



# The Joint Commission

Accreditation Program: Laboratory  
Leadership

### Standard LD.01.01.01

The laboratory has a leadership structure.

Note: If the laboratory is part of a Joint Commission–accredited organization, this standard is not applicable. Laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories) or that are part of an organization not accredited by The Joint Commission are responsible for meeting this standard.

#### Rationale for LD.01.01.01

Every laboratory has a leadership structure to support operations. Many functions need to be carried out, including governance, administration, and oversight of laboratory services. In some laboratories leaders have distinct roles in carrying out these functions; in others a single individual may perform all leadership functions.

#### Elements of Performance for LD.01.01.01

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| 1. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): The laboratory identifies those responsible for governance.                                   | <b>A</b> |
| 2. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance identifies those responsible for planning, management, and operational activities. | <b>A</b> |
| 3. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance identifies those responsible for the provision of laboratory services.             | <b>A</b> |

### Standard LD.01.03.01

Governance is ultimately accountable for the safety and quality of laboratory services.

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#### Rationale for LD.01.03.01

Governance’s ultimate responsibility for safety and quality derives from its legal responsibility and operational authority for laboratory performance. In this context, governance provides for internal structures and resources, including staff, that support safety and quality.

#### Elements of Performance for LD.01.03.01

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| 1. | (D) For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance defines in writing its responsibilities.             | <b>A</b> |
| 2. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance provides for organization management and planning.       | <b>A</b> |
| 3. | (D) For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance approves the laboratory’s written scope of services. | <b>A</b> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 4. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance selects the laboratory director.   | <b>A</b> |
| 5. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance provides for the resources needed to maintain safe, quality laboratory services.   | <b>A</b> |
| 6. | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Governance works with laboratory leaders to annually evaluate the laboratory's performance in relation to its mission, vision, and goals. | <b>A</b> |

### Standard LD.01.07.01

Individual leaders have the knowledge needed for their roles in the laboratory or they seek guidance to fulfill their roles.

#### Elements of Performance for LD.01.07.01

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|    | 2. Leaders are oriented to all of the following: <ul style="list-style-type: none"> <li>- The laboratory's mission and vision</li> <li>- The laboratory's safety and quality goals</li> <li>- The laboratory's structure and the decision-making process</li> <li>- The development of the budget as well as the interpretation of the laboratory's financial statements</li> <li>- The population(s) served by the laboratory and any issues related to that population(s)</li> <li>- The individual and interdependent responsibilities and accountabilities of leaders as they relate to supporting the mission of the laboratory and to providing safe and quality care</li> <li>- Applicable law and regulation</li> </ul> | <b>C</b> |
| 3. | The laboratory director has access to information and training in areas where he or she needs additional skills or expertise.   | <b>A</b> |

### Standard LD.02.01.01

The mission, vision, and goals of the laboratory support the safety and quality of laboratory services.

#### Rationale for LD.02.01.01

The primary responsibility of leaders is to provide for the safety and quality of laboratory services. The purpose of the laboratory's mission, vision, and goals is to define how the laboratory will achieve safety and quality. The leaders are more likely to be aligned with the mission, vision, and goals when they create them together. The common purpose of the laboratory is most likely achieved when it is understood by all who work in or are served by the laboratory.

#### Elements of Performance for LD.02.01.01

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| 1. | Leaders work together to create the laboratory's mission, vision, and goals.                             | <b>A</b> |
| 2. | The laboratory's mission, vision, and goals guide the actions of leaders.                                | <b>A</b> |
| 3. | Leaders communicate the mission, vision, and goals to staff and the population(s) the laboratory serves. | <b>A</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; indicates situational decision rules apply; indicates direct impact requirements apply; indicates Measure of Success if needed; indicates that documentation is required

**Standard LD.02.03.01**

Leaders regularly communicate with each other on issues of safety and quality.

**Rationale for LD.02.03.01**

Leaders, who provide for safety and quality, must communicate with each other on matters affecting the laboratory and those it serves. The safety and quality of laboratory services depend on open communication. Ideally, this will result in trust and mutual respect among those who work in the laboratory.

**Elements of Performance for LD.02.03.01**

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| 1. | Leaders discuss issues that affect the laboratory and the population(s) it serves, including the following:  | <b>A</b> |
|    | <ul style="list-style-type: none"> <li>- Performance improvement activities</li> <li>- Reported safety and quality issues</li> <li>- Proposed solutions and their impact on the laboratory's resources</li> <li>- Reports on key quality measures and safety indicators</li> <li>- Safety and quality issues specific to the population served</li> <li>- Input from the population(s) served</li> </ul> |          |
| 2. | The laboratory establishes time frames for the discussion of issues that affect the laboratory and the population(s) it serves.  | <b>A</b> |
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**Standard LD.03.01.01**

Leaders create and maintain a culture of safety and quality throughout the laboratory.

**Rationale for LD.03.01.01**

Safety and quality thrive in an environment that supports teamwork and respect for other people, regardless of their position in the laboratory. Leaders demonstrate their commitment to quality and set expectations for those who work in the laboratory. Leaders evaluate the culture on a regular basis using a variety of methods, such as formal surveys, focus groups, staff interviews, and data analysis.


Leaders encourage teamwork and create structures, processes, and programs that allow this positive culture to flourish. Disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to patient care. Leaders must address disruptive behavior of individuals working at all levels of the laboratory, including management, clinical and administrative staff, licensed independent practitioners, and governing body members.

**Elements of Performance for LD.03.01.01**

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| 1. | Leaders regularly evaluate the culture of safety and quality.  | <b>A</b> |
| 2. | Leaders prioritize and implement changes identified by the evaluation.   | <b>A</b> |
| 3. | Leaders provide opportunities for all individuals who work in the laboratory to participate in safety and quality initiatives. | <b>A</b> |
| 4. | <b>D</b> Leaders develop a code of conduct that defines acceptable, disruptive, and inappropriate behaviors.                   | <b>A</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 5.  | Leaders create and implement a process for managing disruptive and inappropriate behaviors.   |  A |
| 6.  | Leaders provide education that focuses on safety and quality for all individuals.   | A   |
| 7.  | Leaders establish a team approach among all staff at all levels.  | A   |
| 8.  | All individuals who work in the laboratory, including staff and licensed independent practitioners, are able to openly discuss issues of safety and quality. (See also LD.04.04.05, EP 6) | A   |
| 9.  | Literature and advisories relevant to patient safety are available to all individuals who work in the laboratory.   | A   |
| 10. | Leaders define how members of the population(s) served can help identify and manage issues of safety and quality within the laboratory.   | A   |

### Standard LD.03.02.01





The laboratory uses data and information to guide decisions and to understand variation in the performance of processes supporting safety and quality.

#### Rationale for LD.03.02.01

Data help laboratories make the right decisions. When decisions are supported by data, laboratories are more likely to move in directions that help them achieve their goals. Successful laboratories measure and analyze their performance. When data are analyzed and turned into information, this process helps laboratories see patterns and trends and understand the reasons for their performance. Many types of data are used to evaluate performance, including data on outcomes of care, performance on safety and quality initiatives, patient satisfaction, process variation, and staff perceptions.

#### Elements of Performance for LD.03.02.01

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| 1. | Leaders set expectations for using data and information to improve the safety and quality of laboratory services.                                     | A |
| 2. | Leaders are able to describe how data and information are used to create a culture of safety and quality.   | A |
| 3. | The laboratory uses processes to support systematic data and information use.   | A |
| 4. | Leaders provide the resources needed for data and information use, including staff, equipment, and information systems.                               | A |
| 5. | The laboratory uses data and information in decision making that supports the safety and quality of laboratory services. (See also PI.02.01.01, EP 8) | A |
| 6. | The laboratory uses data and information to identify and respond to internal and external changes in the environment.                                 | A |
| 7. | Leaders evaluate how effectively data and information are used throughout the laboratory.   | A |

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**Standard LD.03.03.01**

Leaders use laboratory-wide planning to establish structures and processes that focus on safety and quality.


**Rationale for LD.03.03.01**

Planning is essential to the following:

- The achievement of short- and long-term goals
- Meeting the challenge of external changes
- The design of services and work processes
- The creation of communication channels
- The improvement of performance
- The introduction of innovation

Planning includes contributions from the populations served, from those who work for the laboratory, and from other interested groups or individuals.

**Elements of Performance for LD.03.03.01**

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| 1. | Planning activities focus on improving patient safety and health care quality.                 | A   |
| 2. | Leaders can describe how planning supports a culture of safety and quality.                    | A   |
| 3. | Planning is systematic, and it involves designated individuals and information sources.        | A   |
| 4. | Leaders provide the resources needed to support the safety and quality of laboratory services. |  A |
| 5. | Safety and quality planning is laboratory-wide.  | A   |
| 6. | Planning activities adapt to changes in the environment.                                       | A   |
| 7. | Leaders evaluate the effectiveness of planning activities.                                     | A   |

**Standard LD.03.04.01**





The laboratory communicates information related to safety and quality to those who need it, including staff, licensed independent practitioners, patients, families, and external interested parties.

**Rationale for LD.03.04.01**

Effective communication is essential among individuals and groups within the laboratory, and between the laboratory and external parties. Poor communication often contributes to adverse events and can compromise safety and quality of laboratory services. Effective communication is timely, accurate, and usable by the audience.

**Elements of Performance for LD.03.04.01**

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| 1. | Communication processes foster the safety of the patient and the quality of care.        | A |
| 2. | Leaders are able to describe how communication supports a culture of safety and quality. | A |

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| 3. | Communication is designed to meet the needs of internal and external users.                                      | A |
| 4. | Leaders provide the resources required for communication, based on the needs of patients, staff, and management. | A |
| 5. | Communication supports safety and quality throughout the laboratory. (See also LD.04.04.05, EP 6)                | A |
| 6. | When changes in the environment occur, the laboratory communicates those changes effectively.                    | A |
| 7. | Leaders evaluate the effectiveness of communication methods.   | A |
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### Standard LD.03.05.01

Leaders implement changes in existing processes to improve the performance of the laboratory.

#### Rationale for LD.03.05.01

Change is inevitable, and agile laboratories are able to manage change and rapidly execute new plans. The ability of leaders to manage change is necessary for performance improvement, for successful innovation, and to meet environmental challenges. The laboratory integrates change into all relevant processes so that its effectiveness can be sustained, assessed, and measured.

#### Elements of Performance for LD.03.05.01

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| 1. | Structures for managing change and performance improvements exist that foster the safety of the patient and the quality of laboratory services.            | A |
| 2. | Leaders are able to describe how the laboratory's approach to performance improvement and its capacity for change support a culture of safety and quality. | A |
| 3. | The laboratory has a systematic approach to change and performance improvement.  | A |
| 4. | Leaders provide the resources required for performance improvement and change management, including sufficient staff, access to information, and training. | A |
| 5. | The management of change and performance improvement supports both safety and quality throughout the laboratory.   | A |
| 6. | The laboratory's internal structures can adapt to changes in the environment.  | A |
| 7. | Leaders evaluate the effectiveness of processes for the management of change and performance improvement.  | A |

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### Standard LD.03.06.01



Those who work in the laboratory are focused on improving safety and quality.





#### Rationale for LD.03.06.01

The safety and quality of laboratory services are highly dependent on the people who work in the laboratory. The mission, scope, and complexity of services define the design of work processes and the skills and number of individuals needed. In a successful laboratory, work processes and the environment make safety and quality paramount. This standard, therefore, applies to all those who work in or for the laboratory, including staff and licensed independent practitioners.

#### Elements of Performance for LD.03.06.01

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| 1. | Leaders design work processes to focus individuals on safety and quality issues.   | <b>A</b>   |
| 2. | Leaders are able to describe how those who work in the laboratory support a culture of safety and quality.   | <b>A</b>   |
| 3. | Leaders provide for a sufficient number and mix of individuals to support safe, quality laboratory services.<br>Note 1: The following indicators demonstrate adequacy of technical and support staff to meet the service needs of the patients, including evenings, weekends, and holidays:<br>- Overtime is not significantly high.<br>- There are no lapses in quality control and proficiency testing.<br>- Performance testing and documentation of equipment maintenance have no lapses.<br>- Turnaround time is not prolonged.<br>- The quality of specimens, cultures, differential testing methods, or results is not jeopardized.<br>Note 2: The following indicators demonstrate adequacy of supervisory staff to meet the service needs of the patients, including evenings, weekends, and holidays:<br>- The background and experience of supervisory staff are consistent with work assignments and responsibilities.<br>- Quality control, proficiency testing, and maintenance are well performed and evaluated.<br>- Policies and procedures are current and well executed.<br>- Turnaround time is satisfactory.<br>- Record systems are well organized and current.<br>- Quality improvement mechanisms are implemented.<br>- Test analyses and specimen examinations are monitored to ensure that acceptable levels of analytic performance are maintained. |  <b>A</b>   |
| 4. | Those who work in the laboratory are competent to complete their assigned responsibilities.  |  <b>A</b> |
| 5. | Those who work in the laboratory adapt to changes in the environment.  | <b>A</b>   |
| 6. | Leaders evaluate the effectiveness of those who work in the laboratory to promote safety and quality.  | <b>A</b>   |

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**Standard LD.04.01.01**

The laboratory complies with law and regulation.

**Elements of Performance for LD.04.01.01**

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| 1. | <p><b>D</b> The laboratory is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the services for which the laboratory is seeking accreditation from The Joint Commission.</p> <p>Note 1: Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare &amp; Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.</p> <p>Note 2: Each laboratory must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state law.</p> <p>Footnote: For more information on how to obtain a CLIA certificate, see <a href="http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf">http://www.cms.hhs.gov/CLIA/downloads/HowObtainCLIACertificate.pdf</a>. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)</p> | <p><b>2</b> <b>A</b></p> |
| 2. | <p>The laboratory provides laboratory services in accordance with licensure requirements, laws, and rules and regulations.</p>  | <p><b>A</b></p>          |
| 3. | <p>Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.</p>  | <p><b>A</b></p>          |
| 4. | <p><b>D</b> Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.</p>   | <p><b>A</b></p>          |

**Standard LD.04.01.03**

The laboratory develops an annual operating budget and, when needed, a long-term capital expenditure plan.

**Elements of Performance for LD.04.01.03**

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| 1. | <p>Leaders solicit comments from those who work in the laboratory when developing the operational and capital budgets.</p> | <p><b>A</b></p> |
| 3. | <p>The operating budget reflects the laboratory's goals and objectives.</p>  | <p><b>A</b></p> |

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### Standard LD.04.01.11

The laboratory makes space and equipment available as needed for the provision of laboratory services.

#### Rationale for LD.04.01.11

The resources allocated to services provided by the laboratory have a direct effect on patient outcomes. Leaders should place highest priority on high-risk or problem-prone processes that can affect patient safety.

#### Elements of Performance for LD.04.01.11

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| 1. | The laboratory director routinely communicates with the leaders of the laboratory about space, equipment, and other resources required for services.<br>Note: Testing activities that require special equipment, staff, and facilities are performed only when the required resources are available. | <b>A</b> |
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### Standard LD.04.02.01

The leaders address any conflict of interest involving licensed independent practitioners and/or staff that affects or has the potential to affect the safety or quality of laboratory services.

#### Elements of Performance for LD.04.02.01

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| 1. | <b>D</b> The leaders define conflict of interest involving licensed independent practitioners or staff. This definition is in writing.   | <b>A</b> |
| 2. | <b>D</b> The leaders develop a written policy that defines how the laboratory will address conflicts of interest involving licensed independent practitioners and/or staff.  | <b>A</b> |
| 3. | Existing or potential conflicts of interest involving licensed independent practitioners and/or staff, as defined by the laboratory, are disclosed.  | <b>A</b> |
| 4. | The laboratory reviews its relationships with other care providers, educational institutions, manufacturers, and payers to determine whether conflicts of interest exist and whether they are within law and regulation. | <b>A</b> |

### Standard LD.04.02.03

Ethical principles guide the laboratory's business practices.

#### Elements of Performance for LD.04.02.03

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| 1. | The laboratory has a process that allows staff, patients, and families to address ethical issues or issues prone to conflict.   | <b>A</b> |
| 2. | The laboratory uses its process to address ethical issues or issues prone to conflict.  | <b>A</b> |
| 3. | The laboratory follows ethical practices for marketing and billing.   | <b>A</b> |
| 4. | <b>D</b> Marketing materials accurately represent the laboratory and address the services that the laboratory provides either directly or by contractual arrangement. | <b>A</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- M** 11. Patients and other customers are billed for only those services provided. **C**

**Standard LD.04.03.01**

The laboratory provides services that meet patient needs.

**Elements of Performance for LD.04.03.01**

1. The needs of the population(s) served guide decisions about which services will be provided directly or through referral, consultation, contractual arrangements, or other agreements. **A**

**Standard LD.04.03.07**

Patients with comparable needs receive the same standard of laboratory services throughout the laboratory.

**Rationale for LD.04.03.07**

Comparable standards of laboratory services means that the laboratory can provide the services that patients need within established time frames and that those providing laboratory services have the required competence. Laboratories may provide different services to patients with similar needs as long as the patient’s outcome is not affected. Different settings, processes, or payment sources should not result in different standards of laboratory services.

**Elements of Performance for LD.04.03.07**

2. Laboratory services are consistent with the laboratory’s mission, vision, and goals. **A**


**Standard LD.04.03.09**

Laboratory services provided through contractual agreement are provided safely and effectively.

**Elements of Performance for LD.04.03.09**

1. Clinical leaders have an opportunity to provide advice about the sources of clinical services to be provided through contractual agreement. **A**
2. **D** The laboratory describes, in writing, the nature and scope of services provided through contractual agreements. **A**  
 Note: A written agreement (such as a formal contract) is not required for reference laboratories; however, it is required for a contractual agreement in which a major portion of laboratory testing is provided by an outside laboratory.
3. **D** Designated leaders approve contractual agreements. **A**

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required



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| 4.  | Leaders monitor contracted services by establishing expectations for the performance of the contracted services.<br>Note: When the laboratory contracts with another accredited organization for patient laboratory services to be provided off site, it can do the following:<br>- Verify that all licensed independent practitioners who will be providing laboratory services have appropriate privileges by obtaining, for example, a copy of the list of privileges.<br>- Specify in the written agreement that the contracted organization will ensure that all contracted services provided by licensed independent practitioners will be within the scope of their privileges. | A   |
| 5.  | <b>D</b> Leaders monitor contracted services by communicating the expectations in writing to the provider of the contracted services.<br>Note: A written description of the expectations can be provided either as part of the written agreement or in addition to it.   | A   |
| 6.  | Leaders monitor contracted services by evaluating these services in relation to the laboratory's expectations.   | A   |
| 7.  | Leaders take steps to improve contracted services that do not meet expectations.<br>Note: Examples of improvement efforts to consider include the following:<br>- Increase monitoring of the contracted services.<br>- Provide consultation or training to the contractor.<br>- Renegotiate the contract terms.<br>- Apply defined penalties.<br>- Terminate the contract.   | A   |
| 8.  | When contractual agreements are renegotiated or terminated, the laboratory maintains the continuity of laboratory services.  |  A |
| 10. | <b>D</b> Reference and contract laboratory services meet the federal regulations for clinical laboratories and maintain evidence of the same.  | A   |

### Standard LD.04.04.01

Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" (PI) chapter.)

#### Elements of Performance for LD.04.04.01

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| 1. | Leaders set priorities for performance improvement activities and patient health outcomes. (See also PI.01.01.01, EPs 1 and 3)                           | A |
| 2. | Leaders give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities. (See also PI.01.01.01, EPs 7, 8, 23) | A |
| 3. | Leaders reprioritize performance improvement activities in response to changes in the internal or external environment.                                  | A |
| 4. | Performance improvement occurs laboratory-wide.  | A |

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### Standard LD.04.04.03

New or modified services or processes are well designed.


#### Elements of Performance for LD.04.04.03





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| 1. | The laboratory's design of new or modified services or processes incorporates the needs of patients, staff, and others.   | <b>A</b> |
| 2. | The laboratory's design of new or modified services or processes incorporates the results of performance improvement activities.  | <b>A</b> |
| 4. | The laboratory's design of new or modified services or processes incorporates evidence-based information in the decision-making process.<br>Note: For example, evidence-based information could include practice guidelines, successful practices, information from current literature, and clinical standards.   | <b>A</b> |
| 5. | The laboratory's design of new or modified services or processes incorporates information about sentinel events. (See also LD.04.04.05, EP 6; LD.04.04.05, EP 11)<br>Note: A proactive risk assessment is one of several ways to assess potential risks to patients. For suggested components, refer to the Proactive Risk Assessment section at the beginning of this chapter. | <b>A</b> |
| 7. | Leaders involve staff and patients in the design of new or modified services or processes.  | <b>A</b> |

### Standard LD.04.04.05

The laboratory manages safety issues.

#### Elements of Performance for LD.04.04.05

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| 6.  | The laboratory provides and encourages the use of systems for blame-free internal reporting of a system or process failure, or the results of a proactive risk assessment. (See also LD.03.01.01, EP 8; LD.03.04.01, EP 5; LD.04.04.03, EP 5)   | <b>A</b>   |
| 7.  | The laboratory defines "sentinel event" and communicates this definition throughout the organization.<br>Note: At a minimum, the organization's definition includes those events subject to review in the "Sentinel Events" (SE) chapter of this manual. The definition may include any process variation that does not affect the outcome or result in an adverse event, but for which a recurrence carries significant chance of a serious adverse outcome or result in an adverse event, often referred to as a near miss. | <b>A</b>   |
| 8.  | The laboratory conducts thorough and credible root cause analyses in response to sentinel events as described in the "Sentinel Events" (SE) chapter of this manual.   |  <b>A</b> |
| 11. | To improve safety, the laboratory analyzes and uses information about system or process failures and, when conducted, the results of proactive risk assessments. (See also LD.04.04.03, EP 5)   | <b>A</b>   |

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**Standard LD.04.05.01**

Laboratory leadership is effective.



**Rationale for LD.04.05.01**





The director of pathology and clinical laboratory services, as listed on the laboratory Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, oversees and is ultimately responsible for the laboratory's activities, but this does not prevent him or her from assigning specific tasks to others (for example, assigning responsibility for consultation to a pathologist). Laboratory directors are responsible for operations and measuring, assessing, and continuously improving their department's performance. Pathology and clinical laboratory services are organized, directed, and staffed in keeping with the scope of services offered.

Appropriate clinically trained individuals provide or supervise clinical consultation, which consists of the interpretation, evaluation, and application of test results in diagnosing and treating a particular patient. It does not include providing a practitioner with data or general information, such as laboratory test results, reference intervals (normal ranges) for test results, general medical information pertaining to differential diagnoses related to a test result, or general information about additional tests that can be helpful.

Note: In a hospital, such clinical consultation is the responsibility of a physician (in the case of oral pathology, a physician or a dental oral pathologist). If the director of the clinical laboratory services in a hospital is a doctoral scientist, clinical consultation is provided by a qualified physician. If the director is a physician, he or she provides the consultation.

**Elements of Performance for LD.04.05.01**

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| <p>1. Oversight required for effective laboratory leadership provides the following:</p> <ul style="list-style-type: none"> <li>- Technical expertise</li> <li>- Supervision</li> </ul> <p>Note: The general supervisor is responsible for the day-to-day supervision of the laboratory operation and staff who perform patient testing. (See also QSA.02.11.01, EP 3)</p> <ul style="list-style-type: none"> <li>- Clinical consultation, including matters related to the quality of the test results reported and their interpretation concerning specific patient conditions and the appropriateness of the testing ordered to meet the clinical expectations and interpretation of test results, to the laboratory's patients.</li> </ul> | <p><b>A</b></p>   |
| <p>2. The technical consultant and/or technical supervisor is responsible for the technical and scientific oversight of the laboratory.</p>  | <p> <b>A</b></p> |
| <p>3. The laboratory director is accessible to the laboratory to provide onsite, telephone, or electronic consultation as necessary.</p>   | <p> <b>A</b></p> |
| <p>4. The laboratory director establishes communication in the laboratory and throughout the organization through participation, to the extent required, in such activities as committees, in-service programs, and other functions.</p>   | <p><b>A</b></p>   |
| <p>5. All cytology slide preparations are evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.</p>  | <p><b>A</b></p>   |
| <p>6. The laboratory director is responsible for no more than five Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates (including nonwaived and PPM certificates) or less if specified by state law.</p>  | <p><b>A</b></p>   |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

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| 7. | The laboratory director is responsible for the proper performance of all of his or her duties, including when those duties are delegated. (See also HR.01.02.03, EPs 2 and 7) | <b>A</b> |
| 8. | The laboratory director approves current reference intervals (normal values).   | <b>A</b> |
| 9. | The laboratory director makes the documentation for the basis of reference intervals (normal values) available to staff upon request.   | <b>A</b> |
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**Standard LD.04.05.03**

The laboratory director is responsible for determining the qualifications and competence of each laboratory staff member.

**Elements of Performance for LD.04.05.03**

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| 1. | The laboratory director determines the competence and qualifications of each staff member. (See also IC.01.01.01, EP 3)   | <b>A</b> |
| 2. | The laboratory director determines that the level of testing complexity is commensurate with the education, training, experience, and technical abilities of each staff member. | <b>A</b> |
| 3. | The laboratory director determines which procedures and tests each staff member is qualified and authorized to perform.   | <b>A</b> |
| 4. | The laboratory director determines that the level of supervision provided is commensurate with the education, training, and experience of each staff member.                    | <b>A</b> |
| 5. | The laboratory director requires that each staff member demonstrate the ability to perform all duties before actually testing patient specimens.                                | <b>A</b> |
| 6. | The laboratory director requires that each staff member maintain the competence to perform required tasks.  | <b>A</b> |
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**Standard LD.04.05.05**

The laboratory director, technical consultant, and/or technical supervisor provide for orientation, in-service training, and continuing education.

**Elements of Performance for LD.04.05.05**

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| 1. | The laboratory director, technical consultant, and/or technical supervisor provide for orientation, in-service training, and continuing education.  | <b>A</b> |
| 2. | The laboratory director defines and approves policies for the following: <ul style="list-style-type: none"> <li>- Orientation</li> <li>- In-service training</li> <li>- Continuing education</li> </ul> | <b>A</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

**Standard LD.04.05.07**

The laboratory director, technical consultant, and/or technical supervisor are responsible for maintaining laboratory performance.

**Elements of Performance for LD.04.05.07**

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| 1. | The laboratory director, technical consultant, and/or technical supervisor define the laboratory's criteria for the following:<br>- Quality control<br>- Proficiency testing<br>- Reporting of results  | <b>A</b> |
| 2. | The laboratory director, technical consultant, and/or technical supervisor define or approve other criteria used in the preanalytical, analytical, and postanalytical phases of testing.  | <b>A</b> |
| 3. | The laboratory director, technical consultant, and/or technical supervisor ascertain that test methodologies and equipment fulfill the following criteria:<br>- They meet the needs of the patient population.<br>- They are verified to determine accuracy, precision, and other pertinent performance characteristics.<br>- They are adequate in scope.<br>- They are capable of providing the quality of results required by the clinical staff. | <b>A</b> |
| 4. | The laboratory director, technical consultant, and/or technical supervisor ascertain that the laboratory is enrolled and successfully participates in an approved proficiency testing program that is relevant for each test performed. (See also QSA.01.01.01, EP 1)   | <b>A</b> |
| 5. | The laboratory director, technical consultant, and/or technical supervisor review quality control and proficiency testing data.   | <b>A</b> |
| 6. | The laboratory director, technical consultant, and/or technical supervisor require corrective action and documentation on unacceptable quality control and proficiency testing results.   | <b>A</b> |
| 7. | The laboratory director, technical consultant, and/or technical supervisor evaluate the test results that appear inconsistent with clinically relevant criteria.  | <b>A</b> |
| 8. | The laboratory director, technical consultant, and/or technical supervisor discuss with the staff any issues that have been identified.   | <b>A</b> |

**Standard LD.04.05.09**

The laboratory director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services.

**Elements of Performance for LD.04.05.09**

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| 1.          | Laboratory procedures are current and complete. (See also DC.02.01.01, EP 1)  | <b>A</b> |
| <b>M</b> 2. | The laboratory director or designee signs and dates new laboratory procedures or changes in laboratory procedures before they are implemented. (See also DC.02.01.01, EP 1) | <b>C</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 3.  | The laboratory director requires that policies and procedures be consistently implemented and maintained.  | <b>A</b> |
| 4.  | Policies and procedures are readily available in writing to staff who do any kind of work for the laboratory, which includes collecting specimens and reporting test procedures. | <b>A</b> |
| 5.  | Satisfactory specimen criteria are established, as are the limitations on the reliability of test results if the specimen is not satisfactory.                                   | <b>A</b> |
| 6.  | The laboratory director requires that test results be accurately reported within a defined time frame.   | <b>A</b> |
| 7.  | The laboratory director and/or clinical consultant require that results be reported with pertinent information as required for specific patient interpretation.                  | <b>A</b> |
| 8.  | The laboratory director develops a process for clinical staff to request and receive test results on an emergency or stat basis.   | <b>A</b> |
| 9.  | The laboratory director develops criteria for notifying the responsible practitioner when critical limits or specified test results are exceeded.                                | <b>A</b> |
| 10. | <b>D</b> The laboratory director or designee annually reviews and approves each laboratory procedure. This review and approval is documented. (See also DC.02.01.01, EP 1)       | <b>A</b> |
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### Standard LD.04.05.11

The laboratory director is responsible for requiring laboratory practices that respect the needs of patients or other customers.

#### Elements of Performance for LD.04.05.11

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| 1. | The laboratory director is responsible for requiring laboratory practices that respect individual privacy and security.  | <b>A</b> |
| 2. | The laboratory director is responsible for requiring laboratory practices that respect the patient's or customer's right to voice complaints about care or service and to have those complaints reviewed and, when possible, resolved. | <b>A</b> |
| 3. | The laboratory director is responsible for requiring laboratory practices that respect the patient's or customer's right to effective communication; this includes the rights of the hearing and speech impaired.                      | <b>A</b> |
| 4. | The laboratory director is responsible for requiring laboratory practices that respect the patient's or customer's right to confidentiality of information. (Refer to the "Information Management" (IM) chapter.)                      | <b>A</b> |
| 5. | <b>D</b> The laboratory documents all complaints reported to the laboratory.   | <b>A</b> |

**Standard LD.04.05.13**

The laboratory director recommends reference laboratory services to the clinical staff for acceptance through the clinical staff's designated mechanism.

**Elements of Performance for LD.04.05.13**

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| 1. | ⓓ The laboratory director provides a written recommendation to the clinical staff for reference laboratory services (including outside services that provide blood and blood components). | <b>A</b> |
| 2. | ⓓ The clinical staff is involved in selecting reference laboratory services, and the laboratory's approval of those services is documented.   | <b>A</b> |

**Standard LD.04.05.15**

Responsibility for administrative direction and clinical direction is defined in writing.

Note: The laboratory director is responsible for the overall operation and administration of the laboratory.

**Elements of Performance for LD.04.05.15**

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| 1. | ⓓ The responsibility for the laboratory's administrative direction is defined in writing. | <b>A</b> |
| 2. | ⓓ The responsibility for the laboratory's clinical direction is defined in writing.       | <b>A</b> |