PROTOCOLS FOR COVID-19 DIAGNOSTIC TESTING AT PRIVATE HEALTHCARE SECTOR RAPID ANTIGEN TESTING, RAPID ANTIBODIES TESTING AND PCR TESTING SCOPE

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The document covers the necessary information for diagnostic testing of COVID-19 in the private health sector that includes rapid antigen testing, rapid antibodies testing and RT-PCR testing.

INTENDED AUDIENCE

Staff involved in the testing process including laboratory staff, nurses, physicians, or other health care providers at the private healthcare sector.

TYPES OF TESTS AT PRIVATE HEALTHCARE SECTOR:

1. Rapid antigen testing
2. Rapid antibodies testing
3. Polymerase Chain Reaction (PCR) testing (swab collection only)

1. RAPID ANTIGEN TESTING

- A test that is intended to provide fast and reasonably accurate screening for Covid-19 on respiratory specimens at the point of care.
- It can be used in clinical and non-clinical settings
- It can detect COVID-19 virus antigen in the first week of infection when most infectious.
- Any positive antigen tests will need to be confirmed by PCR testing.

USES OF THE RAPID ANTIGEN TEST AT THE PRIVATE HEALTHCARE SECTOR

1. Triage patients with respiratory symptoms presenting to clinics.
2. Pre-minor elective procedures without intubation needed or risk of aerosol spread in situations like dental, cosmetic, minor surgery, etc.
3. Pre-admission for minor procedures.
4. Routine screening of persons who are not vaccinated as may be required in non-healthcare settings like workplace, businesses, or schools, particularly employees with direct customer exposure such as gyms, cashiers and restaurant workers.

STAFF PERFORMING THE TEST

- Trained nurses, physicians, or other health care providers can perform the test
- This test can be done in approved healthcare facilities that can assure the quality of test performance.

TRAINING OF STAFF

MOPH with support from HMC- DLMP will provide the training for private healthcare facilities to perform rapid antigen testing.

COMMERCIAL KITS TO BE USED

MOPH through HMC- DLMP will provide the list of approved kits which are validated at HMC.

The private sector is responsible to purchase the validated kits directly from the distributors.

PROCESS FOR RAPID ANTIGEN TESTING

1. The private sector shall submit a request to perform the test to DLMP-HMC lab using the appropriate forms. Only approved private healthcare facilities will perform the rapid antigen tests.
2. The private sector is responsible to record all the results of rapid antigen tests performed in their clinics in a manual or electronic format. Any positive results should be taken as presumptive until confirmed by PCR testing at HMC. All data of rapid antigen testing to be reported daily using the unified excel sheet form to the CDC/MOPH email address **covid@moph.gov.qa**

3. Any person who tests positive by rapid antigen test must have an immediate swab taken for PCR testing and the patient is advised to isolate themselves. if PCR test is positive, testing of contacts will be done by MOPH.
4. All PCR tests done after positive rapid antigen test will have Kashif code "POST ANTIGEN".
5. Auditing will be done regularly by MOPH and any violation will be investigated.
6. Those who test negative as part of screening of unvaccinated staff working in businesses will be given a proof of negative test result to be submitted to their workplace. This is to be provided by the private healthcare facility performing the test.

2. ANTIBODY TESTING

(RAPID TEST AT POINT-OF-CARE AND ANTI-N AND ANTI-S SEROLOGICAL ASSAY)

2.1 RAPID ANTIBODY TESTING:

- For private healthcare facilities, the SARS-CoV-2 Rapid Antibody Test allows for qualitative detection of IgG antibodies or detection of both IgG and IgM antibodies, using a Lateral Flow Device (LFD). The LFD uses capillary blood collected from a finger prick sample. They confirm previous exposure to COVID19 infection or vaccination.

2.2 ANTI-N AND ANTI-S SEROLOGICAL ASSAYS (SAMPLE COLLECTION ONLY)

These are two laboratory-based assays available at HMC that require a blood sample to be collected by a phlebotomist and to be sent to HMC DLMP for running the test. These are:

1. Anti-N assays which detect antibodies to the nucleoprotein of the virus. They are detectable in patients with previous COVID-19 infection.
2. Anti-S assays which detect antibodies to the spike protein of the virus and are detectable in patients with previous COVID-19 infection or previous vaccination.

USES OF ANTIBODY TEST AT THE PRIVATE HEALTHCARE FACILITIES

- Demonstration of current immunity against COVID-19 as a result of a previous infection or vaccination.

STAFF PERFORMING THE TEST

- The rapid LFD test will be done directly in Private healthcare facilities by trained nurses, physicians, or other health care providers
- Where required the Laboratory ELISA assays (Anti-S / Anti-N) can be performed at HMC on blood sample collected at private healthcare facility and **requires prior arrangement with HMC- DLMP**.

TRAINING OF STAFF

MOPH with support from HMC- DLMP will provide the training for private Healthcare facilities to perform rapid antibody tests.

COMMERCIAL KITS TO BE USED IN PRIVATE HEALTHCARE FACILITIES

MOPH through HMC- DLMP will provide the list of approved kits which are pre-approved and validated at HMC. The private healthcare facilities are responsible to purchase the validated kits directly from the distributors.

PROCESS FOR RAPID ANTIBODY TESTING

1. The private healthcare facilities shall submit their request to perform the test to HMC lab using the official forms provided by DLMP-HMC. Only approved facilities will perform the rapid antibody tests.
2. For serological assays that require sending blood samples to HMC laboratory for testing, private healthcare facilities can request the test by filling a special form that contains all patient's details and justification of requesting this test. Once approved by HMC- DLMP, the private sector can send the blood sample to HMC for serology testing.
3. Where indicated the test can be done for any patient to detect if any previous infection has occurred.
4. The private healthcare facility is responsible to record all the results of rapid antibody tests performed in their clinics in a manual or electronic format to the public health department at MOPH. All data of rapid antigen testing to be reported daily using the unified excel sheet form to the CDC/MOPH email address **covid@moph.gov.qa**

5. If a rapid antibody test using both IgG and IgM bands gives a positive result on both bands then a precautionary rapid antigen test should be performed and a swab for PCR sent to HMC. If the rapid antigen test is positive, then appropriate precautions should be applied and maintained until the result of the PCR is available.
6. All PCR tests done after positive rapid antibody test will have Kashif code "POST ANTIBODY".
7. Auditing will be done regularly by MOPH and any violation will be investigated

3. POLYMERASE CHAIN REACTION (PCR) TESTING[1]

- For screening of asymptomatic patients or patients presenting with COVID-19 like symptoms or other respiratory symptoms.
- It can detect COVID-19 virus in the early acute infectious stage of the infection and during the prolonged shedding stage that is often found in recovering patients.

USES OF PCR AT PRIVATE HEALTHCARE FACILITIES

1. For screening of patients presenting with COVID-19 like symptoms or other respiratory symptoms.
2. For travellers who need to do a pre-travel PCR screening test which should be done within 48 – 72 hours pre travel.
3. Prior to major procedures for patients where screening is done 24 – 48 hours before the procedure.
4. Prior to admission to hospital 24 – 48 hours before the admission.
5. For confirmation of infection following a positive rapid antigen test and/or positive rapid IgG and IgM bands Antibodies.

⋆ swabbing of close contacts for contact tracing is not allowed to be done at private healthcare facilities. This is the sole responsibility of the Ministry of Public Health.

STAFF PERFORMING THE TEST

Swabbing shall be done by trained nurses, physicians, or other health care providers.

TRAINING OF STAFF

Training for private healthcare facilities to perform swabbing is the responsibility of MOPH.

COMMERCIAL KITS TO BE USED IN PRIVATE HEALTHCARE FACILITIES

- HMC- DLMP will provide the list of approved swabs which are validated at HMC. The private sectors are responsible to purchase the validated swabs directly from the distributors.
- It is essential that the Private Clinics liaise closely with HMC before purchase of swabs as not all commercial UTMs are compatible with HMC assays.

PROCESS FOR PCR TESTING

1. The private healthcare facilities will be submitting their request to perform the test to HMC lab using the same form utilized for requesting PCR testing that currently exists. Only approved facilities will perform the rapid antigen tests.
2. The swab only will be done at private sector and then sent to DLMP at HMC for PCR testing.
3. The private sector will receive the results either electronically through an FTP or as hard copies in exceptional circumstances.
4. Any positive patient by PCR will require isolation for 14 days for positive results (Ct≤30) or isolation for 7 days for reactive results (Ct≥30) as directed by MOPH. Any inconclusive result by PCR in the Private sector should be repeated after 24 hours.
5. All PCR tests done at private sectors will have Kashif code with private sector name.
6. Auditing will be done regularly by MOPH and any violation will be investigated.

IMPORTANT REMARKS:

- Staff performing the rapid antigen and rapid antibody tests need to strictly follow the manufacturer instructions to avoid reducing the test performance reliability.
- The test kits must be stored and handled properly by the clinic and staff as improper handling reduces performance. The temperature of reagents when used must closely adhere to the manufacturers handling instructions, including strict adherence to the timing of when to read the device, as improper use significantly reduces test performance reliability.

1 Refer to PCR Testing Guidelines for further details through the following link: Interim Guidelines for Sample Collection, Handling, Storage and Transportation of Clinical Specimens from Persons Suspected of Coronavirus Disease 2019 (COVID-19)

مؤسسة حمد الطبية
Hamad Medical Corporation
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Application Request for COVID-19 (SARS-CoV-2) PCR test in Private Hospital/Clinic

Date: .....

Requestor Information:		
Hospital/Clinic Name:	**Facility description:** ☐ **Inpatient** **Number of beds:** ..... ☐ **Outpatient**	
Contact focal point:	**Email:**	**Mobile:**

Test Information:

Is this a:

☐ New Service ☐ Additional to current service

Type of test requested:

☐ COVID-19 PCR Test

Number of tests requested per day:

☐ **Tests**

Scope of work (Target population for testing):

Viral Swab Approval Request Form:

Selection of PCR Swabs and VTM approved by the Department of Laboratory Medicine and Pathology (DLMP), Hamad Medical Corporation (HMC) :

- Kindly refer to the attached Appendix A for more details.

Brand Name: _____

Source (Vendor/Country): _____

Previously Validated by DLMP?

☐ YES Details: _____

☐ NO If No, please provide swabs to DLMP for Validation

Specify number provided (minimum 20 swabs): ☐

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Assessment

Number of PCR samples approved to be submitted per day: ☐

Are swabs accepted in the approved list: ☐ YES ☐ NO

If No, Did Swab pass validation: ☐ YES ☐ NO

Validation completion date: _____

If swabs failed in validation Rejected, give reason:

.....

.....

.....

Reviewed by: ..... **Date:** .....
Signature & Stamp

Approved by: ..... **Date:** .....
Signature & Stamp

Please email the completed application form to the Dept of Laboratory Medicine and Pathology, Hamad Medical Corporation
Email IDs: NYOUNES1@hamad.qa and Svazhayil1@hamad.qa for further process.

Application Request for
Rapid COVID-19 Testing in Private Hospital/Clinic

Date: .....

Requestor Information:		
Hospital/Clinic Name:	**Facility description:** ☐ **Inpatient** **Number of beds:** ..... ☐ **Outpatient**	
Contact focal point:	**Email:**	**Mobile:**

Rapid COVID-19 Antigen / Antibody Testing Request Information:

Type of test requested:

☐ Rapid COVID-19 Antigen Test

☐ Rapid COVID-19 Antibody (IgG/IgM) Test

Please select the COVID-19 test approved by HMC-DLMP to be performed by private sectors:

Rapid COVID-19 Antigen Kits:

Kit Name	**Manufacturer**	**Please select (✓) the kit**
Panbio COVID-19 Rapid Ag Test Device	Abbott	
SARS-CoV-2 Rapid Device Ag Test	Roche	
STANDARD Q COVID-19 Rapid Ag Test	SD Biosensor	
CareStart™ COVID-19 Rapid Ag Test	AccessBio, Inc	

Rapid COVID-19 Antibody (IgG/IgM) Kits:

Kit Name	**Manufacturer**	**Please select (✓) the kit**
COVID-19 IgM / IgG Rapid Test -RDT	Biomedomics	
COVID-19 IgM / IgG Rapid Test Device	Abbott	
SARS Cov-2 Rapid Ab Test	Roche	

*Kindly refer to Appendix A for validated kits

Training of Rapid COVID-19 Antigen / Antibody

Training and competency required for the testing personnel: ☐ Yes ☐ No

Personnel who will be performing the rapid testing:

☐ Nurses ☐ Physician ☐ Laboratory ☐ Others, specify ……

Approximate number of personnel required for training: ……

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HMC-DLMP approval on the request for the Rapid COVID-19 Antigen / Antibody testing.

Rapid COVID-19 Antigen Test	
☐ Approved	☐ Rejected
Reason for rejection:	

Rapid COVID-19 Antibody (IgG/IgM) Test	
☐ Approved	☐ Rejected
Reason for rejection:	

Reviewed by (POCT Supervisor): ……,…… **Date:** ……
Signature & Stamp

Approved by (HMC DLMP Chairperson): …… **Date:** ……
Signature & Stamp

Please email the completed application form to the Dept of Laboratory Medicine and Pathology, Hamad Medical Corporation
Email IDs: jsaid@hamad.qa and apoozhithara@hamad.qa

MOPH Antigen Antibody Test Reporting Form

HOSPITAL	NAME OF PATEINT	HC NUMBER	QID	AGE	GENDER	NATIONALITY	DATE OF TEST	KIND OF TEST	RESULT

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