lined to the correct person.
TPA.3	**Validation of cholera test result** Are test results validated, interpreted and released by appropriately authorized personnel?			Review the evidence that results are interpreted and released by the authorised persons in the policy. This could be a second signature or stamp. Comments on the forms, review of indeterminate or contradictory results etc.
TPA.4	**Cholera reporting requirements** Does the laboratory report align with national cholera reporting guidelines and contain at least the following:.			Review the results reports forms to ensure they contain all of the below, and that they are routinely completed with no gaps.
	- Clear, unambiguous identification of the tests being performed .			e.g. there is no doubt that a report of VC, is from the correct set of identification tests. Results are not just written as positive, without stating which test was positive.
	- Identification of the laboratory issuing the report.			
	- Patient identification, location, date of primary sample collection (and time, relevant to patient care).			
	- Name of the requester.			
	- Type of primary sample and any specific information necessary to describe the sample (e.g. Macroscopic description).			Must be clear if stool or swab, if any transport media or enrichment was used .
	- Identification of the person(s) reviewing and authorizing the release of the report.			The name/position of persons reviewing and releasing report should be indicated .
	- Date and time of the report.			Time, depends on test, sample type requested.
TPA.5	**Cholera reporting** Does the laboratory send one copy of the lab report, both positive and negative, to the clinical team and a duplicate copy to the surveillance team within 24 hours of a positive identification, or 7 days of all negatives following any mandated aggregate reporting formats?			Check where/how old test results are stored. Laboratory should be able to find the result of a case selected in random from previous 3 months.
TPA.6	**Cholera quality indicators** Does the laboratory perform basic statistical analysis on key performance indicators for cholera/bacteriological testing performed and use this to improve testing?			Are quality indicators selected to cover pre-examination, examination, and post-examination processes e.g., turnaround times, rejected samples, stock-outs, etc- routinely monitored and used.
TPA.7	**Surveillance** Does the laboratory report other alert organisms identified during culture procedures?			If pathogenic reportable bacteria are found during cholera testing are they documented and reported to the clinical staff requesting testing and/or appropriate surveillance departments?

GLOBAL TASK FORCE ON
CHOLERA CONTROL

Management Documentation

#	Question	Answer	Comments	Notes for assessor
M.1	**Laboratory legal entity** Does the laboratory have the legal recognition from the country with an agreed mandate and terms of reference to perform it's roles?			A legal entity has formal documentation and recognition from the government that they are entitled to perform the tests and roles which they do.
M.2	**Budget for cholera activities** Is there adequate budget assigned to all laboratory cholera activities?			Budget can be assigned from cholera program, facility budget, from customer payment, research activities, NGO support or other.
	'- Is there an adequate budget assigned for consumable and reagent purchase related to cholera response?			Budget may only be controlled at national level for major items such as bulk reagents, staff salaries and training, but the laboratory/facility should have some assigned budget to compliment activities. This budget should be forecast and planned with the laboratory/facility management, tracked and accounts kept.
	'- Is there an adequate budget assigned for staff and staff training related to cholera response?			
	'- Is there an adequate budget assigned for facility maintenance and equipment purchase/maintenance related to cholera response?			
	'- Is there an adequate budget assigned for cholera surveillance?			
M.3	**Laboratory cholera plan** Is there an available and adequate laboratory strategic plan for cholera diagnostic and surveillance?			Review the plan and confirm it conforms to the national cholera plan, and provides adequate information for the lab to implement all relevant activities to support cholera testing.
M.4	**Minimum package of services** Does the laboratory provide the minimum package of services according to the facility levels aligned with the National cholera plan.			Peripheral - RDTs and referral District - Isolation and referral Regional - Culture, identification, AST National - Culture, identification, AST, molecular, Sequencing or referral for sequencing.
M.5	**Laboratory contingency plan** Does the laboratory have a contingency plan which includes policy and procedures to ensure that there are no interruption to services due to the following: - Utility failures - power, water and/or internet. - HR shortages, when staff are sick, on leave or unable to reach the faculty due to local conflict or environmental disruption such as flooding. - Equipment failure, this includes auxiliary equipment such as autoclaves, incinerators, refrigerators and freezers. - Sample transport failures, Cars are out of service, lack of drivers or changes to schedules etc. - Reagent failures, out of stock, out of date or batches failing verification QC at any time during use. - Local conflict based on local risk - Natural disasters - flooding, earthquakes based on the local risk			A contingency plan covers all eventualities which could impact services at the laboratory. The laboratory should conduct a risk analysis specific for their setting to determine what are the potential causes of disruption, both within and external to the laboratory Contingency plan should be clearly documented and appropriate to avoid long delays or being unable to perform and report accurate results.
M.6	**Laboratory quality system** Is there a current quality manual or equivalent, that details all aspects of the laboratory management system policies and objectives which has been communicated and understood by all personnel? - Description of the quality management system and the structure of its documentation - References policy and procedures for both managerial and technical activities covering all aspects of laboratory operations - Description of the roles and responsibilities of the laboratory manager, quality manager, safety officer and other key personnel - An organisational plan is available and shows all current positions their relationships - Evidence that this quality manual/ equivalent was communicated to internal and external persons.			A document must be available that summarizes the laboratory's quality management system, which includes policies that address all areas of the laboratory service and identifies the goals and objectives of the quality system. Documents can be paper based or electronic, or a combination or both, but must meet the requirements.

Workforce				
#	Question	Answer	Comments	Notes for assessor
HR.1	**Staff levels** Is the staff sufficient to cover daily microbiology/cholera activities.			Based on "General Lab information section, is the staff sufficient to cover all roles for collection, referral packaging, transport, testing, results return, reporting to cholera program.
HR.2	**HR planning**			Organogram must include:
HR.3	**Cholera testing services** Has the laboratory provided uninterrupted testing services for cholera, with no disruptions due to HR shortages in the 6 months?			Interruption to testing is any test which could not be delivered due to staff shortages, it maybe a delay due to short term absence, a single test if the person who can do that test is absent, it doesn't have to be the shut down of the entire laboratory.
HR.4	**Documentation of staff training and competency policy and procedures** How the laboratory will: - perform staff orientation to the laboratory or department, - conduct initial and refresher training, - provide a continuous education program, - identify required training relevant to job title and responsibilities, - keep record of training, - evaluate the effectiveness of training, - assess the competence of personnel to perform all tasks, - establish competency criteria, - schedule of retraining based on competency outcomes, - keep records of competency for all staff.			The entire staff training program should be documented. This could be the laboratory plan, or a higher national schedule of training that staff are enrolled in. Policy should include how records will be maintained. Which training is mandatory at for each job role the system for monitoring and recording competency, including timeframe and clear pass/fail criteria. Competence can be demonstrated through examinations, direct observation, modification of EQA program, review of IQC etc. competence must be performed on a defined schedule with all staff demonstrating competence on all laboratory activities within last 2 years.
HR.5	**Management training** Is there a training program for specialised laboratory roles in place, with documented evidence of completion and competence for the following positions.			This is not assessing the suitability of the training, only that the program has one in place and all staff, in these rolls are enrolled or have completed it with certification, refreshers continuous education. This should be different to the training technicians undertake. If nobody fills this role, mark as "No"
	Laboratory manager.			Laboratory manager can also mean, responsible, director or other title, who does the role of manager.
	Inventory/store manager.			The store manager training should include specific laboratory knowledge, such as chemical safety, storage temperatures etc. Otherwise score partial.
	Quality officer.			This could be part of a separate unit, but if they are responsible for the quality in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Safety officer.			This could be part of a separate unit, but if they are responsible for the safety in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Technical training			
HR.6	**Patient identification, samples collection and transportation.**			"Na" if samples not collected on site. To be asked to persons responsible for collection and persons responsible for packaging of samples for shipment, this may be separate people. The laboratory may also be responsible for sample shipment without sample collection.
	- Patient identification based on country algorithm.			Staff have been trained on the cholera testing algorithms and know the difference between the 2 scenario, looking for the first case and outbreak response.
	- Completion of request forms.			Staff should be able to demonstrate correct document filling.
	- Storage of sample prior to shipment pick up.			Samples should know correct temperature and times of storage of relevant sample types.
	- Sample packaging for transportation.			Staff should be able to describe or demonstrate triple packaging methods, paperwork should be separated from samples.
HR.7	**Cholera RDTs,** Specific to the brand in use at the time of visit.			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera RDT currently in use in the laboratory.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Correct use of APW.			"NA" if APW is not used for RDT testing method.
	- Interpretation of cholera RDTs, including appropriate reading of QC line.			Staff must state they read the control line before reporting the test result and understand next steps if control line is not present.
	- Correct reporting of RDT results.			Reporting must be clear that the RDT was positive, but not report as if VC is confirmed.
	- Competence of the use of available RDTs.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination. All staff performing RDT should have evidence of passing.

HR.8	**Isolation of bacteria from stool culture.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for stool culture.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Media preparation and quality assurance.			
	- Correct use of APW.			
	- Interpretation of stool culture.			
	- IQC use and interpretation for media and culture growth.			
	- Correct reporting of isolation, results.			
	- Competence of isolation bacteria from stool.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
HR.9	**Identification of bacteria from stool culture.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for all methods in use in the laboratory for the identification of VC from culture.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of tests used for identification of VC from culture.			
	- IQC use and interpretation for all identification methods in use.			
	- Competence on all tests used for the identification of Vibrio cholerae.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of identification results.			
HR.10	**AST testing of cholera isolates.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera AST.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of cholera AST with reference to appropriate current standards.			Staff should have access to and understand r appropriate reference standard when interpreting results.
	- IQC use and interpretation for AST.			
	- Competence on AST methods.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of AST results.			
HR.11	**Molecular methods,** this includes, rapid molecular tests, PCR, qPCR and other NAAT tests for identification of cholera sp. or Vibrio cholera identification, but not sequencing methods.			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera molecular methods, this should cover, extraction, master mix, amplification methods.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Interpretation of molecular method.			Staff should understand what the primer targets are in relation to cholera identification, serotype and toxigenicity.
	- IQC use and interpretation for all molecular methods in			Internal controls, extract action controls, amplification controls etc
	- Competence on all molecular tests used for the identification of VC.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of molecular results.			Results are reported correctly e.g. Vibrio cholera only reported when primers used allow identification, not only genus level detection.
HR.12	**Sequencing methods.**			To score "Yes", training should be recorded and include all staff conducting testing and cover the minimum described here. Staff should have passed a competence test in the passed year. No staff who failed competence should be performing testing.
	- Testing methods for cholera sequencing methods.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up to date with current methods.
	- Bioinformatic pipelines in use.			
	- Interpretation of sequencing results.			Staff should also have been trained on the interpretation of results where they are returning results from external reference laboratories.
	- IQC use and interpretation for all sequencing methods in use.			Library, amplification, contamination, bioinformatic controls.
	- Competence on all sequencing methods used.			Competence should be reviewed at least yearly, using direct observation, examination, EQA, IQC review or a combination.
	- Correct reporting of sequencing results.			

Facilities				
#	Question	Answer	Comments	Notes for assessor
F.1	**Patient care areas** Are patient care and testing areas of the laboratory distinctly separate from one another?			Patient care areas (e.g. waiting room, collection areas should be distinctly separate from the testing areas of the laboratory. For biosafety reasons, microbiology and molecular testing should be segregated in a separate room(s) from general laboratory testing with access limited to authorised persons.
F.2	**Laboratory structure** Are all laboratory structures suitable for working? - Cleanable smooth floors. - Roofs do not leak. - Smooth cleanable walls. - No evidence of damage to electrical sockets. - Adequate drainage for sinks, autoclaves etc. - No mould or other growths. - Adequate functional lighting. - Adequate ventilation, air-conditioning, windows. - Adequate security, lockable doors and windows.			Laboratory should be free of damage and provide a safe working environment for testing. If more than 5 are not adequate, or any immediate risk to safety, then score as "No", if all are good score "Yes", all else score "Partial".
F.3	**Laboratory facilities** Is the laboratory area for cholera testing adequate in size and is layout of the laboratory and organized the space so that workstations are positioned to reduce risk, ensure optimal workflow, and prioritize occupational health?			Documentation could be in the form of a floor plan, results from internal audits and risk assessment. The assessor should visually asses the space and workflow and consider if all spaces are sufficient size, well organised, and makes sense in terms of workflow locations.
F.4	**Work environment** Is the physical work environment appropriate for testing?			Environment includes all areas associated for testing, i.e. reception, storage, testing area and data entry areas.
	- Maintained in a functional and reliable condition (e.g., housekeeping and maintenance, etc.) free of clutter and dust?			Clean, no areas have piles of stock or old equipment. Cupboards and draws are clean and organised etc.
	- Are wires and cables properly installed and protected from hazardous factors and from traffic?			"NA" if there are no equipment or computers with cables.
	- Is there a functioning back-up power supply and are there records of maintenance and equipment supported by uninterrupted power source systems?			Automatic generator with adequate fuel Solar power or other back ups which automatically start. "NA" if no testing requires cold sample/reagent storage or use of equipment , including computers/internet, that requires to be plugged in.
	- Is all equipment placed appropriately, i.e., away from water hazards, not in direct sunlight, out of busy areas?			"NA" if no testing requires cold sample/reagent storage or use of equipment , including computers/internet, that requires to be plugged in.
	- Are appropriate provisions made for adequate water supply, including deionized water or distilled water, if needed?			Partial is water is not available onsite but there is a system to access distilled water quickly and easily, such as within the facility.
	- Is clerical work performed in a designated clean area, separate from testing areas?			In small facilities or those conducting RDT this can be a designated clean area, or section of a bench as long as no testing, samples or infected products ever cross into the clean area. Testing forms returned to requester should not be in testing areas to record results. Computers used for testing should not be used for results printing etc.
	- Is safety signage posted and enforced, including “No eating, No smoking, and No drinking”?			All signs clearly posted in appropriate locations and all of them are followed, i.e. if no phones is posted staff should not be observed with their phones in that area.

F.5	**Cholera testing services** Has the laboratory provided uninterrupted services with no downtime due to power failure, water outages or other structural reason?			Interruption to testing is any test which could not be delivered due to a failure in general services such as water or power., it maybe a delay due to short term absence, a single test if the equipment cannot be powered, it doesn't have to be the shut down of the entire laboratory.
F.6	**Laboratory access** Is the laboratory/microbiology section properly secured from unauthorized access with appropriate systems and signage?			For culture and PCR this includes secured from couriers, clinical staff or other departments due to the risk levels.
F.7	**Laboratory storage areas** Is there adequate storage space under the appropriate conditions and properly labelled for the following? - Samples. - Equipment. - Reagents and consumables. - Documents and records. - Patient samples and materials used in examination processes, stored separately. - Hazardous materials and biological waste appropriate to the classification in context of any statutory or regulatory requirements. - Personnel items, food, and drinks in staff areas.			There should be effective separation to prevent contamination of reagents, samples or documentation.
F.8	**Monitoring and recording environmental conditions** Have acceptable ranges for temperatures been defined and environmental conditions monitored and recorded daily?			A document must be available with written ranges for each temperature equipment, i.e. fridges between 4-8°C or 6 ± 2°C All temperature dependant equipment and rooms should be monitored at least daily.
	- Room temperatures.			Including ALL storage areas and all areas involved with testing, e.g., server rooms.
	- Freezers (-20 and -80C).			"NA" if no samples or reagents require storage.
	- Refrigerators.			"NA" if no samples or reagents require storage.
	- Incubators.			"NA" if not present.
	- Water baths.			"NA" if not present.
F.9	**Review of environmental conditions** Is there evidence of documentation for action taken in response to unacceptable conditions?			If not all conditions are monitored then F.9 can not score higher than "Partial". Evidence of action should include immediate action to fix the immediate problem, and preventative action, to prevent reoccurrence.

Safety				
#	Question	Answer	Comments	Notes for assessor
S.1	**Laboratory safety manual** Does the laboratory have an approved safety manual?			Safety manual is accessible, and up to date at the laboratory. "Partial" if a manual is available but has not been reviewed and updated in more than 2 years
S.2	**Laboratory safety manual** Is the laboratory safety manual complete and accessible, communicated to all staff, up to date include guidelines on the following topics? - Safety policy. - Biosafety and biosecurity hazards, where appropriate. - Risk assessment and mitigation. - Biological hazards. - Hazardous waste disposal. - Chemical safety. - Vaccination for at least HepA for Stool handling. - Post-exposure prophylaxis - access to preventative vaccines and follow up health checks. - Fire prevention. - Electrical safety.			If no safety manual S1 then = "No" If manual is out of date S1 = "Partial" If manual doesn't cover all areas required for level of testing = "Partial" Ask to review the safety manual or procedures, ensure appropriate measures are in place for testing level such as instructions for: - BSC II (where appropriate) - PPE - Risk is described and mitigated - Monitoring of staff health.
S.3	**Biosafety training** Are - Laboratory staff, - Drivers/couriers, - Cleaners, trained in biosafety practices based on the safety manual, policy and procedures of the laboratory?			Yes if all, and documented, Partial if only some or no documentation but evidence of training program, No if none, No training program.
S.4	**Personnel protective equipment** Is personal protective equipment easily accessible at the workstation and utilized appropriately and consistently?			Management is responsible for providing appropriate personal protective equipment (gloves, lab coats, eye protection, etc.) in useable condition. Laboratory personnel must always utilize personal protective equipment while in the laboratory. Protective clothing should not be worn outside designated working areas.
S.5	**Safety equipment** Is standard safety equipment available, in use and maintained correctly in the laboratory?			
	- Biosafety cabinet(s).			"NA" if no BSC, BSC certification must be in date.
	- Hand-washing station.			Must be functional and stocked with soap.
	- Eye washing station.			Must be functional, in date and easily available.
	- Spill kit(s).			Must be complete, with instructions.
	- First aid kit(s).			Must be complete and items in date.
	- Fire extinguishers.			Must be maintained, in date and good pressure.
S.6	**Waste disposal separation** Is sufficient waste disposal available, separated into infectious and non-infectious waste, And sharps are handled and disposed of safely in a designated sharps containers?			Evaluate waste inside the laboratory and if appropriate collection areas.
S.7	**Waste disposal, sterilisation** Are all infectious waste autoclaved at appropriate temperatures and times, all infectious waste is incinerated after sterilisation in appropriate incinerators?			Autoclave waste cycle: 121°C at 15 psi for 30 minutes. Autoclave is cleaned after cycle and before sterilisation of any clean materials. Waste should be burnt into powder in a dedicated brick or automated hospital incinerators not in open burn pits. Visit the incineration area and confirm it is appropriately set up.

Equipment

#	Question	Answer	Comments	Notes for assessor
E.1	**Minimum cholera equipment** Does the laboratory have the minimum required equipment for the performance of cholera testing activities?			Based on the technical information section is the equipment sufficient for the laboratory to undertake the minimum cholera testing package as defined for this level of facility? If the minimum package of tests is not implemented, continue to review equipment based on the minimum package.
E.2	**Cholera testing services** Has the laboratory provided uninterrupted testing services for cholera in alignment with the minimum testing services offered at this level of the network, with no disruptions due to equipment failure in the last year?			Interruption to testing is any test which could not be delivered out of the minimum package of testing for this level of laboratory due to any missing equipment, equipment failure, power failure or internet failure, it maybe a delay due to short term outage/repair, a single test if the equipment to perform that test is absent, it doesn't have to be the shut down of the entire laboratory. Includes internet/LIMS systems, if results can not be returned within TAT. Laboratory must be able to perform the tests as per network position, if any test is missing due to missing/ broken equipment = "No" If more than 50% of tests have been disrupted in previous 6 months = "No" "Partial" if less than 50% have been disrupted, for minimal amount of time. "NA" if lab performs only RDT and has no equipment or LIS to fail.
E.3	**Laboratory equipment policy and procedures** How the laboratory will: - select equipment - purchase equipment - manage equipment - maintain equipment records - capture the minimum information on equipment label - manage defective equipment - define the equipment maintenance frequency - record the maintenance - manage obsolete equipment - track and verify completion of repairs?			Review the equipment management SOP that informs staff how equipment is managed to ensure all points are included in the procedure. If the laboratory does not select equipment there should be a description on where equipment comes from, how they review for suitability and accept/reject equipment based on suitability.
E.4	**Training, competency and authorization of equipment users** Is all equipment operated by trained, competent and authorized personnel?			If there is no training and competency program = No Authorisation can be found in SOPs, job descriptions or other similar, without documentation can only score partial.
E.5	**Equipment records** Is current equipment information available for all equipment in the laboratory including: - location of equipment - preventative maintenance checklists - maintenance, service and calibration schedule - repair records			Are records available and complete? There should be a list of all equipment with the equipment information as well as the equipment history- this may be called the "book of life" which contains installation, verification, service, maintenance, training and other records.
E.6	**Equipment manual** Are the manufacturer's operator manuals readily available to testing personnel and available in the language understood by personnel?			Ask to review several manuals for relevant equipment, e.g. Autoclave, refrigerators, molecular equipment, pipettes, microscope etc. see how long it takes to be found confirm they are in a language staff can understand.
E.7	**Equipment installation** Is equipment installed and placed as specified in the operator's manuals and uniquely labelled or marked?			Review the manual for sleeted equipment and confirm it is installed correctly, this could include being out of direct sunlight, adequate ventilation, away from water, connected to UPS, correct computer and printing equipment etc.
E.8	**Equipment verification and documentation** Is all equipment checked to be functioning correctly after installation, servicing and repair before use?			Verification, checks the instrument works as expected, meets manufacturer claims, e.g. holds the correct temperature, measures the correct volume, measures the correct wavelengths etc. Lab can demonstrate this with equipment records.
E.9	**Equipment preventive maintenance** Routine user preventive maintenance is performed on **all** equipment according to manufacturer's minimum requirements?			Preventative maintenance is all routine cleaning and repair to be done by the laboratory as per the equipment manual. check charts match what is specified in the manual, confirm activity is performed and recorded with no unaccounted gaps based on the schedule in the manual includes pipettes and microscope.
E.10	**Equipment service maintenance** Is equipment routinely serviced according to a schedule as per the minimum manufacturer's recommendations by approved internal or external service providers and is this information documented in appropriate logs?			Service maintenance is performed by qualified engineers, on the schedule as per the equipment manual. Confirm activity is performed and recorded with no unaccounted gaps based on the manual, includes pipettes and microscope. Facilities might have service agreements with companies to maintain equipment, this must remain in compliance with manufacturer.
E.11	**Broken equipment** All equipment is functional, if not it is clearly labelled as out of use?			If there is no equipment currently out of service the laboratory should have a policy on how they would manage this situation to ensure broken equipment is not used for testing.

Inventory				
#	Question	Answer	Comments	Notes for assessor
I.1	**Access to cholera materials** Does the laboratory have all materials and reagents necessary for the performance of cholera testing activities based on an approved reagent list?			Includes all reagents and consumables used to manage the minimum cholera testing package the laboratory is tasked to perform, from collection to waste disposal and results reporting etc. If the laboratory does not perform the minimum test package based on the facility level, then score this as a "No" If country doesn't have an approved reagent list = "partial"
I.2	**Cholera testing services** Has the laboratory provided uninterrupted cholera testing services, with no disruptions due to stock-outs in the last year?			Interruption to testing is any test which could not be delivered out of the minimum package of testing for this level of laboratory due to any missing reagents, expired stock or damaged reagents. This can be a single test, such as one antibiotic, it doesn't have to be the shut down all testing. Laboratory must be able to perform the tests as per network position, if any test is unable to be provided = "No" If more than 50% of tests have been disrupted in previous 6 months = "No" "Partial" if less than 50% have been disrupted, for minimal amount of time.
I.3	**Purchasing and inventory control of cholera equipment, reagents, and consumables** Has the laboratory defined a procedure and/or process that addresses, the following? - Requisition, ordering and receipt of stock items - Establishment of acceptance and rejection criteria for stock items - Acceptance testing - Storage of stock items - Management of inventory - Monitoring and handling of expired items.			Defines how the laboratory ensures quality reagents are purchased or received into the facility. If laboratory does not make purchasing choices they still must have a procedure to order stock, check they receive what is ordered in good condition. Is there a procedure/SOP which covers all of these items? All need to be "Yes" to answer "Yes", If some items are in place answer "Partial". If all "No", then answer "No".
I.4	**Inventory records** Do laboratory records contain the minimum criteria for accurate monitoring of inventory? - Identity of the reagent or consumable - Batch code or lot number - Manufacturer or supplier name and contact information - Received date, expiration date, date of entry into service and date material was taken out of service, where applicable - Manufacturer's instruction/package insert - Records of inspection of reagents and consumables when received for expiration or damage.			Review the stock system, cards or electronically to ensure all criteria can be captured. All = "Yes" more than 50% = "Partial" Less than 50% = "No"
I.5	**Laboratory inventory system** Does the laboratory continually monitor stock in the laboratory through routine stock counts, and update when items are put into use so that the inventory log is complete for all cholera testing materials? - Are inventory records complete and accurate with minimum and maximum stock levels denoted and monitored? - Is the consumption rate of all reagents and consumables monitored? - Are inventory/stock counts routinely performed?			Check the current inventory records against the The laboratory inventory system should reliably inform personnel of the minimum amount of stock to be kept to avoid interruptions of service due to stockouts and the maximum amount to be kept by the laboratory to prevent expiry of reagents.

I.6	**Storage area - reagents** Are storage areas where reagents and consumables are stored set up and monitored appropriately? - Is the storage area well organized and free of clutter to prevent damage and deterioration? - Are there designated places for all inventory items for easy access - Is adequate cold storage available? - Is the temperature of the room monitored routinely? - Is storage in direct sunlight avoided? - Is the storage area adequately ventilated? - Is the storage area clean and free of dust and pests? - Are storage areas access controlled?			Storage areas include the lab store, pharmacy, hospital as well as local storage in microbiology or other areas where laboratory reagents are stored. Reagents should be separated from samples or isolates. Includes the storage of media and regents made at the facility
I.7	**Inventory use** Is First-Expiration-First-Out practiced?			FEFO - shortest expiration dates are used first.
I.8	**Product expiration** Are all cholera reagents/test kits in stock and /or in use currently within the manufacturer-assigned expiration or within stability?			Includes locally produced media, controls etc. Within stability refers to products which stability is based on the opening date as well as expiration date, e.g. within 30 days of opening.
I.9	**Storage area - samples, isolates, DNA etc.** Are storage areas where cholera samples, and materials derived from patient materials are stored set up and monitored appropriately? - Is the storage area well organized and free of clutter to prevent damage and deterioration? - Is adequate cold storage available? - Is the temperature monitored routinely? - Is storage in direct sunlight avoided? - Are storage areas access controlled?			Reagents should be separated from samples or isolates. Includes storage of materials in refrigerators and freezers.
I.10	**Material Biobanking** Are all stored materials derived from patient samples stored and inventoried appropriately?			Includes: - Isolates - DNA - Amplicons "Na" if Laboratory does not store any of the above. Check fridges and freezer storage to make sure this is true. Records should allow tracing back to original patient samples. Laboratory should have a detailed inventory of all stored materials.

	Testing Pre-analytical			
#	Question	Answer	Comments	Notes for assessor
TP.1	**Client information** Has the laboratory defined a procedure and/or process which has been communicated to all sites collecting samples? .			This is often found in a client handbook or information distributed to clinical staff or patients. The laboratory receiving samples is responsible for supporting collection staff providing instructions and feedback.
	- Location(s) of the laboratory, operating hours, and contact information.			
	- Instructions for pre-collection activities.			e.g. before antibiotic therapy has been initiated.
	- Procedures for requesting and collection of patient samples.			
	- Instructions for collection activities (including sample types, volume, etc.).			Meeting minimum requirements: https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Preparation and storage conditions and timings prior to dispatch to the laboratory.			Meeting minimum requirements based on the sample type. https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Transportation requirements, triple packaging, temperature etc.			Meeting minimum requirements based on the sample type. https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Scope of laboratory activities and time for expected laboratory results.			Which tests are performed, which are sent for referral and where.
	- Time limits and special handling of patient samples.			Meeting minimum requirements: https://www.gtfcc.org/wp-content/uploads/2020/09/gtfcc-job-aid-specimen-packaging-domestic-transportation-for-laboratory-confirmation-of-vibrio-Cholerae.pdf.
	- Patient sample acceptance and rejection criteria.			All criteria relevant to samples and tests must be documented i.e. '- incorrect sample type/volume for test - sample leakage or contamination - incorrect sample conservation - missing documentation - antibiotics - Extended storage, or out of temperature range.
TP.2	**Sample collection** Does the laboratory, or local facility collect samples correctly and/or is there evidence that laboratory reviews samples and provides feedback to collection sites?			"Na" is sample collection staff can't be addressed.
	- Verification of the identity of the patient from whom a primary sample is collected.			"Na" if samples are collected off-site. If samples collected locally and in doubt of correct procedures try to ask collection staff, or visit clinical collection area.
	- Previous test results are recorded on the request form correctly.			RDT results performed are recorded, "Na" if RDTs are not available to requester.
	- Collection of primary samples, with descriptions of the primary sample containers and any necessary additives.			"Na" if samples are collected off-site. Documented on the request form and/or reception log and/or testing department records.
	- Labelling of primary samples in a manner that provides an unequivocal link with the patient from whom they Are collected - must match the request form.			Patient name alone is not sufficient.
	- Stabilization and proper storage conditions before collected samples are delivered to the laboratory.			"Na" if done off-site and unable to check, e.g. Temperature, out of direct sunlight, drying filter papers etc No if obviously delivered in poor condition.
	- Safe disposal of materials used in the sample collection process.			"Na" if done off-site and unable to check.
TP.3	**Test request** Does the laboratory use the national test request form and adequately collect information needed for examination performance?			The request form should at minimum have space to record all the below, Can not be Yes if a field is not available Review the cholera test request form, and check several examples for completeness of the fields.
	- Are all test requests accompanied by national approved test requisition?			
	- Does the request include patient identifiers, including gender, date of birth, location of patient and unique identifier?			
	- Name, initials/signature of authorized requester is recorded?			
	- Type of sample and examination requested?			
	- Clinically relevant information?			Such as antibiotic start, suspected cholera case etc.

	- Date of sample collection (may include time where appropriate)?			
	- Date and time of sample receipt?			To be completed by the reception.
TP.4	**Test request algorithm** Is testing available, requested and performed appropriately, in-line with national guidance?			Confirm the laboratory has a copy of the national guidelines for test requests and that tests are ordered inline with the guidelines. This includes not doing requested tests if outside of protocol.
TP.5	**Referral facilities** Is there a list of facilities which send samples/isolates for testing to this facility. The list should include contact details for results return? (referral in).			"Na" if no samples referred from other sites to this facility.
TP.6	**Referral feedback** Is there a protocol available detailing how feedback on samples, such as rejections or requests for further information are communicated to the requester?			"Na" if no samples referred from other sites to this facility.
TP.7	**Sample reception** Does the laboratory implement the sample receipt procedures and are there records of implementation of the following:			
	- Unique patient identifier is assigned on arrival to reception?			Assigned by the laboratory or information system, this ID should not repeat each month, e.g. using numbers 1,2,3.
	- Are received samples evaluated according to acceptance and rejection criteria?			Review acceptance/rejection logs - record main reasons for rejection, or improper samples which arrive to the laboratory.
	- is there evidence of feedback to requesters when criteria are not met?			Check call logs, results reported etc.
	- Are time and data recorded for sample reception as appropriate?			Time is relevant to specific samples, date may be sufficient for other sample types.
	- Are samples logged appropriately upon receipt in the laboratory?			Must include date of receipt, time of receipt, and name of receiving personnel. Details in laboratory match the request form.
	- Are samples delivered to the correct workstations as per the laboratory processes?			Do samples go directly to microbiology/ testing area without delay so testing can be performed within time restrictions.
TP.8	**Procedure for referral laboratories** Has the laboratory defined a procedure and/or process for sample/isolate referral? (referral out).			"Na" if no samples referred.
TP.9	**Sample/ isolate referral** Is there a list of referral laboratories with contact details available? (referral out).			"Na" if no samples referred.
TP.10	**Sample/ isolate referral tracking** Are referred samples/isolates tracked properly using a logbook, tracking form or electronically from shipment to results return so that TAT can be calculated? (referral out).			"Na" if no samples referred.
TP.11	**Transportation** Are samples which are sent to an external laboratory from this lab packaged correctly following national guidelines? (referral out).			"Na" if lab does not refer any samples, and does not receive any samples.
	- Samples transport SOP is available, complete and evidence of staff training?			Confirm the SOP has all needed information and staff are trained on referral methods.
	- Request forms/shipping list is provided, packed inside the main package, but separate from samples to avoid contamination?			Confirm lab has a copy of the regulations, if no samples are being sent/received at time of audit ask open ended questions to determine if the guidelines are implemented.
	- Are previous results of tests provided, such as RDT			
	- Are samples collected and transported within acceptable timeframe and temperature intervals?			Shipment at ambient temperature, timeframe bads on sample type and testing - Review transport logs, sample collection times, lab receipt times to confirm.
	- The name of the organism is **not** written on outside of packaging.			
	- When specimens are transported internationally, is the packaging and transportation in full compliance with international (e.g., IATA) regulations?			Reference laboratories only, else "Na".

Analytical Cholera Testing

#	Question	Answer	Comments	Notes for assessor
TA.1	**RDT test kits** Does laboratory use approved or validated VC RDTs for testing?			Approve RDTs include --> Crystal VC O1/O139, SD Bioline O1/O139 If other tests, then ask for validation and verification results and acceptance (this may need to be confirmed with cholera program).
TA.2	**RDT testing** Are current VC RDTs being performed correctly with adequate controls?			Fill all as Na if facility does not perform RDT's
	- Does laboratory have a timer available for performance of VC RDTs.			
	- Does laboratory perform RDTs with samples types as recommended by the manufacturer?			Sample types only: Fresh stool, Stool or rectal swab in APW, NOT direct rectal swab or using Cary Blair
	- Does laboratory have appropriate temperature monitoring of samples and reagents used for VC RDT testing?			This includes room temperatures, storage area temperatures, samples should not be stored in a fridge, in direct sunlight or other condition which could impact results.
	- Where pre-incubation in APW is carried out, is the incubation time (4-6 hrs) and temperature (37°C) correctly observed?			Fill as Na if facility does not use APW for RDT testing.
	- Does laboratory have an SOP for VC RDT testing, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the VC RDT test performed, and specific to the laboratory it is performed in?			The SOP should refer to laboratory specific requirements such as the RDT brand in use with correct timings.
	- Does laboratory perform new batch verification on current RDTs.			At least 1 test compared to old batch when opening a new kit.
	- Does the laboratory record the acceptance of VC RDT control line before reporting patient results? .			
TA.3	**Media preparation** Does the laboratory prepare media and/ or biochemical reagents for growth and identification correctly? .			If laboratory buys media premade appropriate controls must still be documented (B.19) Media = plates, slants, liquid, broth, transport or other growth methods. Biochemical reagents include oxidase, stains locally made.
	- Does laboratory have an SOP for media and reagent preparation, storage and QA, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the VC media preparation, and specific to the laboratory it is performed in?			SOP should include recipes, instructions to calculate based on volume, cooking instructions, how to perform QA, links to record sheets, storage conditions etc.
	Are controls always used, recorded and monitored when making media and reagents for sterility and correct biochemical properties?			QA should be done with characterised control strains. Must include appropriate biochemical reactions - TCBS, colour change due to sucrose fermentation by vibrio, Vibrio chrome - *Vibrio cholerae* strong growth/purple, *Vibrio parahaemolyticus* - strong growth/ blue-green colour. No growth of *E.coli* when plated on selective media etc.
	Are records kept showing: - Adherence to the recipe - Ph adjustment - Autoclave date - QA results - Expiration date - Storage conditions - Disposal of expired media .			This can be in a media log book, or individual sheets per batch of reagents as long as information is captured and can be traced back to test results.
	Are materials stored at the correct temperature for the correct length of time?			As per the manufacturer instructions.
	Are media plates poured correctly? - Uniform depth - Level .			Check plates available in the laboratory at time of visit. Also confirm no old plates are still available for testing.

TA.4	**Bacterial isolation** Does the laboratory currently perform bacterial culture and isolation correctly with adequate controls?			Fill all as Na if facility does not perform bacterial isolation. Bacterial isolation includes all steps required to isolate a pure culture of bacteria for further identification.
	- Does laboratory have an SOP for culture methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the culture methods performed and specific to the laboratory it is performed in?			Describes all methods, from media preparation, sample examination, enrichment, culture, subculture, controls, results reporting colony appearance etc.
	- Does laboratory perform couture from the correct sample types?			Stool or rectal swabs in carry Blair or APW, wet filter paper, Not dry filter paper.
	- Where pre-incubation in APW is carried out, is the incubation time (4-6 hrs) and temperature (37°C) correctly observed?			Fill as Na if facility does not use APW for RDT testing.
	- Does laboratory use appropriate media for culture of bacteria from stool samples? (Non-selective and selective for vibrio).			selective media = TCBS, Vibrio chrome or TTGA non-selective = MH, BHI, TSA etc.
	- Does laboratory have access to ATCC strains (or documented, well characterised strains), and appropriate storage methods to maintain them?			Including storage, and SOPs for regular subculture and maintenance of strains. Strains to be stored at least at -20°C.
	- Does the laboratory incubate cultures for correct time period (18-24 hrs) at the correct temperature (37°C)?			
TA.5	**Bacterial identification** Does laboratory perform identification of VC tests using adequate identification methods and controls?			Fill all as Na if facility does not perform bacterial identification. Bacterial identification includes all steps post pure culture, all biochemical and serological methods to confirm Vc
	- Does laboratory have an SOP for all identification methods performed, which is readily available in the testing area and in a language all testing staff understand?			SOP should describe appearance of suspected cholera isolates and decision tree for identification.
	- Are the testing methods described in the SOP accurate for the identification methods performed and specific to the laboratory it is performed in?			Are the method SOPs correct for the tests performed in the laboratory, with appropriate controls, and materials.
	- Does laboratory select appropriate strains for identification based on initial growth indicators?			"Na" for automated or semi-automated identification where ID is automatically performed from original samples.
	- Are appropriate positive and negative controls always used, recorded and monitored for all identification methods such as microscopy, API, agglutination, automated, MALDI-TOF systems etc.?			Look for evidence of controls - e.g. Positive and negative oxidase and gram stains, calibration standards and database control for MALDI-TOF etc.
TA.6	**Phenotypic bacterial identification - Species** Does laboratory use sufficient testing to accurately determine the vibrio species before reporting as *vibrio cholerae O1 or O139?*			Does the lab do isolate on selective media and do appropriate controls and perform agglutination following accurate methods?
TA.7	**Phenotypic bacterial identification - Serotype** Does laboratory use sufficient testing to accurately determine the VC serotype (Inaba or Ogawa).			Does the lab do appropriate controls and perform agglutination tests for Inaba/Ogawa following accurate methods?

TA.8	**Phenotypic AST testing** Does the laboratory currently perform bacterial AST correctly with adequate controls?			Initial > Erythromycin (EM), *S. Aureus* Initial > Pefloxacin (PEF), *E.coli* Initial > Tetracycline (TE), *E.coli* Confirm > Azithromycin (AZ) S. Aureus Confirm > Ciprofloxacin *E.coli* Confirm > Doxycycline *E.coli* Additional antibiotics must also be appropriately controlled
	- Does laboratory have an SOP for AST methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the identification methods performed and specific to the laboratory it is performed in?			SOP should describe correct preparation of pure isolates, suspension of colonies, controls and use of antibiotics.
	- Does laboratory use fresh, clearly defined isolates for AST testing?			"Na" for automated or semi-automated identification where AST is automatically performed from original samples.
	- Does laboratory use turbidity or other method to correctly inoculate AST cultures?			"Na" for automated or semi-automated identification where AST is automatically performed from original samples.
	- Does the laboratory have adequate antibiotics available, which are stored appropriately and dispensed using a dispenser or good ascetic techniques?			Lab must have all antibiotics they list as testing in stock, in date, stored correctly both before and after opening. Tweezers, burner or dispenser available to score "Yes"
	- Does the laboratory follow GTFCC guidelines, conducting initial testing with at least Erythromycin, Pefloxacin and Tetracycline?			Initial > Erythromycin (EM), (15 mg) Initial > Pefloxacin (PEF), (5 µg) Initial > Tetracycline (TE), (30 µg).
	- Does the laboratory follow GTFCC guidelines, conducting confirmatory testing with Azithromycin, Ciprofloxacin, Doxycycline?			Confirm > Azithromycin(AZ) - MIC measurement for AZ and CIP is not required for case management but is recommended for epidemiological surveillance of the strains Confirm > Ciprofloxacin (CIP) - If resistant to Na, the isolate should be tested for susceptibility to CIP by MIC measurement Confirm > Doxycycline (DO - if TE resistant, doxycycline must be tested individually by MIC measurement.).
	- Does the laboratory incubate cultures for correct time period (18-24hrs) at the correct temperature (37°C)*?			*or other appropriate times and temperatures if using automated methods.
	- Does laboratory have appropriate ATCC strains for controls in AST?			*well characterised strains can also be used, with good documentation. Without documentation = partial.
	- Are control strains run with every batch of AST testing?			
	- Does the laboratory have appropriate standards for AST interpretation, with access to newest standards?			Both Eucast and CLSI must be referenced
	- Does laboratory have access to measuring devices for AST results recording?			Ruler with mm, Automated equipment etc.

TA.9	**Molecular testing** Does the laboratory currently perform molecular methods for cholera species and/or subtype identification correctly with adequate controls?			This could be any rapid or conventional molecular method used to amplify and identify Vibrio, VC and or subtypes.
	- Does laboratory have an SOP for molecular methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Are the testing methods described in the SOP accurate for the molecular methods performed and specific to the laboratory it is performed in?			SOP should describe correct preparation of samples, extraction, master mix - primers used, recipe etc., PCR method (number of cycles, temperature), Controls and methods used to interpret including any cut off values.
	- Does the laboratory have adequate space and separation to perform extraction, reagent preparation and amplification in a manner which minimalizes contamination?			For conventional PCR 3 rooms are required with no backflow. For rapid molecular tests, refer to instructions.
	- Are extraction and amplification controls included in every batch of tests, are control results reviewed prior to test result release?			"Na" if rapid molecular tests contain internal processing controls.
	- Does laboratory have adequate storage for isolates, and nucleic acids before and after testing, which includes a detailed archive of stored samples?			storage at least at -20˚C. Lab must be able to quickly find the location of any requested stored sample through a documentation system.
TA.10	**Genotypic bacterial identification - Species** Do molecular tests have targets to specifically detect VC before reporting as cholera?			Appropriate targets: ompW hlyA 16S rRNa.
TA.11	**Genotypic Bacterial identification - Serotype** Do molecular tests have targets to accurately determine the vibrio cholerae serotype before reporting serotype?			wbe gene for O1 and the wbf gene for O139, .
TA.12	**Genotypic Bacterial identification - Toxigenicity** Do molecular tests have targets to accurately determine toxigenic vibrio cholerae before reporting as toxigenic?			Appropriate targets: ctxA; ctxB; tcpA; rstR; rtxC.
TA.13	**Sequencing testing** Does the laboratory currently perform NGS correctly with adequate controls and have sufficient bioinformatic materials available?			Includes any sequencing methodology.
	- Does laboratory have an SOP for sequencing methods performed, which is readily available in the testing area and in a language all testing staff understand?			An SOP is the step by step instructions specific for the laboratory, bench aids are and package inserts by themselves = partial.
	- Have the sequencing and the bioinformatic methods been validated and approved for use by the laboratory, cholera program and/or regulatory body?			
	- Are the testing methods described in the SOP accurate for the sequencing methods performed and specific to the laboratory it is performed in?			
	- Does the laboratory have adequate space and separation to perform library preparation and sequencing which minimalizes contamination?			separated rooms, with no backflow.
	- Are libraries quality checked prior to sequencing?			
	- Are sequencing controls available, implemented and reviewed prior to results interpretation?			
	- Are appropriate bioinformatic pipelines available and followed?			

TA.14	Quality control and quality assurance Does the laboratory document and plan all quality assurance procedures, and they are sufficient to control all cholera tests performed by the laboratory. How the laboratory will: - use IQC and EQA (Interlaboratory comparison) - define the frequency of processing IQC - define the acceptable ranges - valuate and monitor laboratory performance using EQA and IQC data - troubleshoot unacceptable EQA and IQC.			Review process SOPs for internal control instructions to determine IQC and frequency. EQA is any external program, international, National or interlaboratory comparisons IQC are all controls the laboratory runs during testing e.g. media sterility, RDT control lines, ATCC strains used for AST, positive controls for agglutination etc.
TA.15	**Corrective actions** Is corrective action taken and documented when quality control results fall outside the acceptable range and reviews identify nonconformities in a timely manner?			If quality control is not in place for all methods, TA.15 can only score as "Partial". RDT controls include verification using a previous positive when opening new kits. Corrective actions include, repeating tests, remaking media, opening new kits, informing clinical staff etc Documentation could be as non-conformity reports, corrective actions, meeting minutes, letters to clinical staff etc.
TA.16	**Monitoring** Are quality control results monitored and reviewed to assess the performance of the method and/or identify errors over time for quantitative tests?			The laboratory should have evidence of periodic review looking for trends or repetitive failures as well as the actions taken. This goes beyond immediate action of repeating a test, or remaking media and should be done at least yearly.
TA.17	**Participation in external quality assessment (EQA)** Does the laboratory participate in EQA or alternatives for any microbiology tests?			This is applicable even if country does not yet have a scheme, "Yes" they are currently enrolled, "No" they are not.
TA.18	**If yes,** last 3 EQA schemes results have been reviewed and action taken to improve.			If TA.17 = "No", then score as "No" "Partial" if action was taken but was incorrect or unmonitored, and did not resolve the issue. Actions can include, review of results released since previous EQA pass event, recall of results, investigation to the cause, retraining of staff etc.

Post-Analytical Cholera Testing.

#	Question	Answer	Comments	Notes for assessor
TPA.1	**Procedure and/or process for reporting and release of cholera results** Has the national surveillance and reporting policy been communicated and implemented to testing facilities?			Review the policy and procedure documentation for results release, this could be an individual policy or within the testing SOP, ensure they align with country and cholera minimal requirements.
	- Defining report formats and frequency based on the current outbreak status.			Policy or procedures documenting how cholera results will be reported, Including if It is electronic or paper based, fields and how to complete.
	- Reviewing of patient results authorization.			Who is authorised to review, finalise test results, and is there evidence that this is done, at least 2 people, the person doing the test, and a second person should ensure results are accurate.
	- Communication of alert, urgent and critical patient results (confirmed case 24hr).			Confirmed positives results are reported to relevant surveillance program as soon as possible.
	- Release of results and reports by authorized persons.			Who is authorised to release results, is there a final check that the correct result is sent to the correct places.
	- Reporting of results performed by a referral laboratory.			How results from a referral lab will be reported, this would document if results are directly returned by the testing lab.
	- Deadlines for reporting.			How long are results retained for does it match the policy and are they archived correctly? Ask staff for results within the archive period to confirm.
TPA.2	**Cholera test result reporting system** Are results for all tests completed unambiguously, clearly marked to show which result, from which test type?			Review the results reports and track the result back through the test log books to sample receipt confirming correct results are lined to the correct person.
TPA.3	**Validation of cholera test result** Are test results validated, interpreted and released by appropriately authorized personnel?			Review the evidence that results are interpreted and released by the authorised persons in the policy. This could be a second signature or stamp. Comments on the forms, review of indeterminate or contradictory results etc.
TPA.4	**Cholera reporting requirements** Does the laboratory report align with national cholera reporting guidelines and contain at least the following:.			Review the results reports forms to ensure they contain all of the below, and that they are routinely completed with no gaps.
	- Clear, unambiguous identification of the tests being performed .			e.g. there is no doubt that a report of VC, is from the correct set of identification tests. Results are not just written as positive, without stating which test was positive.
	- Identification of the laboratory issuing the report.			
	- Patient identification, location, date of primary sample collection (and time, relevant to patient care).			
	- Name of the requester.			
	- Type of primary sample and any specific information necessary to describe the sample (e.g. Macroscopic description).			Must be clear if stool or swab, if any transport media or enrichment was used .
	- Identification of the person(s) reviewing and authorizing the release of the report.			The name/position of persons reviewing and releasing report should be indicated .
	- Date and time of the report.			Time, depends on test, sample type requested.
TPA.5	**Cholera reporting** Does the laboratory send one copy of the lab report, both positive and negative, to the clinical team and a duplicate copy to the surveillance team within 24 hours of a positive identification, or 7 days of all negatives following any mandated aggregate reporting formats?			Check where/how old test results are stored. Laboratory should be able to find the result of a case selected in random from previous 3 months.
TPA.6	**Cholera quality indicators** Does the laboratory perform basic statistical analysis on key performance indicators for cholera/bacteriological testing performed and use this to improve testing?			Are quality indicators selected to cover pre-examination, examination, and post-examination processes e.g., turnaround times, rejected samples, stock-outs, etc- routinely monitored and used.
TPA.7	**Surveillance** Does the laboratory report other alert organisms identified during culture procedures?			If pathogenic reportable bacteria are found during cholera testing are they documented and reported to the clinical staff requesting testing and/or appropriate surveillance departments?