

Circular No.: EIAC/LAB/01/2023

DATE: 28 July 2023

To: All accredited and applicant medical laboratories

**Transition to ISO 15189: 2022 Medical Laboratories -
Requirements for quality and competence**

Greetings from Emirates International Accreditation Centre (EIAC)

This is for the information of all medical laboratories that a new version of ISO 15189: 2022 had been released on 6th December 2022. Based on ILAC Resolution GA 26.08; EIAC has issued this circular to update medical laboratories and the related stakeholders on the EIAC actions, transition process and required timelines to this version of the standard as detailed below under (Annexure A).

All medical laboratories shall purchase and hold a copy of ISO 15189: 2022 version which is available through the International Organization for Standardization (ISO) website.

In order to ensure the implementation of this transition period; the medical laboratories are obliged to comply with EIAC Fees Structure Requirements EIAC-RQ-GEN-003 available in www.eiac.gov.ae.

Should you need any clarifications related to this circular, please don't hesitate to contact:

1. Hamda Ibrahim, Senior Specialist Healthcare Accreditation, Hamda.Mohammed@eiac.gov.ae
2. Golkonda Prabhakar, Senior Specialist Healthcare Accreditation, Prabhakar.Golkonda@eiac.gov.ae

Thanks & Regards

Alia Ismail Al-Marzooqi



Director of Laboratory Accreditation Department

ANNEX A.

Activity	Action	Responsibility	Deadline
Accreditation Documents	<ul style="list-style-type: none"> Update Eiac accreditation documents including the following: <ul style="list-style-type: none"> ➤ Accreditation Application for Medical Laboratory & Biobanking (Eiac-PR-02/FM-040) ➤ Quality Document Review Checklist for ISO 15189:2012 (Eiac-PR-002/FM-009) <p>Publish Eiac accreditation documentation in the website www.eiac.gov.ae</p>	Eiac	15 th August 2023
	<ul style="list-style-type: none"> Issue of new form and publish in the Eiac website for the purpsor of GAP Analysis Checklist. <p>Publish Eiac accreditation documentation in the website www.eiac.gov.ae</p>	Eiac	15 th August 2023
	<ul style="list-style-type: none"> Update Eiac accreditation documents including the following: <ul style="list-style-type: none"> ➤ Accreditation Requirements for Medical Laboratory Testing (Eiac-RQ-LB-004) ➤ Accreditation Requirements in the Field of Medical Testing for POCT /Mobile Laboratories (Eiac-RQ-LB-005) <p>Publish Eiac accreditation documentation in the website www.eiac.gov.ae</p>	Eiac	1 st October 2023
Accreditation application	Eiac will not accept any new applications as per ISO 15189: 2012.	Eiac	1 st Febreuary 2024

Document Review	The accredited medical laboratory shall submit “Gap Analysis Checklist Form” along with related supporting documentations at least 2 months before the scheduled assessment visit.	Accredited Medical Laboratories	2 months before the scheduled assessment visit
Assessment	All initial assessments will be carried out based on ISO 15189:2022 version only.	EIAC	1 st February 2024 onwards
	<ul style="list-style-type: none"> All scheduled assessment visits for accredited medical laboratories (Periodic and Reassessment) will be assessed as per ISO 15189:2022 version only. <p>NOTE: In case if the accredited medical laboratory found to be still not complying with the requirements of ISO 15189:2022; EIAC will carry out the scheduled assessment as per ISO 15189:2012, however, an extraordinary/additional assessment will be conducted not later than January 2025, taking into consideration that EIAC will not be responsible for any delay caused that might affect the transition deadline.</p> <ul style="list-style-type: none"> The “Gap Analysis Checklist Form” and the related supporting documentation will be verified during the scheduled assessment. As per ISO 15189: 2022; in case if the accreditation of the medical laboratroy is including medical testing and POCT activities, the assessment for transition will consider the requirements of ISO 15189: 2022 including medical testing 	EIAC	1 st January 2024 onwards

	and POCT.		
	As per EIAC Guidance for Accreditation Process (EIAC-GD-GEN-004) pulished in the website, all findings raised during the assessment must be addressed and closed by the lab before the accreditation officially transit to ISO 15189: 2022.	Applicant/Accredited Medical Laboratories	as per EIAC Guidance for Accreditation Process (EIAC-GD-GEN-004)
Accreditation certificate	<ul style="list-style-type: none"> Following sucessful transition decision, all accreditation certificate will be updated with reference to ISO 15189:2022. All accreditation certificate as per ISO 15189: 2022 will include the fields of medical testing and POCT All issued accreditation certificate for POCT with accreditation number LB-POCT-xxx, will be withdrawn and included in the updated accreditation certificate as per ISO 15189: 2022 and accreditation number LB-MED-xxx. 	EIAC	6 th December 2025
	Medical laboratoris that have not successfully transferred their accreditation certificate by 6 th of December 2025; are subjected to not being recognized by ILAC.	Accredited Medical Laboratories	6 th December 2025 onwards