STANDARDS FOR SARS-COV-2 TESTING

Version 4.0

Dubai Healthcare City Authority Regulatory (DHCR)

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EXECUTIVE SUMMARY

This is the fourth edition of 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 DHCA 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 DHCA licensed health facilities providing SARS-CoV-2 Testing services. DHCA will update these Standards as new information becomes available.

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 DHCA licensed entity that is authorized 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 DHCA 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

CAP	:	College of American Pathologists
COVID	:	Corona Virus Disease
DHCA	:	Dubai HealthCare City Authority
DHCR	:	Dubai HealthCare City Authority Regulatory
HCP	:	Health Care Personnel

HPSD	:	Health Policies and Standards Department
ILI	:	Influenza-like Illness diagnosis
ISO	:	International Organization for Standardization
PCR	:	Polymerase Chain Reaction
POCT	:	Point of Care Testing
PPE	:	Personal Protective Equipment
RT-PCR	:	Reverse Transcription Polymerase Chain Reaction
SARI	:	Severe Acute Respiratory Infections
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 Novel Coronavirus (COVID-19), and to ensure public health protection and efficiency of procedures of diagnosing the disease and proper utilization of the resources, DHCA has set out the following requirements regarding COVID-19 Screening and Testing. The Standard will be updated by DHCA periodically based on changes in National Standards and federal decisions. All relevant facilities are required to adhere to the requirements within the document to avoid noncompliance.

2. SCOPE

2.1. SARS-CoV-2 Testing services in DHCA 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 DHCA 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 DHCA or DHA laboratories from testing and issuing results.

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

4. APPLICABILITY

4.1. DHCA 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 DHCA:

5.1.1. Hospitals.

5.1.2. Day Surgery Centers:

a. Category C/CM.

b. Category B performing upper GI endoscopy procedures.

c. DSC should only collect samples for patients who are scheduled for a procedure.

d. COVID-19 swabs should be collected & processed 72 hours prior to the scheduled procedure.

5.1.3. Home Healthcare Providers – Standalone / service licensed under other. facilities.

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

5.2.1. Standalone Clinical Laboratories.

5.2.2. Clinical Laboratories within Hospitals.

5.3. Healthcare facilities and Clinical Laboratories seeking approval should:

5.3.1. Submit a proposal to DHCA (**Appendix 1, 2, 3 and 4**), through Masaar facility account.

5.3.2. Submit online application through Masaar, for 'COVID swap collection' add-on.

5.3.3. Comply with DHCA inspection requirements.

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

5.3.5. Engage in regular inter-laboratory comparison with DHCA as required.

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

5.5. List of approved laboratories for COVID-19 testing as of (December 2020) can be found in (**Appendix 5**).

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

5.6.1. Samples should not be sent to clinical labs outside the emirate of Dubai after 14th June 2020.

5.6.2. Secondary and tertiary labs should be approved SARS-CoV-2 Testing Laboratories.

6. **STANDARD TWO:** TESTING CRITERIA

6.1. COVID-19 testing should only be requested by a DHCA licensed physician in accordance to the National Clinical Guidelines and based on the attached priority testing criteria (**Appendix 6**).

6.1.1. DHCA and the COVID-19 Command and Control Centre updates 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 DHCA 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-COV2 virus.

7. **STANDARD THREE:** SAMPLE COLLECTION

7.1. Health facilities should gain approval from DHCA prior to starting sample collection services as mentioned in point **5.3**.

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

7.3. Testing Labs are not allowed to collect COVID-19 swabs, directly from patients.

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

7.4.1. Air purification system.

7.4.2. Negative pressure or good air circulation.

7.4.3. Hand washing sink.

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

7.5.1. Obtain prior approval from DHCA.

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

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

7.5.4. Follow infection control measures.

7.5.5. Ensure accurate and timely patient data entry.

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

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

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

7.8. 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).

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

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

7.11. Only trained licensed healthcare professionals (nurse/physician) in an appropriate setting should collect COVID-19 swabs.

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

7.12. Saliva samples should only be collected after obtaining prior approval from DHCR and following quality assurance validation measures.

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

7.13.1. Screening of asymptomatic children up to 16 years of age.

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

7.13.3. Samples should be collected only in hospital or outpatient settings under supervision of a trained healthcare professional.

7.13.4. Samples collection should be done under aseptic conditions, in a closed room equipped with negative pressure and disinfection measures taken after each sample collection.

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

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

7.14.2. 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.

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

7.14.4. Send the sample to an approved DHCA Lab for saliva testing.

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

7.16. 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.

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

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

8. **STANDARD FOUR:** SAMPLE STORAGE

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

8.2. Labelling the collected sample as a biohazard.

8.3. 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

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

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.

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

9. **STANDARD FIVE:** SAMPLE TRANSPORT

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

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

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

9.3.1. 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.

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

9.5. Samples should be labelled as detailed and shown in (**Appendix 7**).

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

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

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

10. **STANDARD SIX:** SAMPLE PROCESSING

10.1. Clinical Laboratories should seek approval from HRS prior to processing any SARSCoV-2 related tests.

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

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

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

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

10.6. Laboratories should follow the protocol in **Appendix 8** to ensure quality measurement steps to prevent laboratory environment and carry over contamination.

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

10.8. Testing Laboratories providing COVID-19 testing services shall use any of DHA approved SARS-CoV-2 kits listed in (**Appendix 9**).

10.9. 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).

10.10. Records of validation should be kept at the lab for DHCA audit and inspection.

10.11. Testing lab that is using another type of kit; not included in the list should contact HRSDHA for assessment and validation.

10.12. 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).

10.13. 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 10**).

10.14. Testing results must be issued within a maximum period of 48 hours.

10.15. 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.

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

11. STANDARD SEVEN: INTERPRETATION OF RESULT

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

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

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

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

11.3.2. Not Detected (Negative for SARS-CoV-2) 11.3.3. Presumptive positive (only one of multiple gene is isolated or a low viral load is possible)

a. Sample should be repeated in 72 hours with clinical correlation.

12. STANDARD EIGHT: RESULT REPORTING

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

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

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

12.2.2. 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.

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 as in (**Appendix 11**).

c. Facilities are required to provide a daily log of patients that have been contacted to CovNotify@dha.gov.ae - as in (**Appendix 12**).

12.2.3. In circumstances of presumptive positive, the requesting health facility should inform the patient to self-quarantine and repeat the test within 72hrs.

13. STANDARD NINE: ANTIBODY TESTING

13.1. Health Facilities should refrain from using point of care testing (POCT) or Rapid Test.

13.2. Health facilities should gain prior approval from DHCA to perform antibody testing.

13.3. Clinical laboratories equipped to provide the COVID-19 serologic test should obtain approval from DHCR- DHCA prior to providing the service and receiving samples.

13.4. Serologic assays used by the approved labs should have the below criteria:

13.4.1. Specificity > 99.5%

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

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

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

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

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

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

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

13.6.4. Research purposes.

13.7. The price for COVID-19 serologic test paid by the client/patient should not exceed AED 100/-, including all fees, to mention (but not limited to) sample collection, Ig processing, issuing the result or certificate, etc.

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

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

13.10. Disclaimers at the end of patient reports should be mentioned for both negative and positive results as outlined in (**Appendix 13**).

13.11. Antibody serology tests for SARS-CoV-2 should not be used as "Immunity passport".

14. **STANDARD TEN:** INFECTIOUS WASTE MANAGEMENT

14.1. All approved testing facilities should comply with DHCA Infectious Waste Management and Disposal standards.

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

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

15. **STANDARD ELEVEN:** SAMPLE RETENTION

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

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

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

15.4. 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 (COVID19) CDC Diagnostic Test for COVID-19. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/testing.html (accessed on 14/10/2020).
2. Centers for Disease Control and Prevention (2020). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. Available at: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html (accessed on 14/10/2020).
3. Centers for Disease Control and Prevention (2020). Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. Available at: https://www.cdc.gov/coronavirus/2019ncov/hcp/infection-control-recommendations.html (accessed 14/10/2020).
4. Centers for Disease Control and Prevention (2020). Coronavirus Disease 2019 (COVID19) SARS-CoV-2 Viral Culturing at CDC. Available at: https://www.cdc.gov/coronavirus/2019-ncov/lab/grows-virus-cell-culture.html (accessed on 14/10/2020).
5. Department of Health Abu Dhabi (2020). Circular No. (44) Regarding Compliance with Laboratories Requirements and Additional Guidelines on COVID-19 Test Indeterminate Results.
6. Dubai Health Authority (2020). Circular regarding Standards for Testing Novel Corona Virus COVID -19.
7. Dubai Health Authority (2020). Circular regarding Serological Testing for COVID-19.
8. Dubai Health Authority (2020). Guidelines on the Management of Quarantine and Isolation Institutional Facilities (Non-Hospital) for COVID-19.May,(2020) Available at: https://www.dha.gov.ae/en/HealthRegulation/Documents/Guidelines%20on%20the%20Management%20of%20Quarantine%20and%20Isolation%20Institutional%20Facilities%20(Non-Hospital)%20for%20Novel%20Coronavirus%20(COVID-19).pdf (accessed on 10/06/2020).

9. Ministry of Health and Prevention (2020). Guidelines for Clinical Management of Critically ill COVID-19 patient. Available at: https://www.dha.gov.ae/en/HealthRegulation/Documents/Clinical%20Managment%20of%20Critically%20ill%20%20COVID-19%20patient%20Version%201.pdf (accessed on 10/06/2020).
10. Ministry of Health and Prevention (2020). Guidelines for Contact Tracing of COVID-19 Positive Cases. April 21, (2020). Available at: https://www.dha.gov.ae/en/HealthRegulation/Documents/ دلي %ل20%فحص20المخالطين.pdf (accessed on 10/06/2020).
11. Ministry of Health and Prevention (2020). Guidelines for Management of a suspected case of COVID-19. April 05, (2020) Available at: https://www.dha.gov.ae/en/HealthRegulation/Documents/Management%20of%20a%20suspected%20case%20of%20COVID-version%204.pdf (acceded 10/06/2020).
12. Ministry of Health and Prevention (2020). Guidelines for Clinical Management and Treatment of COVID-19. April 20th, (2020). Available at: https://www.dha.gov.ae/en/HealthRegulation/Documents/National%20Guidelines%20for%20Clinical%20Management%20and%20Treatment%20of%20COVID-19%20Version%203.1%20April%2020%202020.pdf (accessed on 10/06/2020).
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/communicablediseases/tuberculosis/publications/2020/rapid-communication-on-the-role-of-thegenexpert-platform-for-rapid-molecular-testing-for-sars-cov-2-in-the-who-europeanregion-2020 (accessed on 10/06/2020).
14. Public Health Department Santa Clara Valley Health & Hospital Systems (2020). DriveThrough Medicine.
15. World Health Organization (2020). "Immunity passports" in the context of COVID-19. Available at: https://www.who.int/news-room/commentaries/detail/immunitypassports-in-the-context-of-covid-19 (accessed on 10/01/2020).

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			Provide a Copy of certificate
2	Valid DHCA License			Provide a copy of DHCA facility license.
Qualified personnel				
3	Physician: - DHCA License - Infection control training - Training of COVID-19 sample collection			Provide a copy of DHCA License & training log
4	Registered Nurse: - DHCA License - Infection control training - Training of COVID-19 sample collection			Provide a copy of DHCA License & training log
5	Infection Control Policy			Provide copy of policy
PPE and Sample Collection				
6	PPE: - Contract(s) with Supplier(s)- Current Inventory - Strategy to Optimize Supply			Provide details and copies of original contracts
7	Swab: - Contract(s) with Supplier(s) - Current Inventory - Strategy to Optimize Supply			Provide details and copies of original contracts
8	Sample Transport Policy			Provide copy of the policy
Testing Strategy				
9	Capacity: - Current capacity per day (test/day) - Planned capacity increase with timeline			Provide Details

10	Send out Lab(s)			Provide details and copies of original contracts
11	Testing Strategy (Onsite/offsite, targeted groups, working hours, contracts…etc)			Provide details and copies of original contracts
Result Reporting				
12	HASANA Facility Account			Provide date of registration and user details (name, designation)
13	HASANA Training			Training log
14	Result Reporting Policy			Provide copy of the policy
Note: DHCA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHCA Official Use Only				
Evaluation Report	**…….. (*Facility Name*) has ……..(*met/not met/partially met*) all the required criteria set by Dubai Healthcare City Authority, for performing COVID-19 Testing at their facility.**			
Additional Comments if Any:				

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)			Provide a Copy of certificate
2	Valid DHCA License			Provide a copy of DHCA facility license
Qualified personnel				
3	Licensed Molecular Pathologist with knowledge on interpretation of the Viral PCR test result for Covid-19			Provide a copy of DHCA License of the pathologist & CV
4	Competent and adequate technical/clinical manpower			Provide the list of staff working in PCR lab with their license copy & CV
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			Provide a policy on result interpretation
11	LIS System that can be integrated with HASANA			Provide details
12	TAT for result reporting			Provide policy and/or system generated reporting TAT.
Policy & Documentation				
13	Policy for Sample processing (RNA Extraction), result reporting (Positive, Negative & Inconclusive result)			Please provide a copy of policy/SOP
14	Policy on specimen retention			Please provide a 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)			• List the PPE's and provide the current 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			Provide the policy
Note: DHCA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHCA Official Use Only				
Evaluation Report	**…….. (*Laboratory Name*) has ……..(*met/not met/partially met*) all the required criteria set by Dubai Healthcare City Authority, for performing COVID-19 Testing at their facility.**			

Additional Comments if Any:	

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

VALUATION 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. ○ 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. • Copy of facility license and professionals licenses.
Qualified personnel				
2	Administration staff/Coordinator staff: 1 per shift. RN/Physician for triaging: 1 per testing line per shift. Screening (testing): 1 RN/Physician per testing line per shift Shift supervisor: 1 per shift. Security Officer: 1 per shift			• Provide a copy of DHA License for healthcare professionals. • Infection control training. • Training of COVID-19 sample collection • Staffing details: admin, security, coordinators, HP 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 □	[redacted] •Divided into sections for necessary information. parking, registration, triaging, and screening. •Entrance to be separate from exit. •Proper ventilation system. •Away from the main street with many parking slots or parking structure that will accommodate the anticipated influx of patient vehicles.			
Facility Operations				
5	Timing - As per the allowed time of operation (Currently till 9 PM)			Operational details and standards including sample collection, storing and transportation.
6	Service provided by appointment only. (No on-foot patients accepted)			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: DHCA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHCA Official Use Only				
Evaluation Report	**..... (Facility Name) has .....(met/not met/partially met) all the required criteria set by Dubai Healthcare City Authority, for performing COVID-19 Testing at their facility.**			
Additional Comments if Any:				

APPENDIX 4: COVID-19 TESTING TENT REGISTRATION TEMPLATE

EVALUATION CHECKLIST FOR COVID-19 TESTING TENTS

Facility Name:				
No:	**Criteria**	**Yes**	**No**	**Documents Required**
Accreditation/License				
1	Valid DHCA License			Copy of DHCA facility license Copy of the lab accreditation Layout and picture of the proposed location
	Online application through Masaar, for location of COVID Swabbing 'Add-on'.			Approval from DM, RTA, Dubai Police for operation dates and times & civil defence.
Qualified personnel				
2	RN/Physician; (1) for triaging and (1) for testing per swab collection station per shift. • DHCA License • Infection control training • Training of COVID-19 sample collection			Provide a copy of DHCA License & 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.			Infection Control Policy.

	Hands washing basin / Hand sanitizer distributed throughout all stations.			
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: DHCA will review the above and might request further information from your facility. Physical inspection will be conducted to ensure the accuracy of the provided details.				
For DHCA Official Use Only				
Evaluation Report	***..... (Facility Name)*** **has .....(*met/not met/partially met*) all the required criteria set by Dubai Healthcare City Authority, for performing COVID-19 Testing at their facility.**			
Additional Comments if Any:				

APPENDIX 5: APPROVED COVID-19 LABS

	Name	Location
1.	Agiomix	Dubai - Al Barsha South 2
2.	Al Jalila Hospital Lab	Dubai- DHCC
3.	Al Zahra Private Hospital	Dubai - Al Barsha
4.	American Hospital	Dubai - Oud Metha
5.	CPS Clinical Pathology Services (MenaLab)	Dubai - Al Qouz 4
6.	Eurofins Biomnis	Dubai - Al Bada
7.	Freiburg Medical Laboratory	Dubai - Al Karama
8.	Garhoud Hospital Lab	Dubai - Garhoud
9.	Iranian Hospital Lab	Dubai - Al Badaa
10.	Latifa Hospital Virology Lab	Dubai - Oud Metha
11.	Mediclinic City Hospital / Central Laboratory	Dubai- DHCC
12.	Medsol Dubai Medical Laboratory	Dubai - Al Muraqabat
13.	National Reference Laboratory	Dubai - Al Barsha South 2
14.	Pure Health	Dubai Airport
15.	Scientific Clinical Laboratories (UniLabs)	Dubai - Jumeirah
16.	Star Metropolis Clinical Laboratory	Dubai - Al Hamriya
17.	Thumbay Hospital	Dubai - Al Qusais
18.	Viafet Genomic laboratory	Dubai - Al Badaa
19.	York Diagnostic Laboratories	Dubai - JLT
20.	SRL Diagnostics FZ-LLC	Dubai- DHCC

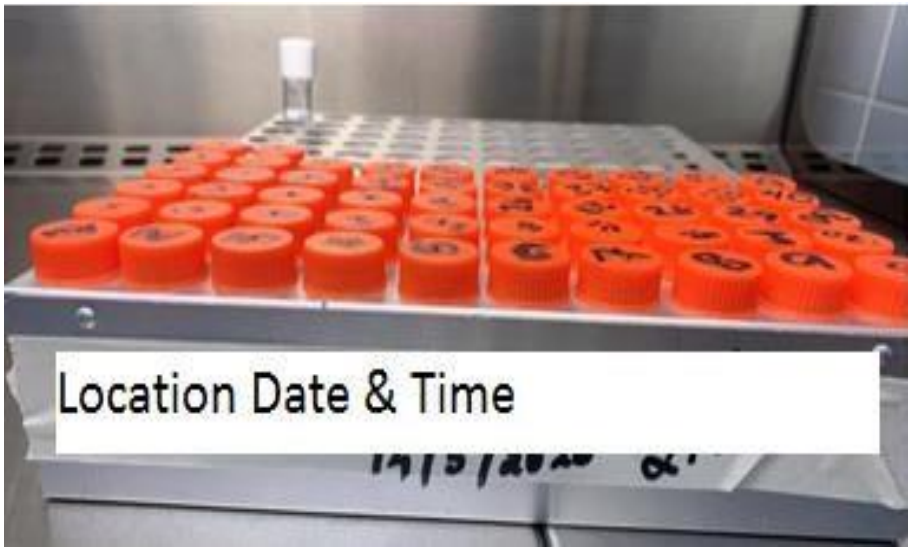
APPENDIX 6: TESTING PRIORITY

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.

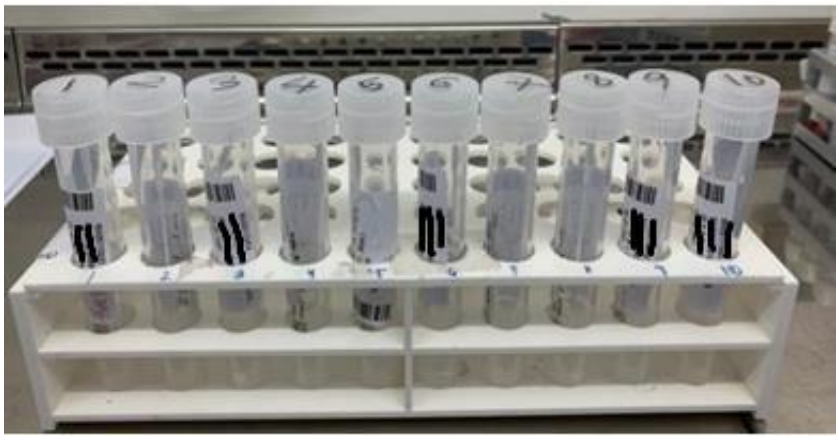
APPENDIX 7: COVID-19 SAMPLE LABELLING

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.

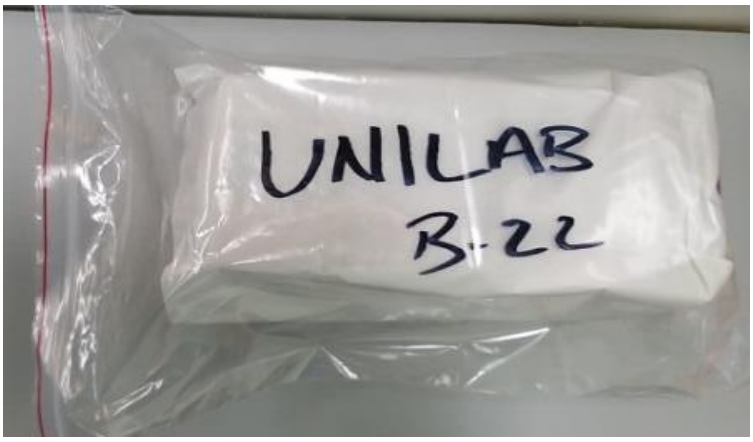
4. Sample racks have to be properly labelled with the Screening location information.



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).

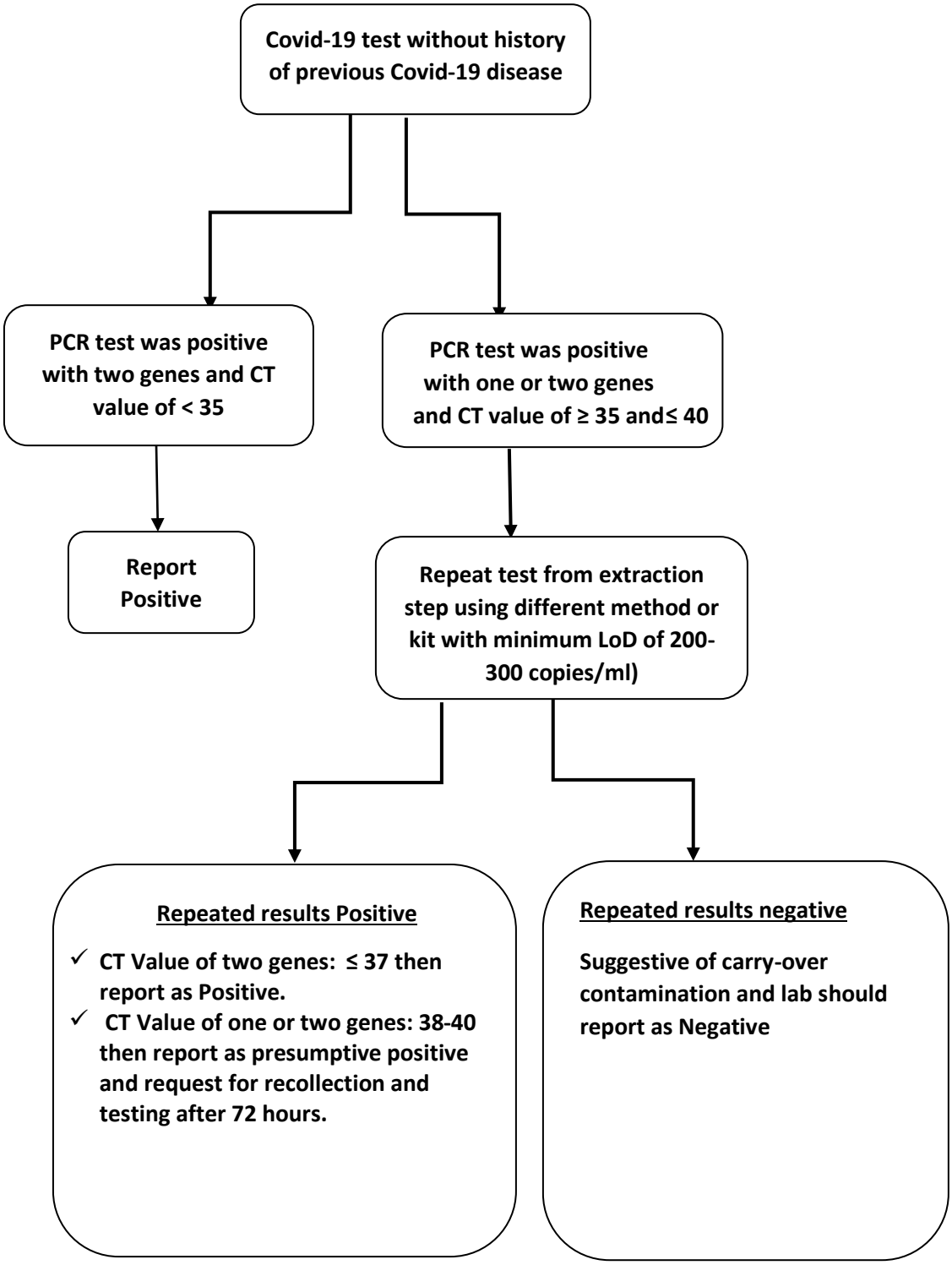


6. To avoid sample hazard leak and label fading, keep the rack in a zip-lock nylon bag surrounded by absorbent material.



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

APPENDIX 8: COVID-19 FALSE POSITIVE DUE TO CARRY-OVER CONTAMINATION



APPENDIX 9: AUTHORIZED RT-PCR KITS FOR SARS-COV2

Sl. No:	PCR PLAT FORM/KIT	TARGETED GENE
1	Perkin Elmer SARS-CoV2	ORF1ab , N gene
2	Roche SARS-CoV2	ORF1ab, N, E
3	Taqpath-Thermofischer	ORF1ab, N , S
4	Sansure BioTech	ORF1ab , N gene
5	UTOP-SEASUN BIOMATERIALS	Orf1ab, N
6	DIA PLEX-SOLGENT	Orf1ab, N
7	Euroimmune-EURORealTime SARS- CoV- 2	ORF1ab, N
8	Seegene Allplex	E, RdRp, N
9	Argene-BioMérieux SARS-COV-2 R-GENE	RdRp, N, E
10	VIASURE SARS-CoV-2-Cer Test	ORF1ab , N gene
11	MasterDiagnostica SARS-CoV2	E, N
12	Neoplex Covid 19 Detection Kit-GeneMatrix	RdRp, N
13	Labsystems Diagnostics-Covid 19Real Time Multiplex RT-PCR Kit	ORF1ab, N & E
14	Inbios International	E, N, ORF1b
15	Cepheid -Xpert Omni SARS-CoV-2	N2, E

APPENDIX 10: 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 11 SMS TEMPLATE for PCR Test Results

NEGATIVE

Dear {PatientName}, registered MRN {PatientMRN} Greetings, your Covid19 PCR test result from {Orderdate} is Negative, indicating that you are not infected with the virus. Please Stay Safe.

عزيزي المتعامل .{PatientMRN}, {PatientName} يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ {Orderdate}
"سلبية"، بما يفيد بأنك غير مصاب بالفيروس . ابقى امنا .

POSITIVE

Dear customer {PatientName}, registered MRN {PatientMRN}. Your COVID-19 test on {Orderdate}, reported that your result is positive indicating that you have the virus. Do not worry our healthcare professionals will contact you. Please click below link for home isolation instructions https://www.instagram.com/p/B-eq57FAl0R/ You can call 800588 from 7am until 11am midnight 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 .{PatientMRN}, {PatientName} يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ {Orderdate}
"إيجابية"، بما يفيد بأنك مصاب بالفيروس. لا تقلق، سيقوم أحد موظفينا بالتواصل معكم. يرجى الضغط هنا للتعرف على إرشادات العزل المنزلي كما https://www.instagram.com/p/B-eoyaFAMob/?igshid=1uua7bfj5ykbh 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.

PRESUMPTIVE

Dear customer {PatientName}, registered MRN {PatientMRN}. Your COVID-19 test on {Orderdate}, 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 72 or 96 hours from this test date, click below link for home isolation instructions https://www.instagram.com/p/B-eq57FAl0R/ 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 .{PatientMRN}, {PatientName} يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ {Orderdate}
"إيجابية مفترضة "، مما يفيد باحتمال إصابتك بالفيروس. لا تقلق، يرجى عزل نفسك حاليا وإعادة الاختبار للتأكيد بعد 72 أو 96ساعة من تاريخ الاختبار هذا. يرجى الضغط هنا https://www.instagram.com/p/B-eoyaFAMob/?igshid=1uua7bfj5ykbh 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 12 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 13 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).