

المديرية العامة للمؤسسات الصحبة الخاصة Directorate General of Private Health Establishments

وتزلارة للضحسنة

Ministry of Health

الرقم: تعميم رقم: 18 / 2022

التاريخ: 16 أكتوبر 2022 م

Ref: Circular No. 18 /2022

Date: 16 / 10 / 2022

To :All Private Health Establishments - Visa **Medical Services**

إلى: جميع المؤسسات الصحية الخاصة - خدمة فحص اللياقة الطبية

الموضوع: وثيقة إشتراطات مراكز فحص اللياقة

Subject: Criteria of Medical Centre Licensing For Expatriates Fitness Residency Requirement

In reference to the article No.2 from the Ministerial Decree no. 272/2022 and to the letter received from the Directorate General for diseases Surveillance and Control.Please إشتراطات مراكز فحص اللياقة ويجب على هذه المراكز Licensing for Expatriates Fitness Residency Requirements.

All Visa Medical Centres should:

- 1- Modify their centers as per the new requirements and request for reevaluation.
- 2- Given a period up to 1st / April /2023 to modify their centers to fit the new criteria's.
- 3- Till all centers are modified to fitt the new criteria they can follow last guidelines circulated.
- 4- All new centers and those in process of licensing should modify their centers as per the new criteria and request for a re evaluation and the audit teams should follow the new visa medical criteria. For inquiries call: 99449971

بالإشارة إلى المادة الثانية من القرار الوزاري رقم 2022/272 وإلى الخطاب الوارد إلينا من المديرسة العامة لمر اقبة ومكافحة الأمراض، عليه نرفق لكم بالطي وثيقة إتباع الاتى:

- 1. على جميع مراكز فحص اللياقة المرخصة حاليا بتعديل أوضاعها حسب الإشتراطات الواردة في الوثيقة والتقدم مجددا للتقييم للإعتماد.
- 2. تمنح المؤسسات فترة لغاية 1/ إبرسل/2023 لتعديل أوضاعها ليتسنى لها تطبيق النظام الجديد من ذلك
- لحين تعديل الأوضاع يتم العمل بالإشتراطات الحالية حسب المدة الممنوحية في القيراروحسب المتفيق عليه بين المؤسسات الصحية الخاصة والوزارة (وزارة الصحة).
- على المراكز التي لم يتم إعتمادها (قيد الإنشاء) والتي لم يتم ترخيصها للآن تعديل أوضاعها حسب الوثيقة وعلى فرق التقييم الأستعانة باللائحة الجديدة لتقييم أي مراكز قيد الإنشاء. للإستفسار التواصل على رقم: 99449971

الدكتور/ مهنابن ناصر المصلحي

Muhanna Bin Nasir Al Muslahi

مدير عام المديربة العامة للمؤسسات الصحية الخاه

Director General- D.G.Private Health Establishments

Office of Undersecretary of Health Affairs

Directors of Department of Private Health Establishments All Governorates

مكتب وكيل الوزارة للشؤون الصحية .

مدراء دوائر المؤسسات الصحية الخاصة - بجميع المحافظات

Cc:-

نسخة:





Sultanate of Oman
Ministry of Health
Directorate General for Disease Surveillance and Control

Criteria for Medical Centers Licensing

for Expatriates Fitness Residency Requirement

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Criteria of Medical Center Licensing

for Expatriates Fitness Residency Requirement

Licensing and approval of new centers to carry out expatriate health checkup for residency requirement, will only be granted following the assessment of demands for such services; moreover, this does not mean that any licensed health clinic or center in the sultanate can cater these services. The approved centers shall be accredited based on the assessment of a technical team.

1- Objectives:

The Objectives of Health Checkup for residency requirement are:

- To ensure that the expatriate is free from communicable diseases for public health security against contagious diseases
- 2. To assess the ability of the applicant to perform the job efficiently and effectively without harming himself, his colleagues or the community
- 3. To provide a baseline medical report to support both employer and employee.
- 4. To provide an opportunity for Health promotion.

2- The approved clinic shall ensure:

- 1. Availability of resources (man-power, equipment's etc.,) to carry out such services.
- 2. Conduct laboratory-required investigations by a highly qualified medical professional.
- 3. Ensure that the examinations and investigations carried out are accurate.
- 4. Violation or a breach or break of these rules and requirements by the approved medical provider will be subjected to punishment by one or more of the following penalties: (Annex-1)
 - Warning
 - Monetary Fine
 - Suspension for a fixed period
 - Withdrawal of approval

3- Duties and responsibilities of the approved clinic:

- 1. To Comply with MOH rules and regulations as regards to the Expatriate Health Checkup for residency requirement.
- 2. To conduct the required medical examination, radiological and laboratory investigations according to the expatriate health checkup components.
- 3. To carry out -Maintenance of equipment and other medical examination tools at a regular interval.
- 4. To use and to register the personal details of expatriates in electronic systems (fingerprint authentication), identity of the candidate shall be verified throughout all phases i.e. from the registration till the issuance of the report, in order to ensure that the results are for the same candidate examined.
- 5. All issued medical, x-ray & laboratory reports should be shared automatically to MOH portal for endorsement.
- 6. Ensure that all medical reports are saved for five years from the date of examination.
- 7. Ensure notification of any detected reportable communicable diseases as per MOH policy using e-notification system.
- To adhere to MOH guidelines and technical instructions regarding vaccination of expatriates.
- 9. To adhere to MOH guidelines and technical instructions regarding infection control and medical waste disposal.
- 10. To maintain confidentiality throughout the process of health checkups.

4- Components of medical checkup:

- 1. Vital signs
- 2. Laboratory investigations: (HIV test, Hepatitis B Surface Antigen (HbsAg), Antibodies to Hepatitis C Virus (Anti HCV), VDRL /TPHA, and stool culture.
- 3. A TB investigation blood sample to be collected, prepared and sent to MOH assigned Public Health

Laboratories (annex 2).

5- Medical centers facilities:

5.1: Reception and Registration area requirements:

- Suitable waiting area space and a suitable number of receptionists compared with the number of candidates. (20 seats per 50 candidates per day), (1 registration disc per 50 candidates per day)
- In-house electronic registration software, which can be integrated with the MOH portal.
- 3. Biometric identification system (fingerprint).
- 4. Ability to save the results for not less than five years.

5.2: Nursing station:

Availability of at least one staff nurse, and the number may be increased according to needs, to perform the following:

- · Confirm the identity of the applicant.
- Check vital signs (blood pressure, pulse, weight, height, visual acuity and color vision)
- Check the status of previous local medical check-ups or the GCC prearrival medical check-ups.

5.3: Sample collection station:

Independent suitable area, with active electronic personal identification system, and availability of at least one phlebotomist or staff nurse to ensure the following:

- Confirm the identity of the applicant.
- 2- Ensure using appropriate sample collection tubes/containers.
- 3- Ensure using barcoded Samples labeling method.
- 4- Adhere to the national medical waste disposal policy.
- 5- Adhere to the infection control policy.
- 6- Ensure that collected samples are handled, stored, and transported to the laboratory using optimum conditions (i.e. temperature ...etc) and packaging.

5.4: Laboratory requirement and test criteria:

5.4.1: General requirement:

1. The laboratory should meet all the national laboratory standards and licensing requirements by MOH.

- 2. At least two lab technicians with Bsc qualification, (one of them with minimum of 5 years of experience) and the numbers should be increased depending on the workload.
- 3. Should be supervised by a general pathologist with Microbiology experience or a microbiologist.
- 4. All types of equipment, methods, and reagents should be FDA and CE approved, validated, and licensed by MOH to be used for medical fitness screening.
- 5. Analyzers should be fully automated and equipped with bar code readers and built-in result retention feature. Analyzers should be auto-connected and interfaced with MFEC (MOH portal) laboratory information system.
- 6. Mandatory participation in external quality control programs for all parameters tested during medical fitness checkups.
- 7. Mandatory participation in the National External Quality Assurance Scheme (NEQAS) program provided by CPHL.
- 8. The daily use of quality controls during testing and the implementation of Levy Jenning and Westgard rules should be mandatory.
- 9. A randomly selected serum sample to be sent to MOH as per the system notification.
- 10. Strict documentation and record-keeping policies and standards to be implemented.
- 11. Strict adherence to bio-safety & bio-security regulations.
- 12. Mandatory service and maintenance contracts for equipment including the annual certification and validation of biosafety cabinets. The lab should provide evidence of regular calibration for all equipment and apparatus that may affect the results such as pipettes and analyzers.

5.4.2: The required laboratory investigations machine specification and tube's specification are:

Test Name	Machine Specification	Tube's Specification	Other Requirements		
HIV	Use FDA and CE s	Use FDA and CE system that is approved, validated and licensed by MOH Use fourth or the latest generation assays			
Anti HCV	validated and lice				
HbsAg	Use fourth or the				

Self line

VDRL/TPHA	Use FDA and CE system that is approved,	EQA 😞
100	validated and licensed by MOH	10
IGRA S	Use QuantiFERON® TB Gold PLUS Test	Follow the collection
(test tubes should be	(QFT®-Plus)	and transport guide
purchased from the local	Use only QuantiFERON Blood Collection	(Annex -2)
authorized dealer)	Tubes	3
Stool culture	Use standardized method and ready-	NEQAS
	made culture media for bacterial	=
	identification and follow CLSI and	
	National Guidelines for Antibiotic	
	Susceptibility Testing	

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5.4.3: The basic required laboratory equipment to conduct the serology and stool culture will include the following minimum equipment list:

No	Equipment description	Minimum Quantity	Remarks
1	Bio-safety cabinet class II	2	1 in serology, 1 in bacteriology
2	Centrifuges with safety lid & biohazard containment cups.	1	To be increased according to workload
3	Immune analyzer	1 000	To add manpower according to needed throughout and workload
4	ELISA WASHER	(1) N	For manual serology, not required for
5	ELISA READER	% 1	automated systems
6	Incubator	2	One with temperature 37 to be used with ambient air/ anaerobic jar & one with temperature 42 to be used with microaerophilic air.
7	Water bath	1	
8	Automatic Media dispenser	1	If media will be prepared in the lab
9	Water distillatory	1	

10	Autoclave 75 L	1	2,000
11	Autoclave 150 L	1 2021	Optional as backup or when sterilization is needed
12	Autoclave 150 L	100	Waste decontamination
13	Laboratory refrigerator 2 - 8	1.8.	3 fridges per 500/day samples workload
14	Laboratory Freezer -20	-	2 freezers per 500/day samples workload
15	Microscope binocular	1	
16	Vortex mixer	2	

6: Results and report generation section:

- 1. All results should be submitted to the MOH portal within 24 hours.
- 2. Results should be stored in electronic format for at least 5 years.
- 3. Applicants with positive findings should be redirected to the Directorate General of Health Service in the governorate for further assessment and follow-up.
- 4. All positive blood samples should be kept for a minimum of 3 months, with proper storage techniques.
- 5. All medical reports (results & notes) should be submitted in MOH portal, taking into consideration the following points:
 - Complete forms only will be allowed to be submitted for issuing the fitness decision;
 any incomplete forms cannot be submitted.
 - For applicants who need more assessment, incomplete forms can be saved in the system for later access.
 - All significant additional information not included in the form should be noted in the 'Notes' section of the form.

7_ (Optional) Vaccination service:

The approved center can provide vaccination services, provided he has MOH registration approval for this service, otherwise, the expatriate can be advised to take the required vaccine in any MOH-approved vaccination center. (Cost of the vaccine will be beared by the candidate)

- Candidates who require vaccination, as per the national vaccination program
 recommendations, should receive the vaccine before going through the medical checkup, and the approved medical center should verify it from the electronic system.
- 2. All data should be entered electronically into the MOH portal.

8- (Optional) X-Ray Service for Expatriate Medical Check-up for Residency Requirement

The approved center can provide radiology service (X-Ray), provided MOH registration approval for this service, otherwise, expatriates can be advised to take chest X-Ray in any MOH approved radiology center and it should be done only if the IGRA test is positive. (Cost of the X-Ray will be beared by the candidate)

- 1. Digital x-ray machine required (C.R or D.R)
- 2. The result should be supported with Artificial Intelligent software.
- 3. Results should be shared or submitted to the MOH portal.
- 4. Ability to save the results for at least two years.

9- Medical test pricing:

Candidate category	Test required	Test price in Omani Rial	
Food handlers, barber's,	With IGRA	27 O.R	
hairdressers and others	1. HIV, HbsAg, Anti HCV,	2	
who require a municipality	VDRL, Stool culture.		
health certificate	2. IGRA sample collection		
	and transport to MOH		
h.	laboratory *	I'	
	Without IGRA	14.5 O.R	
200	HIV, HbsAg, Anti HCV, VDRL,	100	
2/20	Stool culture.	N. S.	
Other candidates	With IGRA	22 O.R	
8 1 m	1. HIV, HbsAg, Anti HCV,	80 V. W.	
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	VDRL.	23.	
,	2. IGRA sample collection		
	and transport to MOH		
_	laboratory *		
	Without IGRA	9.5 O.R	
. *	HIV, HbsAg, Anti HCV, VDRL,		

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*IGRA sample tubes cost 9.4 OR and they should be purchased from the local authorized distributor.

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# Annex-1: Accredited centers noncompliant; administrative, technical offences and result discrepancy:

## 1.Administrative offences:

No	Туре	Action first attempt	Action second attempt	Action third attempt	Action fourth attempt
1	No active Identification system (Fingerprint)	warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the available before reopening
2	No active registration system	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the available before reopening
4	No candidate record for at least 5 years	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the available before reopening

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5 Unavailability of required manpower Warning Penalty 500 Penalty Suspension 3 months, and to evaluate the available before reopening

## 2. Technical offenses:

	N Type		Action first attempt		Action third attempt	Action fourth attempt	
1012	1	No appropriate medical west management program	warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the availably before reopening	
	2	No appropriate Infection control program	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the availably before reopening	
	3	No Lab result at least for 5 years	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the availably before reopening	
	4	No lab result quality control program	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the availably before reopening	

5	Use of Rapid tests to		Penalty 500	Penalty 1000	Suspension 3 months, and to
	diagnose viral infections		Omani Rial	Omani Rial	evaluate the availably before
	23	-	32		reopening
6	Use of expired or poor- quality sample collection (tube/ containers)	Warning	Penalty 500 Omani Rial	Penalty 1000 Omani Rial	Suspension 3 months, and to evaluate the availably before reopening

# 3. Results discrepancy:

N o	Disease	Violation Type	Action
9,	HIV	1 - 3 cases /year	A penalty of 500 Omani Rial for each case.
		4 - 9 cases/year	Suspension for 3 months and penalty of 500 Oman Rial for each case.
1		10 - 15 cases/year	Suspension for 6 months and penalty of 500 Omani Rial for each case.
		16 & more cases/year	Revocation SA
	Hepatitis (HBs Ag, HCV)	1 - 6 cases/year	A penalty of 500 Omani Rial for each case.
		(HBs Ag,	7 - 13 cases /year
2			13 - 19 cases /year
		20 &more cases /year	Revocation
		1 - 4 cases /year	A Penalty of 500 Omani Rial for each case.
3	T.B. OR any pathology in chest X-ray	5 - 10 cases /year	Suspension for 3 months and penalty of 500 Omani Rial for each case.
		11 - 14 cases /year	Suspension for 6 months and penalty of 500 Omani Rial for each case.
		15 & more cases /year	Revocation

# Annex-2 Guideline for Quantiferon TB Gold, Specimen collection and **Transportation**



GUIDELINE FOR QuantiFERON TB GOLD PLUS TEST (QFT- PLUS)
NATIONAL TUBERCULOSIS REFERENCE LABORATORY
CENTRAL PUBLIC HEALTH LABORATORIES

### Specimen collection and transportation



- Use only QuantiFERON Blood Collection Tubes which are purchased from local authorized dealer/supplier.
- Collect 1 ml blood by venipuncture directly into each specified tubes (within the Black Mark only).

QuantiFERON Nil Tube

(Grey cap with white ring)

QuantiFERON TB1 Tube

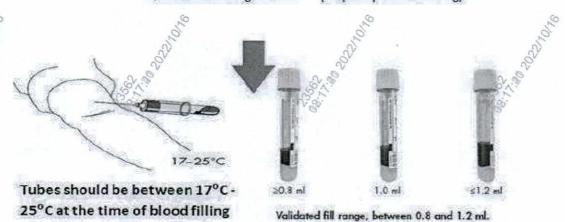
(Green cap with white ring)

QuantiFERON TB2 Tube

(Yellow cap with white ring)

QuantiFERON Mitogen Tube

(Purple cap with white ring)



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17-25°C

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Incubate tubes at collection site (upright at 37 °C for 16-24 hours)





After incubation centrifuge the tubes for 15 minutes at 3000 rpm (Make sure the gel plug will separate the cells from the plasma)



(Ship tubes in upright position to MOH laboratory at 17-27°C in a cool box without ice)

If delay in shipment tubes can be stored at 2-8° C

55%

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