دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

مـركـز أبـوظـبـي
لـلـصـحـة الـعـامـة
ABU DHABI PUBLIC
HEALTH CENTRE

Circular No (105) **تعميم رقم**

Date: 01/10/2020

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To: All Healthcare Facilities & Medical Laboratories in the Emirate of Abu Dhabi

السادة/ جميع المنشآت الصحية والمختبرات الطبية في إمارة أبوظبي المحترمين

Subject: **Updates on Laboratory Diagnostics for COVID19 in Abu Dhabi**

الموضوع: المستجدات في الفحوصات التشخيصية لمرض كوفيد19 في إمارة أبوظبي

Greetings,

تحية طيبة وبعد ،،،

We would like to extend you our greetings wishing you all the best and success.

بدايةً، يسرنا أن نتقدم لكم بخالص التحية والتقدير متمنين لكم دوام التوفيق والسداد.

As part of the continuous efforts to strengthen the health care system's response to the Novel Coronavirus (COVID-19), and to ensure optimal reporting of valid and accurate test results and infected cases. Based on global updates and the latest scientific developments in the detection of the SARS-CoV-2 virus.

في إطار الجهود المستمرة لتقوية استجابة نظام الرعاية الصحية في إمارة أبوظبي لمرض كورونا المستجد (COVID-19)، ولضمان الإبلاغ الأمثل عن نتائج الفحوصات والإصابات بشكل دقيق، وبناءً على التحديثات العالمية وآخر التطورات العلمية في الكشف عن فيروس SARS-CoV-2.

The Department of Health is updating the guidance to approve new diagnostic tests to be used for the diagnosis of (COVID-19) in selected settings.

تعمل دائرة الصحة على تحديث الأدلة لاعتماد اختبارات تشخيصية جديدة لاستخدامها في تشخيص (COVID-19) في أماكن وحالات محددة.

All health care providers to adhere to the requirements of the new tests including the validation of the tools and continuous reporting to DOH systems.

على جميع مقدمي الرعاية الصحية الالتزام بمتطلبات الاختبارات الجديدة بما في ذلك التحقق من صحة الأدوات ومشاركة التقارير المستمرة مع أنظمة دائرة الصحة.

The following tests can be used :

Rapid antigen tests are a new type of diagnostic tests designed for rapid viral detection and in turn providing a simple test procedure that would aid healthcare providers in making quic decisions .

يمكن استخدام الاختبارات التالية:

اختبارات مولدات المضاد السريعة الجديدة هي من الاختبارات التشخيصية المصممة للكشف السريع عن الفيروسات، وبالتالي توفير إجراء اختبار بسيط من شأنه أن يساعد مقدمي الرعاية الصحية في اتخاذ قرارات سريعة.

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Recommended FDA/FDA- EUA and CE approved rapid antigen tests that detect the SARS-COV-2 fluorescence immune assay (FIA);

استخدام الاختبارات الموصى بها من قبل إدارة الغذاء والدواء (FDA/FDA- EUA) / اختبارات المستضد السريع (CE) المعتمدة التي تكشف عن اختبار السارس- COV-2 المناعي الفلوري (FIA)؛

lateral flow immunofluorescent assay or immunochromatographic assay.

مقايسة التدفق الجانبي المناعي أو مقايسة الكروماتوغرافي المناعي.

These tests can be used as point of care in emergency departments or urgent care units and technique can be manual or using an analyzer .

يتم استخدام هذه الاختبارات في أقسام الطوارئ أو الرعاية السريعة ويمكن أن تكون التقنية يدوية أو باستخدام اجهزة التحليل.

Further details about the use of rapid antigen test available in appendix (1)

لمزيد من التفاصيل حول استخدام اختبار المستضد السريع المتاحة راجع الملحق (1)

- Direct loop-mediated isothermal amplification (Direct–LAMP) and reverse transcription loop-mediated isothermal amplification (RNA RT-LAMP), are two new assays that can be used for rapid SARS-COV-2 screening and detection respectively. It can be used by authorized providers and further details about its use is available in appendix (2)

- الفحص التشخيصي (Direct-LAMP) و (RNA RT-LAMP)، هما فحصان جديدان يمكن استخدامهما في الفحص والكشف السريع لـ SARS-COV-2. حيث يمكن استخدامه من قبل مقدمي الرعاية الصحية المعتمدين ويتوفر المزيد من التفاصيل حول استخدامه في الملحق (2)

- Saliva specimens can be used for diagnosis of COVID19 in a limited setting using special saliva collection kits that is FDA/ FDA-EUA/CE approved .

- يمكن استخدام عينات اللعاب لتشخيص كوفيد19 في نطاق محدد باستخدام أدوات جمع اللعاب المعتمدة من إدارة الغذاء والدواء الأمريكية / إدارة الغذاء والدواء-الاتحاد الأوروبي / CE.

Saliva test will be used in school setting for general screening purposes and the collection of the samples must be done by a licensed health care professional. It can be used for children in health care setting if the collection of swab was not possible.

سيتم استخدام اختبار اللعاب في الفحص في المدارس لأغراض المسح العام ويجب أن يتم جمع العينات من قبل عاملين رعاية صحية حاصلين على الترخيص. كما يمكن استخدامه للأطفال في مؤسسات الرعاية الصحية إذا لم يكن جمع مسحة الأنف ممكنًا.

The testing of saliva samples can be done using the following platforms :

يمكن اختبار عينات اللعاب باستخدام المنصات التالية

- Reverse Transcription PCR (RT-PCR)
- Loop-mediated isothermal amplification (LAMP).

- الفحص التشخيصي المعتمد PCR (RT-PCR)
- فحص (LAMP).

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More details are available in Appendix (3).

لمزيد من التفاصيل متوفرة في الملحق (3)

For coordination:
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Thanking you for your kind cooperation,,

شاكرين لكم حسن تعاونكم معنا ،،،

"This circular is designed for regulatory procedures and should not be used as content for media publication"

,

"هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي".

دائرة الصحة US 02 DEPARTMENT OF HEALTH

د. جمال محمد الكعبي
وكيل دائرة الصحة بالإنابة

Appendix1:

Rapid Antigen Test

Background

Based on global updates and the latest scientific developments in the detection of the SARS-CoV-2 virus. Rapid antigen tests are a new type of diagnostic tests designed for rapid viral detection and in turn providing a simple test procedure that would aid healthcare providers in making quick decisions. Rapid antigen tests directly detect the presence or absence of an antigen in a specimen and hence provide a qualitative result rather than a quantitative one. These tests are often point of care tests used to diagnose patients in an outpatient setting whilst providing a short turnaround time.

Intended Use

a. Method of detection & Complexity
   Recommended FDA/FDA- EUA and CE approved rapid antigen tests that detect the SARS-COV-2 fluorescence immune assay (FIA); lateral flow immunofluorescent assay or immunochromatographic assay. These tests are either waived or point of care and technique can be manual or using an analyser.
b. Specimen Collection
   Nasopharyngeal and nasal swabs collected at or soon after symptom onset (maximum of 5 days after symptom onset).
c. Validation
   Method Comparison where RT-PCR using nasopharyngeal swabs is the gold standard method for SARS-COV-2 detection and rapid COVID-19 antigen test is the method to be validated. Limit of detection and cross-reactivity are also recommended.
   Sample collection is to be done simultaneously from a mixed of negative, suspected, confirmed and probable COVID-19 cases (Please refer to circular No. 57 for case definitions). Samples to be processed and results to be compared for acceptable sensitivity & specificity.
d. Application

- Rapid Antigen tests can be used for triaging symptomatic individuals with respiratory symptoms consistent with Covid 19 in Emergency Departments and outpatient clinics.

- Consider use in situations where a positive result would indicate immediate, specific clinical action

- Used only in the first five days post symptoms onset.

- Off hour testing in hospital settings when the patient will benefit from a rapid result and the laboratory will repeat the test by another method when staff are available.

- Symptomatic individuals in remote populations such as small rural hospitals, tribal nations or other jurisdictions with known high prevalence and limited alternative access to testing.

Limitations

- Antigen tests have high specificity but are not robust in sensitivity. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions.

- Only to be used to test symptomatic patients in populations with high disease prevalence (antigen tests produce false negative when disease prevalence is high and false positive when disease prevalence is low)

- Antigen tests provide a qualitative result and do not provide a quantitative one.

- Rapid antigen test results should not be used as the sole criteria for the diagnosis of COVID-19 infection.

- Rapid antigen test results must be considered with other clinical data available.

- Rapid antigen tests should not be used for screening of asymptomatic individuals, healthcare workers, emergency responders and other essential personnel.

- Rapid antigen tests should not be used for population-based surveillance studies.

Appendix2:
Isothermal Amplification (LAMP) Test

Background

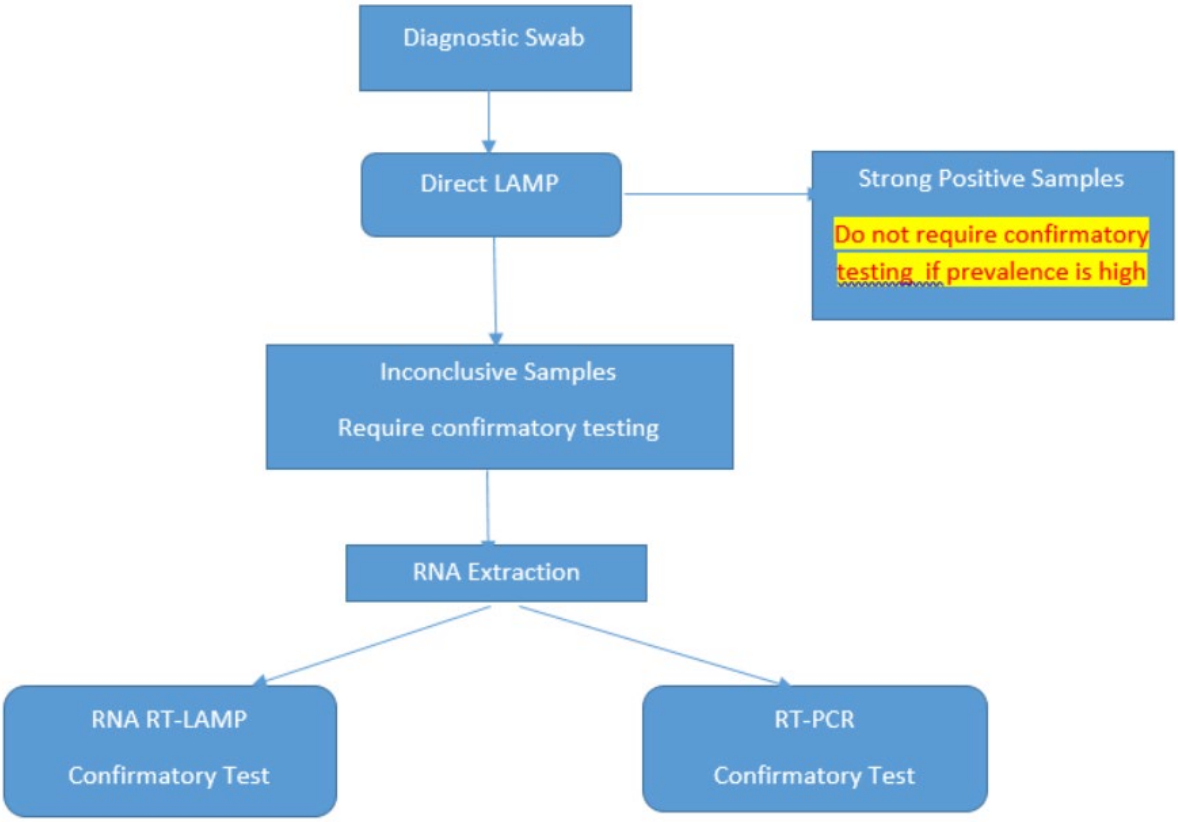
Based on global updates and the latest scientific developments in the detection of the SARS-CoV-2 virus, These tests are based on the use of isothermal amplification (LAMP) which amplifies the viral nucleic acid at a constant temperature of 65 °C, thus omitting the thermal cycling step and achieving rapid SARS-COV-2 detection. LAMP is a cost-effective assay that does not require sophisticated equipment or skilled personnel.

Direct LAMP test detects SARS-COV-2 antigen directly from the nasopharyngeal swab via LAMP technology while the RNA RT-LAMP test requires RNA extraction in addition to the LAMP technology.

Factor	Direct LAMP	RNA RT-LAMP
Technology	Isothermal	Isothermal
Intended Use	Screening	Confirmatory
Confirmatory Testing	Required for negative results and disease prevalence is high.	Not Required
RNA Extraction	No	Yes
Sensitivity	Requires Confirmation with RNA RT-LAMP or RT-PCR	Sensitivity comparable to RT-PCR
Resources	Reduced requirement for critical reagents (extraction kits and RT-PCR reagents	Reduced requirement for critical reagents (RT-PCR reagents)

Intended Use

Direct LAMP test is intended for SARS-COVID-2 screening while RNA-RT LAMP is intended for confirmatory purposes.



a. Specimen Collection Techniques:

- Nasopharyngeal swab
- Oropharyngeal swab
- Saliva

b. Validation Method:

Method Comparison where RT-PCR using nasopharyngeal swabs is the gold standard method for SARS-COV-2 detection and rapid COVID-19 antigen test is the method to be validated. Limit of detection and cross-reactivity are also recommended.
Sample collection is to be done simultaneously from a mix (50 samples) of negative, suspected, confirmed and probable COVID-19 cases (Please refer to circular No. 57 for case definitions).
Samples to be processed and results to be compared for acceptable sensitivity & specificity

Limitations

- Proper designing of primers is a major constraint in this assay.

- LAMP primer efficacy differs for different SARS-COVID-19 antigens.

- RT-LAMP sensitivity is comparable to that of the RT-PCR when the ct is ≤ 30, however it drops significantly when the ct >30.

- LAMP test should not be used for patients with low viral load (onset of the disease and later stages of the disease).

- Improving LAMP test sensitivity would require primer optimization.

Recommendations

- Use only FDA/FDA-EUA /CE approved testing reagents and instruments.

- LAMP method is to be used for patients with high or moderate viral load only (within 5 days from symptom onset and early stages of the disease).

- Primer sets for the RT-LAMP assay may be subject to production-dependent quality fluctuations. Therefore, all reagents must be precisely validated (batch control) before using an RT-LAMP assay diagnostically.

- This method requires extensive validation.

Appendix3:

Saliva Test for Schools

Background:

Based on global updates and the latest scientific developments in the detection of the SARS-CoV-2 virus, saliva was found to be a reliable alternative specimen for the diagnostic detection & quantification of SARS-CoV-2 virus.

Advantages of using Saliva Samples:
•Allows for self-collection and therefore does not require specialized personnel for collection.
•Minimizes risk of transmission to healthcare workers.
•Non-invasive
•Facilitates mass screening
•Has good stability at room temperature

Intended Use:

a. Saliva Collection Kits:

FDA/ FDA-EUA/CE approved Saliva collection kit

b. Time of Saliva Collection:

No food, drink, chewing gum, or smoking for 30 minutes before specimen collection.

c. Target population:
Saliva test will be used in school setting for general screening purposes and the collection of the samples must be done by a licensed health care professional. It can be used for children in health care setting if the collection of swab was not possible

d. Testing Platforms:

- Reverse Transcription PCR (RT-PCR)
- Loop-mediated isothermal amplification (LAMP)

e. Validation Method:

For optimal saliva-based testing at least three conditions have to be improved by standardization and validation:

-A specific saliva collection method should be selected and optimized after systematically comparing the various methods currently used for collecting whole saliva in other clinical and scientific contexts.

-The optimal solution for collecting, transporting and storing saliva samples should be found.

-The RNA assay method, either RT-PCR, loop-mediated isothermal amplification (LAMP) or another protocol, should also be optimized for saliva, using an appropriate internal control.

Method Comparison where RT-PCR using nasopharyngeal swabs is the gold standard method for SARS-COV-2 detection and rapid COVID-19 antigen test is the method to be validated. Limit of detection and cross-reactivity are also recommended.

Sample collection is to be done simultaneously from a mix (50 samples) of negative, suspected, confirmed and probable COVID-19 cases (Please refer to circular No. 57 for case definitions). Samples to be processed and results to be compared for acceptable sensitivity & specificity.

Limitations :

-With progression of the disease, saliva samples' sensitivity drops more rapidly than nasopharyngeal swabs, hence they are not recommended as a diagnostic sample for patients in the later and convalescent stages of the disease.

-A nasopharyngeal swab should be used as a second specimen in patients for whom there is a high index of clinical suspicion and saliva sample result is negative.

-This is a novel approach for SARS-COVID-19 diagnostic testing and hence number of studies and study samples has been limited. Additionally, sample collection protocols, sample transportation and storage as well as testing methods in the currently published studies are diverse.

-Published studies have focused more on the sensitivity of saliva samples for detection of SARS-COVID-19 and not on their specificity.

-Since Saliva may be self-collected, the probability of pre-analytical errors is high and would require clear communication with the patient as well as monitoring of adherence to sample collection requirements.