

Document Type: Policy	Ref No: HRS/CLAP/2/2018	Version Number: 2
Document Title: Clinical Laboratory Accreditation	Effective Date: 1/4/2019	Revision Date: 1/4/2022
Ownership: Health Regulation Sector		
<p>Applicability: All new and licensed clinical laboratories under the DHA jurisdiction mentioned below:</p> <ul style="list-style-type: none"> • Free standing clinical laboratories • Clinical laboratories within diagnostic centers • Hospital based and ambulatory care services clinical laboratories. • Blood banks 		
<p>1. Purpose</p> <p>1.1.To align with the Dubai Health Strategy 2016–2021, Goal #3: Ensuring Patient Happiness by Providing World-class healthcare Services.</p> <p>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.</p> <p>1.3.To ensure all clinical laboratories licensed under the jurisdiction of DHA obtain laboratory accreditation within eighteen (18) months from the date of issuing the health facility license and maintain quality assurance programs.</p> <p>2. Scope:</p> <p>2.1. To identify and standardize a process for all clinical laboratories (independent or associated with other health facilities) under the DHA jurisdiction to be accredited by internationally recognised accreditation organizations as mentioned in this document.</p> <p>3. Definitions/Abbreviations:</p> <p>Accreditation in this document shall mean the process of officially evaluating clinical laboratory to maintain satisfactory standards, conducted by international accreditation organizations.</p> <p>Licensure shall mean issuing a license to operate a health facility to an individual, government,</p>		

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

ACHSI : Australian Council on Healthcare Standards International

CAP : College of American Pathologists

DHA : Dubai Health Authority

HRS : Health Regulation Sector

ILAC : International Laboratory Accreditation Cooperation

ISO : International Organization for Standardization

ISQua : International Society for Quality in Health Care

JCI : Joint commission international

MRA : Mutual recognition arrangement

NABH : National Accreditation Board for Hospitals and Healthcare Providers.

4. Policy Statement:

4.1. All clinical laboratories licensed by DHA are required to be accredited by accreditation bodies as mentioned below:

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

4.1.2. Members of International Society for Quality in Health Care (ISQua), such as Joint Commission International (JCI), Accreditation Canada, Australian Council of Healthcare Standards International (ACHSI) etc.

4.1.3. College of American Pathologists (CAP).

- 4.2. Blood bank accreditation shall be accredited by accreditation bodies such as American Association of Blood Banks (AABB), National Accreditation Board for Hospitals and Healthcare Providers (NABH), JCI, or CAP.
- 4.3. DHA licensed clinical laboratories shall obtain accreditation within eighteen (18) months from the issuing date of the health facility license for all of the tests conducted in the clinical laboratory. In case the laboratories do not have the infrastructure/resources, they can outsource the test to an accredited clinical laboratory meeting the requirement mentioned above.
- 4.4. All accredited clinical laboratories shall update Health Regulation Sector (HRS) regarding their accreditation or renewal status and HRS will follow up the accreditation process.
- 4.5. 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.
- 4.6. 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.
- 4.7. A clinical laboratory, whose accreditation is revoked, suspended or voluntarily withdrawn from the accrediting body, shall immediately cease clinical laboratory services and the HRS shall be instantly notified in writing.
- 4.8. HRS is authorized to conduct an investigation in order to reveal reasons for the revocation or suspension, in collaboration with the accrediting body.
- 4.9. HRS staff or any other authorized personnel are authorized to conduct onsite visits to the clinical laboratories to check their accreditation status. They may request documents to support the validity of the accreditation certificate.

4.10. Clinical laboratory shall not mislead the public by falsely advertising the accreditation status.

4.11. Clinical laboratories shall have a business continuity plan in case of service disruption.

4.12. All clinical laboratories shall comply with the clinical laboratory accreditation requirements as mentioned in **Appendix 1**.

5. References

- ILAC MRA Signatory Search (2017). ILAC. <http://ilac.org/signatory-search/> [Accessed 26th February 2017].
- R101-General Requirements: Accreditation of ISO/IEC 17025 Laboratory (2016). American Association of Laboratory Accreditation <https://a2la.org/requirements/req17025.pdf> [Accessed 6th February 2017].

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 process	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