GLOBAL TASK FORCE ON CHOLERA CONTROL

RDT Site Attendance List.

Complete during all management and facility 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 facility. 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

RDT Site Documentation List

Complete 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	Comment
Safety manual	Safety		
Patient results form	Management review		
SOPs covering technical and management areas	Management review		
All cholera SOPs for testing	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		
Inventory policy	Inventory		
Stock cards/logbook	Inventory		
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		

Document	Checklist Section	Available	Comment
Referral logs	Testing Pre-analytical		
Results return log/ records	Testing Pre-analytical		
Register/ list of sites samples are referred to	Testing Pre-analytical		
Test results form	Testing Post-analytical		
Archived results	Testing Post-analytical		
Reports/alerts of *Vibrio cholerae* to notification bodies	Testing Post-analytical		

GLOBAL TASK FORCE ON CHOLERA CONTROL

RDT Site Checklist 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							
Refrigerator (2-8°C)							
Computer, general lab results							
Printer							
Other equipment (specify):							

GLOBAL TASK FORCE ON CHOLERA CONTROL

RDT Site 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.

Method type	Performed by site	Accept tests from other facilities (referred in)	Send tests to other facilities (referred out)	Comments
Enrichment in alkaline peptone water (APW).				
Rapid test for *Vibrio cholerae* O1 with/without O139.				

Additional testing questions to be asked based on tests performed:	
Name and brand of cholera testing RDT used?	

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 types accepted for testing:	Fresh stool	Stool swab in transport media	Stool swab in APW	Rectal swab	Rectal swab in transport media	Rectal swab in APW	Stool on dry filter paper	Stool on wet filter paper	Isolates	Other sample types?
Which sample types are used for RDT testing?										
Which sample types are referred?										

Cholera cases				
	VC Rapid tests		Sent for culture	
	So far this year	So far this year	Last year	Last year
Tests requested/ performed				
Reactive (Positive) for *Vibrio cholerae* O1 and or O139				
Invalids				

GLOBAL TASK FORCE ON
CHOLERA CONTROL

GTFCC LCA RDT SITE CHECKLIST

#	Question	Answer	Comments	Notes for assessor
M.1	RDT site legal entity Does the RDT site 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.3	RDT site cholera plan Is there an available and adequate RDT site 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 RDT site 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	RDT site contingency plan Does the RDT site 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	RDT site quality system Is there a current quality manual or equivalent, that details all aspects of the RDT site 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 RDT site operations - Description of the roles and responsibilities of the RDT site 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.

#	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 Does the RDT site have an organogram which outlines the hierarchy as well as defined roles and responsibilities (job descriptions) for all RDT site positions which includes cholera testing.			Organogram must include: 1) Manager and deputy 2) Quality officer 3) Safety officer 4) Various levels of testing staff 5) Other roles, cleaners, samples collection staff etc Job descriptions should be available for all roles, include roles and responsibilities.
HR.3	Cholera testing services Has the RDT site 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 RDT site will: - perform staff orientation to the RDT site 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 RDT site 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".
	RDT site 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.
	Quality officer.			responsible for the quality in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Safety officer.			responsible for the safety in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Technical training **Is there evidence that RDT site staff have been trained and are competent in the following tests. "NA" if test is not performed by the RDT site.**			
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
	- 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
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 RDT site.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up
	- 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
	- 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.

#	Question	Answer	Comments	Notes for assessor
F.2	**RDT site structure** Are all RDT site 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	**RDT site facilities** Is the RDT site area for cholera testing adequate in size and is layout of the RDT site 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.
	- 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
F.5	**Cholera testing services** Has the RDT site 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.7	**RDT site 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.			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 avaialble 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
	- Room temperatures.			Including ALL storage areas and all areas involved with testing,
	- Refrigerators.			"NA" if no samples or reagents require storage.
F.9	**Review of environmental conditions** Is there evidence of documentation for action taken in response to unacceptable conditions?			If not all conditions are monitroed then F.9 can not score higher than "Partial". Evidence of action should include immediate action to fix the immediate problem, and

#	Question	Answer	Comments	Notes for assessor
S.1	**RDT site safety manual** Does the RDT site 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
S.3	**Biosafety training** Are - RDT site staff, - Drivers/couriers, - Cleaners, trained in biosafety practices based on the safety manual, policy and procedures of the RDT site?			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 RDT site?			
	- 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.
#	Question	Answer	Comments	Notes for assessor
E.1	**Minimum cholera equipment** Does the RDT site 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.

#	Question	Answer	Comments	Notes for assessor
I.1	**Access to cholera materials** Does the RDT site 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 RDT site 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 RDT site 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 RDT site 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	**RDT site inventory system** Does the RDT site continually monitor stock in the RDT site 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.

#	Question	Answer	Comments	Notes for assessor
TP.1	**Client information** Has the laboratory defined a procedure and/or process which has been communicated to RDT 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.
	- Instructions for pre-collection activities.			e.g. before antibiotic therapy has been initiated.
	- Procedures for requesting and collection of patient			
	- 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-
	- 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-
	- Patient sample acceptance and rejection criteria.			All criteria relevant to samples and tests must be documented i.e. - bleach in container - 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** Are samples collect samples correctly and/or is there evidence that RDT site 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 RDT site 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			
	- 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)?			

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 ouside of
TP.8	**Procedure for referral laboratories** Has the RDT site 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 site 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 results?			
	- 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.			

#	Question	Answer	Comments	Notes for assessor
TA.1	**RDT test kits** Does RDT site 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 tempertaures, 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 (6-8 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.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 RDT site 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.

#	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
	- 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.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 RDT site send report, both positive and negative, to 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 RDT site 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.

GLOBAL TASK FORCE ON
CHOLERA CONTROL

GTFCC LCA RDT SITE CHECKLIST

#	Question	Answer	Comments	Notes for assessor
M.1	RDT site legal entity Does the RDT site 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.3	RDT site cholera plan Is there an available and adequate RDT site 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 RDT site 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	RDT site contingency plan Does the RDT site 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	RDT site quality system Is there a current quality manual or equivalent, that details all aspects of the RDT site 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 RDT site operations - Description of the roles and responsibilities of the RDT site 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.

#	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 Does the RDT site have an organogram which outlines the hierarchy as well as defined roles and responsibilities (job descriptions) for all RDT site positions which includes cholera testing.			Organogram must include: 1) Manager and deputy 2) Quality officer 3) Safety officer 4) Various levels of testing staff 5) Other roles, cleaners, samples collection staff etc Job descriptions should be available for all roles, include roles and responsibilities.
HR.3	Cholera testing services Has the RDT site 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 RDT site will: - perform staff orientation to the RDT site 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 RDT site 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".
	RDT site 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.
	Quality officer.			responsible for the quality in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Safety officer.			responsible for the safety in the laboratory, training should include specific laboratory knowledge otherwise score partial.
	Technical training **Is there evidence that RDT site staff have been trained and are competent in the following tests. "NA" if test is not performed by the RDT site.**			
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
	- 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
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 RDT site.			Look for signed SOPs, training records, direct observation of methods or open ended questions to determine if staff are up
	- 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
	- 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.

#	Question	Answer	Comments	Notes for assessor
F.2	**RDT site structure** Are all RDT site 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	**RDT site facilities** Is the RDT site area for cholera testing adequate in size and is layout of the RDT site 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.
	- 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
F.5	**Cholera testing services** Has the RDT site 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.7	**RDT site 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.			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 avaialble 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
	- Room temperatures.			Including ALL storage areas and all areas involved with testing,
	- Refrigerators.			"NA" if no samples or reagents require storage.
F.9	**Review of environmental conditions** Is there evidence of documentation for action taken in response to unacceptable conditions?			If not all conditions are monitroed then F.9 can not score higher than "Partial". Evidence of action should include immediate action to fix the immediate problem, and

#	Question	Answer	Comments	Notes for assessor
S.1	**RDT site safety manual** Does the RDT site 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
S.3	**Biosafety training** Are - RDT site staff, - Drivers/couriers, - Cleaners, trained in biosafety practices based on the safety manual, policy and procedures of the RDT site?			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 RDT site?			
	- 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.
#	Question	Answer	Comments	Notes for assessor
E.1	**Minimum cholera equipment** Does the RDT site 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.

#	Question	Answer	Comments	Notes for assessor
I.1	**Access to cholera materials** Does the RDT site 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 RDT site 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 RDT site 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 RDT site 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	**RDT site inventory system** Does the RDT site continually monitor stock in the RDT site 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.

#	Question	Answer	Comments	Notes for assessor
TP.1	**Client information** Has the laboratory defined a procedure and/or process which has been communicated to RDT 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.
	- Instructions for pre-collection activities.			e.g. before antibiotic therapy has been initiated.
	- Procedures for requesting and collection of patient			
	- 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-
	- 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-
	- Patient sample acceptance and rejection criteria.			All criteria relevant to samples and tests must be documented i.e. - bleach in container - 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** Are samples collect samples correctly and/or is there evidence that RDT site 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 RDT site 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			
	- 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)?			

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 ouside of
TP.8	**Procedure for referral laboratories** Has the RDT site 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 site 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 results?			
	- 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.			

#	Question	Answer	Comments	Notes for assessor
TA.1	**RDT test kits** Does RDT site 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 tempertaures, 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 (6-8 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.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 RDT site 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.

#	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
	- 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.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 RDT site send report, both positive and negative, to 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 RDT site 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.