دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Circular No (44) تعميم رقم

Date: 16/05/2020

التاريخ: 2020/05/16

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

السادة/ جميع المنشآت الصحية والمختبرات الطبية في إمارة أبوظبي المحترمين

Subject:: **Compliance with Laboratories Requirements and Additional Guidelines on COVID-19 Test Indeterminate Results**

الموضوع: الالتزام بالمتطلبات الخاصة بالمختبرات الطبية وتوجيهات إضافية بخصوص النتائج غير النهائية/غير المحددة لفحوصات كوفيد-19

Greetings,

تحية طيبة وبعد ،،،

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

As part of the continuous efforts to monitor 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, DOH urges all medical laboratories and health care facilities to adhere to the following:

First: Clinical Laboratories Practice Requirements:

1. With reference to DOH circular no. (058/2019) DOH would like to confirm that all medical laboratories in the Country are encourged to have ISO15189 accreditation relating to the requirements for quality and competence particular to medical laboratories in addition to technical requirements issued by Emirates National Accreditation System (ENAS).
2. Adhering to DOH Clinical Laboratory Standards and DOH requirements for COVID-19 testing that includes but not limited to the following:
    a. To perform the required quality control of the PCR testing machine as per manufacturer's guidelines that mandate internal and external availability of quality control.
    b. To Comply with DoH Infectious Waste Management & Disposal standards.
    c. Staff involved in handling, running and interpreting PCR test must have the required qualification and training
    d. To comply with required preventive maintenance and calibration of the lab equipment.

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

في إطار الجهود المستمرة لمتابعة استجابة نظام الرعاية الصحية في إمارة أبوظبي لمرض كورونا المستجد (COVID-19)، ولضمان الإبلاغ الأمثل عن نتائج الفحوصات والإصابات بشكل دقيق، تهيب دائرة الصحة بكافة المختبرات الطبية ومنشآت الرعاية الصحية الالتزام بما يلي:

أولاً: متطلبات الممارسة في المختبرات الطبية:

1. تؤكد دائرة الصحة على ما ورد في التعميم رقم (2019/058) فيما يخص حث المختبرات على الحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189 الخاصة بمتطلبات الجودة والكفاءة في المختبرات الطبية والمتطلبات الفنية الصادرة عن نظام الاعتماد الوطني الإماراتي.
2. الامتثال لمعايير الدائرة الخاصة بالممارسات الطبية في المختبرات، ومتطلبات الدائرة الخاصة بفحوصات كوفيد-19، والتي تشتمل ولا تقتصر على ما يلي:
    a. القيام بضبط الجودة لجهاز الفحص الخاص باختبار PCR وفقاً لتعليمات الشركة المصنّعة مع ضرورة توافر اختبار ضبط الجودة الداخلي والخارجي.
    b. الامتثال لسياسات ومعايير الدائرة الخاصة بإدارة النفايات الطبية المعدية والتخلص منها.
    c. حصول العاملين القائمين على عمل وتشغيل اختبار PCR وتفسير نتائجه على المؤهلات العلمية والتدريبات اللازمة.
    d. الامتثال لمتطلبات الصيانة الوقائية والمعايرة لأجهزة المختبر.
    e. ضمان سلامة الموظفين وتوافر أدوات الوقاية الشخصية اللازمة.

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f. الالتزام بتوجيهات وتعليمات الدائرة الخاصة بالإبلاغ عن النتائج.
g. التعامل الآمن في جمع و نقل ومعالجة عينات المختبر لضمان عدم نقل خطر الإصابة إلى العاملين.

3. الالتزام بما يلي في إدارة نتيجة اختبار عينة SARS-CoV2 PCR:
a. يجب التأكد من أن نتائج اختبار فحص rRT-PCR الناتجة عن أخذ مجموعة عينات من مسحات البلعوم الأنفي/الحلق والبلغم والتي تم جمعها خلال 24 ساعة على الأقل من مريض مصاب بـ SARS-CoV2 PCR هي **نتائج سلبية**، وذلك قبل التوقف عن اتباع احتياطات انتقال العدوى، (تشير المجموعات المأخوذة إلى عينات متعددة، و يتم قبول عينة واحدة لفحص المريض).
b. يتم تكرار الاختبار كل 48-72 ساعة للنتائج الإيجابية لاختبار سارز CoV2 PCR للعينات المأخوذة من البلعوم الأنفي أو عينة الجهاز التنفسي السفلي.

ثانياً: توجيهات إضافية بخصوص النتائج غير النهائية/غير المحددة لفحوصات كوفيد-19

بالإضافة إلى ما ذكر أعلاه، على جميع المختبرات المرخصة لعمل فحوصات كوفيد-19 اتباع التوجيهات الإرشادية التالية فيما يخص النتائج غير النهائية/غير المحددة والتي تبين وجود الفيروس بكميات قليلة في العينات مع إمكانية إعطاء نتيجة إيجابية خاطئة:

1. للمرضى الذين لديهم نتائج أولية غير نهائية/غير محددة، على المختبر القيام بإعادة معالجة العينة في منصة/فحص مختلفة. وفي حال وجود منصة/فحص واحد فقط لدى المختبر، يتوجب الترتيب مع مختبر آخر للقيام بمعالجة العينة باستخدام منصة/فحص مختلفة.
2. إذا كان الاختبار الثاني إيجابيًا، تعتبر النتيجة إيجابية ويعتبر المريض مصاباً بفيروس كوفيد 19.
3. إذا كانت نتيجة الاختبار الثاني غير نهائية/غير محددة، يتم جمع عينة جديدة بعد 24 ساعة من صدور النتائج (حيث أن ذلك قد يكون بسبب العدوى المبكرة وانخفاض الحمل الفيروسي).
4. إذا كان الاختبار الثاني سلبيًا، فإن الحاجة إلى اختبار إضافي تعتمد على الاشتباه في المرض:
a. إذا كان احتمال الاشتباه بالإصابة بالمرض منخفض، تعتبر النتيجة سلبية لكوفيد 19.
b. إذا كان احتمال الاشتباه بالإصابة بالمرض مرتفعًا، يتوجب الأخذ بالاعتبار القيام بأخذ عينة ثالثة (يفضل أن تكون العينة من إفراز النسيج السفلي).

مثال لتفسير نتيجة الفحص:

- تشير النتيجة "المكتشفة" إلى وجود الحمض النووي الريبوزي (الريبي) لفيروس المتلازمة التنفسية الحادة الوخيمة 2 (SARS-CoV-2) مما يستدعي تشخيص مرض فيروس كورونا المستجد (كوفيد-19)، كما يجب دائمًا مراعاة نتيجة الاختبار في سياق التاريخ

e. Ensure staff safety and availability of required PPE
f. To comply with the reporting of test results as per DoH requirements
g. Lab specimens must be collected, transported and handled safely to ensure that no risk of infection can be transferred to the personnel involved.

3. Managing SARS-CoV2 PCR sample test result:
a. Negative rRT-PCR results from sets of nasopharyngeal/ throat swabs and sputum collected at least 24 hours apart from a patient with SARS-CoV2 PCR are needed before discontinuing Transmission-Based Precautions. Sets refer to multiple samples. One sample is accepted for patient testing.
b. A positive SARS-CoV2 PCR test from nasopharyngeal sample or lower respiratory sample is repeated every 48-72 hours.

Second: Additional Guidelines on COVID-19 Test Indeterminate Results:

Further to the above, all laboratories licensed to conducting COVID-19 tests are required to implement the following directives and guidelines regarding the indeterminate results that reflect low levels of virus in the samples but may also represent a false positive:

1. For patients with initial indeterminate results, the lab has to re-run the sample in a different platform/assay. If the lab has only one platform/assay, the lab shall arrange with another lab using a different platform/assay to process.
2. If the second test is positive, the patient should be considered positive for COVID-19.
3. If the second test is indeterminate, a new sample to be collected 24 hours after the results (It could be due to early infection and low viral load).
4. If the second test is negative, the need for additional testing depends on the suspicion of disease:
a. If suspicion is low, consider negative for COVID-19.
b. If suspicion is high, consider third sample (preferentially of lower tract secretion).

Interpretation of the results example:

- A "Detected" result indicates that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test result should always be considered in the context of patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.
- An "Undetected" result indicates that SARS-CoV-2 is not present in the patient's specimen.

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السريري للمريض، والفحص البدني، والتعرض الوبائي عند إجراء التشخيص النهائي.

- تشير النتيجة "غير المكتشفة" إلى أن السارس CoV-2 غير متواجد في عينة المريض. ومع ذلك، قد تتأثر هذه النتيجة بمرحلة العدوى وجودة ونوع العينة التي تم جمعها للاختبار، ولذلك يجب أن يتم ربط النتيجة بالتاريخ المرضي والحالة السريرية للمريض.
- تشير النتيجة "غير المحددة" إلى أن المريض قد يكون مصابًا بفيروس سارس CoV-2 2 أو فيروس كورونا المرتبط بالسارس، وعليه يوصى باختبار إضافي باستخدام طريقة جزيئية بديلة على عينة تم جمعها حديثاً.

ولمزيد من المعلومات فيما يتعلق بالموضوع اعلاه، يرجى التواصل مع healthaudit@doh.gov.ae

آملين من الجميع الالتزام بما ورد أعلاه، لما فيه مصلحة العمل.

شاكرين لكم حسن تعاونكم معنا ،،،

هذا التعميم للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي

د. جمال محمد الكعبي

وكيل دائرة الصحة بالإنابة

However, this result may be influenced by the stage of the infection, quality, and type of the specimen collected for testing. Result should be correlated with patient's history and clinical presentation.

- An "Indeterminate" result suggests that the patient may be infected with a variant SARS-CoV-2 or SARS-related coronavirus. Additional testing with an alternative molecular method is recommended on a newly collected specimen.

For more information, please contact: healthaudit@doh.gov.ae

We hope that all will adhere to the above, for the best interest of work.

Thanking you for your kind cooperation,,,

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

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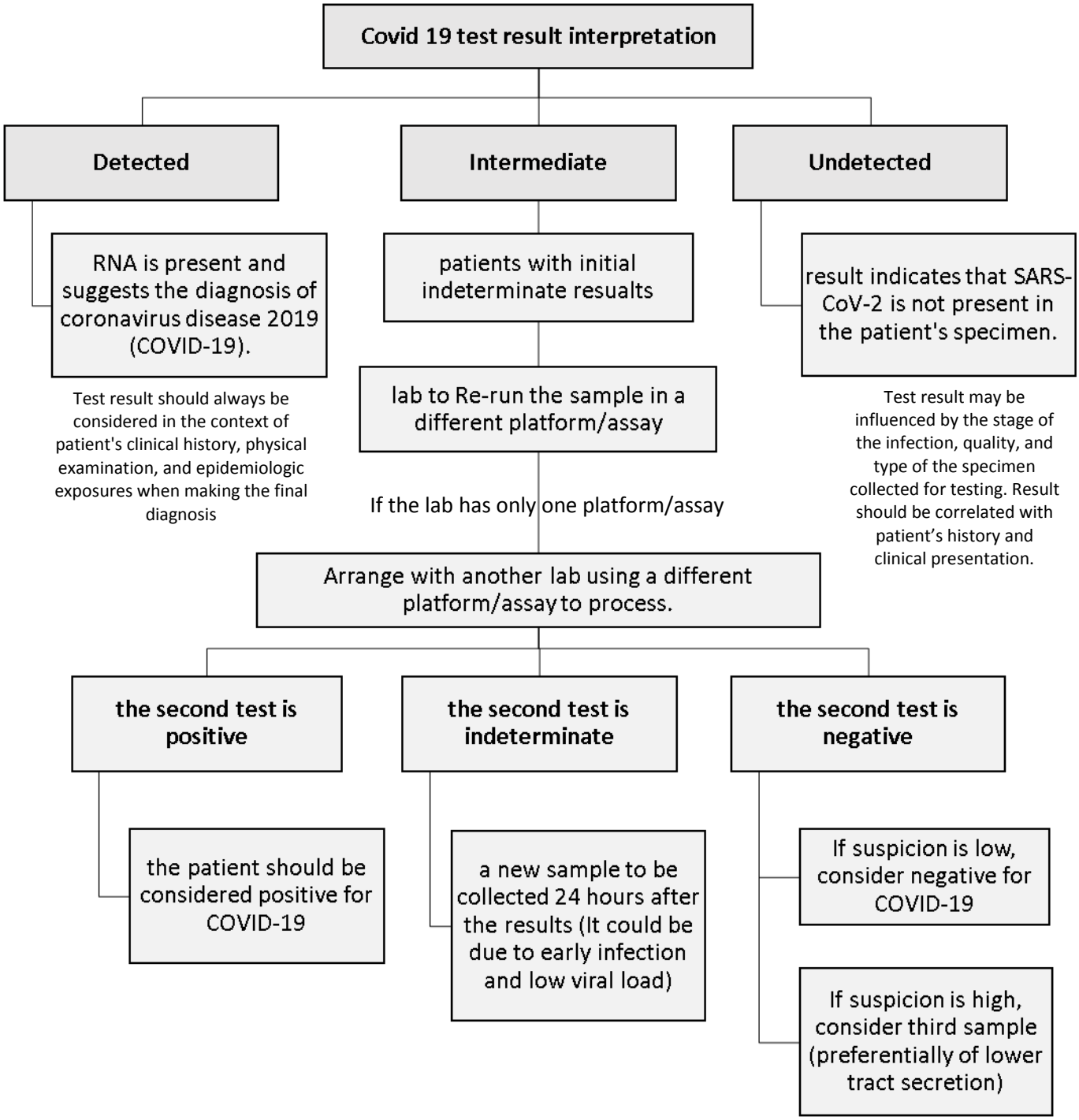
رسم توضيحي لتفسير نتائج فحص كوفيد-19
Covid-19 Test Result Interpretation



Introduction

- The purpose of this audit checklist is to assess & identify laboratories that can perform real time RT-PCR molecular testing for CoViD-19.
- Qualified laboratories have the capacity to do high complexity testing with the infrastructure to analyze, interpret and report molecular testing for CoViD-19
- Laboratories must have DOH approval for molecular testing as part of their existing and approved scope of work. However, new laboratories should start the licensing process or contact HLD team for more information through hfld@doh.gov.ae
- Please note that this checklist is intended to be used for guidance only.

	Criteria Description & measurable items	M	NM	Guidelines
Laboratory Infrastructure, Control, & Environmental Consideration The laboratory has in place the infrastructure, Security and environmental Requirements to perform molecular testing				
1	The laboratory is equipped to limit access control for authorized personnel only.			Sentinel Level Clinical laboratory guidelines for suspected agents of bioterror rim and emerging infectious diseases October 2018
2	The laboratory has in place a molecular PCR setup with contamination control and prevention : • Anteroom • Negative pressure (visual air direction system, visual& audible alarm system in case of failure, high efficiency particulate air filtration of laboratory exhaust system) • Physical arrangement of pre-post PCR • Flow of work is defined			Mifflin, Theodore. (2007). Setting up a PCR laboratory. CSH protocols. 2007. Pdb.top14. 10.1101/pdb.top14. CLSI QMS04 laboratory design
3	The laboratory has in place environmental consideration for molecular testing such as • Air handling • UV irradiation • Protective clothing, • Other measures (specify)			Mifflin, Theodore. (2007). Setting up a PCR laboratory. CSH protocols. 2007. pdb.top14. 10.1101/pdb.top14. CLSI QMS04 laboratory design
4	The laboratory has in place engineering controls that include but not limited to: • Air pressure- resistant door (if applicable) • Aerosol- containment measures			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Laboratory Biosafety The laboratory is a biosafety level 2 BSL-2 or higher. Staffs working in the laboratory are trained to handle pathogens under the supervision of competent and designated person				
1	The laboratory has a biosafety & biosecurity risk assessment policy in place to ensures that risk assessments are routinely performed as part of their quality management program • Risk Assessment Policy • Risk Register & Implementation of control measures. • Biosafety Competencies • Safety Orientation and Training • Audits, Safety Committee MOM • Medical surveillance program is in place in the event of exposure to an infectious' pathogens.			Sentinel Level Clinical laboratory guidelines for suspected agents of bioterror rim and emerging infectious diseases October 2018
2	Based on the laboratory's risk assessment, the laboratory has a functional, certified and maintained Class II or higher Biological safety cabinet -BSC • Planned preventative maintenance is available • BSCs connected to the laboratory exhaust system with a thimble (canopy) connection when minute quantities of volatile chemicals or radionuclides are used • BSCs have flow alarms • BSCs are properly decontaminated before HEPA filters are changed or internal repair work is done. • HEPA filters assessed and replaced at a frequency appropriate to usage in the laboratory			Clinical Laboratory biosafety risk management assessment checklist- Association of public health laboratories
3	The laboratory has a biosafety manual that addresses the following: • Safety policies & Procedures • Biological Spill clean up • Emergency response • medical surveillance program in the event of post exposure to an infectious agent • occupational health program			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES

4	There are posted biohazard signs at all entrance points, Biohazard labels are fixed on medical waste containers, incubators, refrigerators			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES
5	Competency Assessment is available for all staffs handling infectious specimens.			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES
6	The laboratory maintains certification of maintenance for the following: • Biosafety Cabinets (BSCs) • Autoclaves (autoclave is checked for efficiency using biological/ chemical indicators) • HEPA Filters			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES
7	The laboratory has an eyewash station/ Bottles and expiration date is monitored.			A Biosafety Checklist: Developing A Culture of Biosafety ASSOCIATION OF PUBLIC HEALTH LABORATORIES
Personal Protective Equipment				
1	The laboratory has N95 respirator and fit testing is done.			Sentinel Level Clinical laboratory guidelines for suspected agents of bioterror rim and emerging infectious diseases October 2018
2	The laboratory has in place polices and training for appropriate donning and doffing of PPE including laboratory coats, gloves, protective eyewear, face shields, N95.			Sentinel Level Clinical laboratory guidelines for suspected agents of bioterror rim and emerging infectious diseases October 2018
Personnel Training and Competence				
4	The laboratory has allocated staff to handle, run and interpret testing based on competency-based training.			
Specimen Collection, Handling, and Transportation				

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The Laboratory has in place updated policies and procedures for specimen handling including transportation and storage (Applicable to facilities with authorization to collect).
The laboratory is performing testing according to documented and validated procedure including manufacture's recommendation. Cut off points for positive and negative results need to be defined
The laboratory has a defined interpretation procedure for negative and positive test results.

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<tr><td colspan="5">Laboratory Direction and Quality Assurance</td></tr>
<tr><td colspan="5">Molecular PCR laboratory is under the direction of medical microbiology or other qualified director. Please specify.</td></tr>
<tr><td colspan="5">Laboratory Capacity Assessment</td></tr>
<tr><td></td><td>

Availability of Instruments Regents
Number of RNA Extraction Kits
Viral Positive and Negative controls
Reagents enough for xxxxx reactions per kit.
Workload; the laboratory can person xx tests in 24 hours.

<table>
<tr><th>Instrument</th><th>Quantity</th><th>Capacity & throughput</th></tr>
<tr><td>Extraction</td><td></td><td></td></tr>
<tr><td>PCR</td><td></td><td></td></tr>
</table>
</td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Infectious Waste Management & Disposal</td></tr>
<tr><td>8</td><td>The laboratory has in place a policy for proper disposal of wastes including biological and respiratory waste handling.</td><td></td><td></td><td>Laboratory Requirements checklist for testing CoVid-19</td></tr>
<tr><td>9</td><td>The laboratory has a policy in place for decontaminating surfaces after completion of work.</td><td></td><td></td><td>Laboratory Requirements checklist for testing CoVid-19</td></tr>
<tr><td>10</td><td>The laboratory waste is autoclaved before final disposal through medical waste management company</td><td></td><td></td><td>Laboratory General Guidelines</td></tr>
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Data Reporting Management				
	The laboratory has in place laboratory management system that can trace specimen, registration, test run, validation and release of results.			Laboratory General Guidelines

COVID- 19 LABORATORY SPECIMEN PROCESSING AUDIT

Date:	
Healthcare Facility:	
Auditors:	
Auditees:	
Time Audit started:	
Time Audit ended:	
Audit Score:	100
Audit Scoring	Met =2% Partially Met =1% Not Met =0 Not Applicable=NA
Total Number of MEs	50
Number of Audited MEs	50
Met	50
Partially Met	0
Not Met	0
NA	0

References:

1. Coronavirus Disease 2019 Covid-19,SEHA/MED/CPG-034,19 March 2020,Version 2, P1-11.
2. Coronavirus Disease 2019 Covid-19,SEHA/MED/CPG-034,19 March 2020,Version 2, Appendix C: Laboratory Testing of COVID-19 (SARS-CoV2) PCR
3. https://www.cdc.gov/coronavirus/2019-ncov/infection-control/controlrecommendations.
4. World Health Organization https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports
5. COVID-19 Screening Flowchart-24032020 -V5
6. Sentinel Level Clinical laboratory guidelines for suspected agents of bioterror rim and emerging infectious diseases October 2018
7. Mifflin, Theodore. (2007). Setting up a PCR laboratory. CSH protocols. 2007. pdb.top14. 10.1101/pdb.top14.
8. CLSI QMS04 laboratory design.
9. Laboratory biosafety manual Third edition World Health Organization, https://www.who.int/csr/resources/publications/biosafety/Biosafety7.
10. Clinical Laboratory biosafety risk management assessment checklist- Association of public health laboratories

#	#	Measurable Element (ME)	Specification	Observation	Score	Findings/ Evidence verified during the audit	Action Plan
1.0	**Laboratory Infrastructure, Control & Environmental Considerations (**The laboratory has in place the infrastructure, Security and environmental Requirements to perform molecular testing**)**						
1.1	**Laboratory Infrastructure (Biosafety Level 2 (BSL-2)**						
1	1	The laboratory has valid DoH License	Laboratory must have valid DoH approval for molecular testing as part of their approved scope of work.		**2**		
2	2	The laboratory is equipped to limit access control	• There is policy to strict access of the laboratory for authorized personnel only, and the lab is separated from public spaces (e.g., classrooms, offices, break rooms, etc.) by self-closing doors. • The laboratory has in place access limit control for laboratory staff and limit access for authorized staff to work in molecular PCR testing. • Windows must be sealed and fitted to prevent the entrance of pests. • The international biohazard warning symbol and sign must be displayed at all laboratory entrance points.		**2**		
3	3	All laboratory work surfaces and chairs must be made of non-porous, non-absorbent materials	• Lab walls, ceilings, floors and materials used in laboratory fixtures and furniture designed for easy cleaning and disinfection, impervious to water, and resistant to solvents. Floors should be slip-resistant and free of any carpets or rugs. • All surfaces in the laboratory regularly disinfected with an intermediate level disinfectant each day of work. • Appropriate disinfectants with proven activity against enveloped viruses should be used (e.g. hypochlorite (bleach), alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds).		**2**		
4	4	Prohibition of eating, drinking, gum chewing, smoking, contact lens manipulation, application of cosmetics, mouth pipetting, and storage of food stuffs	• Enforce prohibition of the storage of food or drink in the laboratory. • Staff refrain from using cell phone and bringing personal items (purses, backpacks, books, magazines etc.) into the laboratory.		**2**		
5	5	A manual outlining biosafety policies and practices, including spill cleanup, emergency response, and post-exposure follow-up measures, must be available to all employees of the laboratory.	The laboratory has a biosafety manual that addresses the following: - Safety policies & Procedures - Biological Spill clean up - Emergency response - Medical surveillance program in the event of post exposure to an infectious agent - Occupational health program • Utilization of work practices geared toward minimization of biological agent splashes and aerosol generation. • Laboratory have a written biosafety manual that identifies the hazards (Minimum Biosafety Level 2 (BSL-2) practices and an explanation of standard precautions) that will or may be encountered, and that specifies applicable practices and procedures designed to minimize or eliminate exposure to these hazards. • The biosafety-related policies and procedures managed in a document control system to ensure that the most current documents are in use and available.		**2**		
6	6	Biological safety cabinets (BSCs), splash shields, and other physical containment devices must be available.	•The lab supported by ventilation systems that provide an inward flow of air without recirculation to spaces outside of each laboratory. Filtered exhaust air from BSCs can either be recirculated into the laboratory space or can be vented into dedicated plenums. • Does the lab has sufficient Class II BSCs (preferably a Class II, Type A2) connected to the laboratory exhaust system with a thimble (canopy) connection, where needed as determined by each activity-specific risk assessment? • Do Class II Type A2 BSCs with exhaust canopies/ thimble unit connections have flow alarms? • Are BSCs properly decontaminated before HEPA filters are changed or internal repair work is done? • The laboratory maintains certification of maintenance for the following: - Biosafety Cabinets (BSCs). - Autoclaves (autoclave is checked for efficiency using biological/ chemical indicators). - HEPA Filters.		**2**		
7	7	Competency and proficiency assessments of employees engaged in work with infectious materials, including clinical specimens, must be periodically performed.	• Are the training and competency requirements documented in the biosafety plan? • Is completion of training and competency documented? • Are staff that perform molecular amplification trained to use a uni-directional workflow with sample preparation, amplification, & product detection in separate areas? • Is there training on how to use the biological safety cabinet? • Competency Assessment is available for all staffs handling infectious specimens. • Competency and proficiency assessments of employees engaged in work with infectious materials, including clinical specimens, must be periodically performed.		**2**		
8	8	Eyewashes must be available throughout the laboratory.	• Are eyewash stations installed within each lab and maintained in accordance with the most recent edition of ANSI Z358.1 (e.g., flushed and function checked weekly)? • The laboratory has an eyewash station/ Bottles and expiration date is monitored. • The staff need to be trained on the use of eyewash stations.		**2**		
9	9	Vacuum lines connected to aspirators must be protected with in-line high-efficiency particulate air/ arrestance (HEPA) filters and liquid disinfectant traps to minimize the risk of house-vacuum or dedicated pump contamination.	• Are all vacuum lines protected with HEPA filters or their equivalent and assessed and replaced at a frequency appropriate to usage in the laboratory? • Are vacuum lines associated with biohazardous procedures protected with liquid disinfectant traps and assessed and replaced at a frequency appropriate to usage in the laboratory? • Are traps consisting of one or two suction flasks together in series with an inline HEPA filter used for vacuum-assisted devices within BSCs to prevent contamination of the vacuum pump or house vacuum system?		**2**		
10	10	Utilization of appropriate PPE such as laboratory coats, gloves, and eye/ face protection.	• Laboratory coveralls, gowns or uniforms must be worn at all times for work in the laboratory. • Appropriate gloves must be worn for all procedures. After use, gloves should be removed aseptically and hands must then be washed. • Safety glasses, face shields (visors) or other protective devices must be worn when it is necessary. • It is prohibited to wear protective laboratory clothing outside the laboratory. • Protective laboratory clothing that has been used in the laboratory must not be stored in the same lockers or cupboards as street clothing. • Utilization of appropriate PPE such as laboratory coats, gloves, and eye/face protection when the risk of splashes or clothing/skin contamination is likely. • The staff are aware of the correct order of donning and doffing the PPE. • Separation of clean and dirty PPE.		**2**		
1.2	**Control (**The laboratory has in place a molecular PCR setup with contamination control and prevention**)**						**Action Plan**
11	1	Anteroom	• The laboratory has in place molecular PCR setup with contamination control; there are 2 anterooms available, clear flow of work direction - unidirectional, and negative pressure. Visual and audible alarm system are available in case of negative pressure failure. This is monitored by Biomedical Team. • The laboratory must be separated from the areas that are open to unrestricted traffic flow within the building. Additional separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom (e.g. a double-door entry or basic laboratory –Biosafety Level 2), describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space. The anteroom should have facilities for separating clean and dirty clothing and a shower may also be necessary. • Anteroom doors may be self-closing and interlocking so that only one door is open at a time. A break-through panel may be provided for emergency exit use.		**2**		
12	2	Negative pressure (visual air direction system, visual & audible alarm system in case of failure, high efficiency particulate air filtration of laboratory exhaust system)	• Is a visual monitoring device provided at the laboratory entry which confirms directional airflow? • Does the lab have local visual/ audible alarms to notify personnel of airflow disruption? • A visual monitoring device with or without alarm(s) should be installed so that staff can at all times ensure that proper directional airflow into the laboratory room is maintained.		**2**		
13	3	Flow of work	• Create PCR SOP to optimum manage the preparation and testing process from receiving of rRT- PCR Panel reagents and obtaining sample to report the result. • Maintain separate areas for assay setup and handling of nucleic acids. • Always check the expiration date prior to use. Do not use expired reagent. Do not substitute or mix reagent from different kit lots or from other manufacturers. • Change aerosol barrier pipette tips between all manual liquid transfers. • During preparation of samples, compliance with good laboratory techniques is essential to minimize the risk of cross-contamination between samples, and the inadvertent introduction of nucleases into samples during and after the extraction procedure. Proper aseptic technique should always be used when working with nucleic acids. • Maintain separate, dedicated equipment (e.g., pipettes, microcentrifuges) and supplies (e.g., microcentrifuge tubes, pipette tips) for assay setup and handling of extracted nucleic acids. • Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays. • Change gloves between samples and whenever contamination is suspected. • Keep reagent and reaction tubes capped or covered as much as possible. • Primers, probes (including aliquots), and enzyme master mix must be thawed and maintained on cold block at all times during preparation and use. • Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, “DNAZap™” or “RNase AWAY®” to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol.		**2**		
14	4	Physical arrangement of pre-post PCR	• The ideal arrangement of a PCR facility is to have the pre- and post- PCR areas located in separate rooms. • If this is not achievable, different areas designated for sample preparation and PCR setup can be located away from the area for post-PCR analysis. • If all activities are to be performed in a single room, sample preparation should occur inside a laminar flow hood, preferably equipped with a UV light. The walls of the hood should be wiped with a fresh (or freshly made) 10% bleach solution (1 part regular bleach: 9 parts water) before processing samples or preparing PCR samples. • **Pre-PCR Lab**: Benchspace, 4°C frig, –20°C frzr, Sink, Type I H2O UV/VIS spectro, Centrifuge, –80°C upright frzr, Microbial safety hood, Tissue culture incubators and Slight positive air pressure. • **Post-PCR La**b: Benchspace, Sink, Gel imaging system, 4°C frig, –20°C frzr, Real-time PCR instrument, Hyb oven, Gel electrophoresis equipment, 2 Thermal cyclers, PC w/network connection and Slight negative air pressure. • A source of deionized water needs to be present in both rooms, as well as dedicated centrifuges, storage freezers/refrigerators, and storage of supplies. Even telephones, computers, and other electronic communications should also be dedicated. • Each room must have its own separate set of equipment, including pipettes, reagents, pipettor tips, racks, and so forth.		**2**		
1.3	**Environmental Consideration (**The laboratory has in place environmental consideration for molecular testing**)**						**Action Plan**
15	1	Adhesive paper at lab entrance	• This approach effectively prevents trace amounts of dust and debris from entering the laboratory. It is a rather expensive approach to controlling contamination, but may be worth the expense for selected applications. • Cleaning is the removal of dirt, organic matter and stains. Cleaning includes brushing, vacuuming, dry dusting, washing or damp mopping with water containing a soap o detergent. Dirt, soil and organic matter can shield microorganisms and can interfere with the killing action of decontaminants (antiseptics, chemical germicides and disinfectants).		**2**		
16	2	Air handling	• Prevent contamination from the air being recirculated between the pre- and post-PCR laboratories. • In the pre-PCR laboratory, there should be a slight positive pressure compared to the air in the connecting hallway. • The post-PCR laboratory, in contrast, should be at slightly reduced pressure to pull air in from the outside. • The air handlers for the pre- and post-PCR laboratories need to be connected to separate air ducts, and each must lead to a separate location for exhaust. • Lab should be supported by ventilation systems that provide an inward flow of air without recirculation to spaces outside of the Lab. • Consideration should be given to the provision of mechanical ventilation systems that provide an inward flow of air without recirculation. If there is no mechanical ventilation, windows should be able to be opened and should be fitted with arthropod-proof screens.		**2**		
17	3	Personal Protective Equipment	• Use personal protective equipment such as (but not limited to) gloves, eye protection, and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents. • Lab coats should be dedicated for both areas as well. • To further prevent PCR amplicons from leaving the post-PCR lab, each investigator should have a dedicated post-PCR lab coat. • Each investigator should have a general molecular biology lab coat and a separate coat for pre-PCR. In extreme cases, a disposable gown and booties should be worn. • Laboratory protective clothing must be of the type with solid-front or wrap-around gowns, scrub suits, coveralls, head covering and, where appropriate, shoe covers or dedicated shoes. Front-buttoned standard laboratory coats are unsuitable, as are sleeves that do not fully cover the forearms. • The laboratory has N95 respirator and fit testing is done. • The laboratory has in place polices and training for appropriate donning and doffing of PPE including laboratory coats, gloves, protective eyewear, face shields, N95.		**2**		

18	4	UV irradiation	• UV irradiation is done every three months and cleaning with Hydrogen peroxide and Peracetic Acid. • Use of UV inside the cabinet prior to sample preparation or PCR reagent preparation is advisable. Alternatively, any one of a number of small, benchtop-size cabinets that use UV irradiation can also be utilized. • It is possible to exploit further the sensitivity of nucleic acid to UV by using UV to sterilize the entire pre-PCR laboratory. This can be done by having UV lights placed in the ceiling fixtures and connecting their activation to a lock-out mechanism on the exit door so they only illuminate when the last person in the lab closes and locks the external lab door. • If this type of hardware is installed, it must be accompanied by a ventilation system to eliminate the UV-generated ozone and a rigidly enforced schedule of monitoring the performance of the UV bulbs. • If UV used, it is must be cleaned weekly to remove any dust and dirt that may block the germicidal effectiveness of the light. Ultraviolet light intensity should be checked when the cabinet is recertified to ensure that light emission is appropriate. Ultraviolet lights must be turned off while the room is occupied, to protect eyes and skin from inadvertent exposure.		**2**		
19	5	Sterilization of Reagents	• Because PCR laboratories perform some molecular biology methods that require sterile reagents, some may need to be autoclaved. The single most critical reagent is water. Sterile USP water can be quickly converted to PCR water by filtering it through two 0.45-micron nitrocellulose filters. If the laboratory is involved in amplification of very small quantities of bacterial DNA, the USP water should be autoclaved separately from all other reagents before filtration. • While little is known about this novel virus, in the light of the comparable genetic characteristics with SARS-CoV and MERS-CoV suggest that 2019-nCoV may likely susceptible to disinfectants with proven activity against enveloped viruses, including sodium hypochlorite (bleach) (e.g. 1,000 ppm (0.1%) for general surface disinfection and 10,000 ppm (1%) for disinfection of blood spills), 62-71% ethanol, 0.5% hydrogen peroxide, quaternary ammonium compounds and phenolic compounds, if used according to manufacturer's recommendations. Other biocidal agents such as 0.05-0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less effective.		**2**		
20	6	Contamination Control	• The most popular is the use of either positive displacement or barrier pipette tips to prevent aerosols. • An adjunct to these tips is the use of a laminar flow hood or biological safety cabinet to facilitate preparation of PCR samples and reagents. • UV photolinking is most often used in a pre-PCR setting in which the equipment is installed in a small tabletop cabinet that is used for sample preparation. All of the items to create a PCR are placed inside the cabinet and then illuminated before the PCRs are assembled. • Uracil-DNA-glycosylase. This enzyme (also known as UDG) is very effective at destroying PCR amplicons when vigorously used for sample preparation.		**2**		
21	7	Air pressure- resistant door	• Are all penetrations (e.g., spaces around doors and ventilation ducts) capable of being sealed to facilitate gaseous or vapor phase decontamination of the lab if that method of decontamination is appropriate based on risk assessment? • Doors should have vision panels, appropriate fire ratings, and preferably be selfclosing. • Separation may be achieved by placing the laboratory at the blind end of a corridor, or constructing a partition and door or access through an anteroom (e.g. a double-door entry or basic laboratory Biosafety Level 2), describing a specific area designed to maintain the pressure differential between the laboratory and its adjacent space. • Doors must open inwards and be self-closing.		**2**		
22	8	Aerosol- containment(sealed) lids on centrifuge buckets and/ or rotors	• Is all centrifugation performed using centrifuge safety buckets or cups, or sealed centrifuge tubes in sealed rotors as appropriate? • Are all centrifuges and rotors inspected and maintained (i.e. visual inspection of O-rings and gaskets) following manufacturers' instructions to prevent malfunctions and aerosol generation within the centrifuge? • Are appropriate plastic centrifuge tubes with seal-forming screw caps used whenever possible? • Centrifugation of specimens should be performed using sealed centrifuge rotors or sample cups. These rotors or cups should be loaded and unloaded in a BSC. • Work surfaces, pipettes, and centrifuges should be cleaned and decontaminated with cleaning products such as 10% bleach, "DNAZap™" or "RNase AWAY®" to minimize risk of nucleic acid contamination. Residual bleach should be removed using 70% ethanol. • Centrifuge rotors and buckets should be inspected daily for signs of corrosion and for hair-line cracks. Buckets, rotors and centrifuge bowls should be decontaminated after each use. • All sealed centrifuge buckets should be loaded and unloaded in a biological safety cabinet. If breakage is suspected within the safety cup, the safety cap should be loosened and the bucket autoclaved. Alternatively, the safety cup may be chemically disinfected.		**2**		
2.0	**Structure**						**Action Plan**
2.1	**Organization**						
23	1	There is a **policy** that provides guidelines on each flow path in the sampling process including sending/ receiving samples in and out of the HCF	• A copy of Laboratory COVID-19 management policy that provides guidelines on each flow path in the sampling process including sending/ receiving samples in & out of the HCF, preparation and testing process is available at the facility and accessible by staff.		**2**		
24	2	The HCF facility follow a **standardized** DoH/ SEHA related policies			**2**		
2.2	**RISK ASSESSMENT (** All procedures must be performed based on risk assessment and only by personnel with demonstrated capability in strict observance to any relevant protocols at all times**)**						**Action Plan**
25	1				**2**		
26	2	Based on the laboratory's risk assessment, the laboratory has a functional, certified and maintained Class II or higher Biological safety cabinet -BSC	• Planned preventative maintenance is available. • BSCs connected to the laboratory exhaust system with a thimble (canopy) connection when minute quantities of volatile chemicals or radionuclides are used • BSCs have flow alarms (Do Class II Type A2 BSCs with exhaust canopies/ thimble unit connections have flow alarms have flow alarms?) • BSCs are properly decontaminated before HEPA filters are changed or internal repair work is done. • HEPA filters assessed and replaced at a frequency appropriate to usage in the laboratory. • Does each laboratory have sufficient Class II BSCs (preferably a Class II, Type A2) where needed as determined by each activity-specific risk assessment? • Are all Class II BSCs tested and certified in situ by an accredited field certifier initially, annually, and each time a unit is moved, in accordance with Annex F of ANSI/NSF Standard No. 49? • Are traps consisting of one or two suction flasks together in series with an inline HEPA filter used for vacuum-assisted devices within BSCs to prevent contamination of the vacuum pump or house vacuum system? • Are all biological safety cabinets located away from doors and windows that can be opened, heavily travelled laboratory areas, fans, room air supply louvers, and other possible airflow disruptions? • Perform all manipulations of live virus samples within a Class II (or higher) biological safety cabinet (BSC).		**2**		
3.0	**Process (**The Laboratory has in place updated policies and procedures for specimen handling including transportation and storage**)**						**Action Plan**
3.1	**Specimens handling (** Lab specimens must be collected, transported and handled safely to ensure that no risk of infection can be transferred to the personnel involved**)**						
27	1	Specimen containers (transport box) may be of glass or preferably plastic.	• Specimen containers should be robust and should not leak, specimens must be stored in containers with adequate strength, integrity and volume to contain the specimen, and made of an appropriate material for the type of storage required. • No material should remain on the outside of the container and free of any biological material on the outside of the packaging. • Containers should be correctly labelled, marked and recorded to facilitate identification. • Containers should be made of plastic whenever possible autoclavable or resistant to the action of chemical disinfectants, and the seal should preferably have a gasket. Containers should be regularly decontaminated. • Containers temperature should be maintained (cold 2-8 °C) and monitored accordingly. • COVID-19 sample is properly packed (Place specimens for transport in double bagged leak-proof specimen bags in a transport box).		**2**		
28	2	The driver is wearing appropriate **PPE** when handling the sample box	• In the optimum situation drivers no need to wear PPE, but transport box must be decontaminated and safe to be handled. However, wearing gloves and use a surgical masks are preferable. • Ensure that all personnel who transport specimens are trained in safe handling practices and spill decontamination procedures. • When PPE used by driver, the driver removes his PPE and performs hand hygiene accordingly.		**2**		
29	3	Laboratories should designate a particular room or area for this purpose.	• Secure space and a designated laboratory space adequate and appropriate for safe receiving, handling and storage of Laboratory specimens. • Ample space and a designated hand washing basin must be provided with appropriate restriction to access. • Decontaminate work surfaces with a suitable disinfectant at the end of the work procedures and if any material is spilled or obviously contaminated. • Inactivation methods must be appropriately validated whenever an inactivation step is used before transferring the specimens to other areas for further manipulation, such as PCR analysis.		**2**		
30	4	The receiver of the sample is wearing the appropriate **PPE**	• Appropriate personal protective equipment (PPE) as determined by a detailed risk assessment, should be worn by all laboratory personnel handling these specimens. • Avoiding inhalation of biological agents. Use good techniques to minimize the formation of aerosols and droplets when manipulating specimens. • The staff are aware of the correct order of donning and doffing the PPE. • Laboratory coats must be used in laboratories to prevent personal clothing from getting splashed or contaminated by biological agents. • Laboratory coats must have long sleeves, preferably with elasticised or fitted cuffs and must be worn closed. Sleeves should never be rolled up. Coats must be long enough to cover the knees, but not trail on the floor. They should be fastened when worn in the laboratory. • Where possible, the fabric of the laboratory coat should be splash-resistant and overlap to provide a solid front. Laboratory coats must only be worn in designated areas. When not in use, they should be stored appropriately; they should not be hung on top of other laboratory coats, or in lockers or hooks with personal items. • Appropriate disposable gloves must be worn at all times when handling specimens. They must not be disinfected or reused as exposure to disinfectants and prolonged wear will reduce the integrity of the glove and decrease protection to the user. Gloves should always be inspected before use to check they are intact. • Safety glasses, safety goggles, face shields (visors) or other protective devices must be worn whenever it is necessary to protect the eyes and face from splashes, impacting objects and artificial ultraviolet radiation. Eye protection can be used, but must be regularly cleaned after every use. If splashed, it must be decontaminated with an appropriate disinfectant. • Footwear must be worn in the laboratory and must be of a design that minimizes slips and trips and can reduce the likelihood of injury from falling objects and exposure to biological agents.		**2**		
31	5	The temperature is checked/ logged on arrival ensuring maintenance of the **cold chain 2-8 °C.** **Note**: Observe integrity of samples transported over 60 mins.	• The specimen containers temperature must be checked and logged upon arrival. • The integrity of specimen transported over 60 mins must be checked. • Infectious materials should be stored in mechanical deep-freeze cabinets or on dry ice. • There is a documented review of the transport temperature data logger readings.		**2**		
32	6	Specimen Receiving Process	• The sample is received with 24 hours of the sample being taken • The receiver completes the appropriate checking and documentation of the sample • Only one sample type is received per patient. • Are the specimen samples received with an accession number and in double packing. • Specimen received within the pre-identify timeframe. Time for delivering samples documented. How is that monitored? Each lab should have log in which to record KPI data. • Incident management system in place and mechanism to communicate with sending centres accordingly. The receiver reports/documents any discrepancies in the labelling or packing of the sample. • There is a process for the cancellation of tests including communication, documentation and requesting new sample. Is there a KPI for cancellation documentation? • The sample is sent to the lab for testing immediately.		**2**		
33	7	Process for Communication of Critical Results (COVID-19 positive result considered a panic value). If yes, show policy.	• Policy in place to provide guidance about the procedure of communication of critical results in a timely manner. • Results should be communicated in line with accreditation requirements, and incorporate a read back procedure to ensure correct receipt of all information provided.		**2**		
34	8	Storage and Transportation to the Lab	• When handling and processing specimens, including blood for serological testing, laboratory practices and procedures that are basic to good microbiological practices and procedures (GMPP) should be followed. • The handling and processing of specimens from cases with suspected or confirmed 2019-nCoV infection intended for additional laboratory tests such as haematology or blood gas analysis should follow local guidelines for processing potentially infectious material. • Transportation of the sample is direct to the lab (There must be minimal interruptions and direct transport of samples from receiving to molecular lab for testing). • Handling of material with high concentrations of live virus (such as when performing virus propagation, virus isolation or neutralization assays) or large volumes of infectious materials should be performed only by properly trained and competent personnel in laboratories capable of meeting additional essential containment requirements and practices. • All technical procedures should be performed in a way that minimizes the generation of aerosols and droplets.		**2**		
3.2	**Specimen Analysis/Testing**						**Action Plan**
35	1	PPM and Safety test machine is performed as per manufacturers guidelines	• Initial processing (before inactivation) of all specimens should take place in a validated biological safety cabinet (BSC) or primary containment device. • Clinical specimens from patients who are suspected or confirmed to be infected with novel coronavirus, should be conducted adopting practices and procedures described for conventional clinical and microbiology laboratories as described "core requirements" WHO. • All manipulations of potentially infectious materials, including those that may cause splashes, droplets, or aerosols of infectious materials, should be performed in appropriately maintained and validated BSCs or primary containment device by personnel with demonstrated capability. • When handling and processing specimens, "core requirements" (CR), including good microbiological practice and procedure (GMPP), as described in WHO biosafety should be followed at all times. • Consider unpacking the items in the BSC. Personnel unpacking and receiving specimens must be adequately trained in awareness of the hazards involved; how to adopt necessary precautions according to GMPP ; how to handle broken or leaking containers; and how to handle spills and use disinfectants to manage any contamination. • Follow the manufacturers guidelines PPM and Safety of the test machine. •The lab technologist removes the PPE after handling the samples and performs hand hygiene		**2**		
36	2	QC control of the PCR testing machine is performed daily or as per manufacturers guidelines. Internal and external QC must be available.	•The molecular laboratory is under the direct supervision of a specialist microbiologist. • Staff orientation, training and Competence assessment is maintained yearly. • Internal Quality control and Proficiency testing are maintained. • Quality control requirements must be performed in conformance with local and international regulations or accreditation requirements and the user's laboratory's standard quality control procedures. • Quality control procedures are intended to monitor reagent and assay performance. • Test all positive controls prior to running diagnostic samples with each new kit lot to ensure all reagents and kit components are working properly. • Good laboratory practice (cGLP) recommends including a positive extraction control in each nucleic acid isolation batch. • Although Human Specimen Control HSC is not included with the 2019-nCov rRT-PCR Diagnostic Panel, the HSC extraction control must proceed through nucleic acid isolation per batch of specimens to be tested. • Always include a negative control (NTC), and the appropriate positive control (nCoVPC) in each amplification and detection run. All clinical samples should be tested for human RNAse P gene to control for specimen quality and extraction.		**2**		

37	3	Staff performing the PCR test is/ has the required qualification and training	• The laboratory has allocated staff to handle, run and interpret testing based on competency-based training. • Are the training and competency requirements documented in the biosafety plan? • Is completion of training and competency documented? • Is there documentation that the staff has read and understood the Biosafety Manual? • Are staff that perform molecular amplification trained to use a uni-directional workflow with sample preparation, amplification, & product detection in separate areas? • Have employees engaged in waste decontamination and treatment processes been trained, and do they demonstrate requisite competencies? • General familiarization and awareness training. An introduction to laboratory layout, codes of practice, local guidelines, safety manuals, risk assessments, legislative requirements and emergency response procedures. • All personnel involved in the handling of biological agents must be trained on GMPP. • Competency and proficiency assessment must be used and verified before working independently, followed by regular review and refresher training. • All personnel must be aware of hazards present in the laboratory and their associated risks; safe working procedures; security measures; and emergency preparedness and response.		**2**		
38	4	COVID-19 Testing – Lab specimens prioritization (Color code triage)	• There is a KPI monitoring of TAT. • The turn around time for **T1 sample** results is less than 24 hrs • The turn around time for **T2 sample** results is less than 24 -48 hrs • The turn around time for **T3 sample** results is less than 72 hrs • The turn around time for **T4 sample** results is less than > 72 hrs		**2**		
39	5	Manage SARS-CoV2 PCR sample test result	• Negative rRT-PCR results from sets of nasopharyngeal/ throat swabs and sputum collected at least 24 hours apart from a patient with SARS-CoV2 PCR are needed before discontinuing Transmission-Based Precautions. Sets refer to multiple samples. One sample is accepted for patient testing. • A positive SARS-CoV2 PCR test from nasopharyngeal sample or lower respiratory sample is repeated every 48-72 hours.		**2**		
40	6	The surface area of the lab is disinfected after each PCR test.	• Any surface or material known to be, or potentially be, contaminated by biological agents during laboratory operations must be correctly disinfected to control infectious risks. • Appropriate disinfectants with proven activity against enveloped viruses should be used (e.g. hypochlorite (bleach), alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds), for the recommended contact time, dilution and within the expiry date after the working solution is prepared. • 2019-nCoV may likely susceptible to disinfectants with proven activity against enveloped viruses, including sodium hypochlorite (bleach) (e.g. 1,000 ppm (0.1%) for general surface disinfection and 10,000 ppm (1%) for disinfection of blood spills), 62-71% ethanol, 0.5% hydrogen peroxide, quaternary ammonium compounds and phenolic compounds, if used according to manufacturer's recommendations. Other biocidal agents such as 0.05-0.2% benzalkonium chloride or 0.02% chlorhexidine digluconate can be less effective. • Particular attention should be paid not only to the selection of the disinfectant but also contact time (e.g. 10 minutes), dilution (i.e. concentration of the active ingredient) and expiry date after the working solution is prepared.		**2**		
4.0	**Laboratory Scope of Testing and Capacity Assessment**						**Action Plan**
41	1	Currently the Scope of Testing includes Infectious diseases , Upper respiratory diseases, Gastrointestinal and Human Papilloma Virus- HPV	• Availability of Instruments Regents • Number of RNA Extraction Kits • Viral Positive and Negative controls		**2**		
42	2	Current Capacity Assessment	**"InstrumentCapacity Quantity Comment/ Output** **Extraction** **PCR** 		**2**		
43	3	Reagents and Freezer Storage Capacity	• Enough reagents: for only 100 reactions Per Kit for the currently done PCRs (related to SARSII virus). However, the quantity of kits can be increased. • Sufficient storage available of Freezers.		**2**		
5.0	**Outcome**						**Action Plan**
5.1	**Reporting of Results**						
44	1	The Laboratory will inform the concerned departments immediately in case of Positive result? Required documentation is completed.	• The laboratory has in place laboratory management system that can trace specimen, registration, test run, validation and release of results. • Staffs print results and enter them in the laboratory management system, then the specialist microbiologist validates test results as second level validation. • The Laboratory will inform the following concerned departments immediately in case of Positive result - The attending doctor (by whom and how?) - Prevention and control of Infection manager or Infection prevention on call (by whom and how?) - ADPHC (by whom and how?) - SEHA SOS (by whom and how?) - SEHA Infection Control (by whom and how?) • Attending physician(MRP) completes the e-notification to DOH. • There is a process for informing external patients of their results.		**2**		
6.0	**Laboratory Safety Program**						**Action Plan**
45	1	Biosafety and Engineering Controls.	• There are Class II Biological Safety Cabinets BSCs that are maintained by biomedical and facility management. In addition, BSCs are properly decontaminated and documented based on reviewed biosafety cabinet checklist. • The laboratory has in place a risk assessment program, control measures are implemented according to the assessment plan. In addition, staff ensure cleaning of the BSC and the use of UV light. • Planned Preventive Maintenance is done for the BSCs including HEPA filter change.		**2**		
46	2	Biosafety Training and Competencies.	• The laboratory has in place biosafety policies and procedures, reviewed policies included laboratory infection control and safety management program PP/AOP/066/03, management of blood and body fluids spell PP/PCI/019/03. In addition, the laboratory has in place a surveillance program in the event of post exposure of staffs to pathogens. • Staffs working in the laboratory are trained to handle infectious specimens under the supervision of the specialist microbiologist. In addition, competence assessment is done yearly.		**2**		
47	3	Personal Protective Equipment (PPE).	• The laboratory has in place policies and trainings for appropriate donning and doffing of PPEs including laboratory coats, gloves, protective eye wear, face shield and N95 fit test.		**2**		
7.0	**Infectious Waste Management & Disposal**						**Action Plan**
48	1	The laboratory has in place a policy for proper disposal of wastes including biological and respiratory waste handling.	• The laboratory has in place polices for disposal of wastes including biological and respiratory waste handling. • Autoclave is checked for efficiency using biological/chemical indicators. Ensure to have a logbook for documentation. • Is there a written regulated waste management plan? • Is there a contingency waste management plan in the circumstance that waste removal companies refuse to transport specific medical waste? • Is regulated waste segregated to prevent unauthorized access? • Is there a system identified for responding to regulated waste incidents? • Comply with HAAD EHSMS Standard for HCPs 16 - Waste Management v1 0		**2**		
49	2	The laboratory has a policy in place for decontaminating surfaces after completion of work.	• Any surface or material known to be, or potentially be, contaminated by biological agents during laboratory operations must be correctly disinfected to control infectious risks. • Are procedures available for decontaminating equipment prior to maintenance? • Working areas must be decontaminated with a suitable disinfectant at the end of each work period.		**2**		
50	3	The laboratory waste is autoclaved before final disposal through medical waste management company	• If regulated medical waste is autoclaved on site, are all required permits in place and have all autoclave units and cycles been properly validated and verified on an ongoing basis with challenge testing using chemical and/or biological indicators?		**2**		

1	**Laboratory Infrastructure, Control & Environmental Considerations**	
1.1	**Laboratory Infrastructure (Biosafety Level 2 (BSL-2)**	
1	The laboratory has valid DoH Licence	2
2	The laboratory is equipped to limit access control	2
3	All laboratory work surfaces and chairs must be made of non-porous, non-absorbent materials	2
4	Prohibition of eating, drinking, gum chewing, smoking, contact lens manipulation, application of cosmetics, mouth pipetting, and storage of food stuffs	2
5	A manual outlining biosafety policies and practices, including spill cleanup, emergency response, and post-exposure follow-up measures, must be available to all e	2
6	Biological safety cabinets (BSCs), splash shields, and other physical containment devices must be available.	1
7	Competency and proficiency assessments of employees engaged in work with infectious materials, including clinical specimens, must be periodically performed.	2
8	Eyewashes must be available throughout the laboratory.	2
9	Vacuum lines connected to aspirators must be protected with in-line high-efficiency particulate air/ arrestance (HEPA) filters and liquid disinfectant traps to minin	2
10	Utilization of appropriate PPE such as laboratory coats, gloves, and eye/ face protection.	2
1.2	**Control (The laboratory has in place a molecular PCR setup with contamination control and prevention)**	
11	Anteroom	1
12	Negative pressure (visual air direction system, visual & audible alarm system in case of failure, high efficiency particulate air filtration of laboratory exhaust systen	0
13	Flow of work	2
14	Physical arrangement of pre-post PCR	2
1.3	**Environmental Consideration (The laboratory has in place environmental consideration for molecular testing)**	
15	Adhesive paper at lab entrance	2
16	Air handling	1
17	Personal Protective Equipment	1
18	UV irradiation	2
19	Sterilization of Reagents	1
20	Contamination Control	2
21	Air pressure- resistant door	1
22	Aerosol- containment(sealed) lids on centrifuge buckets and/ or rotors	2
2	**Structure**	
2.1	**Organization**	
23	There is a policy that provides guidelines on each flow path in the sampling process including sending/ receiving samples in and out of the HCF	2
24	The HCF facility follow a standardardized DoH/ SEHA related policies	2
2.2	**RISK ASSESSMENT (All procedures must be performed based on risk assessment and only by personnel with demonstrated capability in strict observance to any r**	
25	The laboratory has a biosafety & biosecurity risk assessment policy in place to ensures that risk assessments are routinely performed as part of their quality mana	1
26	Based on the laboratory's risk assessment, the laboratory has a functional, certified and maintained Class II or higher Biological safety cabinet -BSC	2
3	**Process (The Laboratory has in place updated policies and procedures for specimen handling including transportation and storage)**	
3.1	**Specimens handling (Lab specimens must be collected, transported and handled safely to ensure that no risk of infection can be transferred to the personnel invo**	
27	Specimen containers (transport box) may be of glass or preferably plastic.	2
28	The driver is wearing appropriate PPE when handling the sample box	1
29	Laboratories should designate a particular room or area for this purpose.	2
30	The receiver of the sample is wearing the appropriate PPE	2
31	The temperature is checked/ logged on arrival ensuring maintenance of the cold chain 2-8 °C. Note: Observe integrity of samples transported over 60 mins.	2
32	Specimen Receiving Process	1
33	Process for Communication of Critical Results (COVID-19 positive result considered a panic value). If yes, show policy.	2
34	Storage and Transportation to the Lab	2
3.2	**Specimen Analysis/Testing**	
35	PPM and Safety test machine is performed as per manufacturers guidelines	2
36	QC control of the PCR testing machine is performed daily or as per manufacturers guidelines. Internal and external QC must be available.	2
37	Staff performing the PCR test is/ has the required qualification and training	2
38	COVID-19 Testing – Lab specimens prioritization (Color code triage)	2
39	Manage SARS-CoV2 PCR sample test result	2
40	The surface area of the lab is disinfected after each PCR test.	2
4	**Laboratory Scope of Testing and Capacity Assessment**	
41	Currently the Scope of Testing includes Infectious diseases , Upper respiratory diseases, Gastrointestinal and Human Papilloma Virus- HPV	2
42	Current Capacity Assessment	2
43	Reagents and Freezer Storage Capacity	2

5	**Outcome**	
5.1	**Reporting of Results**	
44	The Laboratory will inform the concerned departments immediately in case of Positive result? Required documentation is completed.	2
6	**Laboratory Safety Program**	
45	Biosafety and Engineering Controls.	2
46	Biosafety Training and Competencies.	2
47	Personal Protective Equipment (PPE).	1
7	**Infectious Waste Management & Disposal**	
48	The laboratory has in place a policy for proper disposal of wastes including biological and respiratory waste handling.	2
49	The laboratory has a policy in place for decontaminating surfaces after completion of work.	2
50	The laboratory waste is autoclaved before final disposal through medical waste management company	1
	Total Score	**87**

Circular No (58) تعميم رقم

Date: 16/10/2019

التاريخ: 2019/10/16

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

السادة/ جميع المنشآت الصحية و المختبرات الطبية في إمارة أبوظبي

Subject: Mandating ISO15189 Accreditation for Clinical Laboratori.

الموضوع: الزام المختبرات الطبية بالحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189

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.

Please find enclosed Emirates Authority For Standardization and Metrology's letter concerning the decision no. 18 of year 2018 that mandates all medical laboratories operating in UAE to be accredited according to ISO15189 requirements for quality and competence particular to medical laboratories, in addition to technical requirements issued by Emirates National Accreditation System (ENAS); and to support achievement of the national indicator for increasing number of health facilities that meet the accreditation criteria, including medical laboratories, we hereby inform you that all medical laboratories and sections of medical laboratories in healthcare facilities licensed by Department of Health – Abu Dhabi are mandated to get the accreditation and to proceed in accordance with the following timetable set by the Emirates Authority For Standardization and Metrology (enclosed).

نرفق لكم كتاب هيئة الإمارات للمواصفات و المقاييس بمضمون القرار رقم 18 من العام 2018 و الذي يقضي بإلزام جميع المختبرات الطبية العاملة في الدولة على الحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189 الخاصة بمتطلبات الجودة و الكفاءة في المختبرات الطبية و المتطلبات الفنية الصادرة عن نظام الاعتماد الوطني الإماراتي. و في سبيل دعم تحقيق المؤشر الوطني الخاص بزيادة المنشآت الصحية المستوفية لمعايير الاعتماد بما فيها المختبرات الطبية، فإننا نفيدكم علماً بأنه يجب على جميع المختبرات الطبية و أقسام المختبرات الطبية في المنشآت الصحية العاملة في إمارة أبوظبي و المرخصة من دائرة الصحة البدء بإجراءات الحصول على الاعتماد وفقاً للبرنامج الزمني التالي المحدد من قبل هيئة الإمارات للمواصفات و المقاييس المرفق.

● PUBLIC / عـــام

للمزيد من المعلومات أو الاستفسار بهذا الشأن، يرجى التواصل مع:

- الآنسة/ دانة لطفي – ضابط الاعتماد من إدارة الاعتماد الوطني على الهاتف رقم: 024032633 أو عبر البريد الإلكتروني: dana.c@enas.gov.ae.

- السيدة/ هالة عبد الرحمن – مدقق أول جودة صحية على الهاتف رقم: 025048380 أو عبر البريد الإلكتروني: hrahman@doh.gov.ae

شاكرين لكم حسن تعاونكم معنا ...

For further clarifications, please feel free to contact:

- Miss. Dana Lutfi, Accreditation Officer, Emirates National Accreditation System on phone no.: 024032633, or by email at: dana.c@enas.gov.ae.

- Mrs. Hala Abdul Rahman, Senior Health Quality Auditor on phone no.: 025048380 or by email at: hrahman@doh.gov.ae

Thanking you for your kind cooperation,,,

ع/ محمد حمد الهاملي
وكيل دائرة الصحة

دائـــرة الـصـحـــة
US DEPARTMENT OF HEALTH 01

● PUBLIC / عـــــام

هيئة الإمارات للمواصفات والمقاييس
Emirates Authority For Standardization & Metrology

United Arab Emirates

التاريخ: 2019/05/02

الدكتورة/ أسماء المناعي المحترمة

مديرة دائرة جودة الرعاية الصحية

الموضوع: تطبيق قرار الزام المختبرات الطبية العاملة في الدولة بالحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189

تهديكم ادارة الاعتماد الوطني - هيئة الإمارات للمواصفات والمقاييس أطيب التمنيات و التحيات.

تعزيزاً لأواصر التعاون وتوثيقا للعمل والجهود المشتركة التي تُبذل في رفع مستوى وجودة خدمات تقييم المطابقة عموماً وخدمات الفحص الطبي خصوصاً. وايمانا منا بالدور الذي تقدمه المختبرات الطبية والنتائج الصادرة عنها ضمن المنظومة المتكاملة للخدمات الصحية في الدولة. وبالإشارة إلى قرار مجلس الوزراء (35) للعام 2015 بشأن النظام الإماراتي للرقابة على جهات تقييم المطابقة. تبعا له نود إعلامكم بصدور قرار مجلس إدارة هيئة الإمارات للمواصفات والمقاييس رقم 18 من العام 2018. والي يقضي بالزام جميع المختبرات الطبية العاملة في الدولة على الحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189 الخاصة بمتطلبات الجودة والكفاءة في المختبرات الطبية والمتطلبات الفنية الصادرة عن نظام الاعتماد الوطني الإماراتي Emirates National Accreditation System (ENAS). و استكمالا للتعاون وللجهود المبذولة سابقا في إمارة أبوظبي بشأن اتباع جميع مقدمي خدمة الفحص والإختبارات الطبية لمتطلبات المواصفة الدولية ISO15189 الخاصة بمتطلبات الجودة والكفاءة في المختبرات الطبية. حيث يأتي هذا القرار ليدعم تحقيق المؤشر الوطني الخاص بزيادة المنشأت الصحية المستوفية لمعايير الاعتماد (تتضمن خدمات المختبرات الطبية). والهدف الاستراتيجي الهدف الاستراتيجي الخاص برفع جودة المنتجات والأنظمة بما يدعم التنمية المستدامة وبعزز جودة الحياة ومكانة الدولة كمركز اقتصاد عالمي.

وبناءً عليه يرجى من سعادتكم التكرم بالإيعاز لمن يلزم باعلام كافة المنشأت الصحية والمختبرات الطبية العاملة في الإمارة والمسجلة لديكم بقرار الزام المختبرات الطبية بالحصول على الاعتماد والسير في الاجراءات وفقاً للبرنامج الزمني التالي:

- التقدم بطلب الحصول على الاعتماد وفقاً للمواصفة الدولية ISO15189 من نظام الاعتماد الوطني الإماراتي (ENAS) أو هيئات الاعتماد التي تحددها وتعلن عنها هيئة الإمارات للمواصفات والمقاييس وذلك خلال 6 أشهر من تاريخه.
- استكمال الإجراءات والحصول على الاعتماد خلال سنة من تقديم طلب الاعتماد.

لمزيد من المعلومات المتعلقة باعتماد المختبرات الطبية. يرجى الايعاز للتواصل مع الأنسة دانة لطفي – ضابط الإعتماد من إدارة الاعتماد الوطني على رقم الهاتف: 024032633، أو على البريد اللإلكتروني dana.c@enas.gov.ae

شاكرين لكم حسن تعاونكم ومتمنين لجهودكم التوفيق.

وتفضلوا بقبول فائق الاحترام والتقدير.

د. رحـــاب فرج العـــامري

مدير الإعتمـــاد الوطـــني