

## 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 Immunogenetics (ASHI) and the American Board of Histocompatibility and Immunogenetics (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
<b>G.1.2 Personnel continued</b>			
<b>G.1.2.3</b>	The laboratory is directed by a person or persons with the qualifications, competence and delegated responsibility for the services provided.	AC <sup>1</sup> – 5.5 ISO <sup>1</sup> 15189 – 4.1.1.4 ISO <sup>7</sup> 17025 – 5.2 CAP <sup>2</sup> - GEN.53625 CAP <sup>7</sup> – DRA.10200  Guidance: Refer to Appendix for province specific directives	<p>Do the laboratory director’s qualifications meet the requirements of the appropriate provincial regulatory body?</p> <p>Are there appropriate personnel and structures in place to provide guidance in facilities without an on-site pathologist/medical leader?</p> <p>Where required, are there designated consultant specialists (including consultant technologists, where applicable) appropriate to the scope and level of examination in the facility?</p> <p>Is the consultant specialist(s) reasonably available to members of the medical staff, facility administration and laboratory staff for consultation?</p> <p>Is the number of consultant specialist (including consultant technologists, where applicable) visits in compliance with provincial requirements?</p> <p>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?</p> <p>Are the written recommendations readily available to the laboratory?</p> <p style="text-align: center;">C <input type="checkbox"/> P <input type="checkbox"/> E <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>Observation:</p>

#	Standard	Reference	Assessment of Compliance
<b>G.1.2 Personnel continued</b>			
<b>G.1.2.20</b>	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 <sup>1</sup> 15189 – 4.1.1.4, 4.14.2	<p>Is there evidence of all of the following:</p> <ul style="list-style-type: none"> <li>• a policy/process for delegation of the applicable laboratory director duties to a qualified individual?</li> <li>• formal written delegation of responsibilities to a named designate(s)?</li> </ul> <p>Does the delegation policy define and address all of the following:</p> <ul style="list-style-type: none"> <li>• 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?</li> <li>• that 'practice of medicine' may only be delegated to a licensed medical physician?</li> <li>• that technical functions may be delegated to laboratory physicians or other qualified laboratory personnel as appropriate?</li> <li>• that administrative functions may be delegated to qualified laboratory personnel?</li> </ul> <p style="text-align: center;">C <input type="checkbox"/> P <input type="checkbox"/> E <input type="checkbox"/> N <input type="checkbox"/> N/A <input type="checkbox"/></p> <p>Observation:</p>