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SARS COV-2 Testing Inspection Checklist- Final

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.				
7	STANDARD THREE: SAMPLE COLLECTION				
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:				
7.4.2.	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.				
7.9.	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).				

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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.				
9.3.	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.				
11	STANDARD SEVEN: SAMPLE PROCESSING				
11.4.1	RNA Extraction is a must procedure , direct lysis procedure is not allowed.				
11.9	Testing laboratories providing COVID-19 testing services shall use a DHA approved SARS-CoV-2 kits.				
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).				
11.17	De-isolation measures should be followed as per the National Guidelines for the Management of COVID-19.				
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.				
17	STANDARD THIRTEEN: SAMPLE RETENTION				
17.3.	High security and safety measures should always be implemented for stored samples.				
APPENDIX 1:	TESTING HEALTH FACILITY REGISTRATION TEMPLATE (SAMPLE COLLECTION)				
4	Infection Control Policy				

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7	Sample Transport Policy				
9	Send out Lab(s) (Availability of original contracts upon submission)				
13	Result Reporting Policy				
APPENDIX 2:	CLINICAL LABS REGISTRATION TEMPLATE				
5	<p>Analyzers, Equipment, Reagent supplies for RNA extraction and RT-PCR</p> <p>List the Analyzer details (Extraction and RT-PCR) and provide Laboratory SOPs for the same.</p> <p>Provide the Current Inventory list (Stock) of Extraction tests and PCR tests.</p> <p>Mention the analyzer capacity/day here (N# of tests run/day)</p>				
10	RT-PCR target gene detection (Valid policy on result interpretation)				
13	Policy for Sample processing (RNA Extraction), result reporting (Positive, Negative & Inconclusive result) (Copy of policy/SOP)				
14	Policy on specimen retention				
15	Biological Safety Cabinet Level II				
16	Adequate space to perform COVID-19 Testing				
17	<p>Availability of adequate safety measures to protect all the staff from COVID-19 testing (PPE, safety & infection control training, waste management)</p> <ul style="list-style-type: none"> • 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)				
19	Sample Transport Policy				

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APPENDIX 3:	DRIVE-THROUGH COVID-19 TESTING REGISTRATION TEMPLATE				
2	<p>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"</p> <p>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.</p>				
3	<p>Safety protocols & infection control measures. Hands washing basin / Hand sanitizer distributed throughout all stations. Infection Control Policy.</p>				
4	<p>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.</p>				
7	Availability of Medical Record (Provide details of the HIS.)				
9	Send out Lab(s) (Provide details and copies of original contracts)				
13	<p>Result Reporting Policy Keep patients informed by SMS, email, phone call (Provide copy of the policy)</p>				

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APPENDIX 4:	COVID-19 TESTING TENT REGISTRATION TEMPLATE				
2	<p>Qualified personnel: (1) for triaging and (1) for testing per swab collection station per shift.</p> <p>DHA License</p> <p>Infection control training</p> <p>Training of COVID-19 sample collection</p> <p>Swab collection training log.</p>				
3	<p>Administration staff/Coordinator staff: 1 per shift.</p> <p>Shift supervisor: 1 per shift.</p> <p>Security Officer: 1 per shift"</p> <p>Provide full personnel details.</p>				
4	<p>Safety protocols & infection control measures.</p> <p>Hands washing basin / Hand sanitizer distributed throughout all stations. (Infection Control Policy.)</p>				
5	<p>Seating arrangement, if any, should ensure sufficient social distancing measures.</p> <p>Share seating plans and social distancing measures.</p> <p>A policy in place should be available to avoid overcrowding.</p>				
6	<p>Sample Storage area. (Provide temperature control unit details.)</p>				
7	<p>Separate entry & exit. (Provide patient journey plan.)</p>				
8	<p>Allocate areas for registration and swab collection. (Provide marked plans.)</p>				
9	<p>Enough car park spaces.</p>				
10	<p>Sufficient Air circulation System (Provide details)</p>				
11	<p>Tent operating hours to be displayed/ conveyed to patients (Not less than 12 hours). (Operating hours)</p>				
13	<p>Send out Lab(s) (Provide details and copies of original contracts)</p> <p>(Provide sample transportation policy)</p>				
17	<p>Result Reporting Policy (Provide copy of the policy)</p>				

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