Diagnostic Laboratory
New Facility Registration
Pre-Assessment Data Verification Form

Notes and Instructions:

Section 4: For submission of required documentation, embed document into table beside the specific item

Facilities who are not reporting results for patient management and only testing as part of a screening process are classified as Collection sites and do not require CPSA Accreditation.

Section 1

General Facility Information:

CPSA Facility Number	To be issued by CPSA
Facility Type	To be determined by CPSA
Facility Name	
Address	
Phone Number	
Facility Ownership / Funding Type:	Public: _____ Private: _____

Expected opening date/commencement of patient testing: _____

Hours of Operation:

What are the routine hours of operation?		
Are staff readily available outside of routine hours (on – call)?	Yes	No

Section 2

Personnel:

Zone Medical/Laboratory Director (Public only)	
Name	
Address	
Phone	
E-mail	

Laboratory Director*	
Name	
Address	
Phone	
E-mail	

*Individual defined in CPSA General Standards G.1.2.3 (not the Administrative Director of the Laboratory) – See Appendix A for standard and laboratory director requirements

Note: For facilities without on-site pathologists, please list the consultant specialist(s)

Laboratory Consultant (specify MD or PhD)	
Specialty/discipline	
Name	
Address	
Phone	
E-mail	

Laboratory Consultant (specify MD or PhD)	
Specialty/discipline	
Name	
Address	
Phone	
E-mail	

Laboratory Consultant (specify MD or PhD)	
Specialty/discipline	
Name	
Address	
Phone	
E-mail	

Laboratory Consultant (specify MD or PhD)	
Specialty/discipline	
Name	
Address	
Phone	
E-mail	

Laboratory Liaison Physician (for hospital-based facilities)	
Name	
Address	
Phone	
E-mail	

Laboratory Supervisor (specify MLT or CLXT)	
Name	
Phone	
E-mail	

List as full-time equivalents, the number(s) of (where applicable):	
Pathologists – on-site full-time	
Clinical Laboratory Doctoral Scientists (CLDS)	
Supervisory Technologists (Section Heads)	
Technologists (MLT) other than supervisors	
Technicians (CLXT)	
Laboratory Assistants	
Clerical Staff	
Other (Specify)	

Section 3

Scope of Examinations (Test Menu):

Information is used to determine required assessor resources and to customize Standard document tools for each assessment.

Check the specific examination services provided at the facility:

Note: The CPSA does NOT accredit electrocardiography testing (Holter monitors/ECGs)

Disciplines		√		√
Anatomic Pathology	Surgical Pathology		Digital Image Analysis	
	Histochemistry		Autopsy Pathology	
	Immunofluorescence microscopy		Electron microscopy	
	Immunohistochemistry		Cytopathology	
	Predictive Markers		Telepathology	
Chemistry	General		Gas Chromatography	
	Therapeutic Drug Monitoring		Mass spectrometry	
	Sweat Examinations		Inductively coupled plasma-mass spectrometry	
	Colorimetry/spectrophotometry		Atomic absorption spectrophotometry	
	Thin layer chromatography		Electrophoresis	
	High Performance Liquid Chromatography		Urinalysis	
Fertility Assessment	Post-vasectomy only (see Chemistry – Urinalysis section)		Comprehensive fertility assessment	
			(if yes, indicate which dept. performs testing e.g. Hematology = H)	
Flow Cytometry				
#Hematology	Manual		Hemoglobin variant detection	
	Automated		Coagulation	
Microbiology	Bacteriology		Parasitology	
	Mycobacteriology		Virology	
	Mycology		Immunology/infectious disease serology	
***Point of Care Testing (POCT)**	Includes: Blood Gases, Glucose Meters, urine examinations, etc.		Indicate if Respiratory has oversight of Blood Gases (Y/N)	
Transfusion Medicine	Dispensary only		Hospital-based donations (pre/peri-operative)	
	Pre-transfusion examinations		Home transfusions	
	Neonatal transfusion			

*** - applies only to POCT that is conducted under the auspices of the laboratory director.**
 # - manual hematology includes all manual testing such as manual differentials, fluid counts, ESR etc.

Discipline		√
Laboratory Sections performing molecular diagnostics and/or genetics	Biochemical Genetics	
	Cytogenetics	
	Molecular Genetics	
	Molecular Pathology	
	Molecular Microbiology	
	Molecular Transfusion Medicine	
	Other Molecular:	
Molecular Diagnostics and Genetics – Techniques performed in any of the above sections	Cell Culture	
	Fluorescence in-situ Hybridization (FISH)	
	Non-fluorescent in-situ Hybridization (ISH)	
	Molecular Pathology – FISH/ISH	
	Microarray Analysis	
	Nucleic Acid Extraction	
	Nucleic Acid Amplification	
	Restriction Endonucleases (RE)	
	Sequencing	
	Next Generation Sequencing	
	Electrophoresis	

List Zone Managed Programs/Processes (eg. POCT, LIS, EQA Review)	Program/Process	Contact Name	Location

Section 4

Required Documentation for Submission:

Documentation Required	Embed Document(s) Here
Organization structure (e.g. Organization chart)	
Examples of: • examination request forms (initiated from Facility/Zone) • patient reports (1 example for each discipline where applicable)	
Analyzer/instrument list by lab section (including year of purchase)	
Complete list of examination procedures performed in the laboratory	

Section 5

Signature

I have reviewed and confirm the above facility and assessment information and documentation.

Laboratory Director / Designate Name	
Date	
Signature	

APPENDIX A: REQUIREMENTS FOR ALBERTA DIAGNOSTIC LABORATORIES

A.1 Laboratory Director Requirements (Standard Reference: G.1.2.3)

The laboratory director is approved by the Council of the CPSA to direct a laboratory and is:

- a medical practitioner licensed to practice medicine in Alberta, OR
- a clinical laboratory doctoral scientist (CLDS), and registered Fellow and in good standing with one of the following:

    - *The Canadian College of Medical Geneticists (CCMG) or equivalent*
    - *The Canadian Academy of Clinical Biochemistry (CACB) & the Canadian Society of Clinical Chemists (CSCC) or equivalent*
    - *The Canadian College of Microbiologists (CCM) or equivalent*
    - *The American Society of Histocompatibility and Immuogenetics (ASHI) and the American Board of Histocompatibility and Immunogentics (ABHI)*

CLDSs directing a laboratory must formally identify to the CPSA, the medical leadership individual (CPSA regulated member, licensed to practice medicine in Alberta) that has the appropriate medical accountability and oversight.

This communication, for the regulated physician member must include the following:

- name and contact information
- signature indicating awareness of their role and acceptance of their accountability to the CPSA and responsibility for medical oversight of the laboratory facility
- credentials indicating that they have the appropriate content knowledge

All Laboratory Directors:
The Laboratory Director must review and sign the College of Physicians & Surgeons of Alberta (CPSA) *Laboratory Director Roles and Responsibilities Acknowledgement* Document:

- Prior to a 4 year assessment
- When there is change to Laboratory Director
- Prior to opening a new facility

#	Standard	Reference	Assessment of Compliance
	G.1.2 Personnel continued		
G.1.2.3	The laboratory is directed by a person or persons with the qualifications, competence and delegated responsibility for the services provided.	AC[1] – 5.5 ISO[1] 15189 – 4.1.1.4 ISO[7] 17025 – 5.2 CAP[2] - GEN.53625 CAP[7] – DRA.10200 Guidance: Refer to Appendix for province specific directives	Do the laboratory director's qualifications meet the requirements of the appropriate provincial regulatory body? Are there appropriate personnel and structures in place to provide guidance in facilities without an on-site pathologist/medical leader? Where required, are there designated consultant specialists (including consultant technologists, where applicable) appropriate to the scope and level of examination in the facility? Is the consultant specialist(s) reasonably available to members of the medical staff, facility administration and laboratory staff for consultation? Is the number of consultant specialist (including consultant technologists, where applicable) visits in compliance with provincial requirements? Does the consultant specialist (including consultant technologists, where applicable) provide a prompt written account to the laboratory director and laboratory supervisor of the pertinent findings and recommendations following each visit? Are the written recommendations readily available to the laboratory?
			C ☐ P ☐ E ☐ N ☐ N/A ☐
			Observation:

#	Standard	Reference	Assessment of Compliance
	G.1.2 Personnel continued		
G.1.2.20	If the Laboratory Director has delegated an activity or responsibility to a designate, a policy, process and procedure that identifies the necessary qualifications of the designate and how the delegation is to be carried out is available.	ISO[1] 15189 – 4.1.1.4, 4.14.2	Is there evidence of all of the following: • a policy/process for delegation of the applicable laboratory director duties to a qualified individual? • formal written delegation of responsibilities to a named designate(s)? Does the delegation policy define and address all of the following: • a formal delineation of 'practice of medicine', relevant to the scope of practice of the facility/organization, indicating activities that may only be performed by a licensed medical physician? • that 'practice of medicine' may only be delegated to a licensed medical physician? • that technical functions may be delegated to laboratory physicians or other qualified laboratory personnel as appropriate? • that administrative functions may be delegated to qualified laboratory personnel? C ☐ P ☐ E ☐ N ☐ N/A ☐ Observation:

APPENDIX B: MEDICAL DIRECTOR ROLES AND RESPONSIBILITIES ACKNOWLEDGEMENT

In being appointed Medical Director for:

_____
(Name of Facility)

I, Dr. _____
have read, understand and agree to comply with the roles and responsibilities of the Medical Director as detailed in the Accreditation Standards of the College of Physicians & Surgeons of Alberta (CPSA).

As Medical Director, I am responsible for:

- the overall operation and administration of the facility or service to assure that quality patient services are provided and the facility's accreditation status is maintained:
  - ensuring that examinations and diagnostic or treatment procedures are clinically indicated and appropriate
  - ensuring that examinations and diagnostic procedures are performed only at the request of an authorized person
  - ensuring that the facility or service employs adequate, sufficiently trained, qualified and competent personnel appropriate for the workload, range and complexity of the procedures performed in the facility
  - providing effective direction and supervision of all personnel in the facility, ensuring compliance with applicable Standards of Practice, Code of Conduct, Code of Ethics and applicable laws and regulations
  - ensuring the production of reliable and accurate results and reports by the facility
  - ensuring patient records, whether physical or electronic, are accurate, available and retained securely and in accordance with applicable legislation
  - ensuring that methods employed and equipment used in the facility are selected and performed in accordance with currently accepted best practices
  - providing direction for the production, development and review of testing algorithms, examination protocols and appropriate use of examinations in accordance with best practices in medicine
  - ensuring that an effective program of quality assurance and quality management is in place for all services
- the safety of all personnel, patients, students, visitors and volunteers in the facility:
  - ensuring that effective and appropriate safety and emergency preparedness procedures are in place
- reviewing and approving facility or service policies, processes and procedures, including:
  - Conflict of Interest
  - Ethics
  - Quality/Quality Management System
  - Infection Control
  - Medical Device Reprocessing
  - Occupational and Environmental Health and Safety
- ensuring that delegation of any of my responsibilities to qualified persons is done formally, documented, and effective

_____ _____
(Signature) (Date)