



Standards for SARS-CoV-2 Testing Covid-19 Command and Control Centre Version 2.0

Health Policies and Standards Department

Health Regulation Sector (2020)

Standards for SARS-CoV-2 Testing





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.

The Standards for SARS-CoV-2 Testing aims to fulfil the following overarching DHA Strategic

Objectives and Program within the Dubai Health Strategy (2016–2021):

- **Objective 1:** Position Dubai as a global medical destination by introducing a value-based, comprehensive, integrated and high-quality service delivery system.
- Objective 2: Direct resources to ensure happy, healthy and safe environment for Dubai population.

Strategic Program 10: Excellence & Quality, which promotes excellence in healthcare service delivery in Dubai while enhancing patient happiness, experience, satisfaction and trust.





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





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EXECUTIVE SUMMARY

This is the second 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 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.





DEFINITIONS

Confirmed case: A person with confirmed positive COVID-19 test positive (SARS-CoV-2 PCR) 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

| САР | : | College of American Pathologists |
|-------|---|--|
| COVID | : | Corona Virus Disease |
| DHA | : | Dubai Health Authority |
| НСР | : | Health Care Personnel |
| HPSD | : | Health Policies and Standards Department |
| HRS | : | Health Regulation Sector |
| ILI | : | Influenza-like Illness diagnosis |
| ISO | : | International Organization for Standardization |
| PCR | : | Polymerase Chain Reaction |
| PPE | : | Personal Protective Equipment |
| SARI | : | Severe Acute Respiratory Infections |
| SARS | : | Severe Acute Respiratory Syndrome |





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, 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 facilities are required to adhere to the requirements within the document to avoid noncompliance.

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 SARS-CoV-2 Testing services in Dubai Health Authority (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. Testing services for COVID-19 are limited to DHA government laboratories in addition

to the below facilities following approval by DHA:

- 5.1.1. Clinical Laboratories in hospitals.
- 5.1.2. Standalone Clinical Laboratories.
- 5.2. Laboratories and healthcare facilities seeking approval should:
 - 5.2.1. Submit a proposal for DHA (**Appendix 1 and 2**).
 - 5.2.2. Comply with DHA inspection requirements.
 - 5.2.3. Register in HASANA platform and acquire the necessary training.
 - 5.2.4. Clinical Laboratories; integrate the Laboratory Information System with HASANA platform.
- 5.3. List of approved laboratories for COVID-19 testing as of (August 2020) can be found in

Appendix 3.

- 5.4. Facilities should ensure they have a contract in place with DHA approved clinical labs in Dubai.
 - 5.4.1. Samples should not be sent to clinical labs outside the emirate of Dubai after 14th June, 2020.
 - 5.4.2. Secondary and tertiary labs should be DHA approved SARS-CoV-2 Testing Laboratories.





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 (Appendix 4).
 - 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 shall comply with the fixed service price for testing COVID-19 which is AED 370/- (VAT inclusive); 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 RT-PCR as the approved testing methodology for detection of SARS-COV-2 virus.

7. STANDARD THREE: SAMPLE COLLECTION

7.1. Health facilities should gain approval from DHA prior to starting sample collection services as mentioned in point **5.2**.





- 7.2. Health facilities should have a dedicated room for swab collection with infection control setup including, but not limited to:
 - 7.2.1. Air purification system
 - 7.2.2. Negative pressure or good air circulation
 - 7.2.3. Hand washing sink.
- 7.3. Swabs collection should not be done at home, work, hostels, and labour camps or at testing labs unless approved by DHA or been a part of joined screening campaigns conducted by DHA.
- 7.4. Swabs should be collected under aseptic conditions and shall be placed immediately into sterile transport tube of 2-3 ml Viral Transport Media (VTM).
- 7.5. Healthcare professionals collecting the specimens shall follow infection control measures and use recommended PPE (N95, facemask, eye protection, gloves and a gown).
- 7.6. It is preferable for initial diagnostic testing/specimen for SARS-CoV-2 to be taken from upper respiratory (Nasopharyngeal or Oropharyngeal) sites.
- 7.7. Testing lower respiratory tract specimens (Sputum, Broncho alveolar lavage) are an option for patients with productive cough or receiving invasive mechanical ventilation.
- 7.8. Only trained licensed healthcare professionals (nurse/physician) in an appropriate setting should collect COVID-19 swabs.
 - 7.8.1. Swab collection training videos can be accessed through <u>DHA Medical Education</u> <u>Department.</u>





- 7.9. DHA Approved health facilities should ensure all patient details are filled accurately and on timely manner in HASANA System¹ as per <u>Communicable Disease Notification Policy</u> timeline.
- 7.10. 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.
- 7.11. Health facilities should provide the HASANA client ID to the processing lab to ensure correct test result entry.

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. Labeling 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 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 for specimen transport.

9. STANDARD FIVE: SAMPLE TRANSPORT

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

¹ For HASANA related inquiries contact: <u>HasanaHelpdesk@dha.gov.ae</u>





- 9.2. Lab specimens must be collected, transported and handled safely to ensure that no risk of infection is transferred to the personnel involved.
 - 9.2.1. 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.
 - 9.2.2. Samples should be dispatched within two (2) hours from collection time using double packaging system.
 - 9.2.3. Samples should be labelled as detailed and shown in (**Appendix 6**).
 - 9.2.4. Bio-hazardous materials precautions should be adhered to by transport personnel and couriers during transport of samples.
 - a. Transport personnel or couriers should be trained by the collecting health facility on safe handling practices and infection control procedures.
 - b. All transport personnel are required to wear PPE at all times.

10. STANDARD SIX: SAMPLE PROCESSING

- 10.1. The gold standard for diagnosis of COVID-19 is RT-PCR using SARS-CoV-2 kits.
- 10.2. Testing Laboratories should ensure that the received samples are for clients registered on HASANA prior to processing.
- 10.3. Laboratories should avoid adding up samples from a group of patients (Pooling) before RNA extraction or before PCR runs.





- 10.4. Testing laboratory should implement one or two RNA extraction platforms along with quality control for RNA extraction.
- 10.5. 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).
- 10.6. If one gene is detected with on RT- PCR kit then a second test should be done and the results should be interpreted as per NCEMA guidelines (**appendix 5**).
- 10.7. Testing results must be issued within a maximum period of 48 hours.
- 10.8. 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.
- 10.9. 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.
 - 12.1.1. In circumstances where the processing lab is not integrated with HASANA, the requesting health facility is responsible to enter the test result in HASANA manually.
- 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 7).





- c. Facilities are required to provide a daily log of patients that have been contacted to CovNotify@dha.gov.ae as in (Appendix 8).
- 12.2.3. In circumstances of presumptive positive, the requesting health facility should inform the patient to 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 and Clinical Laboratories should perform serological antibody testing as outlined in the <u>Coronavirus Disease 2019 (COVID-19) Serologic Test Recommendations</u> published by the National Testing Committee without obtaining prior approval from DHA.
- 13.3. Serological test result doesn't need to be entered in HASANA.
- 13.4. Disclaimers at the end of patient reports should be mentioned for both negative and positive results. 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 DHA 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 at -20°C or -70°C for two weeks before sending to Latifa Hospital Virology Laboratory.
- 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.





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<u>19%20Version%203.1%20April%2020%202020.pdf</u> (accessed on 10/06/2020).

10. 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 10/06/2020).

Standards for SARS-CoV-2 Testing





APPENDICES

APPENDIX 1: TESTING HEALTH FACILITY EVALUATION (SAMPLE COLLECTION)

EVALUATION CHECKLIST FOR COVID-19 TESTING FACILITIES

| Facility Name | e: | | | | |
|----------------|---|---|-----|----|---|
| SL. No: | Crit | eria | Yes | No | Documents Required |
| Accreditation | n/License | 2 | | | |
| 1 | Inte | rnational Accreditation | | | Provide a Copy of certificate |
| 2 | Vali | d DHA License | | | Provide a copy of DHA facility license. |
| Qualified per | sonnel | | | | |
| 3 | - DH - Inf - Tra | sician: IA License fection control training aining of COVID-19 sample ection | | | Provide a copy of DHA License & training log |
| 4 | - DH - Inf - Tra | istered Nurse: IA License fection control training aining of COVID-19 sample ection | | | Provide a copy of DHA License & training log |
| 4 | | ction Control Policy | | | Provide copy of policy |
| PPE and Sam | ple Colle | ection | | | |
| 5 | Cur | :- Contract(s) with Supplier(s)- rent Inventory - Strategy to imize Supply | | | Provide details and copies of original contracts |
| 6 | Swa - Co - Cu | | | | Provide details and copies of original contracts |
| 7 | Sam | ple Transport Policy | | | Provide copy of the policy |
| Testing Strate | egy | | | | |
| 8 | Capacity: - Current capacity per day (test/day - Planned capacity increase with timeline | | | | Provide Details |
| 9 | Sen | d out Lab(s) | | | Provide details and copies of original contracts |
| 10 | (Or | ting Strategy nsite/offsite, targeted groups, king hours, contractsetc) | | | Provide details and copies of original contracts |





| Result Reporting | | | | | | | | | |
|-------------------|---------|--|--|---|--|--|--|--|--|
| 11 | HAS | SANA Facility Account | | Provide date of registration and user details (name , designation) | | | | | |
| 12 | HAS | SANA Training | | Training log | | | | | |
| 13 | Res | ult Reporting Policy | | Provide copy of the policy | | | | | |
| | l be co | w the above and might request furth nducted to ensure the accuracy of the Only | | | | | | | |
| Evaluation Report | | | | | | | | | |
| Additional | _ | | | | | | | | |
| Comments if A | Any: | | | | | | | | |





APPENDIX 2: CLINICAL LABS REGISTRATION TEMPLATE

| Laborato | ory Name: | | | |
|-----------|---|-----|----|--|
| SL. No: | Criteria | Yes | No | Documents Required |
| Accredit | ation/License | | | |
| 1 | International Laboratory Accreditation (CAP and /or ISO15189) | | | Provide a Copy of certificate |
| 2 | Valid DHA License | | | Provide a copy of DHA 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 DHA 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 Re | eporting | | | |
| 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 |

EVALUATION CHECKLIST FOR COVID-19 CLINICAL LABORATORIES





| 12 | TAT for re | sult reporting | | Provide policy and/or system generated reporting TAT. | | | | | |
|--------|---------------------|---|------------|---|--|--|--|--|--|
| | | _ | | | | | | | |
| | & Documenta | | | 1 | | | | | |
| 13 | | Sample processing (RNA | | Please provide a copy of | | | | | |
| | |), result reporting (Positive, | | policy/SOP | | | | | |
| | Negative a | & Inconclusive result) | | | | | | | |
| 14 | Policy on s | specimen retention | | Please provide a copy of policy | | | | | |
| Safety | | | | | | | | | |
| 15 | Biological | Safety Cabinet Level II | | | | | | | |
| 16 | Adequate Testing | space to perform COVID-19 | | | | | | | |
| 18 | Availabilit | y of adequate safety measures to | | List the PPE's and provide the | | | | | |
| | protect al | I the staff from COVID-19 testing | | current inventory (stock) list. | | | | | |
| | (PPE, safe | ty & infection control training, | | Infection control training log. | | | | | |
| | waste ma | Waste management policy. | | | | | | | |
| 19 | Adequate | Engineering controls and Facility | | Provide a copy of annual testing | | | | | |
| | design to | perform COVID-19 testing | | record with change of HEPA filter | | | | | |
| | (biologica | I safety level II, testing certificate | | document | | | | | |
| | of BSC wit | h HEPA filter change annually | | | | | | | |
| | and/or ne | gative pressure room) | | | | | | | |
| Sample | e Transport | | | | | | | | |
| 20 | Sample Tr | ansport Policy | | Provide the policy | | | | | |
| Note: | DHA will revie | w the above and might request furth | ner inform | hation from your facility. Physical | | | | | |
| inspec | tion will be co | onducted to ensure the accuracy of the | ne provide | ed details. | | | | | |
| For DH | A Official Use | e Only | - | | | | | | |
| Evalua | ation Report | | | (Laboratory | | | | | |
| | - | Name) has(met/not met/partially met) all the required criteria | | | | | | | |
| | | set by Dubai Health Authority, for performing COVID-19 Testing at their | | | | | | | |
| | | facility. | - | | | | | | |
| Additi | onal | | | | | | | | |
| | ents if Any: | | | | | | | | |
| | | 1 | | | | | | | |





APPENDIX 3: APPROVED COVID-19 LABS

| | Name | Location |
|-----|--|---------------------------|
| 1. | Agiomix | Dubai - Al Barsha South 2 |
| 2. | Al Zahra Private Hospital | Dubai - Al Barsha |
| 3. | American Hospital | Dubai - Oud Metha |
| 4. | CPS Clinical Pathology Services (MenaLab) | Dubai - Al Qouz 4 |
| 5. | Emirates Hospital DHCC Laboratory | Dubai - DHCC |
| 6. | Eurofins Biomnis | Dubai - Al Bada |
| 7. | Freiburg Medical Laboratory | Dubai - Al Karama |
| 8. | Iranian Hospital Lab | Dubai - Al Badaa |
| 9. | Latifa Hospital Virology Lab | Dubai - Oud Metha |
| 10. | Mediclinic Hospitals Group | Dubai |
| 11. | Medsol Dubai Medical Laboratory | Dubai - Al Muraqabat |
| 12. | National Reference Laboratory | Dubai - Al Barsha South 2 |
| 13. | Pure Health | Dubai Airport |
| 14. | Scientific Clinical Laboratories (UniLabs) | Dubai - Jumeirah |
| 15. | Star Metropolis Clinical Laboratory | Dubai – Al Hamriya |
| 16. | Viafet Genomic laboratory | Dubai - Al Badaa |
| 17. | York Diagnostic Laboratories | Dubai - JLT |





APPENDIX 4: 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 5: INTERPRETATION OF COVID-19 RT PCR TEST

| ORF1ab (Gene) /RdRp (gene)^ | N (gene) /S (gene) ^{\$} | E (gene) | ю | Negative Control | Positive Control | RNA Extraction Control (if applicable) | Interpretation | | |
|-----------------------------------|---|-------------|------------|---------------------|---------------------|--|---|--|--|
| + | + | + | <i>†</i> - | - | + | + | 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: <u>"Presumptive positive. Only one of multiple</u> gene is isolated. Low viral load possible, please repeat sample in 72 -96 hours to document the course of the disease." If the 3 rd order run is still positive for single E gene and patient is asymptomatic, report: <u>"Acute disease unlikely,</u> 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 <u>"SARS-CoV-2 detected"</u> |
| + | ÷ | ÷ | +/- | - | ÷ | ÷ | 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 <u>"SARS-CoV-2 detected</u> ". If confirmatory test is negative, report: " <u>SARS-CoV-2 not</u> |
| | | | | | | , | 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 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: SMS TEMPLATE

Dear customer (name), (MRN)

Your COVID-19 test on (date), reported that your result is positive indicating that you have the virus.

Do not worry; DHA professionals will contact you soon.

Please click here for home isolation instructions

We wish you a speedy recovery.

عزيزنا المتعامل (الاسم)، (MRN)

يرجى العلم بأن نتيجة فحصك لكوفيد-19 بتاريخ (التاريخ) "إيجابية"، بما يفيد بأنك مصاب بالفيروس.

لا تقلق، سيقوم أحد موظفين هيئة الصحة في دبي بالتواصل معك قريبا.

يرجى الضغط هنا للاطلاع على إرشادات العزل المنزلي

نحن هنا لمساندتكم. مع تمنياتنا لكم بالصحة والعافية.





APPENDIX 8: 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 |
|------------------|-----------------|------------------------------------|-------------------------------|-------------------|-------------------|--------------------|--------------------|------------------|
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