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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 | | | | | | | | |
| 5.4. | Information System with HASANA platform. | | | | | | | | |
| | Swab collecting facilities should have in place a valid contract | | | | | | | | |
| 5.6. | with a DHA approved and HASANA integrated clinical | | | | | | | | |
| | laboratory. | | | | | | | | |
| 7 | STANDARD THREE: SAMPLE COLLECTION | | | | | | | | |
| | Health facilities should have a dedicated room for swab | | | | | | | | |
| 7.3. | 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 | | | | | | | | |
| 7.4. | comply with the below requirements: | | | | | | | | |
| 7.4.2. | Ensure availability of an online pre-booking appointment | | | | | | | | |
| 7 . 4.2. | system. | | | | | | | | |
| 7.4.3. | Ensure sample collection in an outdoor space or well ventilated | | | | | | | | |
| 7.4.5. | area. | | | | | | | | |
| 7.4.4. | Follow infection control measures. | | | | | | | | |
| | Healthcare professionals collecting the specimens should follow | | | | | | | | |
| 7.9. | infection control measures and use recommended Personal | | | | | | | | |
| 1.3. | Protective Equipment (PPE) (N95, facemask, eye protection, | | | | | | | | |
| | gloves and a gown). | | | | | | | | |

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| 9 | STANDARD FIVE: SAMPLE STORAGE | | |
|--------|---|------|--|
| | Secure designated space with an access restriction, near a | | |
| 9.1. | hand-washing basin must be provided for safe storage of | | |
| | Laboratory specimens. | | |
| | The collected swab along with viral tube media should be | | |
| | collected under aseptic condition and stored immediately in a | | |
| 9.3. | separate fridge in a temperature of 2-8°C or stored in an icebox | | |
| 9.5. | 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 | | |
| 9.4. | 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 | | |
| 11,4,1 | not allowed. | | |
| 11.9 | Testing laboratories providing COVID-19 testing services shall | | |
| 11.9 | use a DHA approved SARS-CoV-2 kits. | | |
| | Testing laboratory should use two different RT-PCR kits. Each | | |
| 11.13 | 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 | | |
| 11.17 | Guidelines for the Management of COVID-19. | | |
| 16 | STANDARD TWELVE: INFECTIOUS WASTE MANAGEMENT | | |
| 16.1. | All approved testing facilities should comply with DHA | | |
| 10.1. | Infectious Waste Management and Disposal standards. | | |
| | Approved testing facilities should have a policy for proper | | |
| 16.2. | 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 | | |

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| | implemented for stored samples. | | | | |
|----------------|---|----------|----------|------------|--|
| APPENDIX 1: | TESTING HEALTH FACILITY REGISTRATION TEMPLATE (SAM | MPLE COI | LLECTION | 1) | |
| 4 | Infection Control Policy | | | | |
| 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 | 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) | | | | |
| 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 | 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. | | | | |

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| | Adequate Engineering controls and Facility design to perform | | | |
|----------------|--|----------|--|--|
| | COVID-19 testing (biological safety level II, testing certificate of | | | |
| 18 | BSC with HEPA filter change annually and/or negative pressure | | | |
| 10 | room) (Provide a copy of annual testing record with change of | | | |
| | HEPA filter document) | | | |
| 10 | · | | | |
| 19 | Sample Transport Policy | | | |
| APPENDIX 3: | DRIVE-THROUGH COVID-19 TESTING REGISTRATION TEMP | LATE | | |
| | 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" | | | |
| 2 | 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. | | | |
| | Safety protocols & infection control measures. | | | |
| 2 | Hands washing basin / Hand sanitizer distributed throughout | | | |
| 3 | all stations. | | | |
| | Infection Control Policy. | | | |
| | Open area. | | | |
| | Proper ventilation system. | | | |
| | One-way passage for vehicles with entrance separate from exit. | | | |
| | Divided into stations for parking, registration, and sample | | | |
| 4 | collection. | | | |
| | Vehicles queue in lanes and pass through a set of designated | | | |
| | testing stations. | | | |
| | Area structure considerations to accommodate the anticipated | | | |
| | 1 | <u> </u> | | |

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| | influx of patient vehicles. | | |
|----------------|--|--|--|
| | Provide the design plan with all necessary information. | | |
| 7 | Availability of Medical Record (Provide details of the HIS.) | | |
| | Send out Lab(s) (Provide details and copies of original | | |
| 9 | contracts) | | |
| | Result Reporting Policy | | |
| 13 | Keep patients informed by SMS, email, phone call (Provide copy | | |
| | of the policy) | | |
| APPENDIX 4: | COVID-19 TESTING TENT REGISTRATION TEMPLATE | | |
| | Qualified personnel: (1) for triaging and (1) for testing per swab | | |
| | collection station per shift. | | |
| 2 | DHA License | | |
| 2 | Infection control training | | |
| | Training of COVID-19 sample collection | | |
| | Swab collection training log. | | |
| | Administration staff/Coordinator staff: 1 per shift. | | |
| 3 | Shift supervisor: 1 per shift. | | |
| | Security Officer: 1 per shift" | | |
| | Provide full personnel details. | | |
| | Safety protocols & infection control measures. | | |
| 4 | Hands washing basin / Hand sanitizer distributed throughout | | |
| | all stations. (Infection Control Policy.) | | |
| | Seating arrangement, if any, should ensure sufficient social | | |
| 5 | 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 | | |

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| | marked plans.) | | | | |
|----|--|--|--|--|--|
| 9 | Enough car park spaces. | | | | |
| 10 | Sufficient Air circulation System (Provide details) | | | | |
| 11 | Tent operating hours to be displayed/ conveyed to patients | | | | |
| 11 | (Not less than 12 hours). (Operating hours) | | | | |
| | Send out Lab(s) (Provide details and copies of original | | | | |
| 13 | contracts) | | | | |
| | (Provide sample transportation policy) | | | | |
| 17 | Result Reporting Policy (Provide copy of the policy) | | | | |

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