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Document Title: Clinical Laboratory Accreditation	Effective Date: 22/09/2020	Revision Date: 21/09/2023

Ownership: Health Regulation Sector

Applicability: All new and licensed clinical laboratories under the DHA jurisdiction mentioned below:

- Free standing clinical laboratories;
- Clinical laboratories within Diagnostic Centers;
- Clinical laboratories within Hospitals and Day Surgical Centers; and
- Blood banks.

1. Purpose:

- 1.1. To align with the Dubai Health Strategy 2016–2021.
- 1.2. To ensure highest standards of practice and safe and quality clinical laboratory services are provided in health facilities licensed under the jurisdiction of DHA.
- 1.3. To ensure all clinical laboratories licensed under DHA jurisdiction are accredited.

2. Scope:

- 2.1. Clinical Laboratory Accreditation.

3. Definitions/Abbreviations:

Accreditation: in this document shall mean the process of officially evaluating clinical laboratory to maintain satisfactory standards, conducted by international accreditation organizations.

Licensure: shall mean issuing a license to operate a health facility to an individual, government, corporation, partnership, limited liability company, or other form of business operation that is legally responsible for the facility's operation.

AABB: American Association of Blood Banks

CAP: College of American Pathologists

DHA: Dubai Health Authority

HRS: Health Regulation Sector

ILAC: International Laboratory Accreditation Cooperation

ISO: International Organization for Standardization

MRA: Mutual recognition arrangement

4. Policy Statement:

4.1. All clinical laboratories under DHA jurisdiction are required to be accredited.

4.1.1. Clinical laboratories that have had their license activated prior to April 2019 must obtain accreditation by October 2020.

4.1.2. Clinical laboratories that have their license activated after April 2019 shall obtain accreditation within eighteen (18) months from the date of license activation.

4.2. The following clinical laboratory accreditation bodies for are approved by DHA:

4.2.1. Signatory members of International Laboratory Accreditation Cooperation (ILAC) under Mutual Recognition Arrangement (MRA) for International Organization for Standardization (ISO) 15189.

a. Emirates International Accreditation Centre (EIAC).

4.2.2. College of American Pathologists (CAP).

4.3. Blood bank accreditation shall be accredited by American Association of Blood Banks (AABB).

4.4. All DHA licensed clinical laboratories shall obtain accreditation within eighteen (18) months from the issuing date of the health facility license.

4.5. All accredited clinical laboratories shall update Health Regulation Sector (HRS) regarding their accreditation or renewal status and HRS will follow up the accreditation process.

- 4.6. The clinical laboratories that fail to achieve the accreditation status within the allocated period shall cease to provide clinical laboratory services immediately in order to avoid noncompliance.
- 4.7. Upon the expiry of the accreditation validity, the clinical laboratories are required to undergo a reaccreditation process and the HRS must be informed of the initiation of the reaccreditation process in writing.
- 4.8. A clinical laboratory, with a revoked, suspended or voluntarily withdrawn from the accrediting body will inform HRS in writing.
- 4.9. HRS is authorized to conduct an investigation in order to reveal reasons for the revocation or suspension, in collaboration with the accrediting body.
- 4.10. HRS staff or any other authorized personnel are authorized to conduct onsite visits to the clinical laboratories to check their accreditation status and request documentation to support the validity of the accreditation certificate.
- 4.11. Clinical laboratory shall not mislead the public by falsely advertising its accreditation status.
- 4.12. Clinical laboratories shall have a business continuity plan in case of service disruption.
- 4.13. All clinical laboratories shall comply with the clinical laboratory accreditation requirements set out in **Appendix 1**.

5. References:

- 5.1. American Association of Blood Banks (2019). Become an AABB accredited facility. *Accreditation phases and expectations*. Available on <http://www.aabb.org/sa/becomeaccredited/Pages/default.aspx> (Accessed on 07/10/2019).
- 5.2. College of American Pathologist (2015). Laboratory Accreditation. Guide to CAP Accreditation for International Participants.
- 5.3. Hindawi S (2009). Systems for accreditation in blood transfusion services. *International Society of Blood Transfusion ISBT Science Series (2009) 4, 14–17*.
- 5.4. ILAC (2017). ILAC MRA Signatory Search. Available on: <http://ilac.org/signatory-search/> (accessed 07/10/2019).
- 5.5. Zima Tomas (2017). Accreditation of Medical Laboratories – System, Process, Benefits for Labs. *J Med Biochem 36: 231–237, 2017. DOI: 10.1515/jomb-2017-0025*.

6. Appendix

Appendix 1 - Requirements and Responsibilities for Clinical Laboratory Accreditation

No.	Clinical Laboratory Accreditation Requirements	Responsibility
1.	Obtain a DHA health facility license/or add service	Clinical Laboratory
2.	Obtain accreditation within eighteen (18) months from the issuing date of the health facility license/add service	Clinical Laboratory
3.	Update HRS regarding accreditation or renewal status	Clinical Laboratory
4.	Follow up the accreditation status	HRS
5.	Cease to provide laboratory services in case fail to achieve the accreditation status within the allocated period	Clinical Laboratory
6.	Undergo a reaccreditation process upon the expiry of the accreditation validity	Clinical Laboratory
7.	Inform HRS of the commencement of the reaccreditation process in writing	Clinical Laboratory
8.	Cease clinical laboratory services in case <ul style="list-style-type: none"> ➤ expiry of the accreditation validity ➤ accreditation is revoked/suspended by the accrediting body ➤ voluntarily withdraw from the accreditation process 	Clinical Laboratory
9.	Conduct an investigation into the reasons for the revocation/suspension, in collaboration with the accrediting body	HRS