Document Type: Policy	**Code:** DHA/HRS/HPSD/HP-12	**Version Number:** 5.1
Document Title: Clinical Laboratory Accreditation	**Issue Date:** 27/03/2023	**Effective Date:** 27/05/2023
Ownership: Health Regulation Sector		
Applicability: All new and licensed clinical laboratories under the Dubai Health Authority (DHA) jurisdiction mentioned below: • Free standing clinical laboratories; • Clinical Laboratories within Polyclinics; • Clinical laboratories within Diagnostic Centers; • Clinical laboratories within Hospitals and Day Surgical Centers; • Blood banks; • Assisted Reproductive Technology (ART) Laboratories within IVF centres and • Histocompatibility & Immunogenetics Laboratory (HLA) Labs. • Cord blood banks that perform cord blood donor management and collection, processing, testing, cryopreservation, storage, listing, search, selection, reservation, release, and distribution.		

1. Purpose:

1.1. Align with the Dubai Health Strategy 2021–2071.

1.2. Make Dubai a model for value-based healthcare.

1.3. Pioneer a human-centred system that promotes trust, safety and quality of care for patients and their families.

1.4. Ensure highest standards of practice and safe and quality clinical laboratory services are provided in health facilities licensed under the jurisdiction of DHA.

1.5. Ensure all clinical laboratories licensed under DHA jurisdiction are accredited.

2. Scope:

2.1. Clinical Laboratory Accreditation.

3. Definitions:

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

Health Facility: Place permitted to provide health examinations for patients and help for diagnosis, treatment, nursing or admission for cure and recovery or any other related medical procedures relating to treatment or rehabilitation post treatment.

Healthcare Professional: is a natural person who is authorized and licensed by the DHA to practice any of the healthcare professions in the Emirate of Dubai.

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 : Association for the Advancement of Blood & Biotherapies

A2LA : American Association for Laboratory Accreditation

ART : Assisted Reproductive Technology

ASHI : American Society For Histocompatibility & Immunogenetics

CAP : College of American Pathologists

CLIA : Clinical Laboratory Improvement Amendments

CMS : Centers for Medicare & Medicaid Services

DHA : Dubai Health Authority

DAkkS : Deutsche Akkreditierungsstelle GmbH

EIAC : Emirates International Accreditation Centre

ENAS : Emirates National Accreditation System

FACT : Foundation for the Accreditation of Cellular therapy

HHS : Department of Health and Human Services

HLA : Histocompatibility & Immunogenetics Laboratory

HRS : Health Regulation Sector

ILAC : International Laboratory Accreditation Cooperation

IVF : In Vitro Fertilization

ISO : International Organization for Standardization

JCI : Joint commission International Standards

MRA : Mutual recognition arrangement

NEQAS : National External Quality Assessment Service

4. Policy Statement

4.1. All clinical laboratories under DHA jurisdiction must take the necessary measures to obtain the International Accreditation Certificate within a period not exceeding two years since the issuance of this policy.

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

4.2.1. Accreditation bodies that are full members with the International Laboratory Accreditation Cooperation (ILAC) and signatories to the ILAC MRA (Mutual Recognition Arrangement) in the scope of medical testing ISO 15189; such as and

not limited to:

a. Emirates National Accreditation System (ENAS)

b. Emirates International Accreditation Centre (EIAC) in UAE.

c. Deutsche Akkreditierungsstelle GmbH (DakkS) in Germany.

d. Accreditation Canada Diagnostics.

4.2.2. Accreditation bodies that are approved by Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS) in United States of America, with deeming authority under the Clinical Laboratory Improvement Amendments (CLIA); such as not limited to:

a. College of American Pathologists (CAP).

b. American Association for Laboratory Accreditation (A2LA).

c. The Joint commission International (JCI) Laboratory Standards.

4.2.3. The American Society For Histocompatibility & Immunogenetics (ASHI) Accreditation.

a. For accreditation of HLA-Labs for Human organ, tissue transfer and transplantation programs.

4.2.4. Association for the Advancement of Blood & Biotherapies (AABB)

a. For facilities and laboratories dealing with blood donors, components preparation and screening, umbilical cord donation, stem cells and cell therapy.

4.2.5. The Foundation for the Accreditation of Cellular therapy (FACT).

a. For facilities that prepare cells derived from cord blood for administration, and

the clinical units that receive and administer them.

4.2.6. Related activities to the clinical lab:

a. The providers of proficiency testing activities (external quality assessment) shall be accredited by ISO/IEC 17043 General requirements for proficiency testing. Example: NEQAS in UK.

b. The reference materials provider should be accredited with ISO/IEC 17034 General requirements for the competence of reference material producers.

c. The biobanking activities should be accredited with ISO 20387 Biotechnology Biobanking General requirements for biobanking.

d. The sample collection centers are recommended to be accredited with ISO/TS 20658 Medical laboratories Requirements for collection, transport, receipt, and handling of samples.

4.3. Clinical laboratories that obtain the license after the issuance of this policy must adjust their conditions in accordance with its provisions, within a period of two years from the date of obtaining the license and at the end of this period, obtaining the international health accreditation certificate is a requirement for renewing the license.

4.4. Clinical Laboratories that where licensed prior to the issuance of this policy must initiate accreditation process in line with their service as mentioned above and submit a proof in writing to Health Regulation Sector (HRS) and HRS will follow up the accreditation process.

4.5. The accreditation shall be given general to all sections/units of the lab and not to be restricted to specific one.

4.6. Clinical Laboratories shall upload their accreditation certificate on the facility's Sheryan account.

4.7. 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.

4.8. 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.

4.9. A clinical laboratory, with a revoked, suspended or voluntarily withdrawn from the accrediting body will inform HRS in writing.

4.10. HRS is authorized to conduct an investigation in order to reveal reasons for the revocation or suspension of the facility's accreditation in collaboration with the accrediting body.

4.11. 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.

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

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

4.14. 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. Become an AABB accredited facility. Accreditation phases and expectations. Available on: Standards & Accreditation (aabb.org) (Accessed on 06/03/2023).

5.2. College of American Pathologist (2018). Laboratory Accreditation. Guide to CAP Accreditation. Available online on: 2018-guide-to-accreditation.pdf (cap.org) (Accessed on 06/03/2023).

5.3. Hindawi S (2009). Systems for accreditation in blood transfusion services. International Society of Blood Transfusion ISBT Science Series. Available online on: Systems for accreditation in blood transfusion services - Hindawi - 2009 - ISBT Science Series - Wiley Online Library (Accessed on 06/03/2023).

5.4. The Ministerial Resolution No. (164) for the year 2021 regarding medical laboratories obtaining the international Lab Accreditation Certificate.

5.5. Zima Tomas (2017). Accreditation of Medical Laboratories - System, Process, Benefits for Labs. Available online on: : Accreditation of Medical Laboratories - System, Process, Benefits for Labs - PubMed (nih.gov) (Accessed on 06/03/2023).

5.6. National Health Services (NHS) in United Kingdom.: Guidance on Governance, quality assurance and accreditation. Available online on: Guidance on Governance, quality assurance and accreditation. (Accessed on 06/03/2023)

5.7. International Laboratory Accreditation Cooperation (ILAC). Information for Regulators. Available online at: Information for Regulators. (Accessed on 06/03/2023)

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 two years 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 ➢ 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