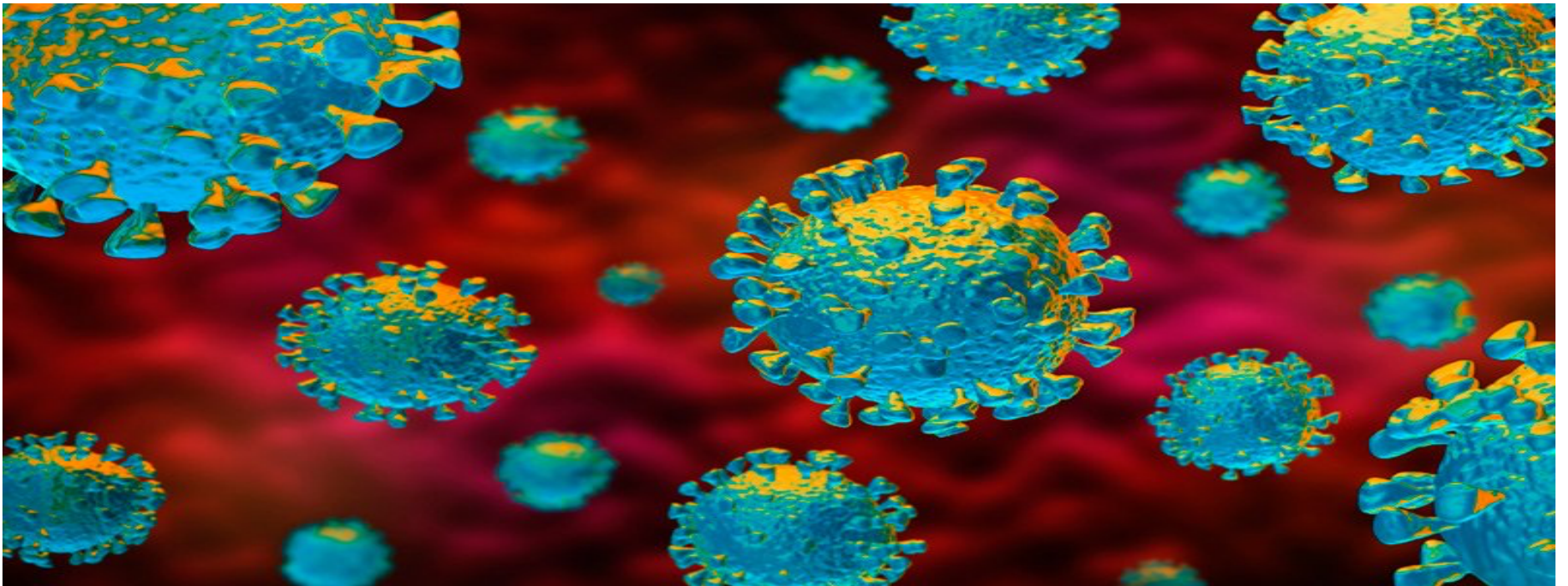




HE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

COVID-19 Rapid Testing Training

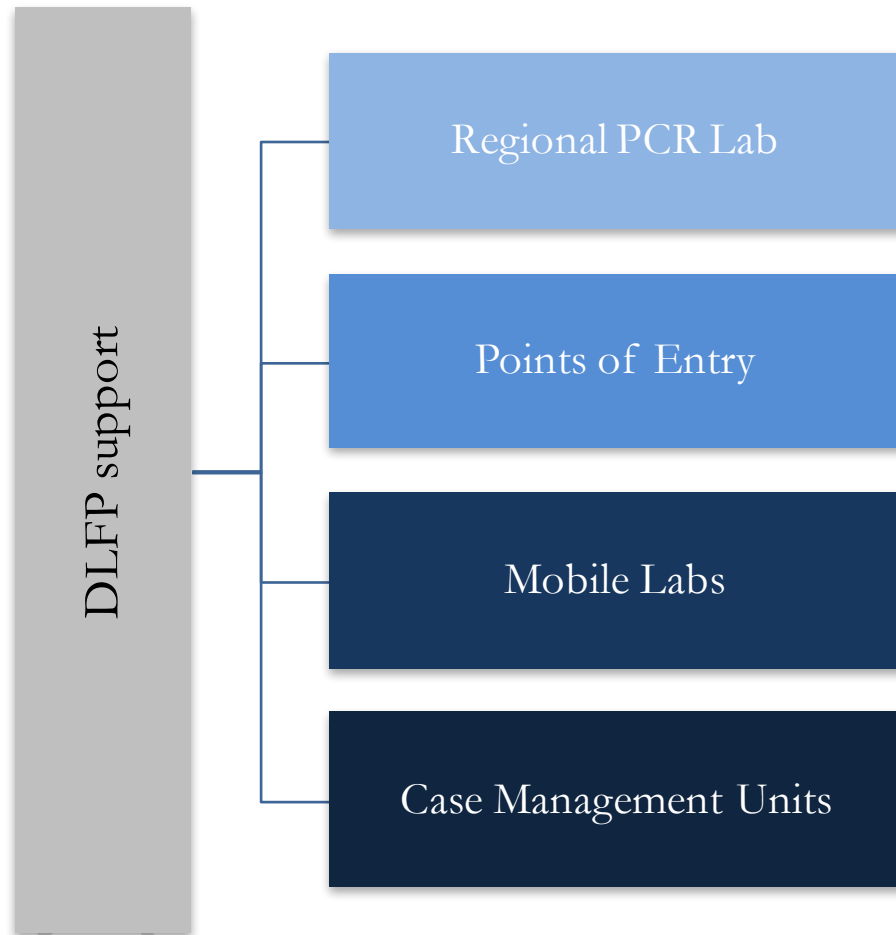


Target Audience

- Laboratory personnel
- District Laboratory Focal Person's
- Implementing Partners



Testing areas to be supervised by DLFPs



- PCR testing
- RDT testing
- Supportive care tests eg CBC, LFT, RFT etc

Lab taskforce to determine to what level DLFP can go eg regional PCR labs?

DLFP supervision roles during COVID-19

Laboratory functionality

- Ensure that accredited testing labs are functional at all times. Ensure labs are adhering to good laboratory practice standards
- Supervise labs at least 2-3 times per month and provide corrective action where needed
- Ensure that areas not covered by the hub riders have access to COVID-19 testing services
- Keep up to date records of testers who have / have not participated on proficiency testing
- Provide oversight of External Quality Assurance activities in the district
- Report any challenges to DHT and UNHLS/CPHL

Supply chain

- Ensure that accredited testing labs have reagents and PPE
- Ensure that requisitions are being submitted on time and follow up with NMS,CPHL/UNHLS and HUBs when deliveries are not made

Information systems

- Ensure that labs submit testing reports on a daily basis
- Ensure that labs have guidelines and information materials eg LIFs, CHOC Form
- Report any challenges to DHT and UNHLS/CPHL

Human resource

- Ensure adequate and appropriate staffing of testing areas
- Ensure that all staff collecting /testing samples are assessed for competency
- Ensure that human resource are being remunerated
- Potentially fill in for staff who might not be able to attend work as replacements are being sourced
- Report any challenges with staffing to DHT and UNHLS/CPHL

Lab Managers for Regional Referral Hosp

- Provide technical oversight to the hubs and facilities in the region on Covid 19 activities .
- Provide technical support supervision and mentorship to the hubs and sites collecting Covid 19 Samples.
- Provide quarterly feedback reports to the stakeholders.
- Build capacity in all sites for sample collection and handling of Covid 19 Samples.
- Coordinates and strengthens on lab Covid 19 activities in the region
- Address the Covid 19 lab related challenges in the Region including sample collection, supplies and results delivery, EQAs.

IP roles during COVID-19

1. Ensure that the testing sites have the necessary capacity to do the testing
2. Facilitate the delivery of proficiency panels to the testing sites
3. Facilitate the DLFPs to execute their roles and responsibilities
4. Support the Ministry of Health in establishing the COVID-19 testing sites

Training Outline

Module 1: Introduction

- Introduction to pandemics
- Overview of COVID 19
- Overview of COVID 19 Testing Technologies
- Role of stakeholders in COVID test

Module 2: COVID-19 testing algorithm

- Antibody screening test algorithm
- Antigen screening test algorithm
- GeneXpert testing algorithm

Training Outline

**Module 3:
Lab investigation form**

**Module 5:
Rapid assessment tool**

**Module 4:
Quality Assurance in
COVID-19 testing**

- GCLP
- Documents and records
- Method verification
- ILC/EQA
- Personnel competency assessment
- WHO guidance on biosafety



***MODULE I:
INTRODUCTION***

DRAFT

DRAFT

Introduction to Pandemics

- A **pandemic** is the worldwide spread of a new disease.



ENDEMIC



EPIDEMIC



PANDEMIC

Introduction to Pandemics

- An **influenza pandemic** occurs when a new influenza virus emerges and spreads around the world, and most people do not have immunity.
- Viruses that have caused past pandemics typically originated from animal influenza viruses

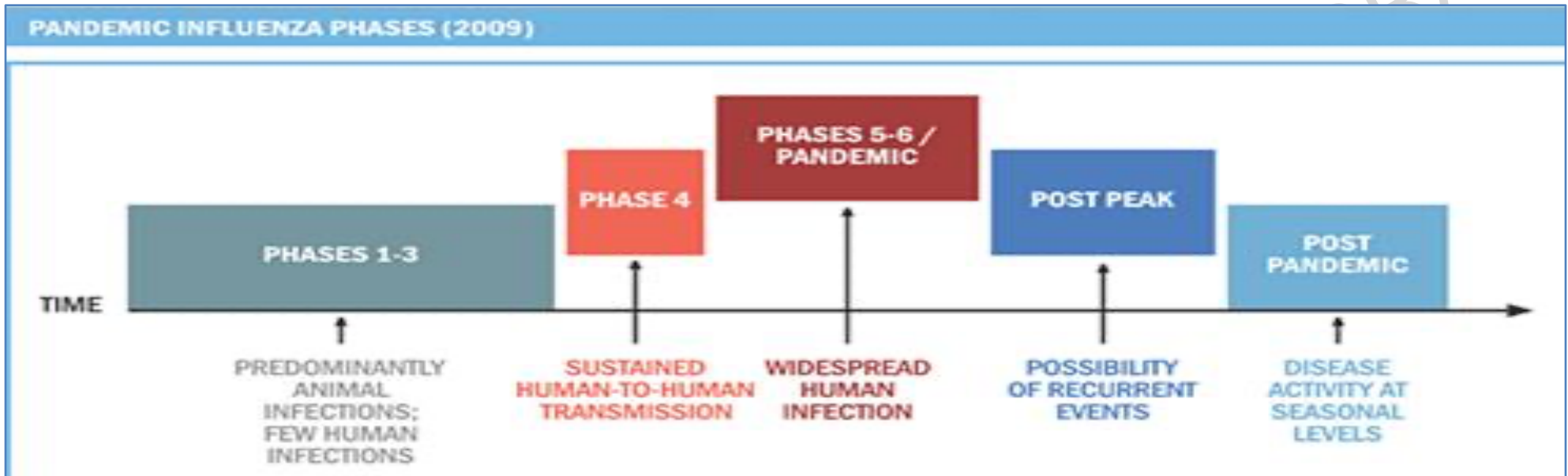
Overview of COVID 19

- Coronavirus disease (COVID-19) is an infectious disease caused by a newly discovered coronavirus strain named Severe Acute Respiratory Syndrome

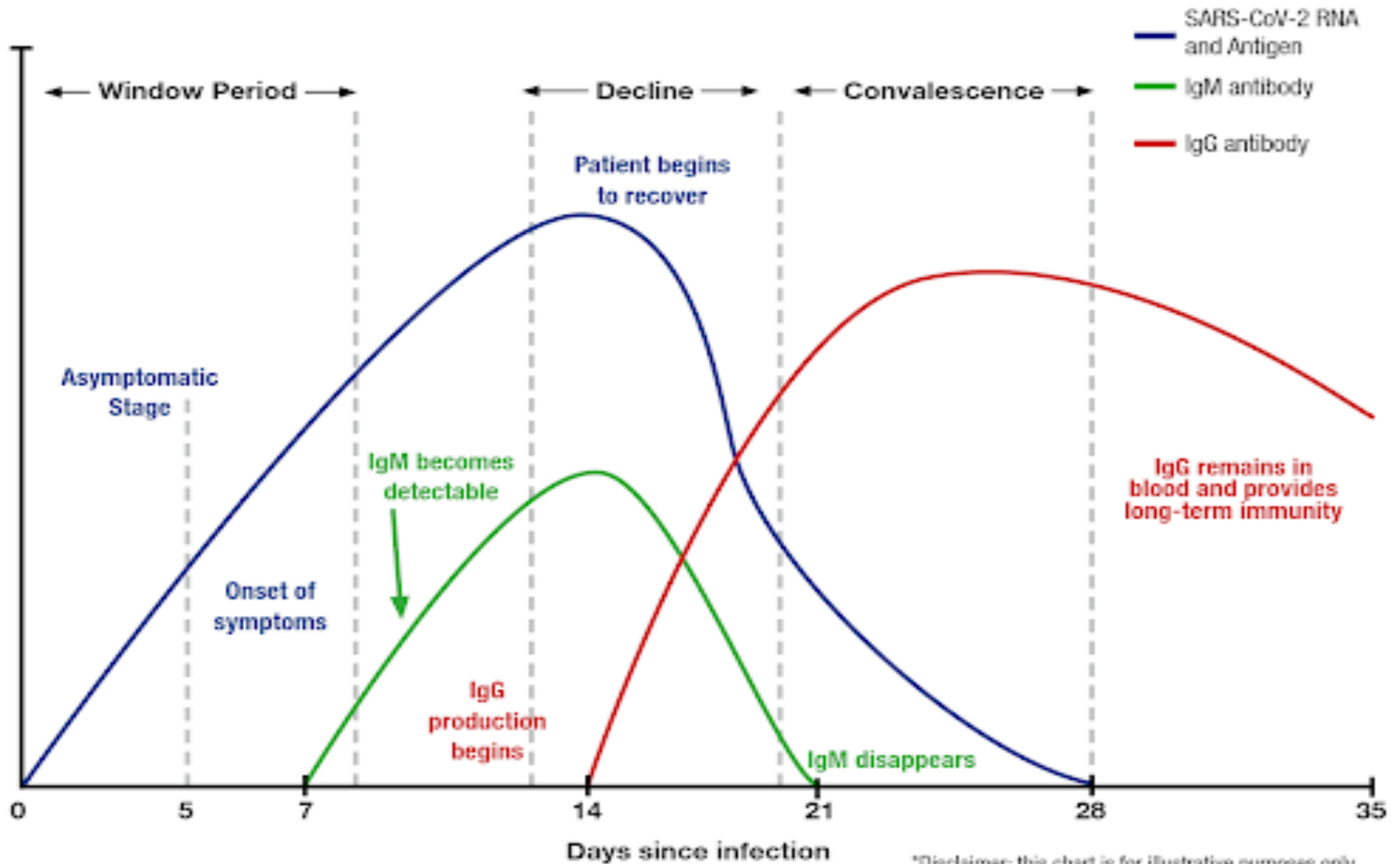
SARS-CoV-2.

- The SARS-CoV-2 virus spreads primarily through droplets of saliva or discharge from the nose when an infected person coughs or sneezes

Overview of COVID 19



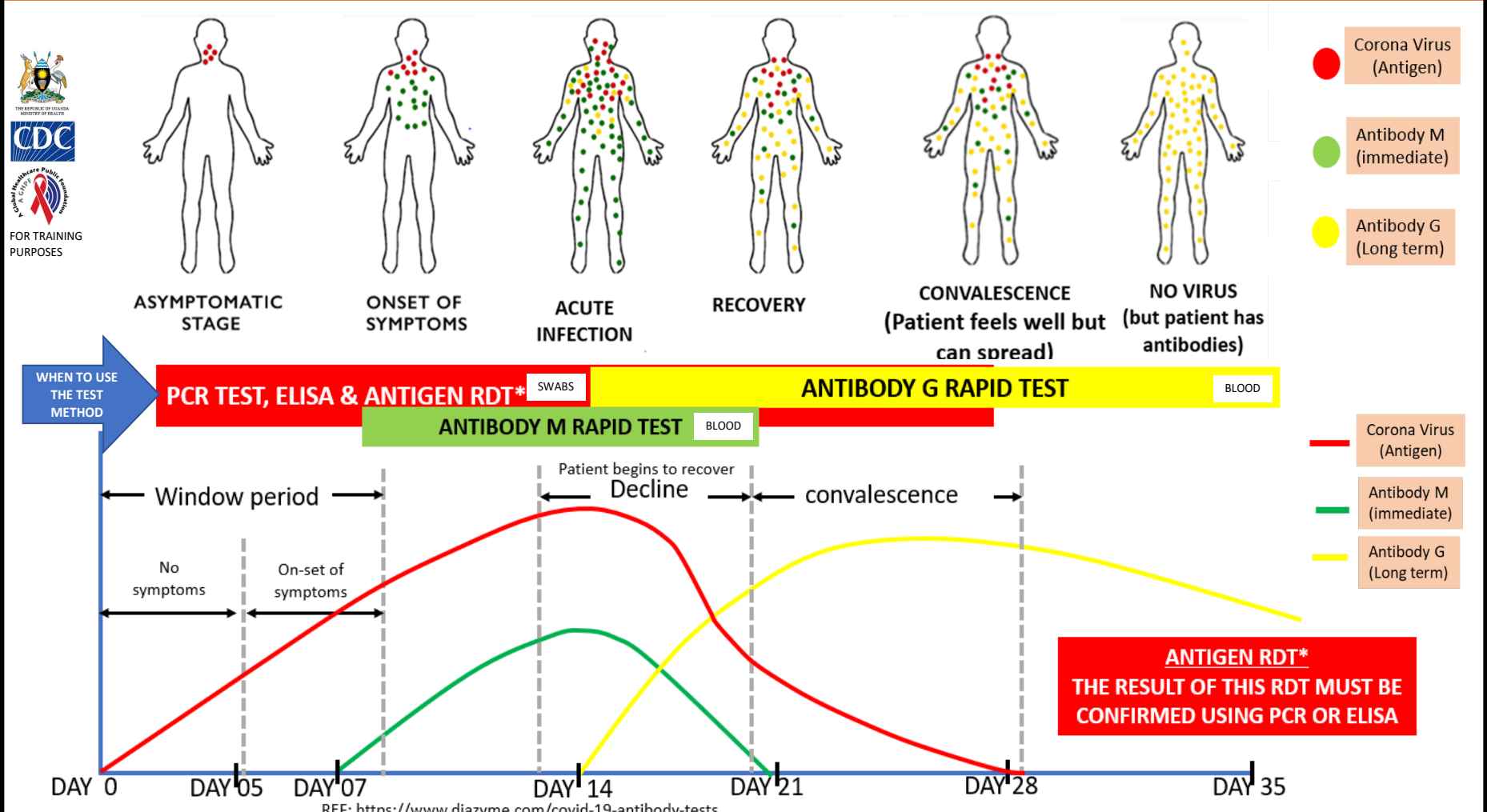
COVID 19 RNA, Ag and Ab Progression









*Disclaimer: this chart is for illustrative purposes only

COVID 19 RNA, Ag and Ab Progression

LAB TEST METHODS ALONG THE COVID 19 ANTIGEN AND ANTIBODY PROGRESSION



COVID 19 Testing Technologies

Use	PCR	Antigen RDT	Antibody RDT
Confirmation of Active Infection			
Monitor Disease Progression			
Previous exposure			
Population Surveillance			

COVID 19 Testing Technologies

Test Results			Clinical Significance
RT-qPCR	IgM	IgG	
+	-	-	Patient may be in the window period of infection
+	+	-	Patient may be in the early stage of infection
+	+	+	Patient is in the active phase of infection
+	-	+	Patient may be in the later or recurrent stage of infection
-	+	-	Patient may be in the early stage of infection RT-qPCR result may be false negative
-	-	+	Patient may have had a past infection and has recovered
-	+	+	Patient may be in the recovery stage of an infection, or the RT-qPCR result may be false-negative

Proposed COVID 19 Testing Technologies for Uganda

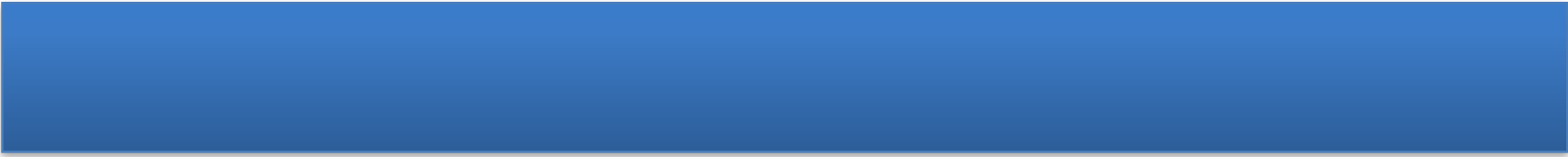
Parameter	SD Bioline Standard Q antigen	Abbott Ab RDT	Cepheid GeneXpert	SD Bioline Std Q antibody (IgG & IgM)
Specimen Type	Nasopharyngeal swab	Whole blood, serum, plasma	Nasopharyngeal swab	Whole blood, Serum, Plasma
TAT	30 minutes	15 minutes	45 minutes	10 minutes
Storage Temperature	2-30°C	2-30°C	2-30°C	2-30°C
Technology	Rapid Chromatographic immunoassay	Rapid Immunochromatography	Real Time-PCR	Rapid Chromatographic immunoassay
Diagnostic purpose	Screening Test	Surveillance test (Effective from 7 days of symptom onset)	Confirmatory	Surveillance test (Effective from 7 days of symptom onset)
Performance characteristics	Sensitivity=80% Specificity=100%	Sensitivity-86.43% Specificity- 99.57%	Analytical sensitivity= \geq 95% Analytical Reactivity=100%	Sensitivity=81.8% Specificity=96.7%

6/11/20 * Other testing platforms are also currently being considered and the list will be updated

Proposed COVID 19 Testing Technologies for Uganda

	Test characteristics	Current status	Planned use
RT RNA-PCR (Uses both Berlin and Chinese protocols)	Screening test: uses E Gene (all SARS viruses including COVID-19) confirmation: uses RdRP gene (unique to COVID-19) TAT: 2-4 hours lab testing, and 24hours result return to HF.	Current molecular test in use for COVID -19 diagnosis	Currently in use as gold standard

** Other testing platforms are also currently being considered and the list will be updated*



***MODULE II:
COVID-19 TESTING
ALGORITHM***

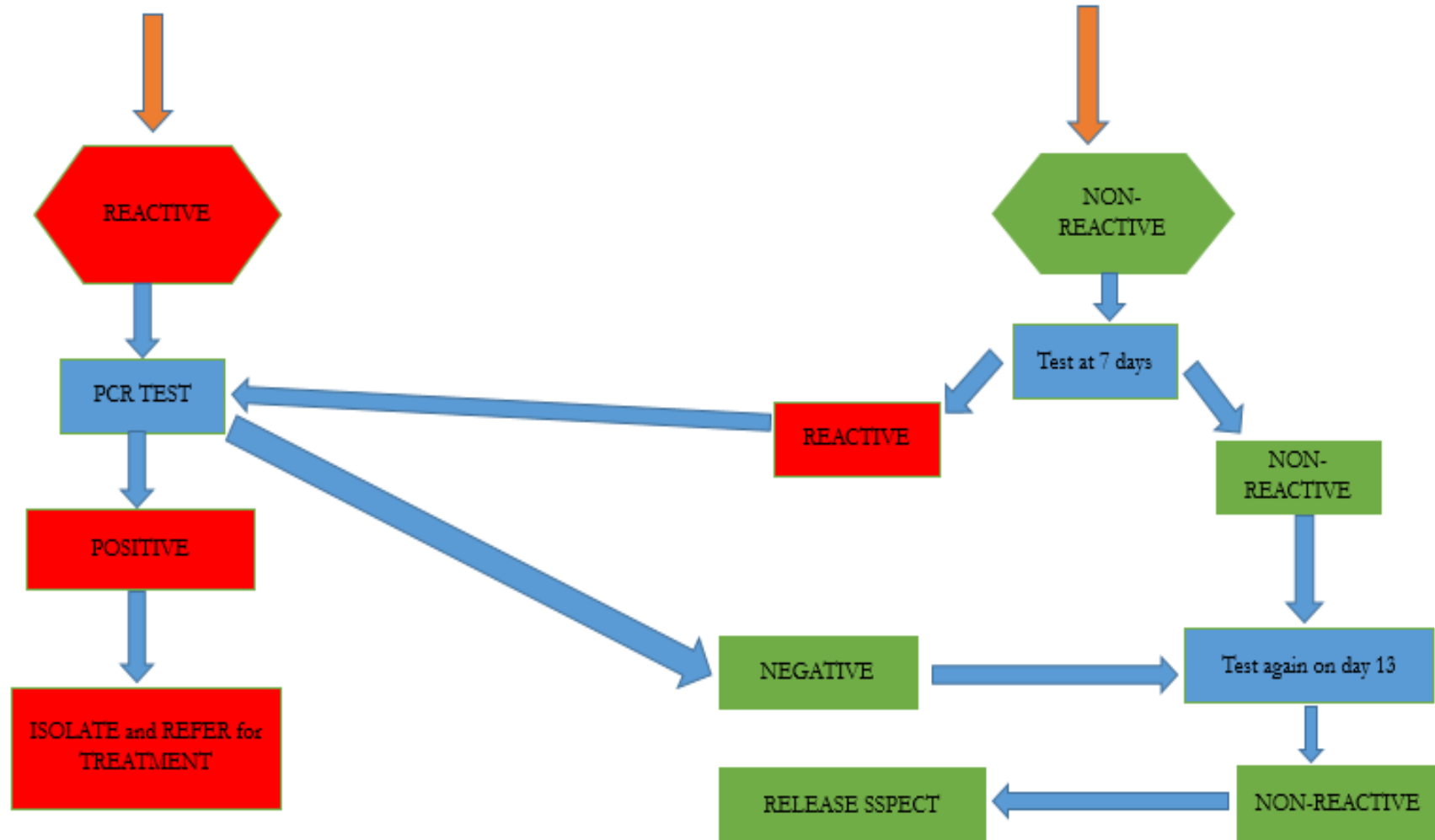
DRAFT

DRAFT

Testing Algorithm for COVID 19

Antibody Screening Testing Algorithm (IgG/IgM)

TEST Suspect with known COVID-19 contact or Suspect with unknown COVID-19 exposure (symptomatic and asymptomatic)

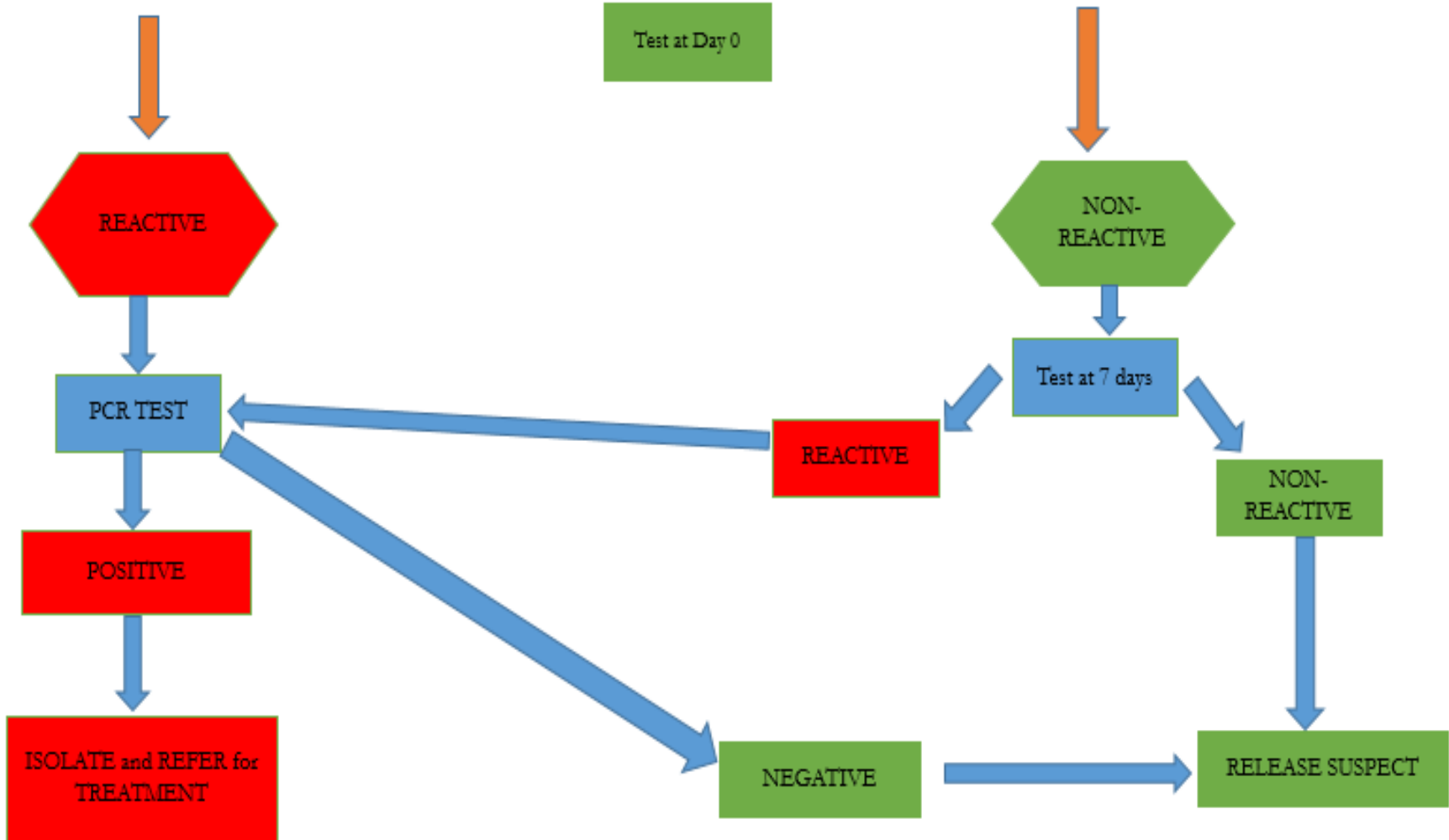


Testing Algorithm for COVID 19

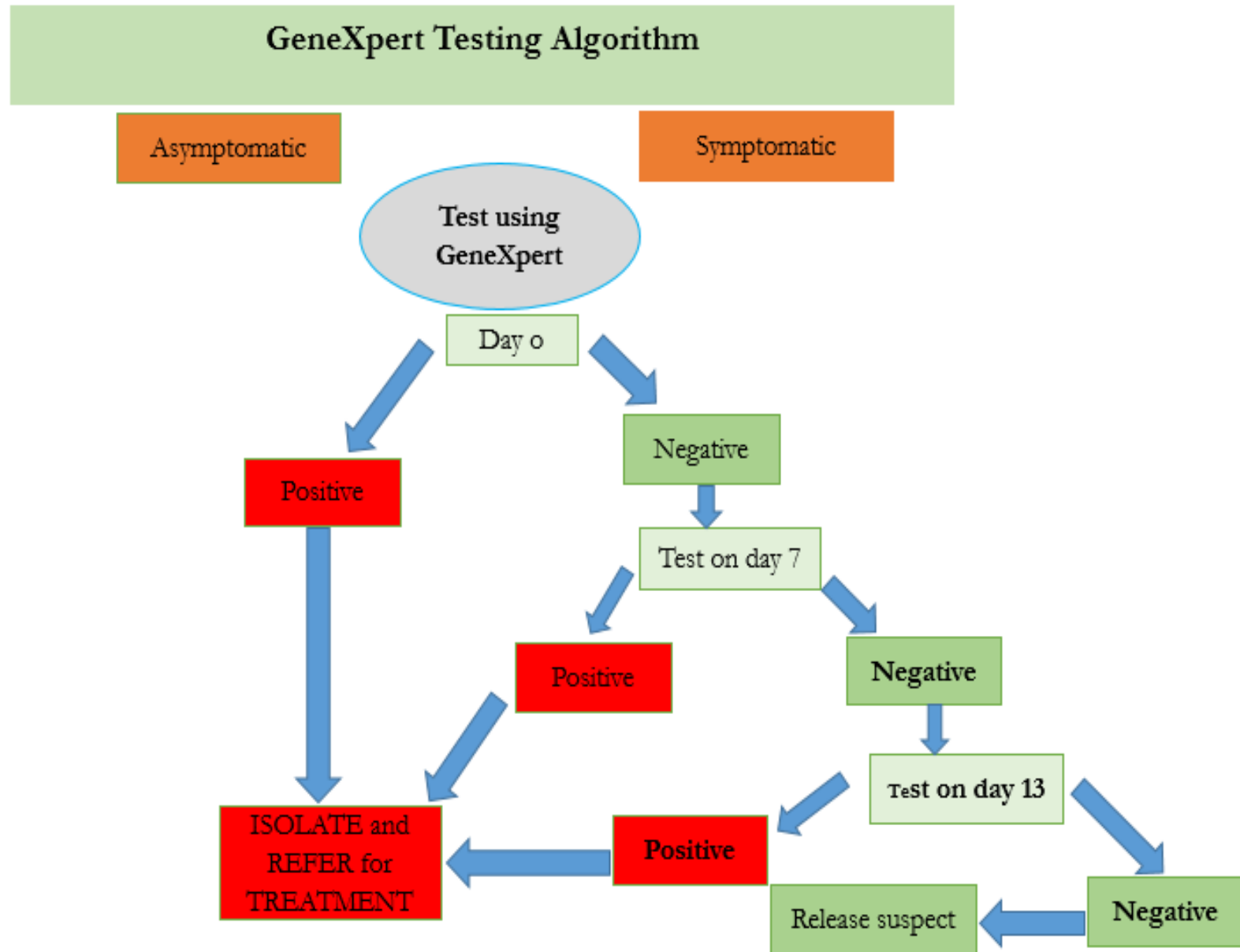
Antigen Screening Testing Algorithm

Test Asymptomatic or Symptomatic Suspect with known or unknown COVID-19 contact or exposure

Test at Day 0

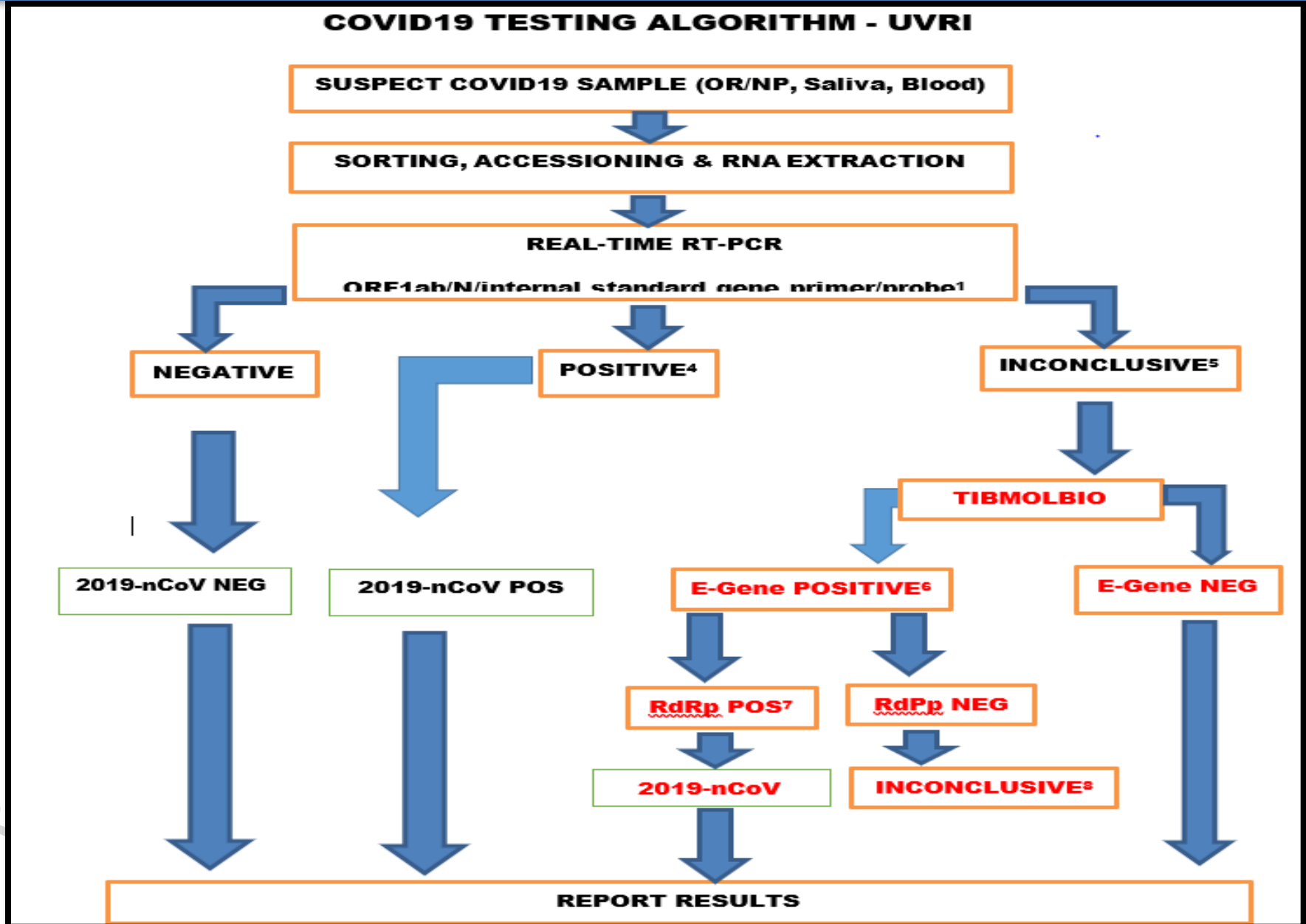


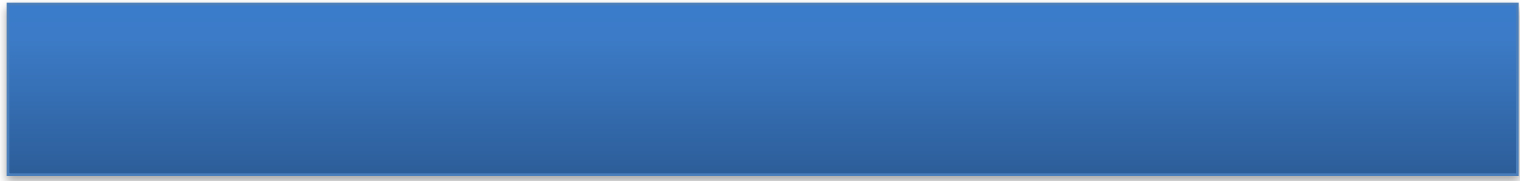
Testing Algorithm for COVID 19



DRAFT

Testing Algorithm for COVID 19





DRAFT

***MODULE III:
LABORATORY
INVESTIGATION FORM***

DRAFT

Lab Investigation Form

The MOH lab investigation form for COVID-19 comprises of 5 sections;

Section: 1	Patient information	Name, sex, DOB/Age, nationality, phone number, Address, Next of Kin
Section: 2	Clinical information	Symptoms, known underlying conditions
Section: 3	Specimen collection	Specimen type, Date of collection, Unique ID, Lab where specimen is sent
Section: 4	Provisional results (Lab copy)	Test, results, date results were returned
Section: 5	Provisional results (Client copy)	Test, results, date results were returned

Lab Investigation Form

Date: [_D][_]/[_M][_]/[_Y][_Y]	Unique Lab ID:				
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 care 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 weeks before onset of symptoms (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: _____

Section 2: Clinical Information

10. Is/was patient symptomatic? Yes No ->If NO, skip to Question 13

11. Date of onset of first symptom: _____

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

13. 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: _____

Lab Investigation Form

Section 3: Specimen collection

Section 3: Specimen collection		Collected by:	Phone:
Specimen type	Date of specimen collection	Unique Lab ID	Lab specimen sent to:
<input type="checkbox"/> NP/OP swab	[_D][_D]/[_M][_M]/[_Y][_Y]		
<input type="checkbox"/> Blood	[_D][_D]/[_M][_M]/[_Y][_Y]		
<input type="checkbox"/> 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:	Patient contact info for return of results (phone, email)
Test	Results	Date of results return	
<input type="checkbox"/> RDT antigen	<input type="checkbox"/> positive <input type="checkbox"/> Negative	[_D][_D]/[_M][_M]/[_Y][_Y]	
<input type="checkbox"/> RDT antibody	<input type="checkbox"/> positive <input type="checkbox"/> Negative	[_D][_D]/[_M][_M]/[_Y][_Y]	
<input type="checkbox"/> PCR (e.g., GXP)	<input type="checkbox"/> positive <input type="checkbox"/> negative	[_D][_D]/[_M][_M]/[_Y][_Y]	

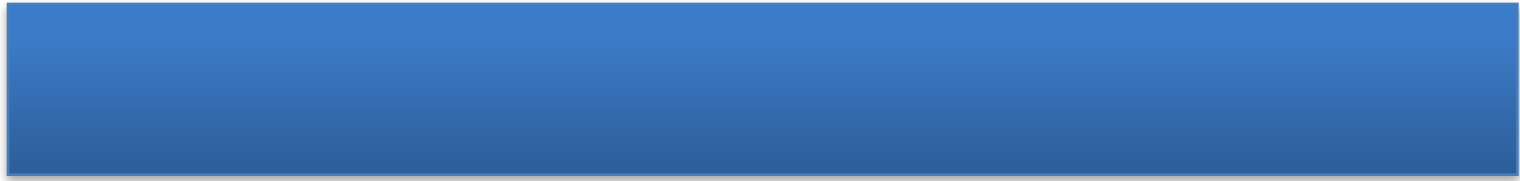
-----tear off here-----tear off here-----tear off here-----tear off here-----tear off here-----tear off here-- tear off here-- tear

Section 5: Provisional results (client copy): Filled in by tester

Patient surname _____		Patient first name _____		Unique Lab ID:
Tester's name	Tester's phone #	Tester's facility:		
Specimen was:	Test	Results	Date of results return	
<input type="checkbox"/> Tested on site	<input type="checkbox"/> RDT antigen	<input type="checkbox"/> positive <input type="checkbox"/> negative	[_D][_D]/[_M][_M]/[_Y][_Y]	
<input type="checkbox"/> Referred to:	<input type="checkbox"/> RDT antibody	<input type="checkbox"/> positive <input type="checkbox"/> negative	[_D][_D]/[_M][_M]/[_Y][_Y]	
_____	<input type="checkbox"/> PCR (e.g., GXP)	<input type="checkbox"/> positive <input type="checkbox"/> 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, contact the Ministry of Health Public Health Emergency Operations Center (PHEOC) at 0800203033 or 080010066



DRAFT

***MODULE IV:
QUALITY ASSURANCE
FOR COVID TESTING***

DRAFT

Quality Assurance

- Total process whereby the quality of laboratory results can be guaranteed.
- Quality assurance involves activities both inside and outside laboratory, good laboratory practice (GCLP) and proper management skill.
- Quality assurance ensures provision of relevant, reliable, timely test results interpreted correctly.

PRE-EXAMINATION PROCESS

DRAFT

DRAFT

Sample collection and handling

- Trained and competent personnel shall collect specimens.
 - Clinicians
 - Laboratory personnel
 - Field surveillance officers
 - Nurses

- Ensure that all the materials required for sample collection, transportation, PPEs are in place before start of process.

Safety procedures during specimen collection

Ensure that adequate standard operating procedures (SOPs) are in use and that staff are trained for appropriate specimen collection, storage, packaging, and transport.

- All specimens collected should be regarded as potentially infectious.
- Ensure that health care workers who collect specimens adhere rigorously to infection prevention and control guidelines.

Sample collection material and storage

Specimen type	Collection Material	Storage temperature until testing	Recommended temperature for shipment according to expected shipment time
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocced swabs*	2-8 °C	2-8 °C if ≤5 days -70 °C (dry ice) if >5 days
Bronchoalveolar lavage	Sterile container *	2-8 °C	2-8 °C if ≤2 days -70 °C (dry ice) if >2 days
(Endo)tracheal aspirate, nasopharyngeal or nasal wash/aspirate	Sterile container *	2-8 °C	2-8 °C if ≤2 days -70 °C (dry ice) if >2 days

* For transport of samples for viral detection, use viral transport medium (VTM) containing antifungal and antibiotic supplements.

- Avoid repeated freezing and thawing of specimens. If VTM is not available sterile saline may be used instead (in which case, duration of sample storage at 2-8 °C may be different from what is indicated above).

Sample collection material and storage

Specimen type	Collection Material	Storage temperature until testing	Recommended temperature for shipment according to expected shipment time
Serum	Serum separator tubes (adults: collect 3-5 ml whole blood).	2-8 °C	2-8 °C if ≤5 days -70 °C (dry ice) if >5 days
Whole blood	(EDTA) Collection tube	2-8 °C	2-8 °C if ≤5 days -70 °C (dry ice) if >5 days
Sputum	Sterile container	2-8 °C	2-8 °C if ≤2 days -70 °C (dry ice) if >2 days
Tissue from biopsy or autopsy including from lung	Sterile container with saline or VTM.	2-8 °C	2-8 °C if ≤24 hours -70 °C (dry ice) if >24 hours
Urine	Urine collection container	2-8 °C	2-8 °C if ≤5 days -70 °C (dry ice) if >5 days

Sample Labelling

Label each specimen container:

- Suspect's ID number (e.g., **case investigation number**),
- Unique specimen ID (e.g., laboratory requisition number),
- Specimen type (e.g., serum)
- Date the sample was collected.



EXAMINATION PROCESS

DRAFT

DRAFT

Verification of Test Kits

- Perform Method verification for COVID 19 test kits before introducing them into routine use and document the procedure used.
- Performance characteristics depend on the test method; For Qualitative COVID 19 testing verify the Sensitivity and Specificity.

Procedure for method verification- Qualitative

- Run 10 Known positive and 10 negative samples for COVID 19
- Consider set acceptance criteria for rejection /acceptance
- Use the contingency tables to calculate the specificity and sensitivity

Performance Characteristics

- **Sensitivity:** Ability of a method to identify true positive samples as positive
- **Specificity:** Ability of a method to identify true negative samples as negative

		The Truth	
		Has the disease	Does not have the disease
Test Score:	Positive	True Positives (TP) a	False Positives (FP) b
	Negative	False Negatives (FN) c	True Negatives (TN) d

	Sensitivity	Specificity
	$\frac{TP}{TP + FN}$	$\frac{TN}{TN + FP}$
Or,	$\frac{a}{a + c}$	$\frac{d}{d + b}$

Verification of Test Kits

- For every new lot/batch/shipment of COVID-19 test kits/reagent, perform lot/batch testing as follows:
 - i. Check and confirm that all the reagents/kits supplies are not expired
 - ii. Pick at least new COVID-19 test devices/kits/reagent
 - iii. Use known COVID-19 positive and negative samples
 - iv. Analyze them on the new lot/batch of kits
- Record and ensure review of the verification results by authorized staff

Limitations

- Source of true negatives and true positives for method verification experiments

Recommendation; Obtain samples from reference laboratory- UVRI

Method Verification

If the kits yield:

- a) the expected COVID-19 **positive** and COVID-19 **negative** results respectively, consider that the kits have **PASSED** the Verification
- b) yield unexpected results or no results at all, consider that the kits have **FAILED** the verification

For PASSED Verification: Use the kits to perform COVID-19 testing

For FAILED verification: Do not use the kits, immediately report to your supervisor and/or NMS and/or UVRI

TEST PLATFORMS

DRAFT

DRAFT

STANDARD Q Antigen Test Kit

STORAGE: Store at 2-40°C

INTENDED USE

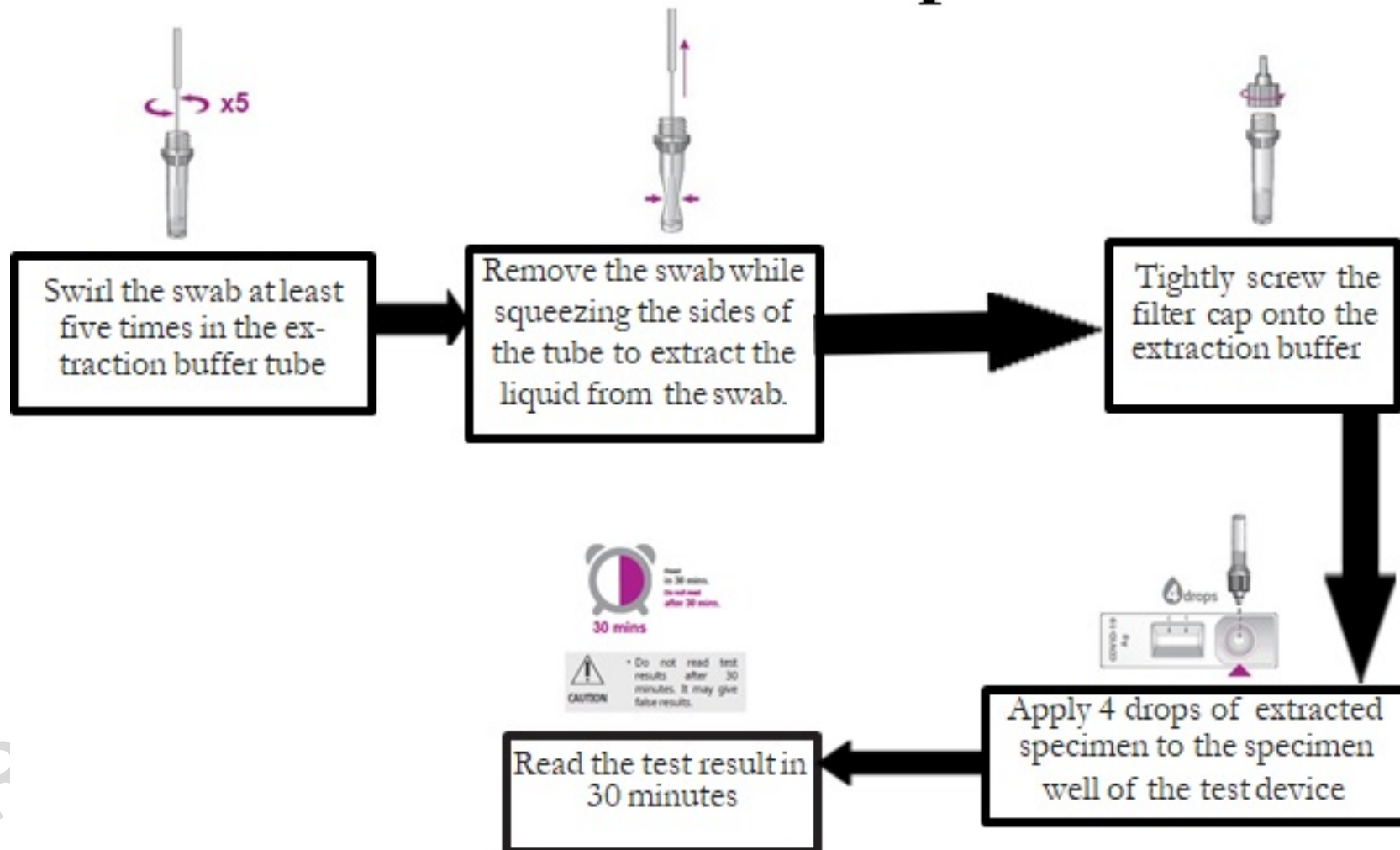
- Rapid chromatographic immunoassay for the qualitative detection of specific antigens to COVID-19 present in human nasopharynx and oropharynx.
- This test is for in vitro professional diagnostic use and intended as an aid to early diagnosis of COVID-19 infection in patient with clinical symptoms with COVID-19 infection.
- It provides only an initial screening test result.

NOTE: The swab used for this RDT should be collected and put directly into the extraction buffer provided in the test kit.

Therefore testing should be done at the sample collection point.

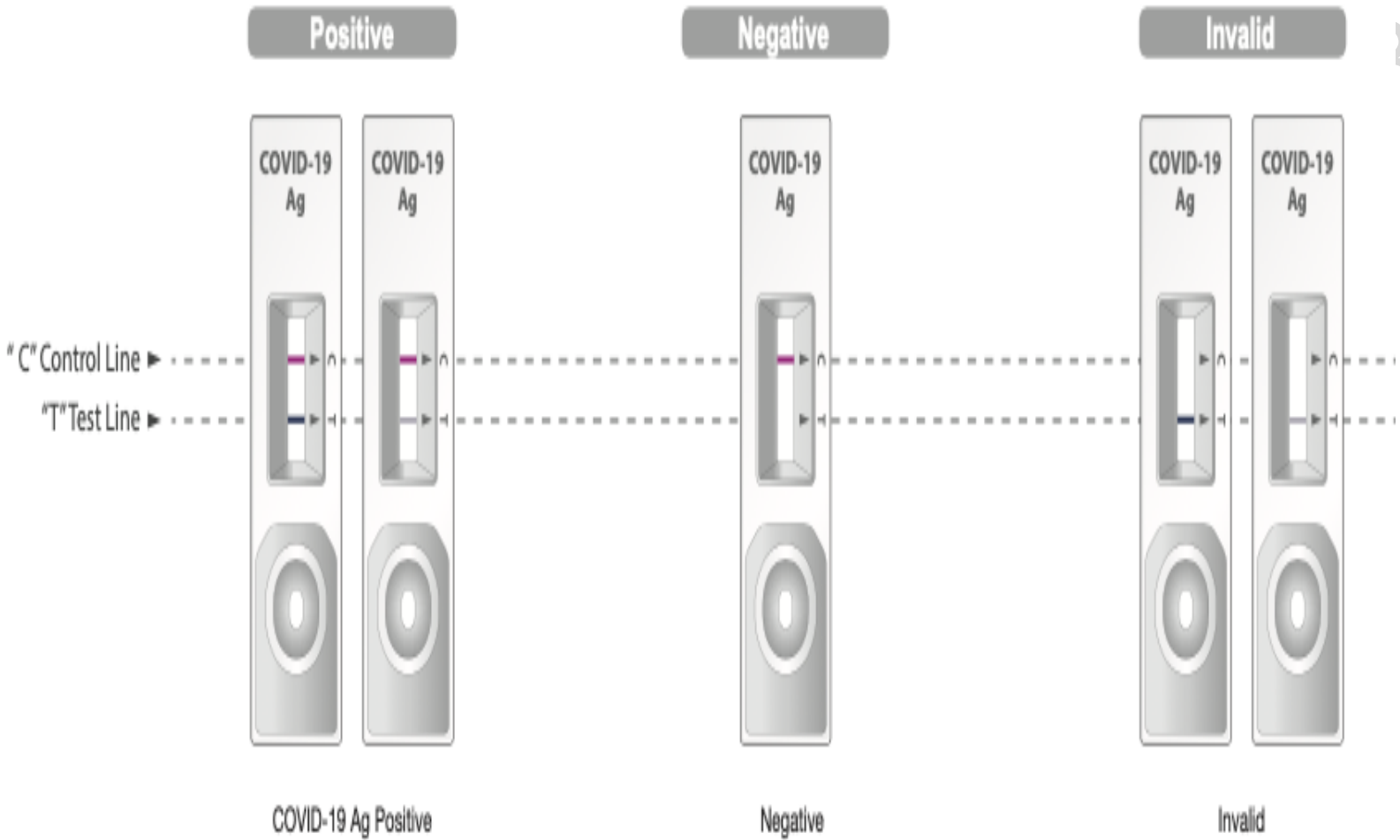
STANDARD Q COVID-19 Antigen Test:

Procedural steps



STANDARD Q Antigen Test Kit

[Interpretation of Test Result]



RAFT

DRA

Limitations of STANDARD Q Antigen Test Kit

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of COVID-19 antigen in human nasopharyngeal swab or Throat swab samples.
- Neither the quantitative value nor the rate of COVID-19 antigen concentration can be determined by this qualitative test.
- Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
- A negative test result may occur if the level of extracted antigen in a sample is below the sensitivity of the test or if a poor quality specimen is obtained
- For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
- The test result must always be evaluated with other data available to the physician.

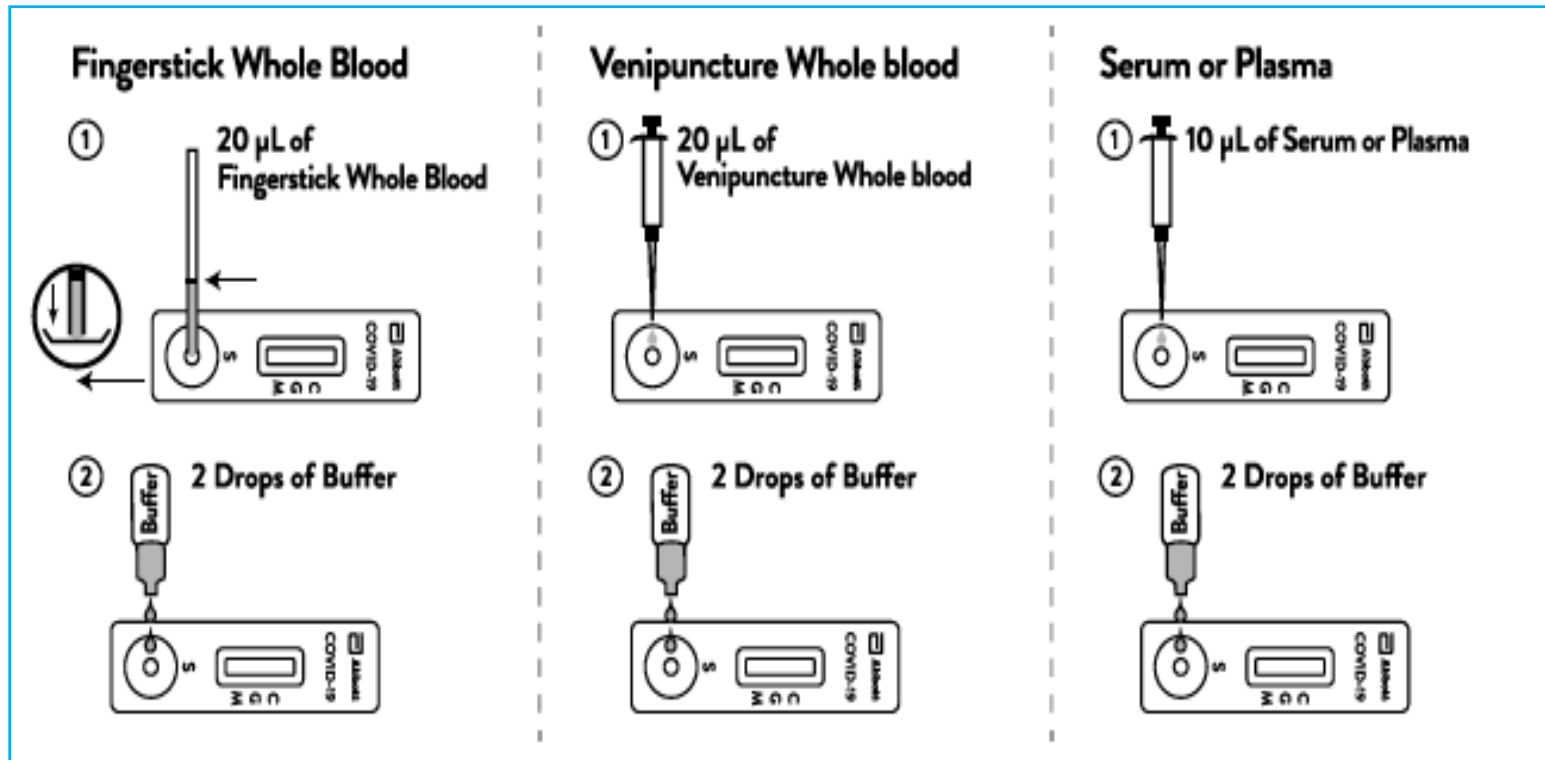
ABBOTT Antibody Test

STORAGE: Store at 2-30°C

INTENDED USE

- Rapid testing for SARS-CoV-2 antibodies within 15 minutes
- Specimen : Whole blood, serum , plasma
- Suitable for Point of Care Testing. No need for extra equipment

ABBOTT-Antibody Test Procedural Steps

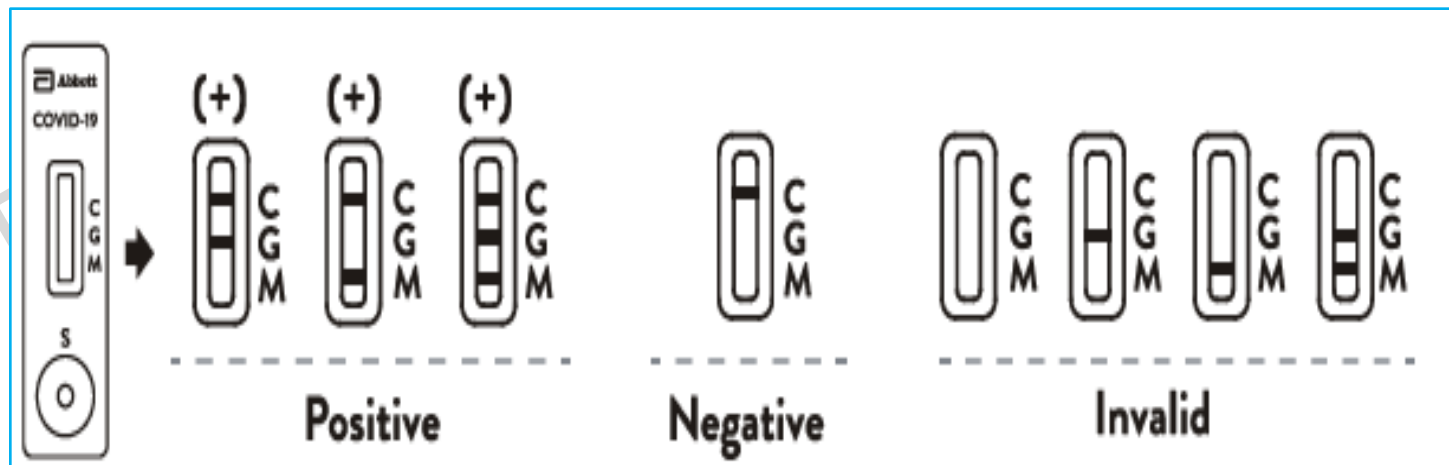


3. Start the timer and wait for 10 minutes.

ABBOTT-Antibody Test

Interpretation of Results

- A red line will appear at the C area of the reading window to show that the test is working properly. This line is the Control line.
- A red line that might appear at the G area of the reading window is the IgG test line.
- A red line that might appear at the M area of the reading window is the IgM test line.

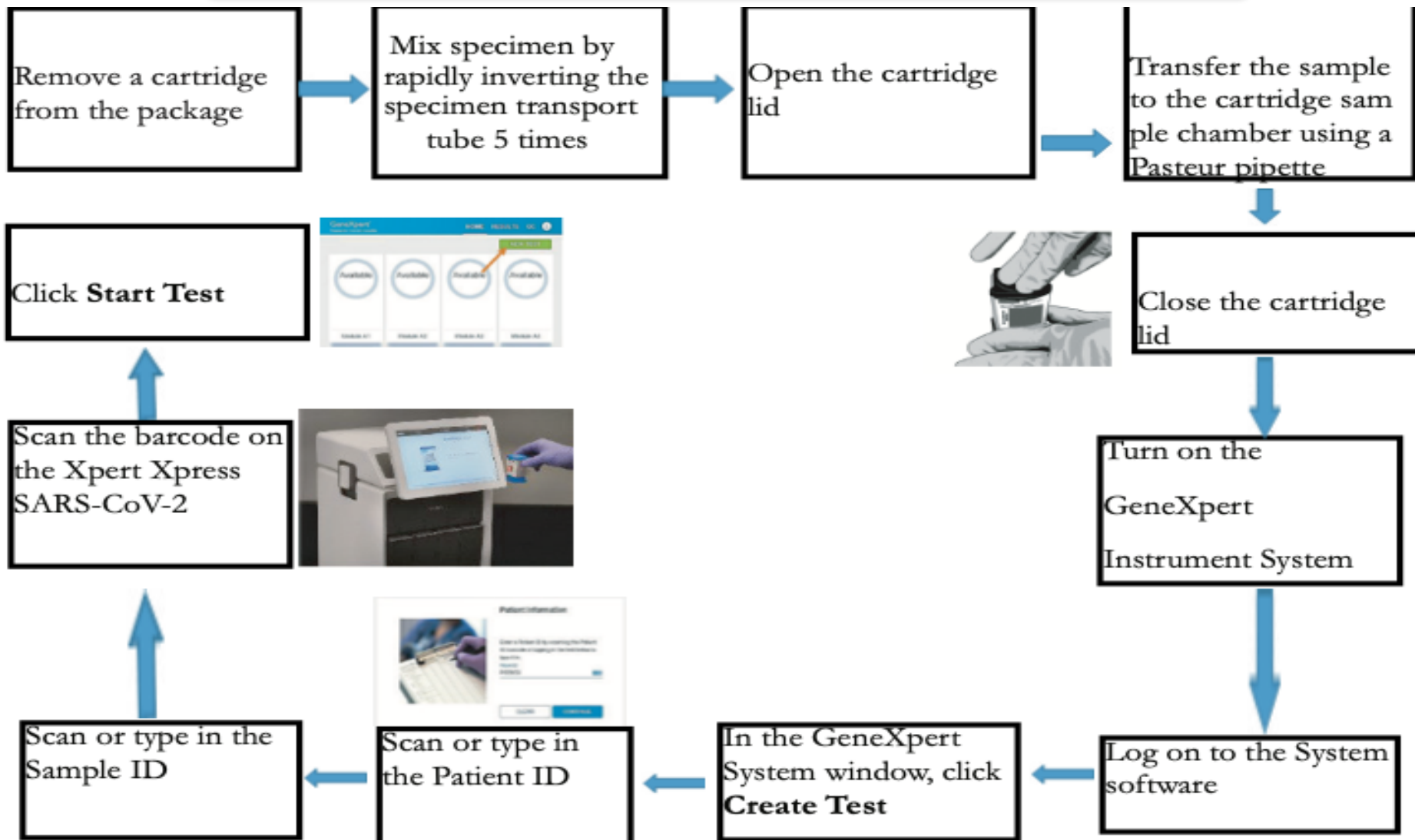


XPERT XPRESS –Gene Xpert

The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in either nasopharyngeal swab and/or nasal wash/aspirate specimens collected from individuals suspected of COVID-19 by their healthcare provider.



XPERT XPRESS GeneXpert testing kit



STORAGE AND HANDLING

- Store the Xpert Xpress SARS-CoV-2 cartridges at 2-28°C.
- Do not open a cartridge lid until you are ready to perform testing.
- Do not use a cartridge that is wet or has leaked

Interpretation of Results

The results are interpreted automatically by the GeneXpert System and are clearly shown in the **View Results** window. The Xpert Xpress SARS-CoV-2 test provides test results based on the detection of two gene targets according to the algorithms shown in Table:

Result text	N2	E	SPC
SARS-CoV-2 Positive	+	+	+/-
SARS-CoV-2 Positive	+	-	+/-
SARS-CoV-2 Presumptive positive	-	+	+/-
SARS-CoV-2 Negative	-	-	+
Invalid	-	-	-

Interpretation of Results

Result	Interpretation
SARS-CoV-2 Positive	SARS-CoV-2 target nucleic acids are detected
SARS-CoV-2 Presumptive positive	SARS-CoV-2 nucleic acids may be present, sample should be retested For samples with a repeated presumptive positive result, additional confirmatory testing may be conducted
Invalid	Presence or absence of SARS-CoV-2 nucleic acids can not be determined. Repeat test
Error	Presence or absence of SARS-CoV-2 nucleic acids can not be determined. Repeat the test
No result	Presence or absence of SARS-CoV-2 nucleic acids can not be determined. A no result indicates that insufficient data was collected. For example the operator stopped a test that was in progress

ENSURING QUALITY OF EXAMINATION RESULTS

Internal Quality Control

Perform internal quality control before analyzing patients' samples for COVID-19 by use of any one or all of the following:

- i. Test kit/device in-built IQC provided by manufacturer
- ii. IQC materials/samples provided by the manufacturer (where applicable)
- iii. Third party reference samples/materials if provided

In addition to IQC performance:

- Ensure accurate sample pipetting (for platforms that require specified sample/reagent volumes)
- Adhere to the manufacturers' procedure (e.g timing, reading/interpreting test results, etc)
- Ensure timely and accurate recording of test results

Inter Laboratory Comparison

- For balance/left over of each sample tested:
 - appropriately store the sample at recommended temperature (2-8°C)
 - submit to MoH/National repository for long term storage

- Perform/participate in ILC/EQA by either and/or both:
 - a) Analyzing COVID-19 PT samples from the reference lab monthly
 - b) Submitting tested sample results to the reference lab for ILC/EQA

NOTE: MoH/CPHL recommends that the testing laboratory sends to UVRI for re-testing the first:

- i. Ten (10) negative samples
- ii. Five (5) positive

POST EXAMINATION PROCESS

DRAFT

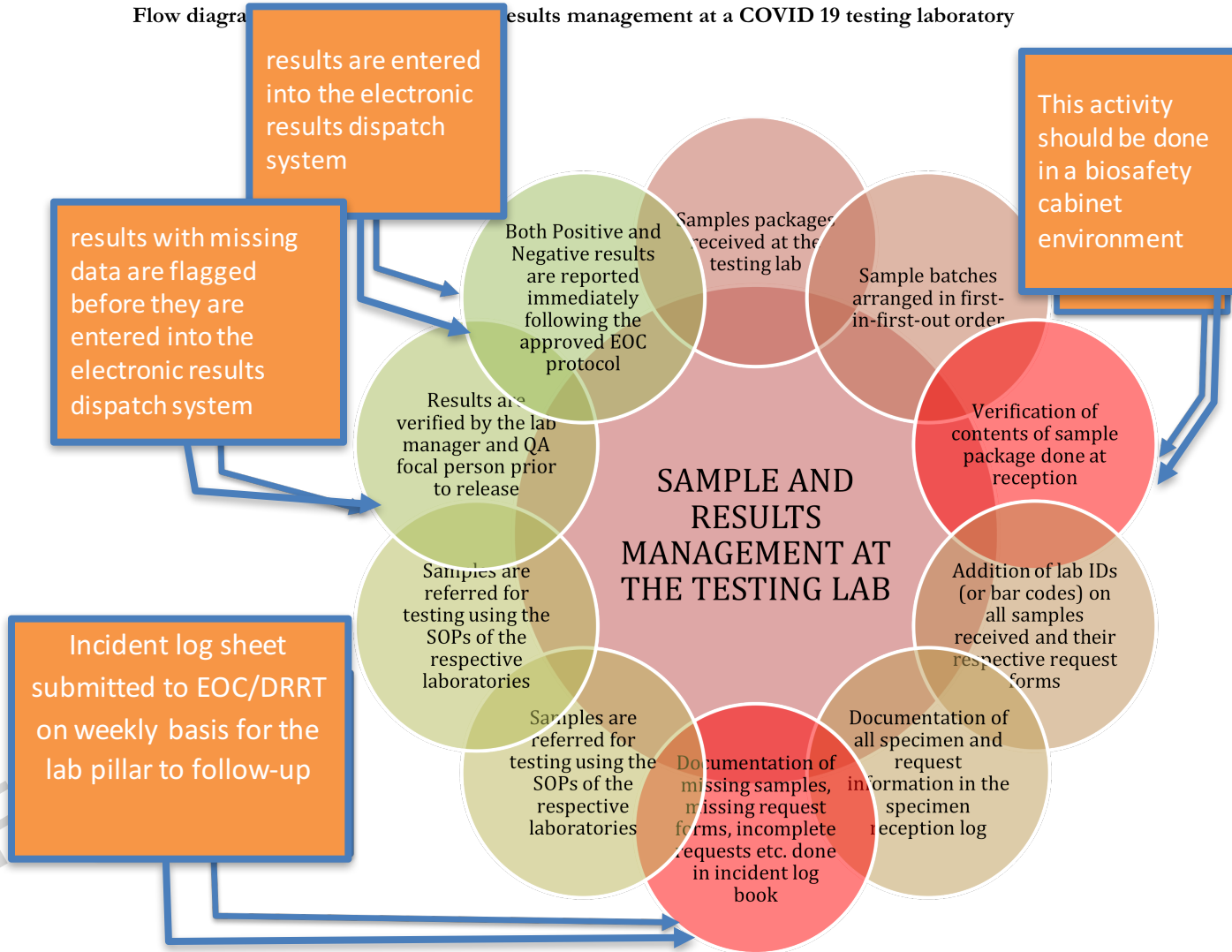
DRAFT

Management of COVID-19 results

- ❑ The results for positives shall be verified by at least two senior laboratory officers prior to dissemination to the managing clinician (case management team) or EOC/DRRT.
- ❑ All the results (both negative and positive) shall be recorded in a dedicated laboratory record book (not in the general laboratory register where other test data is recorded) or electronic laboratory information system ensuring that it aligns with the sample collection information or case investigation form on the respective test request forms.
- ❑ Each individual result (both negative and positive) shall be signed off by the lab manager or approved quality assurance focal person in the laboratory with the date and time of release as a sign of verification. A laboratory results' stamp should be used if available at the facility.

Management of COVID-19 results

Flow diagram illustrating results management at a COVID 19 testing laboratory



Effective Date: 16/05/2020

Page 53 of 54

Release of COVID-19 result

- ✓ Only approved laboratory staff shall release the results from the laboratory following the approved chain of custody from requester, EOC/DRRT, to final results owner.
- ✓ The return of the results to the EOC and DRRT shall be implemented using the appropriate electronic information systems for results management
- ✓ The case management, laboratory supervision teams and EOC/DRRT are the primarily justified stakeholders to access COVID 19 results.
- ✓ Do not share patient identifiable information unless it is absolutely necessary; e.g. in cases of aggregate data collection, analysis and reporting, patient identifiers should not be shared.
- ✓ Access to patient identifiable information should be on a strict need-to-know basis or as pronounced in the study/testing protocol

DRAFT

DOCUMENTS AND RECORDS

DRAFT

COVID-19 related documents

- Ensure that you adhere to manufacturer COVID-19 diagnostic inserts/instructions
- Adhere to the established national COVID-19 testing algorithm
- Adhere to national infection control guidelines
- All the necessary approved documents (e.g test inserts, SOPs, National guidelines/policies) must be available at any COVID-19 testing points before COVID-19 testing

Document and Records

Records

- All records pertaining COVID-19 must be maintained as prescribed by the national COVID-19 pandemic guidelines/policies.
- Patient records and COVID-19 test results at the testing facility/lab/point must be accurately and appropriately recorded/entered into the Laboratory Investigation Form for COVID 19 designated by MoH
- Ensure the test results are released and dispatched in accordance with MoH standard established criteria for COVID-19 test results
- Records for each COVID-19 test report released **MUST** be kept by the testing laboratory/point

PERSONNEL

DRAFT

DRAFT

Personnel Competency Assessment

Only trained personnel deemed competent and authorized to perform COVID-19 RDT are mandated to carry out COVID-19 testing.

The personnel must:

- Have undergone and passed the mandatory COVID-19 testing training in technical and safety procedures.
- Given authorization to handle, process and/or perform COVID-19 tests
- Competency assessment must be conducted before working independently, followed by regular review and refresher training by authorized regional/assigned Trainer.
- Relevant information such as new procedures must be updated and communicated to applicable personnel.
- All personnel must be aware of hazards present in the laboratory and their associated risks

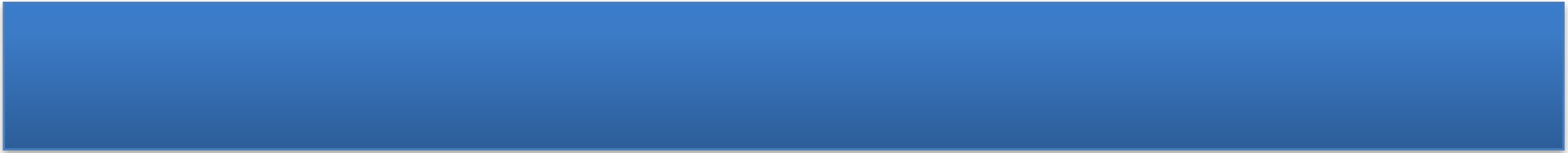
LABORATORY SAFETY

DRAFT

DRAFT

WHO Guidance on Laboratory Biosafety

- All procedures must be performed based on risk assessment and only by competent personnel
- Initial processing of specimens should take place in a validated BSC/ primary containment device.
- Appropriate disinfectants with the proven activity against enveloped viruses should be used(hypochlorite, alcohol etc)
- Patient samples from suspected or confirmed cases should be transported as “Biological substance category B”
- Sequencing , nucleic acid amplification tests should be conducted at a facility using procedures equivalent to Biosafety Level 2



DRAFT

***MODULE V:
RAPID ASSESSMENT TOOL***

DRAFT

Rapid Assessment Checklist

- Adapted tool

Laboratory biosafety guidance related to coronavirus disease (COVID-19)

Interim guidance
19 March 2020



- **Purpose:** assess preparedness for COVID-19 Testing
- Ensure **Safety** of Health Care Workers
- Used to assess district level health labs such as laboratory hubs, Clinical research labs, Centers of Excellence and public health labs

DRAFT

Conducting the Assessment

- *Assessment-Internal/External*
- Assessors: *Certified in auditing LQMS/ Lab Safety*
- *Minimum of One (01) to maximum of Two (02) Assessors*
- *Assessment should not last more than 03 - 04 hours*

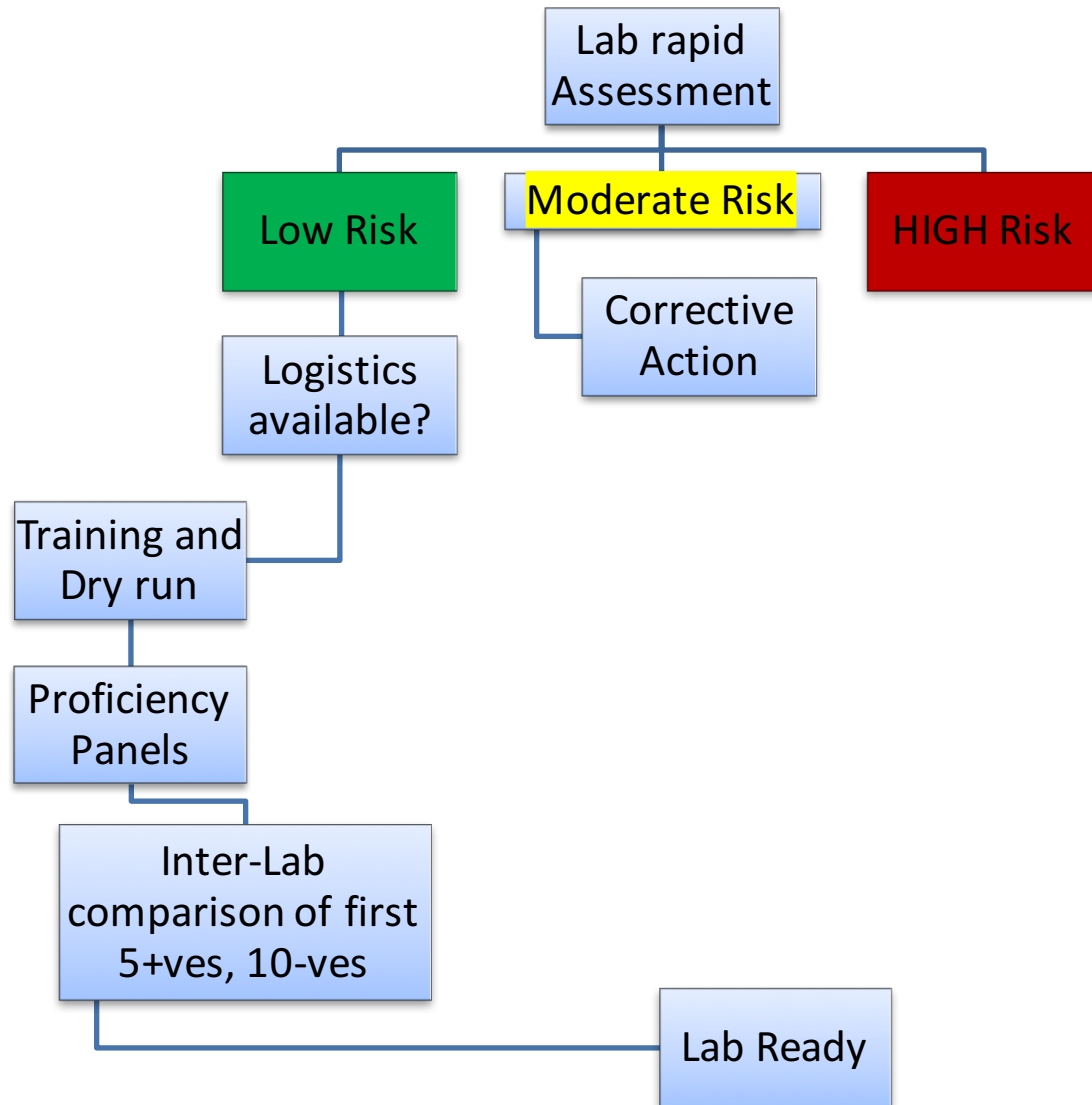
Laboratory biosafety guidance related to
coronavirus disease (COVID-19)

Interim guidance
19 March 2020



DRAFT

Conducting the Assessment



DRAFT

DRAFT

Completing the Checklist

Sections

1. Instructions
2. Competency Check
3. Preliminary Information
4. Assessment Checklist
5. Dashboard and Remediation Plan

Laboratory biosafety guidance related to
coronavirus disease (COVID-19)

Interim guidance
19 March 2020



DRAFT

COVID-19 Risk assessment

The level of impact exposure risk is categorised as;

Risk level	Colour code	Average score
Low	Green	Up to 33%
Moderate	Yellow	34-68%
High	Red	> 68%

Only laboratories with low level of risk for exposure will be considered for COVID-19 testing.

Laboratories with moderate exposure risk will be supported by MOH with corrective actions for the gaps identified to bring down the risk of exposure before they are allowed to test for COVID-19.

Thank You

