STANDARDS FOR SARS-COV-2 TESTING

Version 6.0

Issue date: 31/05/2022

Effective date: 31/05/2022

Health Policies and Standards Department

Health Regulation Sector (2022)

INTRODUCTION

Health Regulation Sector (HRS) forms an integral part of Dubai Health Authority (DHA) and is mandated by DHA Law No. (6) of 2018 to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld.
- Managing health advertisement and marketing of healthcare products.
- Governing the use of Narcotics, Controlled and Semi-Controlled Medications.
- Strengthening health tourism and assuring ongoing growth.
- Assuring management of health informatics, e-health and promoting innovation.

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

TABLE OF CONTENTS

EXECUTIVE SUMMARY

This is edition 6.0 f the Standards for SARS-CoV-2 Testing in health facilities. This document is based on current knowledge of the situation in the UAE and across the globe; it is aligned with current international guidelines and circulars issued by DHA related to the subject. The document aims to ensure public and patient health protection and to ensure efficiency and integrity of testing services applied to handle negative and positive cases of COVID-19, in all DHA licensed health facilities providing SARS-CoV-2 Testing services. DHA will update these Standards as new information becomes available.

The key updates on Version 6.0 are set out below:

- Standard One: Registration and Approval Requirements-page no. 09-10.
- Standard two: Testing Criteria-page no.11.
- Standard Seven: Sample Processing- page no.17.
- Standard Eight: Interpretation of Result- page no. 19.
- Standard Nine: Result reporting- page no. 20.
- Standards Ten: Nucleic Acid Amplification for Detection of SARS-COV2 As Point of Care Test (POCT) for COVID-19 -page no. 20.
- References: page no. 23-25.
- Appendices: page no. 26-42.

DEFINITIONS

Confirmed case: A person meeting the clinical and laboratory diagnostic criteria for COVID-19 with positive SARS-CoV-2 PCR test by an approved laboratory.

Health Facility: A DHA licensed entity that is authorised to provide medical services whether its owner or manager is an individual or an organization.

Healthcare Professional: is a natural person who is authorized and licensed by the DHA to practice any of the healthcare professions in the Emirate.

Isolation: is separation of patients and/or staff into a secluded area or room for infection control purposes. Isolation may include self-isolation in a room, home or residential institution.

Quarantine: Separation and restriction of movement of patients or people who are exposed to a contagious disease to determine if they have been exposed or become sick.

Suspected COVID-19: Patient who presents upper or lower respiratory symptoms with or without fever (≥37.5°C) AND fulfilling any one of the following criteria:

- International travel history during the 14 days prior to symptom onset.
- Been in contact with a confirmed COVID-19 case within 14 days.
- Residing in a community setting where COVID-19 cases have been detected **OR**
- Presence of influenza-like symptoms without history of travel or known possible exposure.

ABBREVIATIONS

AN	:	Assistant Nurse
CAP	:	College of American Pathologists
COVID	:	Corona Virus Disease
CP	:	Convalescent Plasma
DHA	:	Dubai Health Authority
EUA	:	Emergency Use Authorization
HCP	:	Health Care Professional
HPSD	:	Health Policies and Standards Department
HRS	:	Health Regulation Sector
ISO	:	International Organization for Standardization
PCR	:	Polymerase Chain Reaction
POCT	:	Point of Care Testing
PPE	:	Personal Protective Equipment
RN	:	Registered Nurse
RT-PCR	:	Reverse Transcription Polymerase Chain Reaction
SARS	:	Severe Acute Respiratory Syndrome
VTM	:	Viral Transport Media

1. BACKGROUND

As part of the continuous efforts to monitor healthcare system's response to the Corona Virus Disease (COVID-19), and to ensure public health protection and efficiency of procedures of diagnosing the disease and proper utilization of the resources, DHA has set out the following requirements regarding COVID-19 Screening and Testing. The Standard will be updated by DHA periodically based on changes in National Standards and federal decisions. All relevant DHA Licensed Health Facilities are required to adhere to the requirements within the document to avoid non-compliance.

2. SCOPE

2.1. SARS-CoV-2 Testing services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality in SARS-CoV-2 Testing services in DHA licensed health facilities.

3.2. To ensure patients who are tested for SARS-CoV-2 are provided with timely, reliable and valid results.

3.3. To prevent the use of non-approved DHA laboratories from testing and issuing results.

3.4. To reject COVID-19 test results from non-approved DHA laboratories and impose disciplinary actions.

4. APPLICABILITY

4.1. DHA licensed health facilities providing SARS-CoV-2 Testing services.

5. **STANDARD ONE:** REGISTRATION AND APPROVAL REQUIREMENTS

5.1. Swab collection services for COVID-19 are limited to below healthcare facilities following approval by DHA:

5.1.1. Hospitals.

5.1.2. Day Surgery Centres (DSC).

5.1.3. Outpatient Clinics.

5.1.4. Clinical Laboratories approved for COVID-19 testing, with dedicated area for sample collection.

5.1.5. Home Healthcare Providers–Standalone or service licensed under other DHA licensed health facilities.

5.1.6. School Clinics.

5.2. SARS-CoV-2 Test processing services are limited to below healthcare facilities following approval by DHA:

5.2.1. DHA Clinical Laboratories.

5.2.2. Standalone Clinical Laboratories.

5.2.3. Clinical Laboratories within Hospitals.

5.3. Healthcare facilities and Clinical Laboratories seeking DHA approval should:

5.3.1. Submit online application through Sheryan, for 'COVID swabbing' add-on.

5.3.2. Comply with DHA inspection requirements refer to (**Appendices 1, 2, 3 and 4**).

5.3.3. Register in HASANA platform and acquire the necessary training.

5.3.4. Engage in regular inter-laboratory comparison with DHA as required.

5.4. Clinical Laboratories should integrate their Laboratory Information System with HASANA platform.

5.5. The updated List of DHA approved laboratories for COVID-19 testing can be found with the below Medical Registry-DHA link, following the steps:

Open the link ➔Facilities ➔ Add-Ons ➔ COVID RT-PCR Testing ➔ Apply filters

https://services.dha.gov.ae/sheryan/wps/portal/home/medical-directory

5.6. Swab collecting facilities should have in place a valid contract with a DHA approved and HASANA integrated clinical laboratory.

5.6.1. Samples should not be sent to clinical labs outside the emirate of Dubai.

6. **STANDARD TWO:** TESTING CRITERIA

6.1. COVID-19 testing should only be requested by a DHA licensed physician in accordance to the National Clinical Guidelines and based on the attached priority testing criteria refer to (**Appendix 5**).

6.1.1. DHA and the COVID-19 Command and Control Centre should update testing criteria regularly.

6.1.2. For suspected COVID-19 cases, the treating physician should give clear and comprehensive instructions to the patient regarding self-quarantine until the results reported.

6.1.3. It is the responsibility of the treating physician to report the test result to the patients and to provide the necessary information and guidance based on the national guidelines.

6.2. All health facilities should comply with the fixed service price for testing COVID-19 as announced by DHA through circulars and refrain from adding any additional fees for delivery of the test result including but not limited to phone, call, text, VIP or expedite services.

6.3. Testing Laboratories should implement molecular testing Polymerase Chain Reaction (PCR) for diagnosis of COVID-19 and Reverse Transcription Polymerase Chain Reaction (RT-PCR) as the approved testing methodology for detection of SARS-COV-2 virus.

6.4. Authorized testing laboratories for Covid 19 can use Rapid PCR as Point of Care Testing (POCT) and shall be FDA approved.

7. **STANDARD THREE:** SAMPLE COLLECTION

7.1. Health facilities should gain approval from DHA prior to starting sample collection services as above.

7.2. Swab collecting facilities must adhere to all DHA regulations relevant to the facility category.

7.3. Health facilities should have a dedicated room for swab collection with infection control setup including, but not limited to:

7.3.1. Air purification system.

7.3.2. Negative pressure or good air circulation.

7.3.3. Hand washing sink.

7.4. Swabs collection conducted at non-healthcare setup should comply with the below requirements:

7.4.1. Obtain prior approval from DHA.

7.4.2. Ensure availability of an online pre-booking appointment system.

7.4.3. Ensure sample collection in an outdoor space or well ventilated area.

7.4.4. Follow infection control measures.

7.4.5. Ensure accurate and timely patient data entry.

7.4.6. Ensure following sample storage and transport measures as listed in this standard.

7.5. Swabs should be collected under aseptic conditions and should be placed immediately into sterile transport tube of 2-3 ml Viral Transport Media (VTM).

7.6. VTM should be validated with each Extraction platform and Each PCR kit to exclude the possibility of inhibitors to extraction/amplification platforms.

7.7. HF shall ensure that nasal sample fulfil the below requirements:

7.7.1. Brand name

7.7.2. Manufacturer name and address

7.7.3. CE Marking

7.8. HF should maintain the following documents for nasal sample swabs:

7.8.1. The manufacturer's EU declaration of conformity

7.8.2. The CE sterility certificate

7.9. Healthcare professionals collecting the specimens should follow infection control measures and use recommended Personal Protective Equipment (PPE) (N95, facemask, eye protection, gloves and a gown).

7.10. It is preferable for initial diagnostic testing/specimen for SARS-CoV-2 to be taken from upper respiratory (Nasopharyngeal or Oropharyngeal) sites.

7.11. Testing lower respiratory tract specimens (Broncho alveolar lavage) are an option for patients with productive cough or receiving invasive mechanical ventilation.

7.12. Only trained and privileged licensed healthcare professionals in an appropriate setting should collect COVID-19 swabs.

7.12.1. Swab collection training videos can be accessed through DHA Medical Education Department.

7.12.2. Training logs and privileges by the medical director shall be maintained.

7.13. DHA Approved health facilities should ensure all patient details are filled accurately and on timely manner in HASANA System[1] as per Communicable Disease Notification Policy timeline.

7.14. Health facilities collecting swabs from patients should ensure the type of swab used corresponds to the testing devices of the approved lab processing the test.

7.15. Health facilities should provide the HASANA client ID to the processing lab to ensure correct test result entry.

[1] For HASANA related inquiries contact: HasanaHelpdesk@dha.gov.ae

7.16. Health facilities should update swab collection data in Sheryan system daily, before 12 am.

8. STANDARD FOUR: SALIVA SAMPLE COLLECTION

8.1. Saliva samples can be collected by all approved facilities for sample collection.

8.2. Saliva samples should only be collected as a non-invasive alternative sample for RT-PCR in the below conditions:

8.2.1. Screening of asymptomatic children up to 17 years of age.

8.2.2. Children who are likely to be uncooperative for nasopharyngeal swab sampling.

8.2.3. Screening for People of Determination.

8.2.4. Samples should be collected under supervision of a trained DHA licensed healthcare professional.

8.3. Saliva samples should be taken following the below steps:

8.3.1. Patient must be dry fasting at least thirty (30) minutes to one (1) hour before collection of saliva.

8.3.2. Saliva must be pooled in mouth for 1-2 minutes prior to collection, and then gently spit 1-2 mL into the sterile, leak-proof, screw-cap sputum collection cup or a sterile dry container.

8.3.3. Close container tightly, seal with para film and place in hazardous bag.

8.3.4. Send the sample to an approved DHA Laboratory for SARS-C0V-2 Test Processing refer to (**Appendix 5**).

8.4. DHA Approved health facilities should ensure all patient details are filled accurately and on timely manner in HASANA System[2] as per Communicable Disease Notification Policy timeline.

8.5. Health facilities should provide the HASANA client ID to the processing lab to ensure correct test result entry.

8.6. Health facilities should update sample collection data in Sheryan system daily, before 12 am.

9. **STANDARD FIVE:** SAMPLE STORAGE

9.1. Secure designated space with an access restriction, near a hand-washing basin must be provided for safe storage of Laboratory specimens.

9.2. Labelling the collected sample as a biohazard.

9.3. The collected swab along with viral tube media should be collected under aseptic condition and stored immediately in a separate fridge in a temperature of 2-8°C or stored in an icebox until it is delivered to the testing laboratory as soon as possible with the availability of thermometer to register the temperature.

9.4. The specimens should be stored in a (-20) freezer where there is a delay of over 12 hours in specimen transport.

10. **STANDARD SIX:** SAMPLE TRANSPORT

10.1. All materials transported within and between laboratories should be placed in a secondary packaging, to minimize the potential for breakage or a spill.

[2] For HASANA related inquiries contact: HasanaHelpdesk@dha.gov.ae

10.2. Transport of COVID-19 samples should be through cold chain logistics.

10.3. Laboratory specimens must be collected, transported and handled safely to ensure that no risk of infection is transferred to the personnel involved.

10.3.1. Samples should be transported on timely basis, avoiding delay and batching.

a. In case of delay, proper cold chain storage and transport procedure should be maintained by the collecting health facility and the testing Laboratory should be notified about the delay.

10.4. Samples should be dispatched within two (2) hours from collection time using double packaging system.

10.5. Samples should be labelled as detailed and shown in (**Appendix 6**).

10.6. Bio-hazardous materials precautions should be adhered to by transport personnel and couriers during transport of samples.

10.6.1. Transport personnel or couriers should be trained by the collecting health facility on safe handling practices and infection control procedures.

10.6.2. All transport personnel are required to wear PPE at all times.

11. **STANDARD SEVEN:** SAMPLE PROCESSING

11.1. Clinical Laboratories shall fulfil the facility design requirements as outlined in the Health Facility Design Guidelines.

11.2. Clinical Laboratories should seek approval from HRS prior to processing any SARS-CoV-2 related tests.

11.3. Clinical Laboratories should process SARS-CoV-2 test types as per the approval received from HRS.

11.4. The gold standard for diagnosis of COVID-19 is RT-PCR using SARS-CoV-2 kits.

11.4.1. RNA Extraction is a must procedure , direct lysis procedure is not allowed.

11.5. Testing Laboratories should ensure that the received samples are for clients registered on HASANA prior to processing.

11.6. Laboratories should refrain from adding up samples from a group of patients (Samples Pooling) before RNA extraction or before PCR runs.

11.7. Laboratories should follow the protocol in (**Appendix 7**) to ensure quality measurement steps to prevent laboratory environment and carry over contamination.

11.8. Testing laboratory should implement one or two RNA extraction platforms along with quality control for RNA extraction.

11.9. Testing laboratories providing COVID-19 testing services shall use a DHA approved SARS-CoV-2 kits.

11.9.1. For the DHA approved SARS-CoV-2 kits, please refer to the below link:

https://www.dha.gov.ae/Documents/HRD/RegulationsandStandards/standards/AUTHORIZED%20RT-PCR%20KITS%20FOR%20SARS-COV2%20BY%20DHA.pdf

11.10. Testing laboratories should validate each new PCR kit for sensitivity (lower detection limit) and specificity to avoid false results and be able to detect low viral load. The new PCR kit should allow testing laboratories to report detected, not detected and presumptive positive (low viral load or single gene).

11.11. Records of validation should be kept at the lab for DHA audit and inspection.

11.12. Testing lab that is using another type of kit; not included in the list should contact HRS-DHA for assessment and validation.

11.13. Testing laboratory should use two different RT-PCR kits. Each RT-PCR kit should cover at least two or more of the following genes (ORF1ab/RdRp, N, S, E, M).

11.14. If one gene is detected with one RT- PCR kit then a second test should be done and the results should be interpreted as per NCEMA guidelines (**Appendix 8**).

11.15. Testing results must be issued within a maximum period of 24 hours from the date of swab collection.

11.16. Approved labs must ensure they perform the required quality control for RNA extraction and RT-PCR protocols as per manufacture's guidelines and comply with required preventive maintenance and calibration of lab equipment.

11.17. De-isolation measures should be followed as per the National Guidelines for the Management of COVID-19.

12. **STANDARD EIGHT:** INTERPRETATION OF RESULT

12.1. Interpretation of results should be correlated with patient history and clinical presentation.

12.2. Interpretation of results should align with the published NCEMA guidelines for interpretation of PCR test.

12.3. Test for SARS-CoV-2 result can be one of the following:

12.3.1. Detected (positive for SARS-CoV-2)

12.3.2. Not Detected (Negative for SARS-CoV-2)

12.3.3. Presumptive positive (only one of multiple gene is isolated or a low viral load is possible)

a. Sample should be repeated after 48-72 hours with clinical correlation.

13. STANDARD NINE: RESULT REPORTING

13.1. Testing results should be entered in HASANA immediately by the processing lab through integration.

13.2. Facilities are required to inform their patients of COVID-19 test result.

13.2.1. Negative test results should be reported to the patient and/or guardian via phone call and/or mobile text message (SMS) within 24 hrs of result interpretation refer to (**Appendix 9**).

13.2.2. Positive test results:

a. Should be reported to the patient and/or guardian via phone call and/or mobile text message (SMS) within 24hrs of result interpretation refer to (**Appendix 9**).

b. Patients and/or their legal guardian should be provided with infection control guidelines and be informed that they will be contacted by The Public Health and Protection Department for further assessment and management.

c. Facilities are required to provide a daily log of patients that have been contacted to CovNotify@dha.gov.ae refer to (**Appendix 10**).

13.2.3. In circumstances of presumptive positive, the requesting health facility should inform the patient to self-quarantine and repeat the test 48-72 hours with clinical correlation.

14. STANDARD TEN: NUCLEIC ACID AMPLIFICATION FOR DETECTION OF SARS-COV2 AS POINT OF CARE TEST (POCT) FOR COVID-19.

14.1. Authorized testing laboratories for Covid 19 can use Rapid PCR as Point of Care Testing (POCT) and shall be FDA approved, refer to the DHA Standards for Point of Care Testing (POCT) Services.

14.1.1. Positive tested samples do not require confirmation as FDA approved Rapid PCR tests have high sensitivity and specificity. Positive SARS-CoV-2 results must be reported in Hasana.

14.1.2. Negative tested samples do not require confirmation if tested on FDA approved rapid PCR.

14.1.3. Negative test for symptomatic patient with Covid 19 symptoms OR patients with exposure history to Covid 19 needs to be confirmed with RT-PCR.

15. STANDARD ELEVEN: ANTIBODY TESTING

15.1. Health Facilities should refrain from using Point Of Care Testing (POCT) or Rapid Test.

15.2. Antibody testing is permitted in COVID-19 treating hospitals only.

15.3. Serologic assays can be carried out only in Clinical Laboratories (standalone or hospital laboratory) approved for RT-PCR meeting the following criteria:

15.3.1. Specificity > 99.5%

15.3.2. FDA approved or have been granted Emergency Use Authorization (EUA)

15.3.3. Kits with CE Mark (European Conformity) are acceptable as long as there is evidence that the kit/analyser have been verified through independent conformity assessment body.

15.3.4. Anti-S and Anti-S/RBD IgG titre shall be reported in the international unit of BAU/ml.

15.4. Clinical laboratories should have the above evidences available and presented upon request or visit by HRS.

15.5. Serologic testing should not be used for the diagnosis of acute COVID-19 infection nor to make decisions about returning persons to the workplace.

15.6. Serology test should be used for the below purposes only:

15.6.1. Support the diagnosis of COVID-19 illness in late disease presentation with negative PCR (9-14 days)

15.6.2. Support establishing the diagnosis of multisystem hyper-inflammatory syndrome in children or cases presenting late in the course of illness

15.6.3. Selection of Convalescent Plasma (CP) donors for CP therapy

15.6.4. Research purposes.

15.7. The price for COVID-19 serologic test should be followed as per latest DHA circulars.

15.8. Serological test result should not be entered in HASANA.

15.9. Serological test result should not be reported as SMS.

15.10. Disclaimers at the end of patient reports should be mentioned for both negative and positive results as outlined in (**Appendix 11**).

15.11. Antibody serology tests for SARS-CoV-2 should not be used as "Immunity passport" and eligibility to receive the vaccine.

16. STANDARD TWELVE: INFECTIOUS WASTE MANAGEMENT

16.1. All approved testing facilities should comply with DHA Infectious Waste Management and Disposal standards.

16.2. Approved testing facilities should have a policy for proper disposal of waste including biological and respiratory waste handling and decontaminating surfaces.

16.3. Laboratory waste should be disposed through medical waste management company.

17. STANDARD THIRTEEN: SAMPLE RETENTION

17.1. Negative (not detected) and (presumptive positive) samples should be stored at fridge (2-8°C) for three days before discarded.

17.2. Positive (detected) samples should be stored in the clinical labs at -20°C.

17.3. High security and safety measures should always be implemented for stored samples.

17.4. Samples should be labelled clearly and should include patient details, MRN and demographics.

REFERENCES

1. Centers for Disease Control and Prevention (2020). Coronavirus Disease 2019 (COVID-19) CDC Diagnostic Test for COVID-19. Available online at: https://www.cdc.gov/coronavirus/2019-ncov/lab/testing.html (accessed on 18/05/2021).
2. Centers for Disease Control and Prevention (2021). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Available online at: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html (accessed on 18/05/2021).
3. Centers for Disease Control and Prevention (2021). Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. Available online at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html (accessed on 18/05/2021).
4. Centers for Disease Control and Prevention (2021). Coronavirus Disease 2019 (COVID-19) SARS-CoV-2 Viral Culturing at CDC. Available online at: https://www.cdc.gov/coronavirus/2019-ncov/lab/grows-virus-cell-culture.html (accessed on 18/05/2021).
5. COVID-19 Command and Control Centre (2022). COVID-19 Patient Pathway. Sixth issue.

6. Department of Health Abu Dhabi (2020). Circular No. (44) Regarding Compliance with Laboratories Requirements and Additional Guidelines on COVID-19 Test Indeterminate Results.
7. Dubai Health Authority (2020). Circular regarding Standards for Testing Novel Corona Virus COVID -19.
8. Dubai Health Authority (2020). Circular regarding Serological Testing for COVID-19.
9. Covid-19 Command and Control Center (2021). Quarantine and Isolation Guidelines in the Context of Community Transmission of the Novel Coronavirus (COVID-19). January 5, 2021. Available online at: https://www.dha.gov.ae/en/HealthRegulation/Documents/Attachment%204.pdf (accessed on 18/05/2021).
10. NCEMA (2021). National Guidelines for Clinical Management and treatment of COVID-19. February 18, 2021. Available online at: https://www.dha.gov.ae/en/HealthRegulation/Documents/NationalGuidelinesforClinicalManagementandTreatmentofCOVID-19.pdf (accessed on 18/05/2021).
11. NCEMA (2020). Guidelines for Contact Tracing of COVID-19 Positive Cases. April 21, 2020. Available online at: https://www.dha.gov.ae/en/HealthRegulation/Documents/دليل%20فحص%20المخالطين.pdf (accessed on 18/05/2021).
12. NCEMA (2020). Guidelines for Management of a suspected case of COVID-19. April 05, (2020) Available online at:

https://www.dha.gov.ae/en/HealthRegulation/Documents/Management%20of%20a%20suspected%20case%20of%20COVID-version%204.pdf (accessed on 18/05/2021).

13. World Health Organization (2020). Rapid communication on the role of the GeneXpert® platform for rapid molecular testing for SARS-CoV-2 in the WHO European Region (2020). Available at: http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/publications/2020/rapid-communication-on-the-role-of-the-genexpert-platform-for-rapid-molecular-testing-for-sars-cov-2-in-the-who-european-region-2020 (accessed on 18/05/2021).
14. Public Health Department Santa Clara Valley Health & Hospital Systems (2020). Drive-Through Medicine.
15. World Health Organization (2020). "Immunity passports" in the context of COVID-19. Available online at: https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19 (accessed on 18/05/2020).

APPENDICES

APPENDIX 1: TESTING HEALTH FACILITY REGISTRATION TEMPLATE (SAMPLE COLLECTION)

EVALUATION CHECKLIST FOR COVID-19 TESTING FACILITIES

Facility Name:				
SL. No:	**Criteria**	**Yes**	**No**	**Documents Required**
Accreditation/License				
1	International Accreditation			Valid copy of certificate
2	DHA License			Valid DHA facility license
Qualified personnel				
3	HCP: • Trained and privileged licensed healthcare professionals • Infection control training • Training of COVID-19 sample collection			DHA Training log/Certificate
4	Infection Control Policy			Infection control policy
PPE and Sample Collection				
5	PPE:- Contract(s) with Supplier(s) - Current Inventory - Strategy to Optimize Supply			Evidence of contractual documents
6	Swab: • Contract(s) with Supplier(s) • Current Inventory • Strategy to Optimize Supply			• Evidence of contractual documents • Stock availability
7	Sample Transport Policy			Availability of the policy
Testing Strategy				
8	Capacity: • Current capacity per day (test/day) • Planned capacity increase with timeline			Details upon submission
9	Send out Lab(s)			Availability of original contracts upon submission
10	Testing Strategy: (Onsite/offsite, targeted groups, working hours, contracts...etc)			Provide information upon submission
Result Reporting				
11	HASANA Facility Account			Provide date of registration and user details (name, designation)
12	HASANA Training			Training log
13	Result Reporting Policy			Available policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

APPENDIX 2: CLINICAL LABS REGISTRATION TEMPLATE

EVALUATION CHECKLIST FOR COVID-19 CLINICAL LABORATORIES

Laboratory Name:				
SL. No:	**Criteria**	**Yes**	**No**	**Documents Required**
Accreditation/License				
1	International Laboratory Accreditation (CAP and /or ISO15189)			Valid copy of certificate
2	Valid DHA License			Valid DHA facility license
Qualified personnel				
3	Licensed Pathologist with knowledge on interpretation of the Viral PCR test result for Covid-19			Valid DHA facility license of the pathologist & CV
4	Competent and adequate technical/clinical manpower			Valid DHA facility license of all staff
Analyzer & methodology				
5	Analyzers, Equipment, Reagent supplies for RNA extraction and RT-PCR			• List the Analyzer details (Extraction and RT-PCR) and provide Laboratory SOPs for the same. • Provide the Current Inventory list (Stock) of Extraction tests and PCR tests. • Mention the analyzer capacity/day here (N# of tests run/day)
6	Validation records for COVID-19 test			Provide a copy of validation records
Quality				
7	Internal Quality Control for COVID-19 test, as required			Provide a copy of QC run -Positive/Negative samples, Internal control (IPC)
8	External QC program/Alternative assessment for COVID-19 test or enroll in any such PT program			Provide a copy of External QC/alternative assessment record
Result Reporting				
9	Confirmatory testing for screening			
10	RT-PCR target gene detection			Valid policy on result interpretation
11	LIS System that can be integrated with HASANA			Evidence of integration
12	TAT for result reporting			Valid policy and/or system generated reporting TAT.

Policy & Documentation				
13	Policy for Sample processing (RNA Extraction), result reporting (Positive, Negative & Inconclusive result)			Copy of policy/SOP
14	Policy on specimen retention			Copy of policy
Safety				
15	Biological Safety Cabinet Level II			
16	Adequate space to perform COVID-19 Testing			
17	Availability of adequate safety measures to protect all the staff from COVID-19 testing (PPE, safety & infection control training, waste management)			• Availability of PPE and inventory (stock) list. • Infection control training log. • Waste management policy.
18	Adequate Engineering controls and Facility design to perform COVID-19 testing (biological safety level II, testing certificate of BSC with HEPA filter change annually and/or negative pressure room			Provide a copy of annual testing record with change of HEPA filter document
Sample Transport				
19	Sample Transport Policy			Copy of policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

APPENDIX 3: DRIVE-THROUGH COVID-19 TESTING REGISTRATION TEMPLATE

EVALUATION CHECKLIST FOR DRIVE-THROUGH COVID-19 TESTING

Facility Name:				
No:	**Criteria**	**Yes**	**No**	**Documents Required**
License				
1	Valid DHA License: • Online application through Sheryan, for COVID Swabbing **"Add-on Drive through service".**			• Official proposal letter. • Target group. • Location. • Copy of authorization / approval from other authorities, if available. o Approval for operation dates and times: DM, RTA, Dubai Police and Civil defense. • Setup and Infrastructure details *(Layout details).* • Information on maintenance of medical record. • Valid facility and professionals licenses.
Qualified personnel				
2	Administration staff/ Coordinator staff: 1 per shift. AN/RN/Physician for triaging: 1 per testing line per shift. Screening (testing): 1 HCP per testing line per shift Shift supervisor: 1 per shift. Security Officer: 1 per shift			• Valid License for healthcare professionals. • Infection control training. • Training of COVID-19 sample collection • Staffing details: admin, security, coordinators, HCP details who will provide the service, training etc. • Staff support equipment.
Infection Control				
3	Safety protocols & infection control measures. • Hands washing basin / Hand sanitizer distributed throughout all stations.			• Infection Control Policy.
Design Requirements				
4	• Open area. • Proper ventilation system. • One-way passage for vehicles with entrance separate from exit. • Divided into stations for parking, registration, and sample collection.			Provide the design plan with all necessary information.

	• Vehicles queue in lanes and pass through a set of designated testing stations. • Area structure considerations to accommodate the anticipated influx of patient vehicles.			
Facility Operations				
5	Timing - As per the allowed time of operation and manpower capacity			Operational details and standards including sample collection, storing and transportation.
6	Service provided preferably by appointment.			Call Center / Hotline details. Brochures (For testing procedures, how to self-quarantine, infection precautionary measures).
7	Availability of Medical Record			Provide details of the HIS.
Testing Strategy				
8	Current capacity per day (test/day) Planned capacity increase with timeline			Testing capacity details.
9	Send out Lab(s)			Provide details and copies of original contracts
10	Testing Strategy (targeted groups, contracts...etc)			Provide details and copies of original contracts
Result Reporting				
11	HASANA Facility Account Reporting through HASANA			• Provide date of registration and user details (name , designation) • Reporting and communication channels with patients.
12	HASANA Training			• Training log
13	Result Reporting Policy Keep patients informed by SMS, email, phone call			• Provide copy of the policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

APPENDIX 4: COVID-19 TESTING TENT REGISTRATION TEMPLATE

EVALUATION CHECKLIST FOR COVID-19 TESTING TENTS

Facility Name:				
No:	**Criteria**	**Yes**	**No**	**Documents Required**
License				
1	Valid DHA License: • Online application through Sheryan, for COVID Swabbing **'Add-on'.**			• Layout and picture of the location. • Approval from DM, RTA, Dubai Police for operation dates and times & civil defence.
Qualified personnel				
2	- (1) for triaging and (1) for testing per swab collection station per shift. - DHA License - Infection control training - Training of COVID-19 sample collection			• Swab collection-training log
3	Administration staff/ Coordinator staff: 1 per shift. Shift supervisor: 1 per shift. Security Officer: 1 per shift			Provide full personnel details.
Infection Control				
4	Safety protocols & infection control measures. • Hands washing basin / Hand sanitizer distributed throughout all stations.			Infection Control Policy.
Design Requirements				
5	Seating arrangement, if any, should ensure sufficient social distancing measures.			Share seating plans and social distancing measures. A policy in place should be available to avoid overcrowding.
6	Sample Storage area.			Provide temperature control unit details.
7	Separate entry & exit.			Provide patient journey plan.
8	Allocate areas for registration and swab collection.			Provide marked plans.
9	Enough car park spaces.			
Facility Management				
10	Sufficient Air circulation System			Provide details
11	Tent operating hours to be displayed/ conveyed to patients (Not less than 12 hours).			Operating hours

Testing Strategy				
12	Capacity: - Current capacity per day (test/day) - Planned capacity increase with timeline			Provide Details
13	Send out Lab(s)			• Provide details and copies of original contracts • Provide sample transportation policy
14	Testing Strategy (targeted groups, contracts...etc)			Provide details and copies of original contracts
Result Reporting				
15	HASANA Facility Account			Provide date of registration and user details (name, designation)
16	HASANA Training			Training log
17	Result Reporting Policy			Provide copy of the policy
Note: DHA inspection will be conducted to ensure the accuracy of the provided details.				

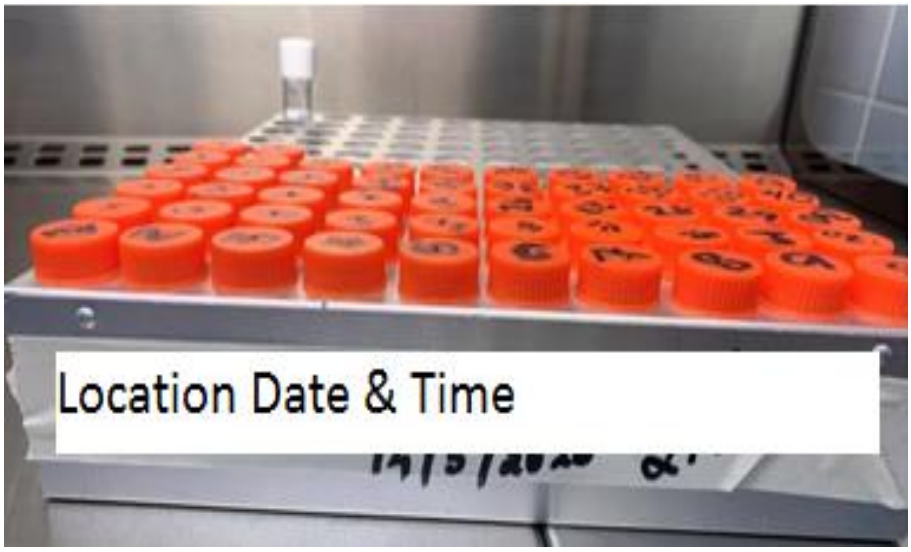
APPENDIX 5: TESTING PRIORITY

Priority	Criteria
High Priority	• Hospitalized patients. • Health facility workers, workers in congregate living settings, and first responders with symptoms. • Residents in long-term care facilities or other congregate living settings with symptoms. • Persons identified through public health cluster and selected contact investigations.
Priority	• Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat. • Persons identified through National Guidelines Contact Tracing and Isolation Guidelines.

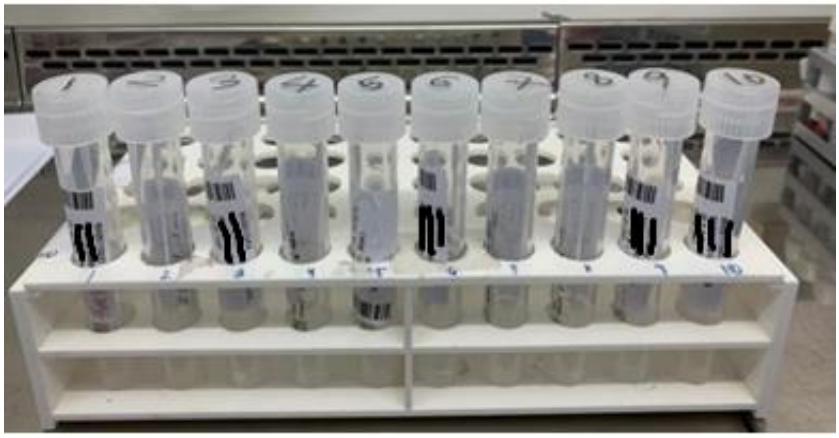
APPENDIX 6: COVID-19 SAMPLE LABELLING

1. Patient information has to be checked to confirm correct labeling and avoid mislabeling.
2. Please avoid handwritten information on labels.
3. Patient swab labels have to be labelled in vertical direction to avoid barcode scanning issue.

4. Sample racks have to be properly labelled with the Screening location information.

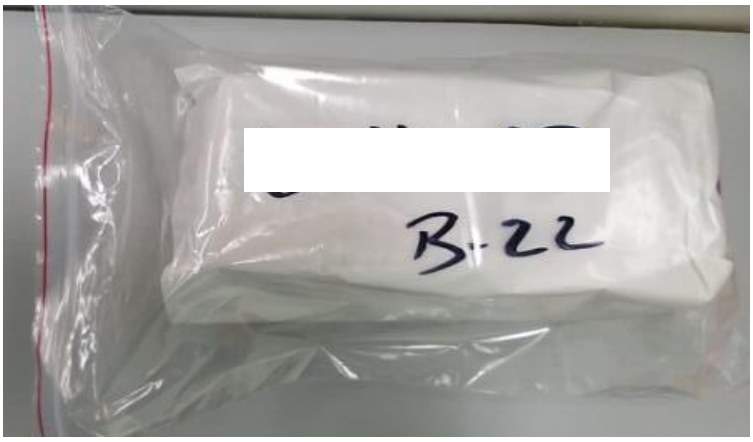


5. Arrange the sample tubes in the rack in the same order as the excel sheet (i.e. sample number 1 in position one in the rack).

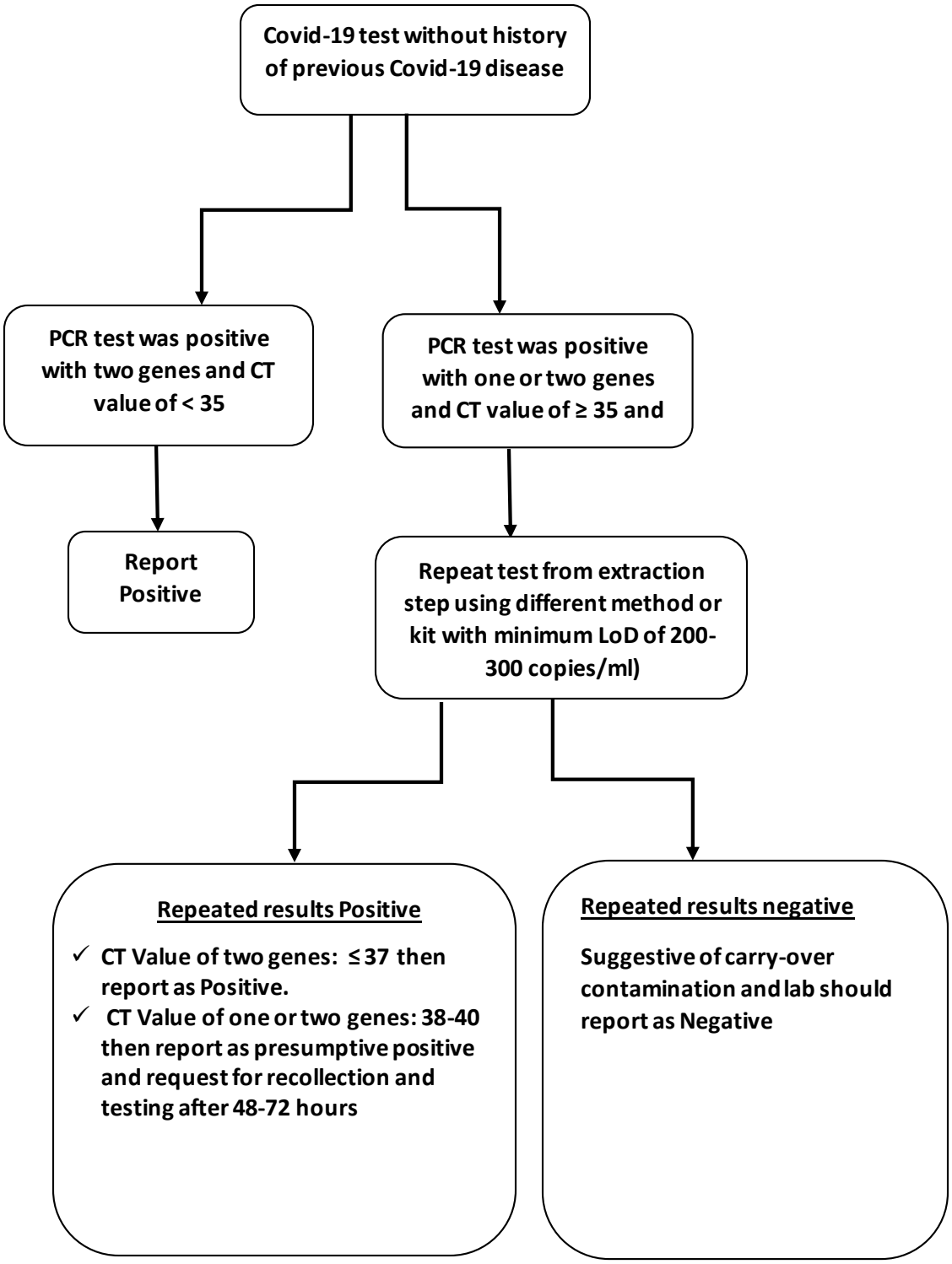


6. To avoid sample hazard leak and label fading, keep the rack in a zip-lock nylon bag surrounded by absorbent material.

7. To avoid samples shaking, please arrange the samples racks in transport box with ice packs properly.



APPENDIX 7: COVID-19 FALSE POSITIVE DUE TO CARRY-OVER CONTAMINATION



APPENDIX 8: INTERPRETATION OF COVID-19 RT-PCR TEST

ORF1ab (Gene) /RdRp (gene)^	N (gene) /S (gene)$	E (gene)	IC	Negative Control	Positive Control	RNA Extraction Control (if applicable)	Interpretation
+	+	+	+ / -	-	+	+	**SARS-CoV-2 detected**
+	+	-	+ / -	-	+	+	**SARS-CoV-2 detected**
-	+	+	+ / -	-	+	+	**SARS-CoV-2 detected**
+	-	-	+ / -	-	+	+	**SARS-CoV-2 detected**
-	-	-	+	-	+	+	**SARS-CoV-2 not detected**
-	-	+	+ / -	-	+	+	**First time sample*:** Single E gene detected positive. Repeat on a second platform and if repeatedly still positive as single gene report as: **"Presumptive positive. Only one of multiple gene is isolated. Low viral load possible, please repeat sample in 72 -96 hours to document the course of the disease."** If the 3rd order run is still positive for single E gene and patient is asymptomatic, report: **"Acute disease unlikely, please correlate clinically."**
-	-	+	+ / -	-	+	+	**Second time sample**:** Single E gene detected positive with a historical confirmed positive; this patient could be at the end of infection period. Report as: **"SARS-CoV-2 detected "**

-	+	-	+ / -	-	+	+	**First time sample:** Single N or S gene detected positive. Repeat on another platfrom for confirmation. If still positive will report as **"SARS-CoV-2 detected"** and if it is negative on the other platform report: **Presumptive Positive."Only one of multiple gene is isolated. Low viral load possible, please repeat sample in 72 hours and correlate clinically.** **First time sample:** Single N gene detected positive, however, 2 targets for N gene available within the assay, report as **"SARS-CoV-2 detected"**
+	+	+	+ / -	-	+	+	If any of Orf1ab / RdRp or N gene or S gene or E gene OR combined are showing a signal of amplification in the late cycles of amplification and the RFU is just above the Baseline Threshold cutoff value , It's Presumptive positive and confirm by another Extraction/PCR platform and follow the manufacturer procedure for enhancement of the reaction. If it is still positive report as **"SARS-CoV-2 detected".** If confirmatory test is negative, report: **"SARS-CoV-2 not detected, repeat test if deemed necessary."**
-	-	-	-	-	-	+/-	**Invalid run**
+	+	+	+	+	+	+/-	**Invalid run**

First time sample: No patient history of previous SARS-CoV test done.

****Second time sample: Patient had previous history of SARS-CoV test.***

^ RdRp gene is reported to be less sensitive than the other genes due to mismatch in the reverse primers

$ For labs using S gene as SARS-CoV-2 specific gene and E gene follow the same rule of N gene

APPENDIX 9: SMS TEMPLATE FOR PCR TEST RESULTS

NEGATIVE

Dear (Patient Name), (registered MRN)

Greetings, your Covid19 PCR test result from (Order date) is Negative, indicating that you are not infected with the virus. Please Stay Safe.

عزيزنا المتعامل) الاسم بحسب المستندات الرسمية) (رقم الملف الطبي)

يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ (تاريخ) "سلبية"، بما يفيد بأنك غير مصاب بالفيروس. ابقى امنا.

POSITIVE

Dear (Name) (MRN)

Your COVID-19 test on (date) reported that your results is “positive", please download the COVID19 - DXB Smart App to guide you during your isolation period. https://dxbcovid19.page.link/smart-app

If you require any kind of support, please call 800DHA.

Wishing you a speedy recovery

عزيزنا المتعامل) الاسم بحسب المستندات الرسمية) (رقم الملف الطبي)

نتيجة فحصك لفيروس كورونا كوفيد-١٩ بتاريخ (تاريخ) "إيجابية"، يرجى تحميل تطبيق COVID19 - DXB Smart App لدعمكم خلال فترة عزلكم الصحي.

https://dxbcovid19.page.link/smart-app

في حال الحاجة الى المساعدة، الرجاء الاتصال على 800DHA

مع تمنياتنا لكم بالشفاء العاجل.

PRESUMPTIVE

Dear (Name) (MRN),

Your COVID-19 test on (Order date), reported that your result is presumptive positive indicating that you could have the virus. Do not worry; please isolate yourself and repeat the test for confirmation after 48-72 hours from this test date.

You can call 800588 from 7am until 11pm for all related inquiries and 800342 for any other inquiry. We are here to support you and we wish you a speedy recovery.

عزيزي المتعامل(الاسم بحسب المستندات الرسمية) (رقم الملف الطبي)

يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ (تاريخ)" إيجابية مفترضة "، مما يفيد باحتمال إصابتك بالفيروس. لا تقلق، يرجى عزل نفسك حاليا وإعادة الاختبار للتأكيد بعد 48 أو 72ساعة من تاريخ الاختبار هذا.

للتعرف على إرشادات العزل المنزلي كما يمكنك الاتصال على الرقم 800588 بين الساعة السابعة صباحا والحادية عشر للرد على استفساراتك بهذا الشأن، وعلى الرقم 800342 للاستفسارات الأخرى. نحن هنا لمساندتكم. مع تمنياتنا لكم بالصحة والعافية.

APPENDIX 10: CALL LOG REPORT TEMPLATE

Facility Name	Patient Name	Guardian Name (if available)	Patient Number (HASANA)	Contact number	Date of Result	Date of Contact	Time of Contact	Name of Staff

APPENDIX 11: DISCLAIMER STATEMENT IN SEROLOGICAL TESTING FOR COVID-19

- **Negative result:**

  "This sample does not contain detectable SARS-CoV-2 IgG (or IgG/IgM as applicable) antibodies. This negative result does not rule out SARS-CoV-2 infection. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended.
  A negative result may be due to performing the test prior to development of antibodies (1-4 weeks). Rarely, some people who are infected may not develop antibodies. **Serologic results should not be used as the sole basis to diagnose or exclude recent or past SARS-CoV-2 infection.** This assay was performed using (specify platform & technology used)"

  This test is not suitable for diagnosis of COVID-19 Infection; and any suspected case should be testing with RT- PCR.

- **Positive result:**

  "Results suggest recent or prior infection with SARS-CoV-2 or Vaccination. Correlation with epidemiologic risk factors and other clinical and laboratory findings is recommended. Protective immunity cannot be inferred based on these results and all preventive measures should be maintained. Infrequently, **false positive results may be due to prior infection with other human coronaviruses.** Serologic results should not be used as the sole basis to diagnose or exclude recent or past SARS-CoV-2 infection. This assay was performed using (specify platform & technology used)".

  This test is not suitable for diagnosis of COVID-19 Infection; and any suspected case should be testing with RT- PCR.
  Results of antibody testing should be interpreted with caution in immunocompromised patients (immunodeficiency, cancer, transplant, use of biologics, etc.)