THE REPUBLIC OF UGANDA

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MINISTRY OF HEALTH

Coronavirus Disease-2019 (COVID-19) Preparedness and Response Plan

Laboratory manual

January -June 2020

ACKNOWLEDGMENT

The Ministry of Health, Uganda wishes to acknowledge all efforts from partners and stakeholders who functioned through the Surveillance and Laboratory subcommittee to develop the COVID-19 laboratory response guidelines. This document will provide a framework for implementation of COVID-19 Preparedness and Response Plan January-June 2020.

I thank you

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Dr. Henry G. Mwebesa

Director General Health Services - Ministry of Health

List of Acronyms

VTM	Viral transportation media
UTM	Universal transportation media
UVRI	Uganda Virus Research Institute
IDI	Infectious Diseases Institute
IRR	International reagent resource
MRC	Medical Research Council
CPHL	Central Public Health Laboratory
JCRC	Joint Clinical Research Center
IAVI	International AIDS Vaccine initiative
CIF	Case Investigation Form
LIF	Laboratory Investigation Form
CHOC	Chain of Custody Form
QPPU	Quantification Procurement Planning Unit

List of tables / figures

TABLE OF CONTENTS

Introduction

On 31st December 2019 the World health Organization was notified of a cluster of cases displaying symptoms of a "pneumonia of unknown cause" linked to the Huanan Seafood Market, Wuhan, Hubei province. By 7th January 2020, Chinese Health Commission confirmed the identification of a new corona virus as a causative agent for severe pneumonia like illness. The novel Corona Virus was named SARS-CoV-2 being responsible for a new corona virus disease-2019 (COVID-2019). As of 24th March 2020, approximately 381,739 confirmed cases worldwide with 16,558 deaths and 102,429 recoveries. Uganda reported the first COVID-19 case on evening on 21 March 2020.

Goal

To streamline laboratory coordination and management of COVID-19 response efforts.
The implementation of this plan will be multi-sectoral involving Ministries, Departments, Agencies, Partners, private sector entities and other stakeholders.

Specific objectives

1. To outline specimen coordination, standard operating procedures for sample collection, transportation, testing and results return
2. To provide guidance on testing technologies and their appropriate utilization to meet diagnostic demands for COVID 19.
3. To guide the role out of diagnostic support through planning, training and implementation of laboratory-based interventions
4. To provide guidelines for biosafety and biosecurity practices to health workers and the public while handling COVID-19 samples, confirmed cases and suspects
5. To provide guidance on quantification of laboratory supplies and equipment management

SECTION I

1.0 COVID-19 SPECIMEN COORDINATION AND MANAGEMENT

1.1 Purpose

To provide guidance on clinical specimen collection, packaging and transportation from health facilities and/or designated points of entry (PoE) to the testing laboratory.

Only trained and competent personnel shall collect specimen. These maybe:

- Clinicians
- Laboratory personnel
- Field surveillance officers
- Nurses

The specimen shall be accompanied by an appropriately completed MoH standardized chain of custody form (CHOC form) and a Laboratory Investigation form (LIF)

- Patient name
- Date of collection
- Specimen type
- Other demographic information
- Necessary Epidemiological information
- Basic Clinical Information

Key documents accompanying a specimen

1. Chain of Custody form (CHOC)
2. Laboratory Investigation Form

Note 1:

Personnel collecting specimens should ensure that the Laboratory Investigation Form (LIF) and chain of custody (CHOC) form are properly filled and specimen collected according to SOPs to avoid substandard specimen that will not provide useful results.

Personnel collecting specimens must have the following personal protective equipment (PPE):

- a clean, non-sterile, long-sleeved waterproof gown
- If gowns are not fluid-resistant, a waterproof apron
- gloves
- Medical face mask FFP2 or N95
- Eye goggles or face shields
- Absorbent materials in case of spillage
- Disinfectant for spillage (10% bleach)
- Hand sanitizer (10% bleach, 70% alcohol-based hand rub)
- soap, running water, disposable tissue
- Tissue / face mask for the patient
- Biohazard bags (red) and waste bins for waste management.

1.2 specimen collection.

1. Trained person collects samples
2. Ensure that all the materials required for shipments are available and PPEs are in place before start of process.

   Specimens must be triple packaged immediately after collection then sent to health facility lab for transportation to testing laboratory.

1.3 specimen packaging

Specimens must be triple packaged immediately after collection then sent to health facility lab for transportation to testing laboratory. Ensure that all the materials required for shipments are available and PPEs are in place before start of process.

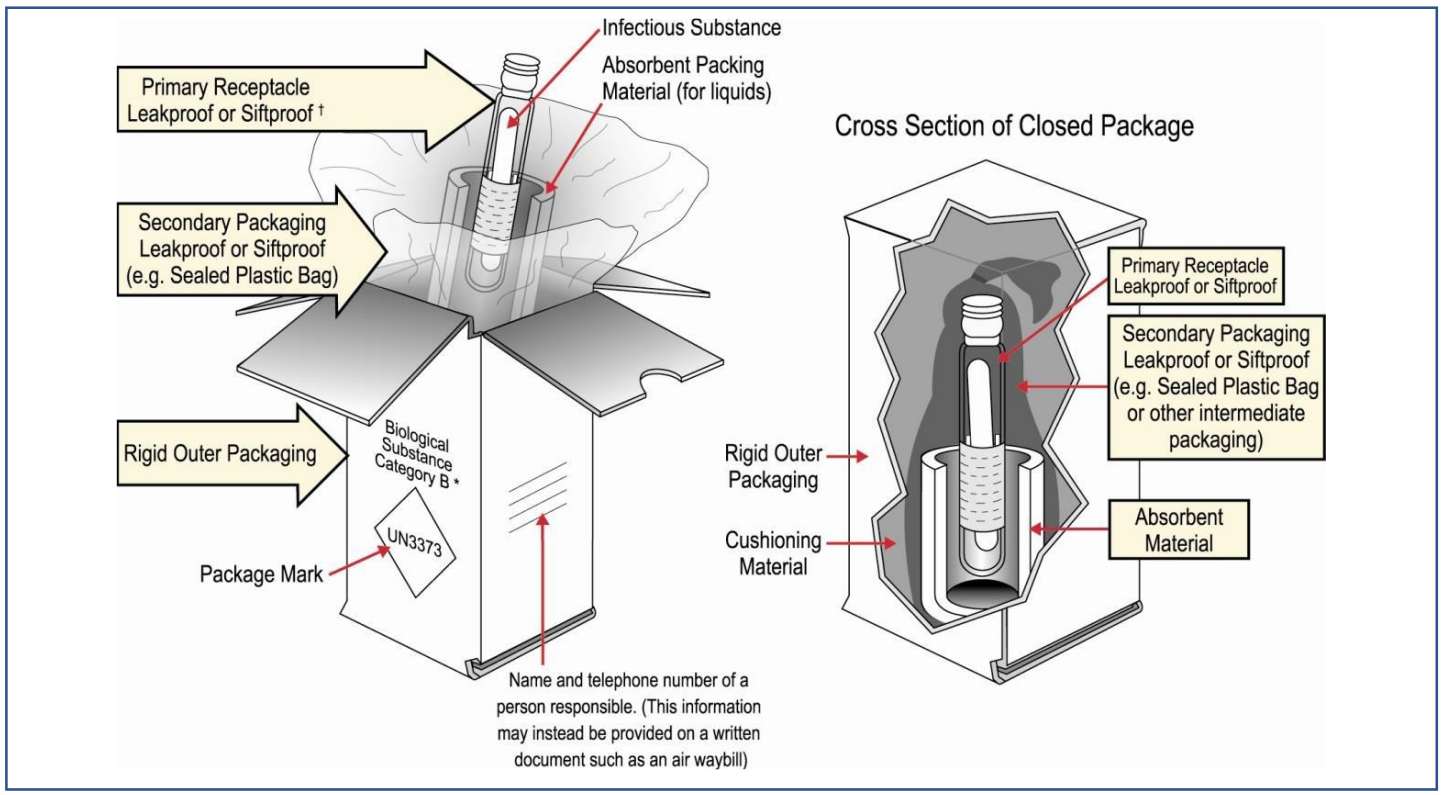
Minimum Packaging materials

1. Primary container
2. Secondary container
3. Polythene bags (Zip lock bags)
4. Absorbent materials (e.g. cotton wool or paper towels)
5. Specimen labels (PINs)

Procedure

1. Place the specimen in the primary container (receptacle) and close tightly. Closing tightly is to avoid leakage for body fluid specimens.
2. Wrap the specimen with absorbent materials for body fluid specimens. No need to wrap if the specimen is nasal swab.
3. Place the specimens in the secondary watertight, leak-proof container (receptacle). The secondary container may be zip-lock plastic bag or screw cap container with a lid.
4. Several cushioned primary receptacles may be placed in one secondary packaging, but enough additional absorbent material should be used to absorb all fluid in case of breakage for body fluid.
5. The secondary container with the specimens is then placed in a cool box or an outer shipping packaging with suitable cushioning material. Outer packaging protects the contents from outside influences, such as physical damage while in transit.
6. The completed package is correctly marked, labelled and accompanied with appropriate shipping documents (LIF, CHOC) as applicable ready for transportation

Figure 1Diagram Illustrating triple packaging

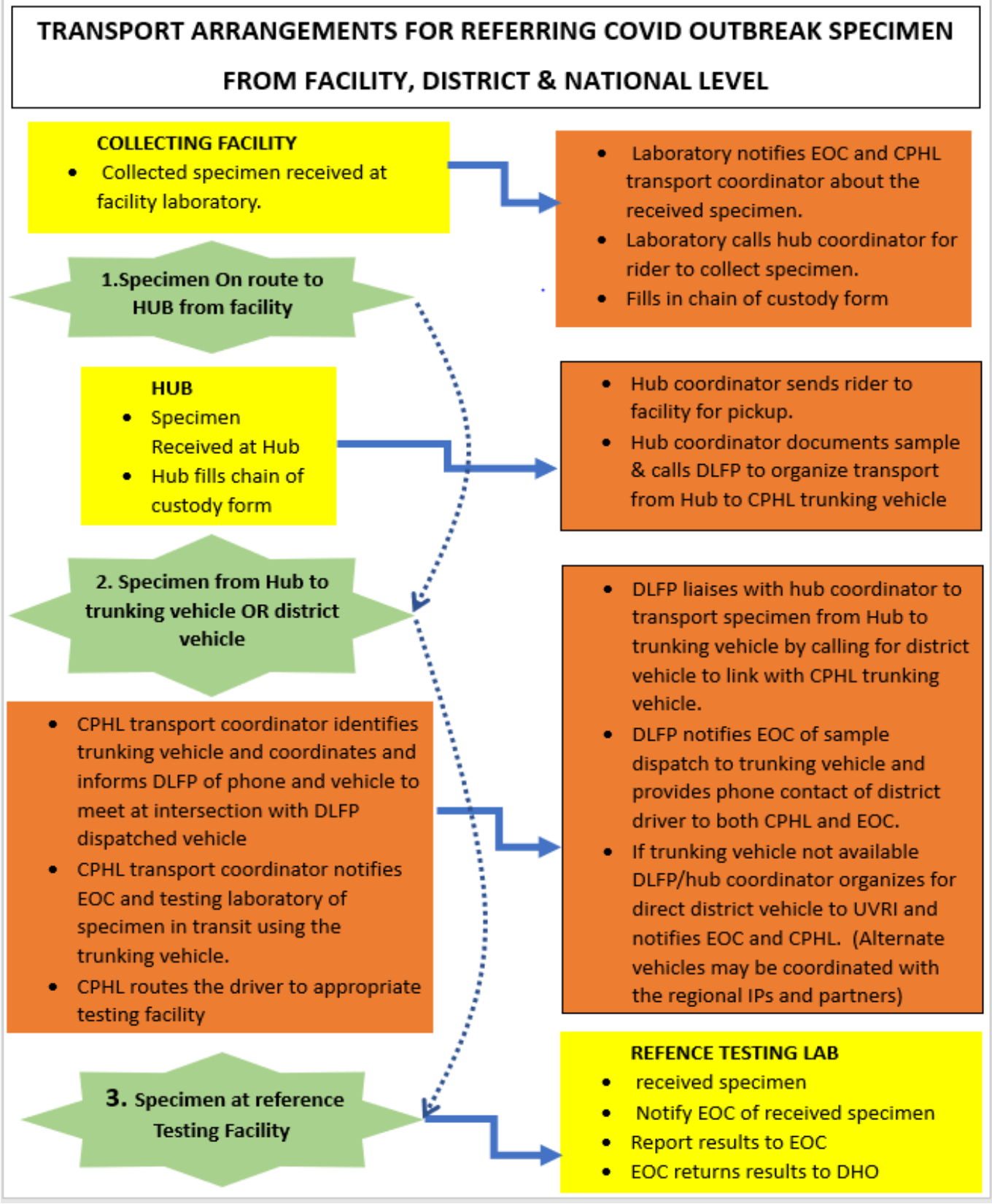


1.4 Sample referral

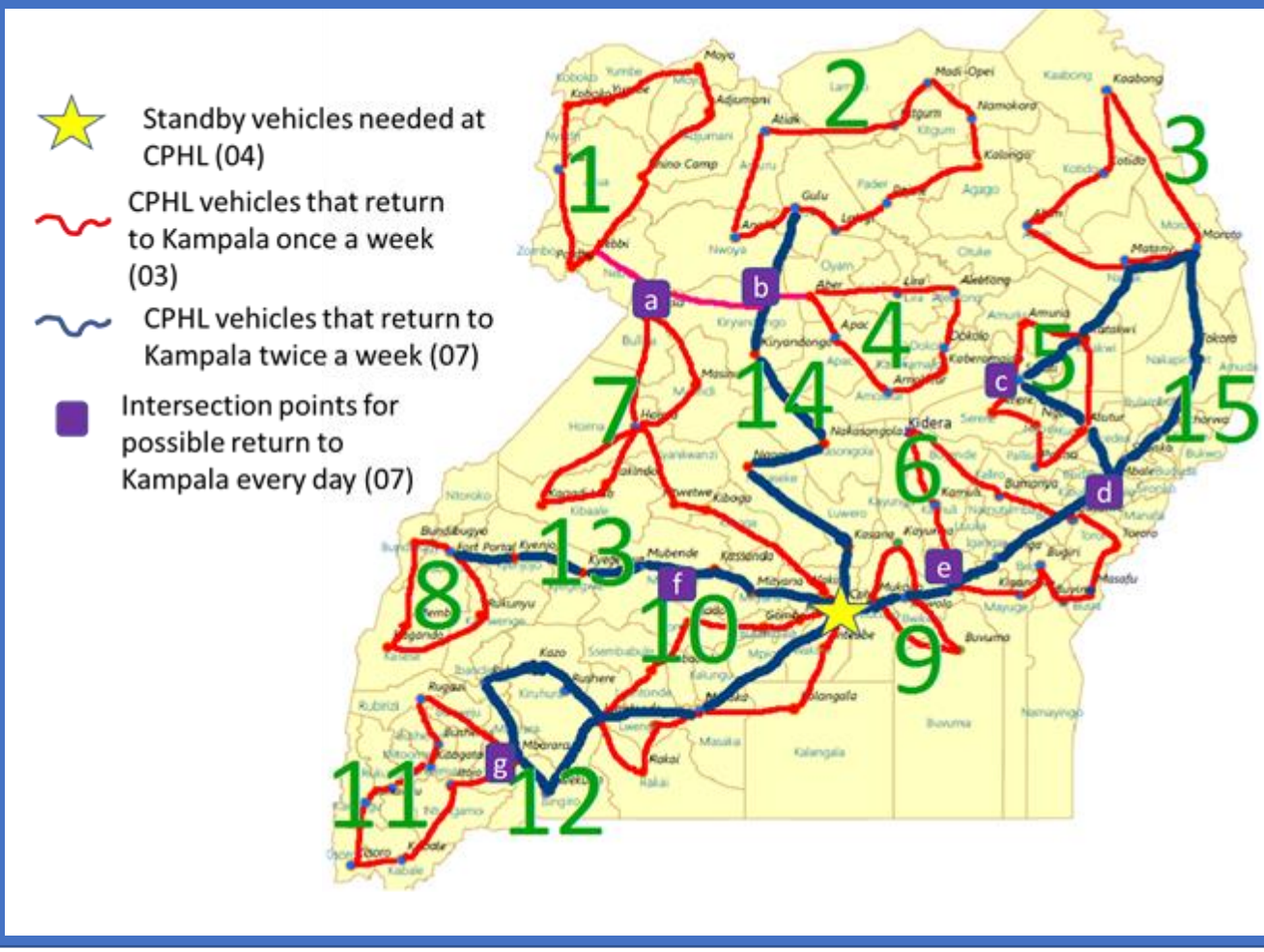
CPHL is responsible for the overall coordination of the COVID-19 specimen transportation.

1. Facility lab calls EOC to notify them of the completed sample received.
2. Facility lab calls the hub coordinator to send over a bike rider to relay the sample to the hub.
3. The hub coordinator shall provide feedback within 30 minutes to the facility lab on the confirmed rider that is coming to collect the specimen.
4. In case the routine bike rider is not available, the hub coordinator shall inquire from the DLFP and lab advisor to provide an alternate rider from among the district teams.
5. The hub rider records the sample in the logbook and transport sample the hub.
6. Hub staff registers the sample and calls DLFP to refer specimen to CPHL
7. Hub coordinator calls the DLFP to arrange district vehicle to reach CPHL trunking vehicle.
8. DLFP calls the CPHL transport Coordinator to arrange the trunking vehicle.
9. CPHL transporter shall informs public health emergency operational center (PHEOC) about COVID-19 suspect specimen under transportation
10. DLFP shall provide feedback to hub of available vehicle (district or CPHL vehicle) within 30 minutes and
11. The DLFP shall notify EOC of specimen in transit as soon as vehicle has been dispatched.
12. The district (or CPHL) transporter shall informs EOC about specimen in transit

Figure 2: Diagram Illustrating transport arrangements for COVID specimen



MAP SHOWING THE INTERSECTION POINTS FOR TRANSPORTING EID/VL & COVID19 SPECIMEN



1.5 Considerations for Specimen testing

- Diagnostic methods for COVID-19 testing are rapidly changing and it is anticipated to have alternative diagnostic strategies such as antigen/antibody rapid testing kits, point of care (POC) devices, mobile lab testing, serological assays and other technologies to be available.
- Laboratories shall conduct testing according to approved protocols/methods. These shall be validated against the WHO Berlin protocol and integrated into the testing strategy as they become available.
- In some cases combination of testing methods may be used in defined algorithm. Scale up of alternative tests will be informed by the pattern of the epidemic, availability of POC

platforms and demand for community and border point testing. POCs shall only be deployed at hubs and prisons.

1.5.1 RDT utilization strategy

- All serological tests (RDTs) will be used in the community guided by the case definition criteria.
- All RDT positives shall be confirmed by PCRs.
- All persons in quarantine will be tested with RDTs prior to discharge.
- All symptomatic patients who are RDT non-reactive shall have a sample taken for PRC confirmation.

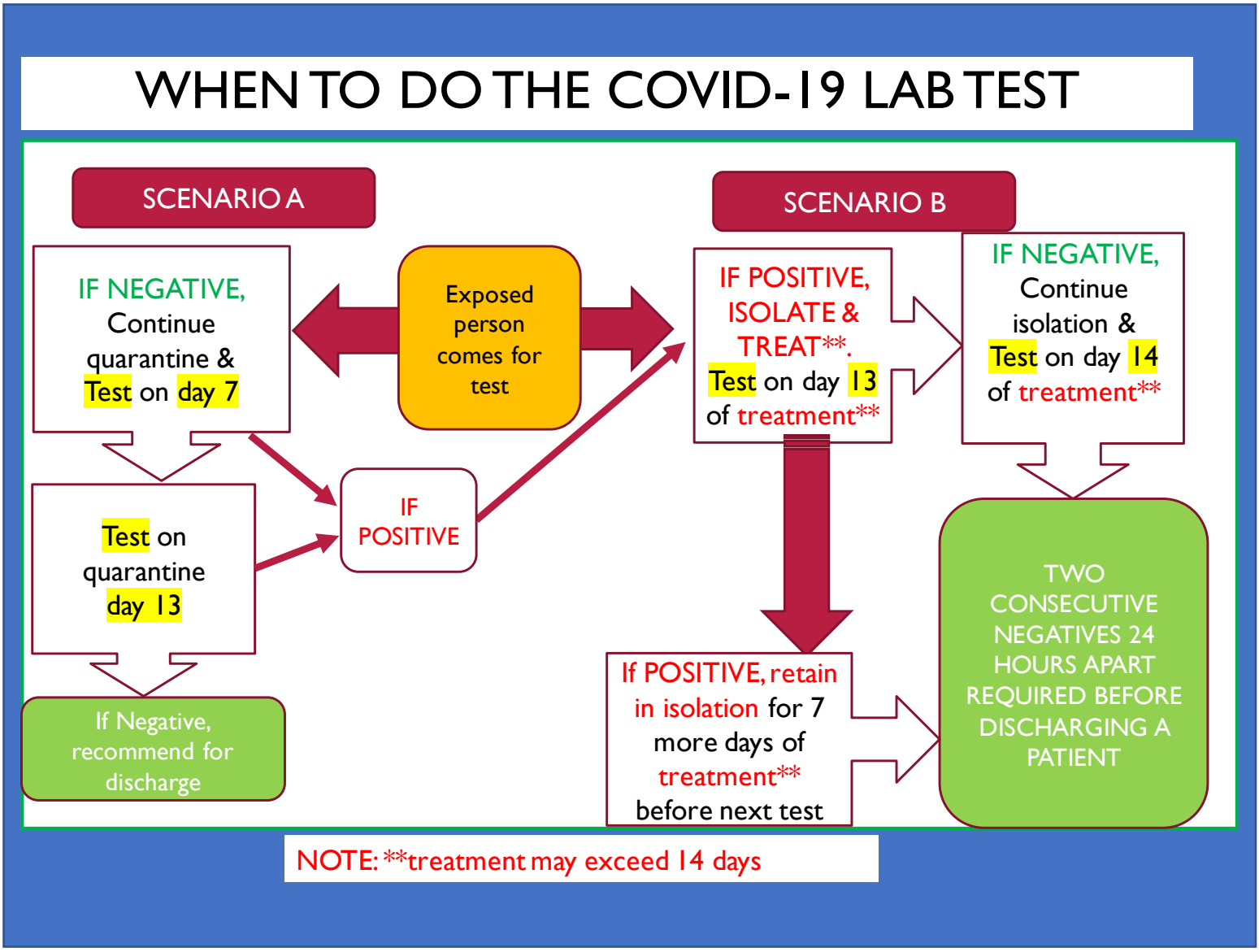
1.5.2 When to do the COVID 19 lab test.

	Country with NO reported COVID 19 cases yet	Country dealing with sporadic cases OF COVID 19	Country dealing with clusters of COVID 19 cases	Country dealing with community transmission of COVID 19
Description of scenario:	There is no confirmed case of COVID 19	occurring at irregular intervals or only in a few places; scattered or isolated.	Cases of small groups of people positioned or occurring closely grouped together in a geographic location e.g. in a town.	transmission happens over large areas of the country; laboratories will need to be prepared for the significant increase in the number of specimens
Actions by surveillance team epidemiologists:	• Assessment of possible risk areas and populations (e.g. related to travel to high-risk countries) • Refer suspect for testing if suspect meets case definition	• Assessment of possible risk areas and populations (e.g. related to travel to high-risk countries) • Refer suspect for testing if suspect meets case definition	• Assessment of possible risk areas and populations (e.g. related to travel to high-risk countries • Refer suspect for testing if suspect meets case definition	• Assessment of possible risk areas and populations (e.g. related to travel to high-risk countries) • Refer suspect for testing if suspect meets case definition
Lab task	• Collect samples and test all	• Collect samples and test all probable cases	• Collect samples and test all probable cases	• Testing constraints should be anticipated

	probable cases that fit case definition • Give daily updates of total samples referred through CPHL transport coordinator • Use of reference lab at UVRI	that fit case definition • Give daily updates of total samples referred through CPHL transport coordinator • Use of reference lab at UVRI as volumes remain manageable for accepted TAT	that fit case definition • Give daily updates of total samples referred through CPHL transport coordinator • Use of reference lab at UVRI and back up lab as volumes • Consider <u>minimal use</u> of RDTs alongside POC PCR tests • Maintain reporting channels through district rapid response team and EOC <u>for all results</u>	• Prioritization will be required to assure the highest public health impact of reducing transmission • Consider <u>greater use</u> of RDTs alongside POC PCR tests • Maintain reporting channels through district rapid response team and EOC <u>for all results</u>
How the lab team Deals with COVID 19 suspects in quarantine (both symptomatic and asymptomatic) (This guidance shall evolve based on availability of test kits and updated consultation with surveillance teams)	• Test for COVID-19: (1) on arrival (2) after 7 or 8 days and (3) on day 13 or day14 before discharge. • If negative on both (PCR), recommend discharge. • If positive, report to clinical team urgently for isolation & case management.	• Test for COVID-19: (1) on arrival (2) after 7 or 8 days and (3) on day 13 or day14 before discharge. • If negative on both (PCR), recommend discharge. • If positive, report to clinical team urgently for isolation & case management.	• Test for COVID-19: (1) on arrival (2) after 7 or 8 days and (3) on day 13 or day14 before discharge. • If negative on both tests (using PCR or RDT), recommend discharge • If positive, report to clinical team urgently for isolation & case management.	• Test for COVID-19: (1) on arrival (2) after 7 or 8 days and (3) on day 13 or day14 before discharge. • If negative on both tests (using RDT), recommend discharge • If positive, report to clinical team urgently for isolation & case management.
How the lab team Deals with confirmed COVID 19 patients who are in care	• Test before discharge (PCR) • If positive, retain in care. • If negative, recommend for discharge	• Test upon discharge (PCR) • If positive, retain in care. • If negative, recommend for discharge	• Test upon discharge (POC PCR or RDT) • If positive, retain in care.	• Test upon discharge (POC PCR or RDT) • If positive, retain in care.

	• For laboratory-confirmed cases, 2 negative specimens at least 1 day apart indicate recovery from infection (usually day 13 & day 14).	• For laboratory-confirmed cases, 2 negative specimens at least 1 day apart indicate recovery from infection (usually day 13 & day 14)..	• If negative, recommend for discharge • For laboratory-confirmed cases, 2 negative specimens at least 1 day apart indicate recovery from infection (usually day 13 & day 14).	• If negative, recommend for discharge • For laboratory-confirmed cases, 2 negative specimens at least 1 day apart indicate recovery from infection (usually day 13 & day 14).

Flowchart showing when a lab should do a COVID 19 test



Note: when the testing for COVID 19 is decentralized to the districts and community level, the reporting protocol should remain aligned with the EOC regulations i.e. use the approved EOC channels. An example is shown in the diagram below.

Flow chart of reporting channel for COVID 19 testing at district and community level

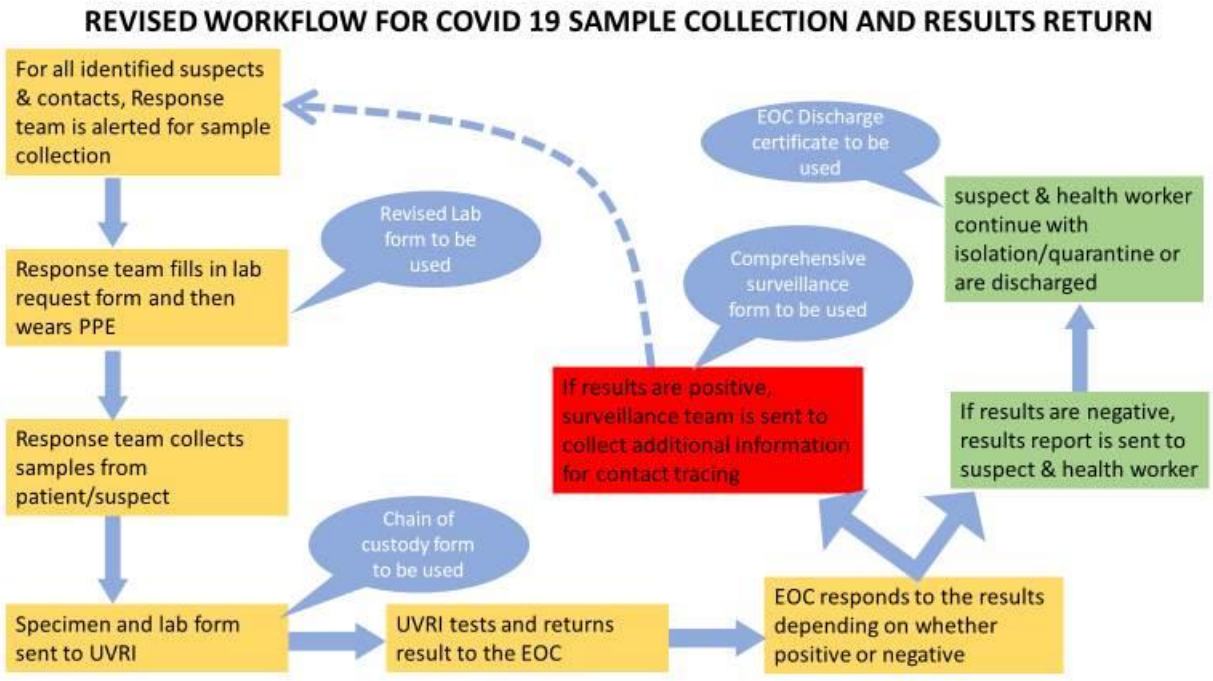


Table1 Available Laboratory Testing Capacity (PCR)

Testing lab/s	**Lab capacity (No of tests/day)**	**Testing methods and Technologies**	**Comments/notes**
UVRI*	500	Conventional PCR PCR-ABI	WHO International Reagent Resource (IRR)
CPHL	5000	Cobas8800 Abbott m2000rt/sp	We shall allocate up to 1000 tests per day
JCRC	500	Real time PCR using Abbott 2000rt; Roche Ampliprep/ Taqman; Genexpert machine, and conventional PCR	The capacity 600 per day is dependent on additional HR working in shift.
NTRL	228	Qiagen Viral RNA Extraction Kits using 7500 Fast Realtime PCR system , **and** 3 Genexpert 4 modules machines	The 3Genexpert runs 36 samples per day and PCR 96 sample per run times 2 runs per day.
Makerere microbiology	378	Qiagen Viral RNA Extraction using Rotor Gene Q real time PCR system, and Quant Studio real time PCR system	The capacity is estimated at 3 runs a day; more HR required.
Walter Reed Kampala lab (COVAB)	288	Qiagen Viral RNA Extraction Kits using7500 Fast Realtime PCR system	The capacity is estimated at 3 runs a day
IDI core lab	800	2 Roche realtime PCR machines, 2 Abbott real time PCR machines, four Genexpert machines	Require additional HR
Hubs with GeneExpert	16	Genexpert 4 modules machine	The capacity estimated at 4 runs per day

*UVRI complex including MRC, IAVI, Rakai Health Sciences and other potential laboratories.
UVRI will be responsible for validation and EQA of other testing labs.

1.6 Quality assurance

1- UVRI currently serves as the reference and quality assurance laboratory. It shall lead the selection of back-up laboratories for activation, training of staff, validation of technologies and external quality assurance (EQA).

2- Additional labs shall be assessed for testing capacity using the WHO check list for capacity and safety before being enrollment to provide testing services.

3- Scaling up of testing to additional labs shall be done in a phased approach informed by the testing demands, locations, and availability of reagents for the different platforms.

4- RDTs shall only be used by community response teams or lower health facilities and may require confirmation of results

5- When several labs are testing, CPHL shall coordinate the flow of specimen and results from the different labs based on the lab through puts and TAT.

6- Testing lab shall receive and record specimen details in the specimen tracking log.

7- Releases of results shall follow the national incidence management protocol: starting with return to the EOC which dispatches them to the attending clinician and other appropriate key stakeholders.

8- All laboratories shall comply to the SOPs of their assays. All assays shall be validated by UVRI against the WHO berlin protocol.

9- Every lab shall send their first ten (10) negative and five (05) reactive tests for validation.

10- UVRI shall periodically send proficiency panels to the back-up testing facilities.

11- Discrepancies between the testing laboratories and UVRI will be subjected to appropriate discrepancy investigation and a WHO accredited reference laboratory engaged where a resolution fails.

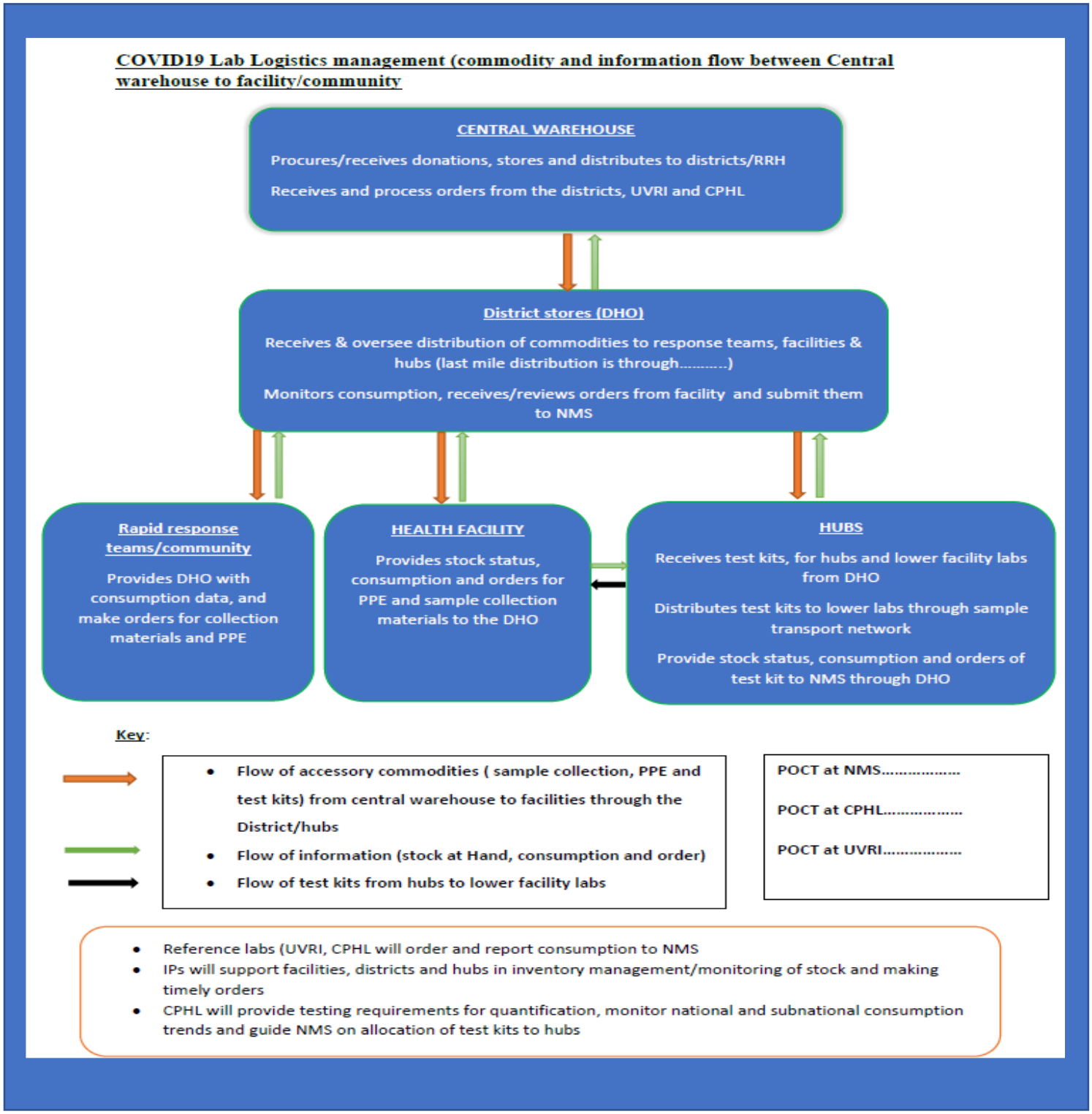
1.7 Specimen Archival

- All testing laboratories shall submit leftover specimen to the national repository at CPHL for archival.
- The specimen shall be stored according to the national biorepository guidelines which include the retrieval and disposal criteria.

1.8 Supplies

- Laboratory supply chain shall be coordinated by CPHL and will work in collaboration with QPPU to forecast and quantify laboratory commodity requirements. The covid19 lab commodities will include specimen collection materials, PPE and test kits.
- NMS shall procure/receive donation, store and distribute to the district stores/RRHs. Last mile delivery will be done by a third party on behave of NMS. From the district stores commodities will be delivered to hubs and using the sample transport network, commodities will be taken to the facilities.
- Health facility labs/hubs shall maintain good stores and inventory management, report weekly consumption, stock on hand and make one month's order.
- CPHL will review logistics data from hubs/facilities and make an allocation list to NMS.
- IPs will support facilities to monitor stock status, consumption and provide weekly reports and orders to DHO and CPHL in a bid to ensure consistent supply of commodities and minimize wastage.

Flowchart showing the logistics management from national to facility level



SECTION 2

2.0 JOB AIDS / STANDARD OPERATING PROCEDURES (SOPs)

2.1 SOP for Specimen collection (SOP-COVID-001)

2.1.1 Purpose

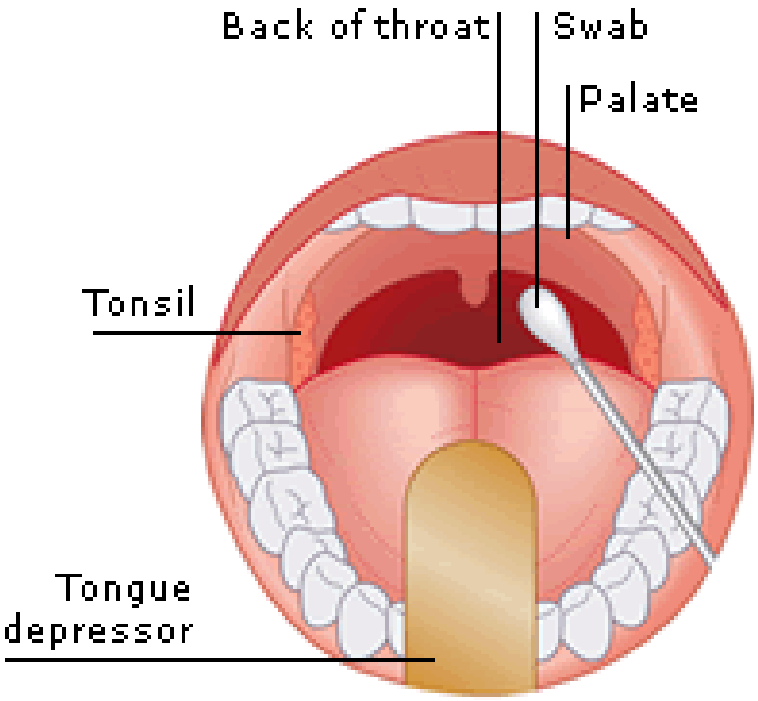
Outline the procedure for collection of throat and nasopharyngeal swabs from eligible COVID-19 suspect and probable cases including retesting for confirmed positive cases to determine recovery

2.1.2 Specimen collection materials

- 2ml Cryovials (sterile; outside thread)
- Dacron swabs
- Universal Viral Transport Media (UTM) or Viral Transport Media (VTM)
- Face mask (for infection control)
- Tongue depressor (spatula)
- Gloves
- Permanent marker pens
- Cool box (with ice packs) if possible dry shipper
- Patient files/ case investigation form (CFI)
- Polythene bags (Zip lock bags)
- Absorbent materials (e.g. cotton wool or paper towels)
- Small plastic container
- Examination torch with cells/batteries
- Specimen labels (PINs)
- Apron/ lab coat
- Tracking forms

2.1.3 collection of throat swab

1. Ensure that all the collection equipment is in place
2. Provide an explanation to the patient of what you are just about to do and obtain consent (consent form) from the patient or guardian if underage or patient is incapacitated. For children aged 8 years and below 18, also obtain their assent (assent form) in addition to their parent's/guardian's consent
3. Fill in the LIF with all the required information
4. Put on the appropriate PPE
5. Label the cryovial containing UTM or VTM appropriately with Initials, date of collection and unique sample identifier
6. Instruct the patient to open his/her mouth widely
7. Use tongue depressor to depress the tongue slightly to allow easier access to pharynx
8. *If the patient is cooperative, try get him/her to say "Auugh"*
9. Put a Dacron swab stick into oral cavity and swab the lateral wall of the pharynx (i.e. "tonsillar" area) without touching the buccal mucosa or tongue.
10. Remove the swab stick from the oral cavity carefully without touching the buccal mucosa or tongue
11. Put the swab stick immediately into UTM, cut off the shaft short enough to allow closure of the cryovial.



View of throat

2.1.4 Collection of Nasopharyngeal Swabs

1. Ensure that all the collection equipment is in place
2. Provide an explanation to the patient or guardian (if underage or patient is incapacitated) of what you are just about to do. For children aged 8 years and below 18, also obtain their assent (assent form) in addition to their parent's/guardian's consent
3. Fill in the LIF with all the required information
4. Put on the appropriate PPE
5. Label the cryovial containing UTM appropriately with patient Initials, date of collection and unique sample identifier
6. Ask the study participant to extend the neck to allow easy visibility of the nasal cavity
7. Insert swab with flexible shaft into *nasopharynx,* just past point of resistance. See figure below.

a. 

8. Leave the swab in place for 10-15seconds or rotate to dislodge respiratory epithelial cells
9. Remove and place this swab in cryovial containing the throat swab
10. Place specimens on cryo cane and transfer to a charged dry shipper. In case a cool box with frozen icepacks is to be used, the specimens in cryovials are placed in specimen transportation bags. The specimen transportation bags are placed on frozen icepacks and must be delivered to the laboratory within 48 hours of collection
11. Remove and dispose off all soiled gloves and put on new pair of gloves prior to labeling specimens
12. Check to ensure the specimen cryovial bears the correct identifiers
13. Any unused cryovials containing UTM or VTM should be stored at 2-8ºC in a refrigerator
14. Lock the dry shipper and store safely in the designated storage area

2.1.5 collection of autopsy specimens

The preferred specimens would be a minimum of eight blocks and fixed tissue specimens representing samples from the respiratory sites (including liver, spleen, kidney, heart, GI tract) in addition to specimens from major organs and any other tissues showing significant gross pathology. Only trained personnel should collect autopsy specimens. The recommended respiratory sites include:

- Trachea (proximal and distal)
- Central (hilar) lung with segmental bronchi, right and left primary bronchi
- Representative pulmonary parenchyma from right and left lung

2.1.6 Steps for collection of blood specimens

1. Ensure that all the collection equipment is in place
2. Provide an explanation to the patient of what you are just about to do and obtain verbal consent from the patient or guardian if underage or patient is incapacitated.
3. Fill in the LIF with all the required information
4. Put on the appropriate PPE
5. Label the EDTA tube (purple top) with Patient Initials, collection date and unique sample identifier using waterproof marker before collecting blood.
6. Collect an elbow venous specimen (about 3ml)
7. Centrifuge the sample at 1000 rpm for 10 Minutes within 6 hours of collection.
8. Pipette off 1.5 mls of plasma into the cryogenic vial tube incase the EDTA TUBE USED IS NOT PPT (plasma preservation tubes).
9. Store the plasma samples at 2 - 8^{o}C until transportation. Samples must be transported from health facility within 2 days of collection.
10. For packing for transportation, transfer samples on racks into the cooler boxes. Place frozen ice packs on top of the samples in the cooler box, insert the electronic temperature loggers.
11. Health workers at lower facilities should send the parcel with hub rider within 6 hours after collection.

2.2 Standard operating procedure for preparation of VTM/UTM (UGCOVID-003)

2.2.1 Purpose

This Standard operating procedure outlines the step by step process making sterile VTM/UTM in the labs

2.2.2Materials required

- Distilled water
- Gentamicin sulphate
- Amphotericin
- Sterile tubes
- Nacl

2.2.3 Procedure for preparing *Virus Transport Medium*

1. Add 10 g veal infusion broth and 2 g bovine albumin fraction V (7.5%) to sterile distilled water to a volume of 400 ml.
2. Add 0.8 ml gentamicin sulphate solution (50 mg/ml) and 3.2 ml amphotericin B (250 μg/ml).
3. Sterilize by filtration using a 0.22 μm pore-size membrane and aseptic technique.
4. Aliquot between 1-3mls into sterile tubes, (use an appropriate volume for the tube size e.g 1-1.5ml in a 2ml cryovial, 3mls in a 5ml or 10ml tube) using aseptic techniques and store at -20°C.
5. Thaw prior to use.

2.2.4 Procedure for Physiological saline

1. Prepare a 20 x stock solution by dissolving 170 g NaCl in deionized distilled water to a total volume of 1 litre.
2. Sterilize by autoclaving.
3. To prepare physiological saline (0.85% NaCl) add 50 ml 20x stock solution to 950 ml of deionized distilled water.
4. Sterilize by autoclaving.
5. Aliquot between 1-3mls into sterile tubes, (use an appropriate volume for the tube size e.g 1-1.5ml in a 2ml cryovial, 3mls in a 5ml or 10ml tube) using aseptic techniques and store at 4°C until use.
6. Do not store aliquots for longer than 2 weeks at 4 °C
7. Store opened physiological saline at 4 °C for no longer than 3 weeks.

2.3 Standard operating procedure for Specimen transportation and reception

2.3.1 Purpose

This Standard operating procedure outlines the step by step process of transporting and reception of samples

2.3.2 Procedure

1. Put on the appropriate PPE
2. Notify the surveillance focal person and Hub rider to make necessary arrangements for sample pick up.
3. Ensure that the LIF is stamped by the Health facility.
4. Prepare a clean specimen carrier with a thermometer
5. Place at least two frozen ice packs into the specimen carrier.
6. Place the triple packaged specimen into the specimen carrier bag with a thermometer.
7. Tightly close the specimen carrier.
8. Check the LIF to ensure the right form for the right sample.
9. After at least 5 minutes withdraw the thermometer, read and record the temperature, time & date at the bottom of the Sample transportation log sheet.
10. Tightly close the specimen carrier.
11. Stick the LIF onto the specimen carrier.
12. Hand over a well packaged specimen(s) to the Hub rider for transportation to the hub. The NSTN sample transporters will transport to NHLS.
13. From NHLS the sample will be transported by Entebbe hub rider to UVRI.

2.4 Standard operating procedure for waste management

This waste management guidance supplements the infection prevention and control (IPC) guidelines, the main MoH national guiding document. It's line with the WHO guidance on water, sanitation and health care waste relevant to coronaviruses including other viruses.

For all laboratory activities generating infectious wastes, best practices for safely handling should be followed. The Centers for Disease Control and Prevention (CDC) also guided that medical waste generated in the treatment of COVID-19 patients and patients under investigation be managed in accordance with routine procedures. The lab Biosafety officer (BO) should take full responsibility of waste management ensuring that handling meets the national requirements. Despite no evidence yet available that direct and unprotected human contact when handling health care waste has resulted in the transmission of the COVID-19 virus, all health care waste produced during testing of COVID-19 samples should be treated as highly infectious. Collection should be done safely in designated bin liners with biohazard bags, treated, and then safely disposed, preferably onsite or transferred to an external incineration facility. If waste is moved off-site, it is critical to understand where and how it will be treated and destroyed. The BO should ensure all staff handling health care wastes wear appropriate PPEs (boots, apron, long-sleeved gown, thick gloves, mask, and goggles or a face shield) including hand hygiene after removing as a must. He or she should train the staffs who are assigned in handling and disposal of waste and supervise the entire waste management process.

2.4.0 SOP for waste management

Purpose

1. This SOP outlines step by step process of handle laboratory waste generated as a result of testing suspected or confirmed COVID-19 patient specimens. The person handling the waste must have received required training.

PPEs and Materials Required

- Heavy Duty Glove
- Gowns
- Face Shields
- Head Covers
- Mask
- Gumboots
- Waste collection bins with labels
- Biohazard liners following (Red, black, yellow)

Procedures

a. Ensure labeled bin containers are available for infectious, non-infectious, sharps and regular trash. The bin container for infectious materials should be lined with DOUBLE red bag.
b. Collect infectious materials in the bin container with DOUBLE red bag (gloves used for COVID-19 samples, bench tissues, swabs etc.).
c. Collect sharps in puncture proof container labeled sharps.
d. Collect non-infectious waste in the bin container with yellow bag labeled non-infectious waste.
e. Collect regular wastes (e.g. paper trash) in a black bin container labeled regular wastes
f. Close and tie properly each container when 2/3rd full
g. Label date of waste collection and place in an area of temporary storage.
h. Decontaminate the infectious waste before transferring for final disposal, making sure appropriate PPE is worn as guided during training.
i. Wearing appropriate PPEs, when transporting waste for and during incineration OR burning-away from the facility.
j. Report the BO and document as appropriate.

2.5 Standard Operating Procedure for results return

1. Results approved by lab manager
2. Results communicated to PHEOC mailing list
3. PHEOC communicates results to the facility/patient
4. PHEOC communicates results to central database at CPHL
5. CPHL runs a comparison of results out relative to specimens shipped and takes corrective action as necessary

2.6 Key Biosafety Biosecurity considerations

a) Ensure good communication channels between referral lab & field where the samples have been collected
b) All specimens must be packaged in transport media or within their respective swab collection tubes
c) If packaged in nitrogen tacks for freezer temperatures of -20 ◦C, -70 ◦C, or on dry ice if delayed >48 hours, ensure the following
    - Avoid repeated freeze/thaw cycles: this will denature the quality of the collected specimen.
    - Samples carried in a dry shipping cylinder should ideally be labeled using Cryogenic stickers; other types of stickers do fall off due to the sub-zero temperatures.
    - Warning: Dry shipper cylinders MUST be transported on the open-air trunks of a car; they MUST NOT be transported inside a car/van
    - Warning: Dry shipper cylinders should not be tilted or bent
    - Warning: dry shipper cylinders should be carried in an aerated place because in case of a leakage, the nitrogen gas displaces oxygen and can cause suffocation as it is heavier than air
d) Use Triple packaging materials and procedures (SOP)
e) Training biosafety, sample packaging and transportation is a requirement for sample handlers and transporters
f) Filling sample request form is a requirement
g) Ensure emergency contact available in case of an incidence
h) Cool boxes for cold chain maintenance & temperature monitors should be in place
i) Spill management kits in case of an incident including PPEs should be available

In addition to the above, personnel working in laboratories should observe the following biosafety precautions

• All procedures must be performed based on risk assessment and only by personnel with demonstrated capability, in strict observance of any relevant protocols at all times.

• Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.

• Non-propagative diagnostic laboratory work (for example, sequencing, nucleic acid amplification test -NAAT]) should be conducted at a facility using procedures equivalent to Biosafety Level 2 (BSL-2)

• Propagative work (for example, virus culture, isolation or neutralization assays) should be conducted at a containment laboratory with inward directional airflow (BSL-3).

• Appropriate disinfectants with proven activity against enveloped viruses should be used (for example, hypochlorite [bleach], alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds).

• Patient specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance Category B". Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans".

SECTION III

NATIONAL CONSIDERATION FOR COVID-19 LAB TRAINING

3.0 Training plan

Training in sample collection, packing and transportation will target all tiers of the health system from HCIIIs to National referral Hospitals.. Training of trainer's courses are targeted for national level to be cascaded subnational levels

The methods of training shall range from hands-on, video based and online demonstrations. Despite this, trainees shall ensure to follow a mentor who has had a hand-on experience with sample collection and referral.

Table 2 National lab training plan per facility level

Facility level	Target # to train	Total trainees (3,106)	Comments
National level pool	27 trained (UVRI and CPHL)	N/A (done)	Completed training to serve greater Kampala region
National Hospitals	5	5*5 (25)	To be trained
National Private hospitals	3	3*40 (120)	To be trained
National referrals	5	5*1 (5)	To be trained
Regional referrals	3	3*16 (48)	To be trained
District hospital	3	3*136 (408)	To be trained
HCIV	3	3*500 (1500)	To be trained
HCIII	1	1*1000 (1000)	To be trained
Private hospitals and clinics	Dependent on staffing		These sites are most susceptible to COVID 19

After the training, trainees will be furnished with a COVID19 sample collection and packaging kit which will be the starter kit at the facilities where they work. Replenishing of these kits will be done through the districts

COVID19 sample collection and packaging kit contents:

- Specimen collection kit
    - Powder free gloves (full boxes of 100 will be issued to facilities)
    - N95 respirators (full boxes of 20 will be issued to facilities)
    - face shield
    - Sample collection: 1 Tube of Universal Transport Media (UTM), 1 Nasopharyngeal swab, 1 Ziploc specimen bag containing absorbent pad
- Coverall protection suit

3.1Training budget

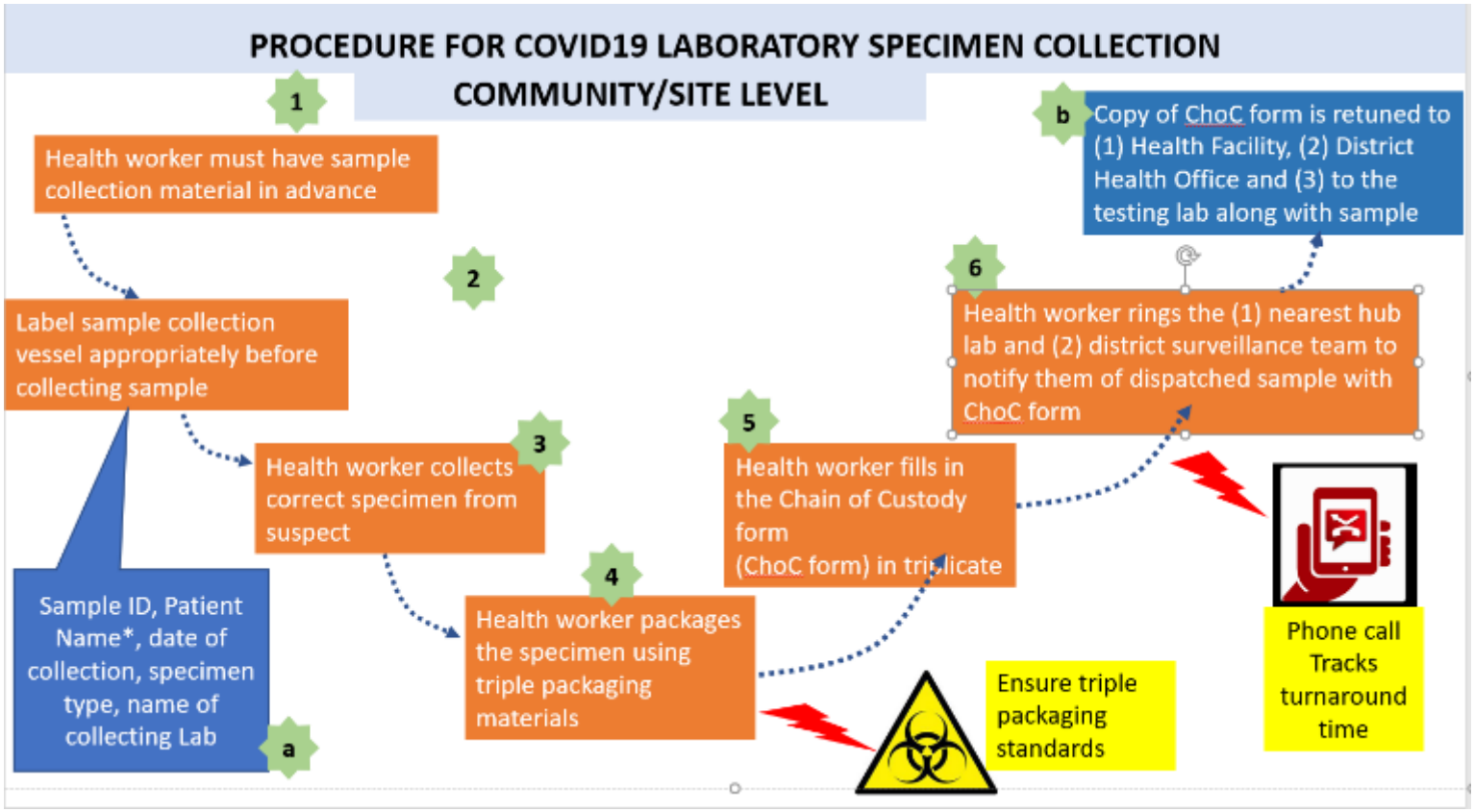
Includes sample collection and packaging starter kits, facilitation of field sample collectors? Collection of samples on facility while off duty? Extra time for laboratory staffs?

Table 3 training budget estimate

Item	**unit**	**Each cost ($)**	**Days**	**Total**
COVID-19 kit*	3106	50	NA	155,300
Conference package	10	5000	2	100,000
# participants	3106	55	3	512,490
Grand total for training				**767790**

*Kit contains sample collection and packaging kit

ANNEX 1: FLOW CHART FOR SPECIMEN COLLECTION AND REFERRAL



Annex 2: Triple Packaging materials Pictorial for Body Fluid, Swabs and Tissues

Unpack the EXAKT-PAK® box (use the containers and biohazard bags as needed, you may not need to use them all); the box also contains adhesive tape to seal the box shut during transport to the laboratory

Note how the styrofoam cover is pulled up and out of the EXAKT-PAK® box and the plastic liner is tucked into the styrofoam box and held in place by the styrofoam cover.

Three (3) plastic biohazard containers are present in the styrofoam box; they are packed with biohazard bags and foam specimen holder inserts

Clean reusable gel cryopacks can be inserted into the spaces between the containers to keep them cold during transport of the samples to the laboratory.

Properly label and identify all samples.

Left: One small plastic biohazard container holds smaller items such as tissues, syringes, and plastic slide holders

Middle: The tall plastic biohazard container holds large items such as swabs and syringes

Right: The other small plastic biohazard container with the six holes in a foam insert holds specimen tubes

Place blood and tissue samples in biohazard bags

Place blood/body fluid smears in slide holders and then in biohazard bags

Seal all biohazard bags and place in the container, position the foam insert, and tightly twist-close the lid

Place tissue swabs (stored in their containers) in biohazard bags

Seal all biohazard bags and place in the container, position the foam insert, and tightly twist-close the lid

Place tissue samples stored in 50ml "orange cap" tubes in the container as shown, push the tubes down into the foam insert (as shown with the 3 tubes in front), and tightly twist-close the lid

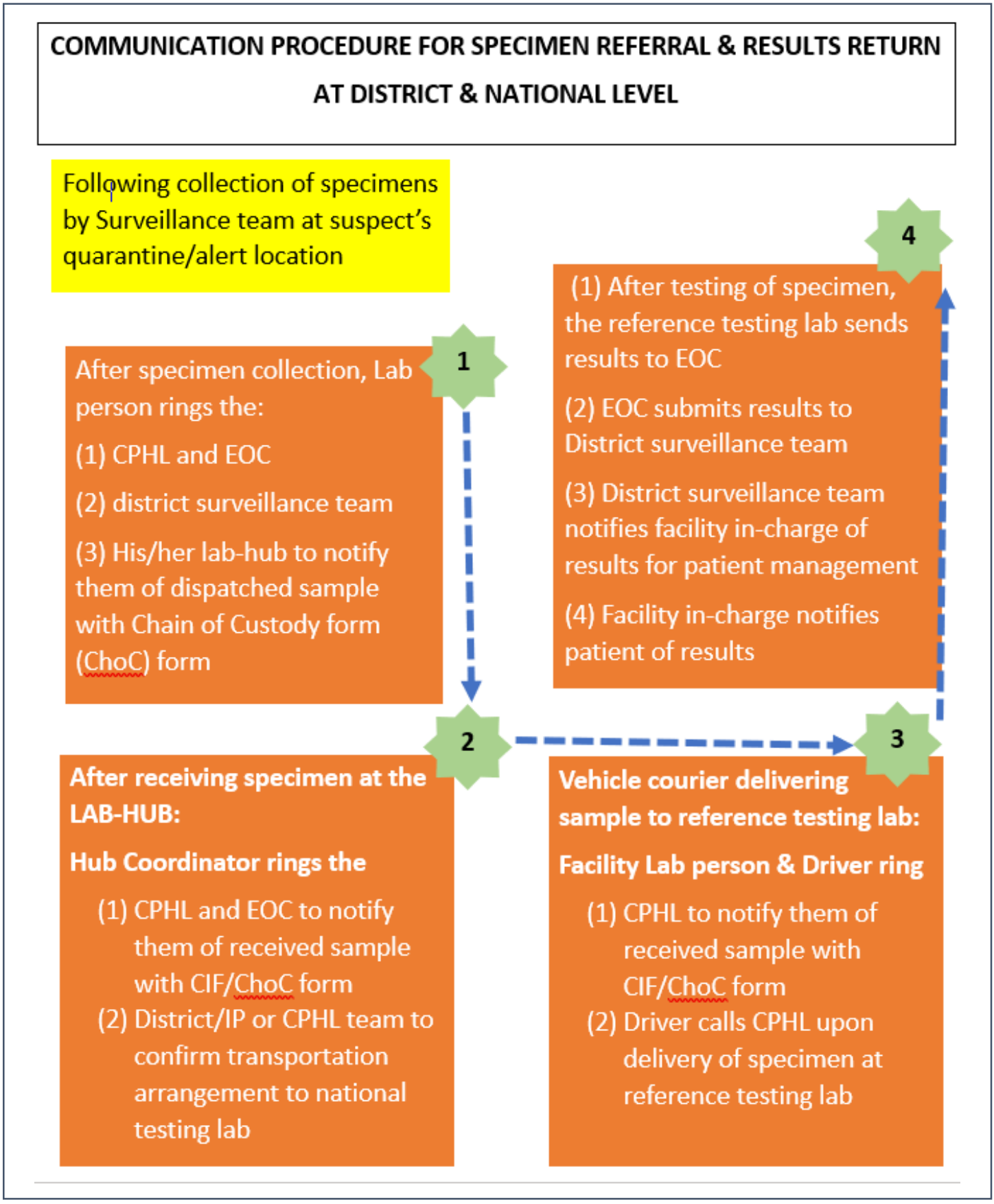
To protect laboratory personnel, all sample tubes should be cleaned and disinfected as instructed in the section "Personal Safety in the Field".

Place the containers in the box; pack the plastic liner and styrofoam cover

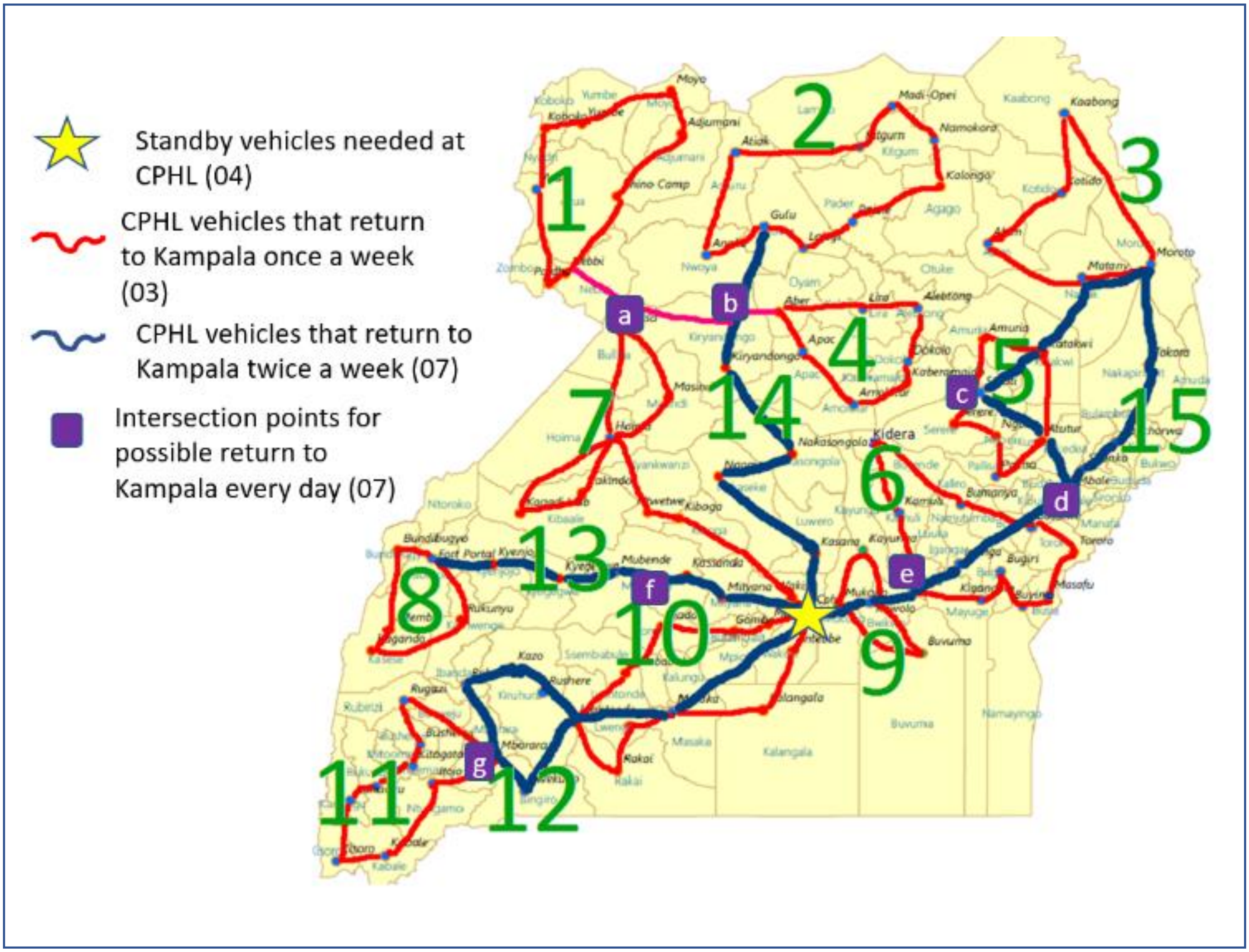
Place the epidemiology field report form as shown and seal the box shut with the adhesive tape provided

Deliver the EXAKT-PAK® box to the laboratory as quickly as possible

ANNEX 3: GUIDELINES ON KEY COMMUNICATIONS AT DISTRICT & NATIONAL LEVEL



ANNEX 4: MAP SHOWING THE INTERSECTION POINTS OF THE TRUNKING ROUTES



ANNEX 5: Ministry of Health Laboratory Investigation Form for Coronavirus Disease (COVID-19)

Date:[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]	Unique Lab ID:			Serial number:

Requester's info	**NAME**	**FACILITY**	**PHONE**

1. Where is sample collected? □ Patient home □ Health facility (specify): _____
□ Point of entry (specify): _____ □ Institution (specify): _____ □ Other: _____

2. Who is being tested? □ Case □ Contact □ Point-of-entry □ Quarantine □ Alert □ Health worker □ Other: _____

3. Reason for health worker (HW) testing? □ Routine exposure □ Quarantine □ Other_____ □ **HW's facility:** _____

4. If person is isolated/quarantined, specify day of testing: □ Day 0 □ Day 7 □ Day 13 □ Other: _____

5. Patient traveled out of Uganda in 2 wks before onset (or sample-taking, if no symptoms)? □Yes □No

6. If yes, where: **7. Return date**: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

Section 1: Patient information

1. Surname **2. First name** **3. Sex** □ M □ F

4. DOB: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_] ***or***
estimated age: [___][___] years if <1 year, [___][___] months if <1 month, [___][___] days

5. Nationality **6. Phone #**:

7. Address: Village _____ Parish _____Sub-county_____ District_____

8. Next-of-kin: **9. Next-of-kin phone number:**

10. Car vehicle plate number: **11. Vehicle destination:**

Section 2: Clinical Information

12. Is/was patient symptomatic? □ Yes □ No **-->If NO, skip to Question 15**

13. Date of onset of first symptom: [_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

14. Symptoms □ Cough □ Fever □ Sore throat □ Shortness of breath □ Headache
□ Chest pain □ Runny nose □ General weakness □ Chills □ Other, specify: _____

15. Known underlying conditions: □ Pregnancy (trimester: ____) □ Post-partum (< 6 weeks) □ TB □ HIV
□ Neurological disease □ Cardiovascular disease □ Hypertension □ Diabetes □ Renal disease
□ Chronic lung disease □ Liver disease □ Malignancy, specify: _____ □ Other, specify: _____

Section 3: Specimen collection

Specimen type	**Date of specimen collection**	**Unique Lab ID**	**Lab specimen sent to:**
□ NP/OP swab	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]		
□ Blood	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]		
□ Other, _____	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]		

Section 4: Provisional results (Lab copy): Filled in by tester

Tester's name **Tester's phone #** **Tester's facility:**

Test	**Results**	**Date of results return**	**Patient contact info for return of results (phone, email)**
□ RDT antigen	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]	
□ RDT antibody	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]	
□ PCR (e.g., GXP)	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]	

-------tear off here-------tear off here-------tear off here-------tear off here-------tear off here-------tear off here--

Section 5: Provisional results (client copy): Filled in by tester **Unique Lab ID:**

Patient surname _____ **Patient first name** _____

Specimen was:	**Test**	**Results**	**Date of results return**
□ Tested on site	□ RDT antigen	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]
□ Referred to:	□ RDT antibody	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]
_____	□ PCR (e.g., GXP)	□ positive □ negative	[_D_][_D_]/[_M_][_M_]/[_Y_][_Y_]

Is an additional test required? □ YES □ NO Next date of testing: DD/ MM/ YYYY

If you have questions, conact the Ministry of Health Public Health Emergency Operations Center (PHEOC) at 0800203033 or 0800100066

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WHO interim considerations in the investigation of cases and clusters of COVID-19: https://www.who.int/publications-detail/considerations-in-the-investigation-of-cases-and-clusters-of-covid-19