CLINICAL LABORATORY SERVICES

STANDARD

Department: Quality Improvement

Document Identifier: DHCR/SD/HCO/012/01

STANDARD FOR CLINICAL LABORATORY SERVICES

INTRODUCTION

Laboratory services are an essential component of quality healthcare delivery at every level of the healthcare system. Laboratory services are required to support clinical diagnosis, rationalize and monitor treatment/therapy, for the screening for epidemiological purposes, surveillance and control of diseases of public health importance, and to provide early warning of disease outbreaks.

A Diagnostic Clinical Laboratory is a laboratory where tests are usually done on clinical specimens; body fluids such as blood, urine, sputum, stool, cerebrospinal fluid (CSF), peritoneal fluid, pericardial fluid, and synovial fluid, as well as other specimens, in order to obtain information about the health of a patient as pertaining to the diagnosis, treatment, and prevention of disease.

Diagnostic Clinical Laboratories may provide different investigations as follows;

1. Clinical Pathology: Hematology, Microbiology and Clinical Biochemistry.
2. Anatomic Pathology: Histopathology
3. Clinical Microbiology: Bacteriology, Mycobacteriology, Virology, Mycology, Parasitology, Immunology, Serology
4. Clinical Biochemistry: Biochemical analysis, Hormonal assays, Toxicology etc.
5. Molecular Diagnostic/ Molecular Biology and Cytogenetics.

A Non-Diagnostic Medical Laboratory may include:

1. Stem Cell Processing/Storage Centre; an operator that provides facilities and services for the procurement, testing, processing, preservation and storage of human cord blood, bone marrow and peripheral blood derived stem cells.
2. Therapeutic Biological Product Manufacturing Laboratory; for the manufacture of biological products for therapeutic use, excluding human cord blood, bone marrow and blood derived stem cells.
3. Blood Bank; as a part of the main laboratory is a section where approved blood or its components is typed, cross matched, and stored for future transfusion no blood donation is permitted.
4. Assisted Reproductive Technology (ART) laboratories.

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1. PURPOSE	
1.1	This standard and the supporting documents (*appendix 1,2 and 3)* defines the minimum requirements including licensing and service specifications to ensure acceptable minimum levels of quality, performance, safety and reliability for the use and management of Laboratory activities within Dubai Healthcare City (DHCC).
1.2	This standard and the supporting documents (*appendix 1,2 and 3)* address issues which are generic across the laboratories such as qualified personnel, scope of practice and service limitations for the provision of Laboratory activities in DHCC.

2. SCOPE OF APPLICATION	
2.1	This Standard is applicable to all Healthcare Operators and Healthcare Professionals licensed under Diagnostic or Non-Diagnostic Laboratory within DHCC.
2.2	This standard is applicable to all healthcare professionals and healthcare organizations providing laboratory services.

3. STANDARD

3.1 **LICENSURE OF LICENSED HEALTHCARE OPERATOR (HCO) PROVIDING LABORATORY SERVICES / QUALIFIED PERSONNEL**

3.1.1 Clinical Laboratory license shall be issued on three main categories:

3.1.1.1 Licensed Hospital Laboratory; laboratories which are part of a hospital and receive samples from the same hospital, as well, as other healthcare operators and may act as a reference laboratory.

3.1.1.2 Diagnostic clinical or medical laboratory; standalone laboratories that may receive clinical samples from practitioners, or clinical research sites for analysis.

3.1.1.3 Licensed Non-Diagnostic Medical Laboratory; for Stem cell processing and storage, Cryopreservation, Blood Bank, Embryology, Therapeutic Biological Product Manufacturing, etc.

3.1.2 Each Healthcare Operator providing Laboratory Services shall comply with this standard, equivalent accreditation standards, and other applicable DHCR regulations, standards and policies.

3.1.3 Each Healthcare Operator providing Laboratory Services shall appoint appropriately qualified Licensed Healthcare Professionals, as per DHCA Healthcare Professionals Licensure requirements, to deliver the services consistent with type of services provided.

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3.1.4 All such Licensed Healthcare Professionals shall at a minimum hold a current and valid certification in Basic Life Support (BLS).

3.1.5 All qualified personnel must undergo a color blindness Test to determine whether they are able to verify urine dipstick results.

3.1.6 Each Healthcare Operator shall have a documented process for determining appropriate staffing needs, by number and type of staff for the provision of Laboratory activities.

3.1.7 The leadership of the HCO must appoint a designated Laboratory Clinical Director.

3.1.7.1 The Laboratory Director in an independent Clinical Laboratory or laboratory in hospital setup shall be a DHCC licensed pathologist (clinical Pathologist or Anatomical Pathologist), which may be appointed on a full time or part time basis.

3.1.7.2 In case of a laboratory with specialized scope of services for e.g. a genetics laboratory; a DHCA licensed Clinical Pathologist with experience in Genetics or a Clinical Laboratory Scientist (Medical Laboratory Technologist with Doctoral degree) in Genetics and appropriate training and experience may serve as the Laboratory Director.

3.1.8 The Laboratory Director shall act as a Clinical Director/ Manager; who is overall responsible in accordance with all applicable regulations, rules, policies and standards of DHCR for all laboratory operations, applicable accrediting bodies, including the following:

3.1.8.1 Develop a clear strategic plan which should include written values, vision and mission at the operational level to assist all staff in the organization to work towards achieving common goals.

3.1.8.2 Develop the laboratory governance.

3.1.8.3 Ensure that the laboratory meets all federal and local laws and regulations.

3.1.8.4 Assures that the laboratory provides for the type and scope of service to meet the needs of ordering clinicians and the patient population served.

3.1.8.5 Ensures that there are adequate numbers of appropriately qualified and competent technical staff including appointing a Quality and Safety Officer.

3.1.8.6 Ensures qualified and trained specialists are available to analyze specialized tests, at least twice a year.

3.1.8.7 Oversee delineation of tasks; coordinating the proficiency and update

	of clinical knowledge and skills, education and training; monitoring s staff competency and clinical evaluation of the laboratory staff. 3.1.8.8 Provide a safe and adequate laboratory environment and facilities. 3.1.8.9 Plan and provide adequate resources for the provision of laboratory services, essential equipment and ensuring its functionality and maintenance. 3.1.8.10 Ensure an adequate supply of laboratory chemicals, reagents, test kits and supplies. 3.1.8.11 Establish an effective system for documentation and recordkeeping. 3.1.8.12 Establish and monitor an effective quality management system (QMS) including internal, and external quality control, covering all aspects of laboratory operations; proficiency testing program, developing, implementing, approving and maintaining standards, policies and procedures. 3.1.8.13 Ensure adequate communication with laboratory users, including patients and clients. 3.1.8.14 Provide for required services either directly, or through referral to another laboratory and assure the consistent performance of reference and contract laboratory services in accordance with DHCR laboratory standards, when they are used. 3.1.8.15 Establish practices that respect the needs of patients, including providing privacy, security, and confidentiality of information. 3.1.8.16 Monitor turnaround time, and other analytical parameters. 3.1.8.17 Manage customer complaints and monitor patient satisfaction. 3.1.8.18 Oversee and verify tests results as appropriate. 3.1.8.19 Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.
3.2	**LABORATORY QUALITY MANAGEMENT SYSTEM (QMS)** 3.2.1 All laboratories must develop detailed Standard Operating Procedures (SOPs) which should include all laboratory analytical and operational procedures according to the scope of services provided by the facility. 3.2.2 The SOPs must be documented using a step-by-step approach and all procedures must be subject to a quality monitoring process.

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3.2.3 Written SOPs and Policies and Procedures shall address all aspects of document management, including but not limited to; document and record management; development, review, archiving, and confidentiality.

3.2.4 The laboratory director shall develop a quality manual, this manual should contain all documents, policies and procedures in current use.

3.2.5 The manual should include:

- 3.2.5.1 Organizational structure
- 3.2.5.2 Personnel management; Professionals' recruitment, job descriptions, training and Professional expertise and competency requirements
- 3.2.5.3 List of examinations/tests
- 3.2.5.4 Equipment management;
  - 3.2.5.4.1 Equipment selection and procurement
  - 3.2.5.4.2 Equipment commissioning
  - 3.2.5.4.3 Inventory of instruments
  - 3.2.5.4.4 Periodic technical assessment and validation of equipment
  - 3.2.5.4.5 Records of repair and preventive maintenance
  - 3.2.5.4.6 Calibration and functioning of all instruments
  - 3.2.5.4.7 Decontamination
  - 3.2.5.4.8 Decommissioning
- 3.2.5.5 Reagents, consumables and materials management;
  - 3.2.5.5.1 Selection and procurement
  - 3.2.5.5.2 Inventory of reagents
  - 3.2.5.5.3 Quality control
- 3.2.5.6 Quality Control (QC) program
  - 3.2.5.6.1 Quality assurance (QA) systems including Internal and external quality assessment schemes (EQAS).
  - 3.2.5.6.2 All Licensed Laboratories must enroll and participate in Proficiency Testing programs and surveys through an Approved Accreditation Agency.
  - 3.2.5.6.3 Each Licensed Laboratory must treat all Proficiency Testing Samples in the same manner as Patient Samples.
  - 3.2.5.6.4 For those Tests for which Proficiency Testing programs are not available, each Licensed Laboratory is responsible for performing internal Proficiency Testing for each Test respectively.
  - 3.2.5.6.5 Internal and External audits must be included in the QC program.

3.2.5.7 Infection control and Environmental Health and safety management

3.2.5.8 Information Management

3.2.5.9 Customer service and Customer Focus improvement processes

3.2.5.10 Outsourcing Clinical Laboratory Services

3.2.5.11 Nonconforming Event Management

3.2.5.12 Facilities and Laboratory Safety

3.2.5.13 Waste management including an emergency contingency plan in case of a spill or exposure.

3.2.5.14 Management of samples, specimens and biological material including;

- 3.2.5.14.1 Specimen collection, labelling and transport
- 3.2.5.14.2 Specimen/sample receiving and processing (detailed test by test);
- 3.2.5.14.3 Specimen/sample handling, preparation and storage;
- 3.2.5.14.4 Sample retention and disposal;
- 3.2.5.14.5 Minimizing the risk of interchange of Samples and subsamples;
- 3.2.5.14.6 Minimizing risk to ensure the safety of the specimen, collector, carrier, the general public and the receiving Laboratory.

3.2.5.15 Tests and Results;

- 3.2.5.15.1 The methodology for performing the tests
- 3.2.5.15.2 Turnaround times
- 3.2.5.15.3 Results validation and reporting
- 3.2.5.15.4 Quality control limits for each test, reference ranges, and reportable ranges to ensure that when patient results are reported, they reflect actual normal and abnormal conditions.

3.2.5.16 Laboratory Decontamination

3.2.5.17 Nonconforming Event Management

- 3.2.5.17.1 Correction, and prevention of nonconforming events in all aspects of the quality management system including pre-examination, examination and post-examination processes.

3.2.5.18 Continual Improvement

3.2.5.19 Health safety and environment plan to ensure safety of the patients, staff and visitors

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3.3	**HEALTH INFORMATION MANAGEMENT** 3.3.1 Medical records must be kept confidential and comply with the requirements of the DHCC Health Data Protection Regulation No. 7 of 2008. Medical records may only be released in accordance with the provisions outlined in the DHCC Health Data Protection Regulation. 3.3.2 Licensed Laboratories must comply with the DHCC Medical Records Policy. 3.3.3 Medical records must contain the specific data elements required by the Healthcare Information Reporting and Analysis System (HIRAS) which are detailed in the DHCC Minimum Data Requirement Rule2008. 3.3.4 Records related to Patient testing must be kept for at least ten (10) years following the date of testing, or for such other time as may be required by the Licensing Board. Such records shall include, at a minimum, Test order, Test report, specimens, blocks, slides and all documentation created during the testing process.
3.4	**PATIENT RIGHTS AND RESPONSIBILITIES** 3.4.1 Each Healthcare Operator licensed to provide laboratory services shall provide patients and families with information regarding the DHCA Patients' Rights and Responsibilities in accordance to Schedule Two of the DHCA Governing. 3.4.2 Regulation Number (1) of 2013.This information shall be displayed in English and Arabic throughout the facility for patients and visitors to review Each Healthcare Operator providing laboratory services shall provide processes that support patients' and families' rights during care. 3.4.3 Informed Consent shall be obtained as applicable through a process defined by each Healthcare Operator providing laboratory services and carried out by trained staff in a manner and language the patient can understand in accordance with the DHCR Informed Consent Policy. 3.4.4 Legal guardians, in the case of minors or legally incompetent adult, shall be informed of and agree to the laboratory service provided.
3.5	**MINIMUM FACILITY REQUIRMENTS** 3.5.1 Each Facility shall comply with the minimal facility requirements of the most current FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities, and in accordance to its approved class. 3.5.2 The design of each facility offering laboratory services shall make provision for accessible, efficient, and safe care in a secure, supportive and functional environment.

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	3.5.3 Each laboratory shall provide suitable infrastructure according to the services provided by the laboratory. The basic infrastructure shall include: 3.5.3.1 Reception room/area 3.5.3.2 Phlebotomy room 3.5.3.3 Specimen collection room/area, with nearby toilet 3.5.3.4 Laboratory Work/Testing area 3.5.3.5 Specimen/Sample/slide storage facility including cold storage where applicable 3.5.3.6 Area for the collection of medical waste, general storage for supplies and equipment in addition to a storing area/cabinet for hazardous materials 3.5.3.7 Autoclave and Sterilization Areas 3.5.3.8 Fume hoods 3.5.3.9 Biological safety cabinets 3.5.3.10 Eye wash station 3.5.3.11 Water supply suitable for analytical purposes 3.5.3.12 Adequate power supply 3.5.3.13 Adequate ventilation, climate control and lighting arrangements 3.5.3.14 Separate room/area for meetings/administrative work 3.5.3.15 Separate facilities/area for staff for eating and storing food, drinks etc. 3.5.3.16 Communication facility with referral centers 3.5.3.17 Additional infrastructure facilities may be added for special tasks
3.6	**QUALITY OVERSIGHT AND ACCREDITATION** 3.6.1 Each licensed Healthcare Operator providing laboratory services shall be subject to this standard, the DHCR quality oversight policies, and other applicable DHCA regulations, standards and policies. 3.6.2 In addition to satisfying the other provisions of this standard, each licensed HCO offering clinical laboratory services is to obtain accreditation for the laboratory services from a DHCR approved accreditation organization as appropriate to its scope of laboratory services within one (1) year of commencing services in the laboratory and shall ensure maintaining accreditation for all its services all times throughout its operations. The following accreditation organizations are recognized and approved by DHCA to survey and award accreditation to laboratories in DHCC: 3.6.2.1 College of American Pathologists (CAP); 3.6.2.2 Accreditation Canada (CA);

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	3.6.2.3 Joint Commission International Accreditation, Standards for Laboratories (JCIA); 3.6.2.4 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); 3.6.2.5 American Association of Blood Banks; 3.6.2.6 Foundation for the Accreditation of Cellular Therapy; 3.6.3 Each Licensed Laboratory must, on an annual basis, notify DHCR as to the accreditation and Proficiency Testing program in which it is participating. 3.6.4 The Licensing Department shall not renew the Clinical Operating Permit of a Licensed Laboratory if such Laboratory and its services are not accredited at the time of such renewal by an approved accreditation organization. 3.6.5 Prior to commencing the laboratory activities each Licensed Healthcare Operator shall have in place a documented quality manual which shall include all the required written policies and procedures including, but not limited to, electronic quality control, internal quality control, proficiency testing and external quality control procedures to monitor and evaluate the quality of the analytical testing process of each method it employs. 3.6.6 The manual should include written policies and procedures required for safe and effective practices in compliance with the accreditation standards of the approved accreditation agency and all other applicable regulations, policies and standards. Written documents, including policies, procedures, and programs shall be managed in a consistent and uniform manner. 3.6.7 The policies and procedures shall include provision for annual / biennial review and revision as necessary as well as for provision of training of all staff of the facility, on the content of the policies and procedures. 3.6.8 Laboratories shall establish quality indicators to monitor and evaluate performance of its processes. Management should ensure the review of SOPs reported incidents and the overview of staff training and continuing professional development. Results shall be used to ensure continuous improvement. 3.6.9 Laboratories shall conduct internal audits and take appropriate corrective actions to close any identified gap or nonconformity in performance such as revision of SOPs, further staff training, education and support.

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4	APPENDICES
1	Guidelines on Specific Services
2	Supplementary Guidelines
3	Record Retention: Patient Results, Records and Materials

5	DEFINITIONS
5.1	**Accreditation:** procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks.
5.2	**Assisted Reproductive Technology (ART):** A range of methods used to circumvent human infertility by insemination or fertilization of the oocytes in the laboratory environment. These techniques include but are not limited to the following procedures: Intrauterine Insemination (IUI), In vitro Fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI), Gamete Intra-fallopian Transfer (GIFT), Zygote Intrafallopian Transfer (ZIFT).
5.3	**Blood Banks:** a center where blood gathered as a result of blood donation is stored and preserved for later use in blood transfusion before which proper testing is performed (to reduce the risk of transfusion related adverse events). The term "blood bank" typically refers to a division of a hospital where the storage of blood product occurs however, or it may refer to an individual center, where collection storage and testing takes place.
5.4	**Cryo-preservation**: is a process where organelles, cells, tissues, extracellular matrix, organs or any other biological constructs susceptible to damage caused by unregulated chemical kinetics are preserved by cooling to very low temperatures (typically −80 °C using solid carbon dioxide or −196 °C using liquid nitrogen.
5.5	**Cytogenetics:** Is the study of chromosome structure, number, location, abnormalities and their relationship to human genetic diseases.
5.6	**DHCA:** The Dubai Healthcare City Authority established under Article (4) of the Law, and comprises the Chairperson, the DHCC Board of Directors and the Executive Body.
5.7	**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.
5.8	**DHCC**: (Dubai Healthcare City): means the Dubai Healthcare City established in the Emirate of Dubai under Resolution No. (9) of 2003.
5.9	**Diagnostic Clinical laboratory**: Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for

	the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.
5.10	**External Proficiency Test:** The use of inter-laboratory comparisons to determine the performance of a laboratory with respect to individual test(s), measurement(s) or observation(s), and to monitor a laboratory's continuing performance.
5.11	**FGI:** Facility Guidelines Institute, USA.
5.12	**Licensed Healthcare Operator (HCO):** A hospital, clinic, laboratory, pharmacy or other entity providing Healthcare Services in DHCC, holding a Clinical Operating Permit duly issued by DHCR electronically generated in accordance with the Healthcare Operators Regulation and the applicable Rules, Standards and Policies.
5.13	**Licensed Healthcare Professional (HCP):** A natural person engaged in a Healthcare Profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies.
5.14	**Medical Laboratory Technologist or Clinical Laboratory Scientist (CLS)**: Is a healthcare professional who performs chemical, hematological, immunologic, histopathological, cytopathological, microscopic, and bacteriological diagnostic analyses on body fluids such as blood, urine, sputum, stool, cerebrospinal fluid (CSF), peritoneal fluid, pericardial fluid, and synovial fluid, as well as other specimens. Medical laboratory scientists work in clinical laboratories at hospitals, reference labs, biotechnology labs and non-clinical industrial labs.
5.15	**Molecular diagnostics**: Is the analysis or the detection of nucleic acid variants by hybridization, with or without amplification. It is mainly to detect changes in a chromosome that leads to a genetic disorder.
5.16	**Point-of-care testing (POCT):** Medical testing at or near the site of patient care by specially trained healthcare professionals. These are tests which can be performed at the bedside and typically involve blood and urine testing which is often accomplished through the use of transportable, portable, and handheld instruments. The goal of POCT is to collect the specimen and obtain accurate results in a very short period of time at or near the location of the patient leading to possible change in the care of the patient.
5.17	**Post-examination processes/ Post analytical phase**: Processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results.
5.18	**Primary Sample or Specimen:** Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole.

5.19	**Referral laboratory:** A laboratory may often require the assistance of an outside facility or facilities to perform unique or unusual services, as a backup service, or for routine services that the referring (primary) laboratory does not perform.
5.20	**Reference laboratory:** Is an external laboratory in DHCC to which another laboratory management chooses to submit a sample or sub-sample for examination or when routine examinations cannot be carried out. It may also be a laboratory that performs reference or calibration measurement procedures or assigns reference values to test objects, later potentially providing those associated reference values for references or sources of traceability of test results.
5.21	**Sample:** Gathered matter of a medical patient's tissue, fluid, or other material derived from the patient used for laboratory analysis to assist differential diagnosis or staging of a disease process. Common examples include throat swabs, sputum, urine, blood, surgical drain fluids and tissue biopsies, etc.
5.22	**Turnaround time (TAT)**: Clinicians consider TAT from the time the test is ordered to results reporting, whereas laboratory professionals usually use specimen receipt to reporting of results as the TAT. It is the time elapsing between two points through the Pre analytical, Analytical and Post analytical examination processes. It is a reliable indicator of laboratory effectiveness.
5.23	**Validation**: Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.
5.24	**Verification**: Confirmation, through provision of objective evidence, that specified requirements have been fulfilled.

6 REFERENCES

6.1	International Standard ISO 15189,Third edition, 2012
6.2	International Standard ISO 17000
6.3	International Standard ISO 17025:2005
6.4	Center for Disease Control www.cdc.gov
6.5	FDA Policies and Procedures www.fda.gov
6.6	American Association for Laboratory Accreditation (A2LA) Accreditation Criteria
6.7	Standards for Medical / Clinical Director for Healthcare Operators Document #: SD/HCO/03/01
6.8	Licensure Requirements for Allied Health Professionals Guidance for Applicants, July 2016
6.9	HAAD Clinical Laboratory Standards, Version 1.0, 2010
6.10	DHA Clinical Laboratory Regulation, 2012
6.11	HAAD Standard for Point of Care Testing in Healthcare Facilities HAAD/POCT/SD/0.9, 2015

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Appendix 1: Guidelines on Specific Services

1. Point of Care Testing (POCT) Laboratory

1.1. DHCA licensed healthcare providers may apply for authorization to provide POCT services under their existing license either at the time of facility license renewal, or at any time prior to the due date for license renewal. For facilities that have DHCA license for its laboratory, this license will cover POCT applications.
For non-licensed entities, applicants may include the provision of POCT services as part of their application for new facility license
Provision of POCT will be authorized under the DHCA issued facility license; that is, no separate license will be issued for POCT services.

1.2. A Licensed Point of Care Testing Laboratory (POCT) must engage a different Licensed Laboratory to oversee and supervise the overall operation of the POCT Laboratory.

1.3. A POCT laboratory may perform the following Tests and such other Tests as may be approved by the Licensing Board in issuing and renewing the Licensed Laboratory's Clinical Operating Permit:

- blood gas analysis;
- complete blood counts, including hemoglobin and hematocrit analyses;
- chemistry profiles;
- blood glucose;
- O2 saturation;
- ionized calcium;
- lactate;
- International Normalized Ration ("INR"); and/or
- urine analysis (dipstick)
- pregnancy urine test

1.4. A Licensed Point of Care Testing Laboratory (POCT) director must ensure must ensure that POCT is performed by qualified staff with appropriate skills, knowledge, training and competency.

1.5. The POCT device methods must be validated to prove they are analytically (in terms of reproducibility and accuracy) and clinically (in terms of the population served and clinical requirements) fit for purpose.

1.6. Calibration must be carried out as per manufacturer recommendations where calibration ensures results obtained are accurate and traceable to defined standards.

1.7. Suitability of the method/assay must be confirmed and documented for the required population e.g. a glucose meter used for neonates must have a suitable lower limit because neonates may have lower blood glucose

levels than adults.

1.8. Performance of the assay must be under continuous scrutiny by performing quality control procedures: internal quality control, external quality control and periodic patient sample exchange with an accredited laboratory when possible.

1.9. Deviations and discrepancies must be documented, investigated and remedial action taken to ensure clinically reliable results.

1.10. POCT devices used for multi-patient use should be purposefully manufactured for multi-use purposes and not a single-use device.

1.11. Evidence based reference intervals and clinical decision limits should be used for each POCT test to aid the interpretation of patient results;

1.12. Correlation studies should be conducted at least once every six months if more than one device is used to perform the same test.

2. Blood Bank and Transfusion Services

Applicable to facilities that collect, test, process, store, distribute, and/or infuse blood and blood components.

2.1 The director of the blood bank and/or transfusion services ensures that proper storage of blood and blood components is provided at the appropriate temperatures, with continuous monitoring of temperature-controlled spaces.

2.2 The director of the blood transfusion services provides policies and procedures to guide acceptable practices for blood and blood component transfusion, including:

- Blood screening for Transmissible Infections Prior to Transfusion
- Reliability of ABO and Rh Reagents
- Administration of Blood
- Selecting Blood and Components for Transfusion
- Blood Issuance and Transfusion
- Recognizing Suspected Transfusion Reactions
- Donor Selection and Testing
- Donor Blood Testing
- Autologous Blood Collection
- Blood Component Preparation or Modification
- Donor and donation records

- Quarantine and discard of blood units
- Transportation and storage of blood

3. Cytogenetics Testing

3.1 Genetic testing should not be sold direct-to-consumers without physician's consultation. It is not allowed to initiate the request received from non-physicians such as individual patients, companies, Gym, schools, etc.

3.2 Counseling with specialist physician before and after genetic testing is required.

3.3 Genetic results should not be communicated to the patients directly; it should be referred to the requested/referral physician.

3.4 All genetic testing should be supported by enough scientific evidences regarding their clinical validity and utility. Diagnostic Genetic Testing will only be approved by DHCC, if they are among those tests approved by FDA.
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm330711.htm

3.5 Clinical justifications should be provided for any genetic testing.

3.6 The laboratory is not allowed to make recommendations for patients to use Medicines or Healthcare Products based on laboratory results which should be referred to the treating physician.

3.7 Non-Clinical facility is not allowed to provide any clinical services, which include genetic counseling or even referring to a lab.

3.8 All advertisement and marketing materials should be reviewed by DHCR

3.9 The Cytogenetics laboratory should follow the International System for Human Cytogenetic Nomenclature.

3.10 Test results should not be reported unless control processes are acceptable.

3.11 The laboratory's records and results should accurately and completely reflect all stages of the process and all results obtained.

3.12 Records shall include the:

- media used;
- reactions observed;
- number of cells counted;
- number of cells karyotyped;
- number of chromosomes counted for each metaphase spread; and
- Quality of the banding.

3.13 The resolution should be appropriate for the type of tissue or specimen and the type of study required, based on the clinical information provided to the laboratory.

3.14 An adequate number of karyotypes should be prepared for each patient.

3.15 The laboratory shall permanently retain slides, negatives, prints, or magnetic media for all abnormal cases.

3.16 The laboratory report should include:

- Correct use of appropriate nomenclature
- A summary of the observations
- The number of cells counted and analyzed
- Documentation of any preliminary report, such as a verbal or telephone report
- All required clinical information

3.17 Samples shall be identified in all phases of analysis, including the following:

- Specimen collection and accessioning
- Cultures
- Cell preparations
- Photography or other image reproduction technique
- Photographic printing and storage

3.18 The laboratory shall notify practitioners wishing to order a cytogenetic test that an informed consent is required and shall make available to the practitioner test-specific information for patient use in decision-making and the informed consent process.

3.19 Laboratories must obtain the subject's written consent, or if the individual lacks the capacity to consent, the signature of the person authorized to consent for the individual, before records, findings or results may be re-disclosed to any individual or organization other than those authorized on the test requisition to receive the result.

4. Molecular Testing

4.1 The laboratory should develop and follow written policies and procedures for molecular testing that describe the following:

- Appropriateness of testing (Note: For genetic testing, additional information might be required to select appropriate tests and to ensure accurate test interpretation and reporting of results).
- Prevention of nucleic acid contamination (including in work areas, equipment, personal protective equipment, and reagents) during specimen preparation and testing.
- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test.
- Quality and quantity of nucleic acid needed for a particular test.
- Investigation and corrective action taken for internal controls that fail to amplify.
- Competition between target and internal controls (for example, false negatives or presence of a target signal is strong, with a negative internal control signal).
- Investigation of discrepant results between different methods.
- Reuse of patient specimens for quality control purposes.

4.2 Validation studies shall include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.

4.3 The laboratory shall perform validation studies including:

- Positive and negative representatives from each specimen type expected to be tested in the assay.
- Specimens representing the scope of reportable results.

4.4 Molecular testing reports shall include specific testing information including the following information:

- Testing methodology used
- Limitations of the method used
- Any interpretation of findings
- Any recommendations for additional testing

5. Molecular Genetics

5.1 The laboratory shall follow written policies and procedures that address recommending referral for genetic counseling.

5.2 Molecular genetic testing reports include specific testing information including the following information:

- List of mutant genes for alleles tested.
- Any recommendations for referral to a genetic counselor.
- Detection rate of the test.
- Use of standard nomenclature for genes and mutations.
- Clinical implications of mutations detected.

5.3 The laboratory should consider three categories of test performance in the evaluation process:

- Analytic validity
- Clinical validity
- Clinical utility

5.4 All tests carried out should be FDA approved.

5.5 Tests should be carried out against a physician order only.

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Appendix 2: Supplementary Guidelines

1. Laboratory Safety

Laboratory staff, customers and visitors entering the laboratory environment may be at risk of chemical, electrical, physical, mechanical, and biological or radiation hazards so it is important for all laboratory staff to recognize the potential dangers and reduce risk to a minimum. Laboratories are required to develop a safety manual to include all laboratory safety related SOPs.

Laboratory director shall ensure:

1.1 Safety rules are established to reduce risks to staff, customers and visitors.

1.2 SOPs must be prepared to ensure safe handling and testing of laboratory equipment. A system shall be established for regular assessment and testing of each equipment as recommended by manufacturer and international standards. Equipment shall be labeled with date of testing and records shall be maintained.

1.3 SOPs shall be developed to ensure the safe handling, identifying of all specimens, samples and procedures such as phlebotomy, sample transport, subsampling, analytical procedures, storage and disposal of samples. They should be available at all work stations and communicated and made readily available to appropriate staff.

1.4 A list of diseases of national and international concern that require emergency action must be available in the laboratory.

1.5 Provision of appropriate Fire Safety equipment.

1.6 All staff handling patient samples and other biological materials must wear appropriate personal protective equipment (PPE). These must be removed before leaving the laboratory or undertaking clerical work. Hands must be washed immediately after removing the protection and before leaving the laboratory.

1.7 SOPs for Handling, storage, disposal and use of biohazardous or infectious materials and waste, including sharps.

1.8 SOPs must be available in the event of a spillage/leakage of biological, chemical or radiochemical materials or patient samples, including when containers are broken in a centrifuge.

1.9 First-aid materials and facilities must be readily available to deal with accidents including

provision for an eye wash station and Safety showers. All accidents, however small, or accidents that might have occurred ("near misses"), must be recorded and reported.

1.10 Provision of biosafety cabinets.

1.11 Provision of staff orientation and training in personal protective equipment and safe handling of lab equipment, hazardous materials and specimens. Competency should be assessed on staff and records maintained for ensuring adequate protection of laboratory personnel to avoid occupational hazards. This includes the following:

- Use of vaccines, for example, against hepatitis B virus (HBV) infection;
- Use of post-exposure prophylaxis (PEP) procedures against HIV infection in case of needle-stick injury;
- Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work;

2. Equipment

2.1 Each Licensed Laboratory must have sufficient laboratory equipment and instruments to perform all tests that are listed as available at its location or locations.

2.2 If the Licensed Laboratory is unable to conduct tests that are listed as available with the equipment and instruments that it has available, it must refer the tests to a different Licensed Laboratory qualified to perform such tests.

2.3 Each Licensed Laboratory must maintain all of its equipment and instruments, and calibrate them on a regular basis, to ensure their proper functioning.

2.4 Each Licensed Laboratory must create, and retain for a minimum of three (3) years following each Calibration, records accurately reflecting such activity.

2.5 Each Licensed Laboratory shall have in place procedures for the procurement and management of equipment that includes:

- an assessment and justification of need;
- selection;
- acceptance;
- training in use of the equipment;
- maintenance, service and repair of the equipment;
- decontamination;
- record of instrument failure and subsequent corrective action;
- planned replacement and disposal; and
- adverse incident and vigilance reporting.

2.6 Each Licensed Laboratory shall maintain an inventory of its equipment with regard to each unit of equipment which includes:

- name of manufacturer;
- serial number;
- date of acquisition;
- record of contracted maintenance; and
- record of equipment breakdowns.

2.7 Licensed Laboratory Facilities shall maintain a written preventive maintenance program for all equipment and related procedures.

3. Safe Handling and Management of laboratory samples and specimens

3.1 Each Licensed Laboratory must employ and maintain a system that provides for proper Patient preparation; specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. Such system must ensure optimum specimen integrity, identification, and testing.

3.2 Each Licensed Laboratory must only perform tests at the written or electronic request of an Authorized Person. The Licensed Laboratory must retain all test request forms.

3.3 Each Licensed Laboratory must ensure that all test requisitions contain the following:

- Patient name and another unique identifier;
- Gender, age, and the date of birth of the Patient;
- Specimen source;
- Name and address of the Authorized Person;
- Test(s) to be performed;
- Date and time of specimen collection;
- All other relevant and pertinent information to the test(s) being requested (such as, for a PAP smear request, the date of last menstrual period);
- Specific data elements required by DHCC as outlined in the DHCC Minimum Data Requirements Rule.

3.4 Each Licensed Laboratory must maintain a system to ensure reliable identification of Patient specimens as they are processed and tested to ensure that accurate test results are reported. The records in such system must also identify the person performing the Tests.

3.5 Each Licensed Laboratory must have an adequate system in place to report Patient results in a timely, accurate, reliable and confidential manner.

3.6 Each test result report must contain the name and address of the Licensed Laboratory that performed the test; the name(s) of the test(s) performed; the test result(s); the units of measurement; and the relevant normal Reference Ranges.

3.7 Each Licensed Laboratory must have a procedure in place for reporting Critical Values to the Authorized Person immediately.

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Appendix 3: Retention of Patient Result Records and Materials

Material/Record	Period of Retention
General Laboratory	
Accession log	2 years
Maintenance/instrument maintenance records	2 years
Quality control records	2 years
Surgical Pathology (including bone marrows)	
Wet tissue	2 weeks after final report
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Cytology	
Slides (negative-unsatisfactory)	5 years
Slides (suspicious-positive)	5 years
Fine needle aspiration slides	10 years
Reports	10 years
Non-Forensic Autopsy	
Wet tissue	3 months after final
Paraffin blocks	10 years
Slides	10 years
Reports	10 years
Forensic Autopsy	
Wet stock tissue	1 year
Paraffin blocks	Indefinitely
Reports	Indefinitely
Slides	Indefinitely
Gross photographs/negatives	Indefinitely
Accession log	Indefinitely
Body fluids and tissues for toxicology	1 year
Representative tissue suitable for DNA Analysis	Indefinitely
Clinical Pathology	
Patient test records	2 years
Serum/heparinized or EDTA plasma/CSF/Body fluids (except urine)	48 hours
Urine[2]	24 hours*
Peripheral blood smears/body fluid smears	7 days
Permanently stained slides – microbiology (gram, trichrome, etc.)	7 days
Cytogenetics	
Permanently stained slides	3 years
Fluorchrome stained slides	At the discretion of the laboratory director

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Material/Record	Period of Retention
Wet specimen/tissue	Until adequate metaphase cells are obtained
Fixed cell pellet	2 weeks after final report
Final reports	20 years
Diagnostic images (digitized, prints or negatives)	20 years
Flow Cytometry	
Gated dot plots and histograms	10 years
Blood Bank	
Donor and recipient records	10 years
Patient records	10 years
Records of employee signatures, initials, and identification codes	10 years
Quality control records	5 years
Specimens from blood donors units and recipients	7 days post-transfusion

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REVISION HISTORY

S No	Summary	Amend Type*	Page	Issue No	Issue Date
1	Technically Reviewed	New	All	1	16/9/2018
2					
3					
4					
5					
6					

*** Amend Type: New / Add/ Modify / Cancel**