QUALITY OVERSIGHT, AND ACCREDITATION OF CLINICAL LABORATORIES

Policy and Procedure

Department: QID

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POLICY AND PROCEDURE – QUALITY OVERSIGHT, AND ACCREDITATION OF CLINICAL LABORATORIES

INTRODUCTION

Laboratory testing involves multistep processes that are susceptible to multiple sources of error. These errors can lead to significant result variability and decreased accuracy, which in turn can potentially lead to incorrect diagnosis and inappropriate treatment. High quality laboratory results are required to provide reliable clinical data that can be used for evidence-based decision making to improve care of patients.

Laboratory accreditation is a widely accepted process of evaluation of a laboratory's quality, performance, reliability and efficiency. It is a means to promote and enforce better quality in laboratory testing and to ultimately reduce testing errors. Accreditation also increases the credibility of the results and services delivered by a laboratory through providing recognition that it is compliant with quality and competence standards considered necessary for accurate, reliable and safe testing. The value of accreditation lies in promoting the delivery of reliable results for patient management or generation of reliable data for critical public health interventions.

	1. PURPOSE:
1.1	The purpose of this Policy is to define the minimum Quality Oversight and Accreditation Requirements for Clinical Laboratories licensed by Dubai Healthcare City Authority (DHCA).

	2. APPLICABLE TO:
2.1	This Policy is applicable to all Licensed Healthcare Operators (HCOs) which provide clinical laboratory services including Diagnostic Laboratory Services, Cord Blood Banks, Blood Banks, and other laboratories which provide clinical laboratory support or services.
2.2	This Policy is not applicable to medical laboratories that are involved in the production of products including biological products.
2.3	The quality oversight processes defined in this Policy shall be applied by the Quality Improvement Department (QID) of Dubai Healthcare City Regulatory (DHCR) and the DHCR relevant departments.
2.4	This Policy must be read in conjunction with all applicable Dubai Healthcare City Authority (DHCA) regulations, standards and policies.

	3. POLICY STATEMENTS:
3.1	Each HCO that provides clinical laboratory services is required to comply with the requirements as specified in this Policy and in accordance with other relevant DHCA regulations, Standards, and policies.
3.2	Each licensed HCO offering clinical laboratory services is to obtain accreditation for the laboratory services from a DHCR approved accreditation organization within one (1) year of commencing services in the laboratory and shall ensure maintaining accreditation for all its services all times throughout its operations.

3.3	Each HCO shall allocate staff and resources as necessary to effectively implement and maintain full compliance with this policy.
3.4	It is the responsibility of the HCO to take all necessary action in preparation for the assessments and accreditation requirements as described in this Policy and to ensure full compliance with this Policy.
3.5	The HCO is responsible for taking actions based on reports or recommendations from DHCR following the assessments.
3.6	It is the responsibility of the HCO to communicate with the selected accreditation agency to apply for, arrange and finance such accreditation service as required by this Policy.
3.7	It is the responsibility of the relevant DHCR Departments to facilitate and perform the assessments as described and to ensure the HCO is and remains compliant to the requirements as defined in this Policy and all other applicable rules and regulations.

4. PROCEDURE SEQUENCE	
4.1	**Pre-Operating Assessment**
4.1.1	Each HCO that provides clinical laboratory services shall undergo a pre-operating assessment prior to commencing operations of their facility. The pre-operating assessment is intended to ensure that all clinical, technical and non-clinical operating requirements deemed necessary for the safe initial operation of the HCO are met.
4.1.2	The pre-operating assessment is conducted by relevant DHCR Departments including QID.
4.1.3	Each HCO that provides laboratory services must demonstrate compliance with the pre-operating assessment requirements as set by DHCR and in accordance with local rules, regulations, standards and policies.
4.1.4	Assessment of the requirements will be relative to the anticipated scope of services of the clinical laboratory that the HCO intends to operate at the commencement of the issuance of the Clinical Operating Permit (COP). Only those services which are assessed and satisfactorily meet the requirements will be allowed to operate following the issuance of the COP.
4.1.5	As a requirement of the pre-operating assessment and prior to receiving approval for issuance of the COP, evidence must be presented to QID that the HCO has an agreement with a DHCR approved accrediting organization to undergo survey to achieve accreditation of the clinical laboratory (see 4.3).
4.1.6	The relevant Departments of DHCR may allow conditional approval of the pre-operating assessments subject to remediation of any non-conformances or various alterations or changes being made by the HCO within a set period of time. Such conditions may also require subsequent on-site visits to ensure remediation or required changes have been completed successfully (see 4.2.1).
4.2	**Post-Operational On-Site Visit**

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4.2.1	Following the issuance of the COP and commencement of services by the HCO, post-operational on-site visits may be conducted by QID to ensure continued levels of quality and safety and to assess any corrective actions or improvements that were required following the pre-operational assessment.
4.2.2	If the HCO wishes to add new services or increase the scope of services of the clinical laboratory the HCO is required to notify DHCR and obtain prior approval. DHCR Departments, including QID conduct additional assessments as necessary prior to approving the new services or increasing the scope of existing services.
4.2.3	At the completion of six (6) months of operation a planned on-site visit to the clinical laboratory is conducted by the QID. The purpose of the on-site visit is to conduct an assessment to ensure continued levels of quality and safety and to evaluate progress towards meeting the standards of the selected approved accreditation organization.
4.2.4	If following an on-site assessment, the QID identifies a serious and imminent risk to the health or safety of its employees, patients or the public, the QID shall notify CPU immediately as per clause 125 of the DHCA HCO Regulation number (4) of 2013.
4.2.5	If any findings are identified during any assessment conducted, remedial action may be proposed by the QID for implementation within a specific time period. The QID may conduct a second on-site visit of the HCO; to follow up on non-conformances and recommendations provided at any time deemed necessary.
4.2.6	If the identified findings continue to exist or if the QID is not satisfied that the breaches have been rectified, then as per clause 124 of the DHCA HCO Regulation number (4) of 2013 the QID may notify CPU.
4.3	**Accreditation of Clinical Laboratory Services**
4.3.1	The following accreditation organizations are recognized and approved by DHCR to survey and award accreditation to laboratories in DHCC: 4.3.1.1 College of American Pathologists (CAP); 4.3.1.2 Accreditation Canada; 4.3.1.3 Joint Commission International; 4.3.1.4 Emirates International Accreditation Centre (ISO 15189) 4.3.1.5 Accreditation against ISO 15189 Standards by other International Laboratory Accreditation Cooperation (ILAC) registered accreditation organizations with prior approval of the Quality Council. *(Examples include CPA - UK, NATA - Australia)*; 4.3.1.6 American Association of Blood Banks; 4.3.1.7 Foundation for the Accreditation of Cellular Therapy.

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4.3.2	When applying or registering for accreditation with the accrediting organization each HCO must include all services offered by the clinical laboratory in the scope of accreditation of the application. And must send a copy of the completed application to QID.
4.3.3	The QID at its discretion may assign members of its staff in the role of observers to accompany the accrediting organization's survey team during the accreditation visit. Each HCO shall facilitate the presence of the QID members during the survey of the DHCR approved accrediting body.
4.3.4	The QID will not interfere before or during the accrediting organization's survey. However, the QID reserves the right to contact the HCO and/or accrediting organization after the completion of the survey regarding some observations or issues identified by the QID observers during the accreditation survey.
4.3.5	If following the survey by the accreditation organization, the HCO fails to achieve accreditation for all or part of the clinical laboratory services then those services not accredited are to be discontinued. Approval to recommence all or part of the clinical laboratory services not accredited will be subject to the approval of QID with input and recommendation of relevant DHCR Departments. All services shall again be subject to successful accreditation within a time frame set by DHCR.
4.3.6	The HCO is required to forward a copy of the complete report of the accreditation survey result including any non-conformances and corrective actions required within 30 calendar days, and when available a copy of the certificate of accreditation including details of the services included and the scope of the accreditation to QID
4.3.7	The QID may assess the implementation of corrective actions taken for any outstanding non-conformances reported by the accrediting organization and the successful remediation resulting from Strategic Improvement Plans or reported corrective action plans.
4.3.8	If for any reason the clinical laboratory fails to retain all or part of its accreditation then similar to 4.3.5 above, those services not accredited are to be discontinued. Approval to recommence all or part of the clinical laboratory services not accredited will be subject to the approval of QID with input and recommendations from relevant DHCR Departments. All services shall again be subject to successful accreditation within a time frame set by QID.
4.3.9	DHCR shall verify that each licensed HCO, after achieving its first accreditation as per 4.3.1, has valid and current accreditation of all services offered by its clinical laboratory at all times during its operations. The verification may be performed as part of the Comprehensive Assessment Survey or as a separate focused assessment. Failure to maintain valid and current accreditation of all clinical laboratory services at all times of its operations may lead to exclusion or removal of clinical laboratory services from the approved services of the COP.
4.3.10	If the HCO fails in obtaining or maintaining accreditation from the DHCR approved accrediting organization within the set timeframe then as per clause 136 of the DHCA HCO Regulation number (4)

	of 2013 this may serve as grounds for the Fitness to Practice Panel to impose conditions or restrictions, suspending or revoking the HCO's COP in full or in part.
4.3.11	Should any DHCC clinical laboratory decide to send specimens to another clinical laboratory whether within UAE or abroad then the clinical laboratory receiving the specimen has to be an accredited clinical laboratory. It is the responsibility of the DHCC clinical laboratory to ensure that the clinical laboratory receiving the specimen maintains its accreditation during the referral period of the specimens. HCO is responsible to maintain the copy of the contracted lab's valid accreditation certificate.

5. COMMUNICATION (check all that apply)	
☒	Announcement
☒	Awareness
☐	Training
☐	On the Job Training

6. DEFINITIONS	
6.1	**Clinical Laboratory:** 6.1.1 Place where tests are done on clinical specimens for the purpose of getting information about the health of a patient as pertaining to the diagnosis, treatment; and prevention of disease, and for the purpose of health assessment; 6.1.2 Place where umbilical cord blood is stored for future use; and a 6.1.3 Place where blood is collected from donors, typed, separated into components, stored, and prepared for transfusion to recipients.
6.2	**COP:** Clinical Operating Permit
6.3	**CPU:** Customer Protection Unit
6.4	**DHCA:** Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
6.5	**DHCC**: Dubai Healthcare City
6.6	**DHCR:** is the regulatory arm of Dubai Healthcare City Authority. An independent licensing and regulatory authority for all healthcare providers, medical, educational and other business operating within DHCC.
6.7	**Healthcare Operator (HCO):** in DHCC, this is an all-inclusive term meaning a hospital, clinic, laboratory, pharmacy or other entity providing healthcare, engaging in one or more clinical activities
6.8	**Healthcare Professional (HCP):** in DHCC, a licensed HCP is Healthcare Professional holding a License duly issued by the DHCC Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable practice rules

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6.9	**ISO**: International Organization for Standardization.
6.10	**QC:** Quality Council.
6.11	**Quality Improvement Department (QID):** The QID is a department within DHCR. It is responsible for accreditation of Outpatient Clinics and the implementation of the quality oversight processes, policies, and procedures for the DHCA licensed Healthcare Operators.

	7. RELATED REFERENCES / DOCUMENTS
7.1	DHCC Governing Regulation No. 1 of 2013
7.2	DHCC Healthcare Operators Regulation No. 4 of 2013
7.3	Global Health Laboratories https://globalhealthlaboratories.tghn.org/articles/laboratory-accreditation/
7.4	The Clinical and Laboratory Standards Institute (CLSI). QMS04 Third Edition-June 2016 https://clsi.org/media/1520/qms04ed3_sample.pdf
7.5	Medical laboratories — Particular requirements for quality and competence- International Organization for Standardization (ISO)- ISO 15189:2012(E) https://www.iso.org/standard/56115.html
7.6	Clinical Laboratory Improvement Amendments (CLIA). Accessed on 22-April-2020: http://www.aafp.org/practice-management/regulatory/clia.html
7.7	Med terms. Accessed on 22-April-2020: http://www.medterms.com/script/main/art.asp?articlekey=13184
7.8	Commission On Laboratory Accreditation Laboratory, Accreditation Program Atomic Pathology Checklist-College of American Pathologists (CAP)-2018 https://www.cap.org/laboratory-improvement/accreditation

REVISION HISTORY

S No	Summary	Amend Type*	Page	Issue No	Issue Date
1					
2					
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***Amend Type: New / Add / Modify / Cancel**