SARS COV-2 Testing Inspection Checklist- Random

Name of the Facility: _____

Date of Inspection:_____/_____/_____

Ref.	Description	Yes	No	N/A	Remarks
5	**STANDARD ONE: REGISTRATION AND APPROVAL REQUIREMENTS**				
5.4.	Clinical Laboratories should integrate their Laboratory Information System with HASANA platform.				
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**				
6.2.	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.				
7	**STANDARD THREE: SAMPLE COLLECTION**				
7.1.	Health facilities should gain approval from DHA prior to starting sample collection services as above.				
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.				

7.4.	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.				
7.4.4.	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).				
7.9.	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).				
7.12.	Only trained and privileged licensed healthcare professionals in an appropriate setting should collect COVID-19 swabs.				
8	**STANDARD FOUR: SALIVA SAMPLE COLLECTION**				
8.1.	Saliva samples can be collected by all approved facilities for sample collection.				
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.				
10.2.	Transport of COVID-19 samples should be through cold chain logistics.				
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).**				
10.6.2.	All transport personnel are required to wear PPE at all times.				
11	**STANDARD SEVEN: SAMPLE PROCESSING**				
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.				
11.5	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.				
11.8	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.				
11.10.	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.				
11.13	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).				

11.15	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.				
13	**STANDARD NINE: RESULT REPORTING**				
13.1	Testing results should be entered in HASANA immediately by the processing lab through integration.				
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).**				
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.				
15.7.	The price for COVID-19 serologic test should be followed as per latest DHA circulars.				
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.				
16.3.	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.				
APPENDIX 1:	**TESTING HEALTH FACILITY REGISTRATION TEMPLATE (SAMPLE COLLECTION)**				
1	International Accreditation (Valid copy of certificate)				
2	DHA License (Valid DHA facility license.)				
3	HCP: (DHA training log/ Certificate) Trained and privileged licensed healthcare professionals Infection control training Training of COVID-19 sample collection				
9	Send out Lab(s) (Availability of original contracts upon submission)				
11	HASANA Facility Account (Provide date of registration and user details (name, designation))				
APPENDIX 2:	**CLINICAL LABS REGISTRATION TEMPLATE**				
1	International Laboratory Accreditation (CAP and /or ISO15189) (Valid copy of certificate)				
2	Valid DHA License (Valid DHA facility license)				
3	Licensed Pathologist with knowledge on interpretation of the Viral PCR test result for Covid-19 (Valid DHA License of the pathologist & CV)				
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.)				
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)				
9	Confirmatory testing for screening				
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.)				
15	Biological Safety Cabinet Level II				
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)				
APPENDIX 3:	**DRIVE-THROUGH COVID-19 TESTING REGISTRATION TEMPLATE**				
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.				
3	Safety protocols & infection control measures. Hands washing basin / Hand sanitizer distributed throughout all stations. Infection Control Policy.				
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. Vehicles queue in lanes and pass through a set of designated testing stations. Area structure considerations to accommodate the anticipated influx of patient vehicles. Provide the design plan with all necessary information.				
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.)				
9	Send out Lab(s) (Provide details and copies of original contracts)				
11	HASANA Facility Account Reporting through HASANA Provide date of registration anduser details (name , designation) Reporting and communication channels with patients.				
APPENDIX 4:	**COVID-19 TESTING TENT REGISTRATION TEMPLATE**				
2	Qualified personnel: (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.				
4	Safety protocols & infection control measures. Hands washing basin / Hand sanitizer distributed throughout all stations. (Infection Control Policy.)				
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.)				
11	Tent operating hours to be displayed/ conveyed to patients (Not less than 12 hours). (Operating hours)				
13	Send out Lab(s) (Provide details and copies of original contracts) (Provide sample transportation policy)				
15	HASANA Facility Account (Provide date of registration and user details (name , designation))				
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.				
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.				