



Laboratory Standard Intents

LB.1 Laboratory services are available to meet patient needs and are in accordance with applicable national standards.

- LB.1.1 The laboratory has a clearly defined scope of services.
- LB.1.2 The laboratory services are in compliance with applicable national standards.
- LB.1.3 Basic laboratory services (e.g., hematology, blood bank and biochemistry) are available twenty-four hours a day, seven days a week.
- LB.1.4 When laboratory services are provided through a contract, the hospital provides oversight and management of the contract through the process described in the “Leadership” chapter in this manual.
- LB.1.5 The laboratory has a defined organizational chart that displays key positions including the laboratory director, sections’ heads and supervisors, quality management officer, facility and safety officer, and, as applicable, infection control officer, point of care testing coordinator, and training and education coordinator.

Standard Intent:

Developing and maintaining current scope of services that meets the needs of patient population, clients, and customers is a sign of commitment to quality and professional practice. The laboratory scope of services should be clearly defined in writing, easily accessible to all staff, as well as internal and external customers.

LB.2 The laboratory has adequate and functional space and facilities that maintain safe and proper working conditions.

- LB.2.1 There is a space allocated for the laboratory which provides:
 - LB.2.1.1 Proper location and design.
 - LB.2.1.2 Adequate patient and donor waiting areas and lavatories.
 - LB.2.1.3 Adequate area for each laboratory activity/section.
 - LB.2.1.4 Proper, safe, and adequate storage space for reagents, supplies, consumables, samples, records, paraffin blocks, and glass slides.
 - LB.2.1.5 Adequate area for administrative and clerical staff.
- LB.2.2 The laboratory management ensures the availability of the following facilities:
 - LB.2.2.1 Adequate water taps and sinks.
 - LB.2.2.2 Adequate electrical outlets and emergency power.
 - LB.2.2.3 Adequate temperature and humidity control.
 - LB.2.2.4 Adequate ventilation.
 - LB.2.2.5 Adequate lighting.
 - LB.2.2.6 Adequate emergency exits, access control, and all ways are not obstructed.

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- LB.2.2.7 Adequate safety signs.
 - LB.2.2.8 Clean and well maintained floors, walls, ceilings, bench tops, and sinks.
 - LB.2.2.9 Conveniently located telephones.
- LB.2.3 Personnel safety, quality of work, patient care, and donor care are not compromised by the allocated laboratory space.
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Standard Intent:

Deficiencies in lab space and design are regarded as minor unless they are so severe as to interfere with the quality of work or safety, in which case they become a major issue.

LB.3 The laboratory services are carried out by qualified staff.

- LB.3.1 The laboratory services are provided by staff qualified by education, training, and experience.
 - LB.3.2 The laboratory director, section heads and supervisors are appropriately qualified according to the complexity of laboratory scope of services.
 - LB.3.2.1 The laboratory director of a high complexity laboratory (laboratories of tertiary care hospitals/referral facilities or laboratories providing anatomical pathology and/or transfusion medicine services) is a licensed/registered anatomical or clinical pathology consultant (board certified or equivalent).
 - LB.3.2.2 The laboratory director of a moderate or low complexity laboratory (laboratories with no anatomical pathology and transfusion medicine services) is a licensed/registered clinical scientist or laboratory specialist.
 - LB.3.2.3 The sections' heads/supervisors are qualified (by education, training and experience) in the discipline of their assigned sections.
 - LB.3.2.4 The laboratory staff participate in relevant hospital committees.
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Standard Intent:

The director of the laboratory must be recognized as the main authorized and responsible person for establishing and maintaining all of the quality and operational policies, processes and procedures. The necessary education, training, skills, experience, certifications, and licensure of the director need to be specified and kept current with the applicable national, professional and accreditation requirements. The director of a high complexity laboratory (laboratories of tertiary care hospitals/referral facilities or laboratories providing anatomical pathology and/or transfusion medicine services) must be an MD licensed to practice medicine and either possess qualifications required for board certification in clinical pathology or have at least one-year training or experience in the discipline he/she serves.
