



The Joint Commission

Accreditation Program: Laboratory
Human Resources

Standard HR.01.01.01

The laboratory has the necessary staff to support the services it provides.






Elements of Performance for HR.01.01.01





- | | | |
|----|---|----------|
| 1. | An individual qualified to provide technical consultation or supervision and general supervision is on duty or is available whenever testing requires consultation or supervision.
Note: This individual can be available on site, by telephone, or by electronic consultation.
Footnote: Qualifications to provide technical consultation or supervision and general supervision are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
|----|---|----------|

Standard HR.01.02.03

One or more qualified professionals direct pathology and clinical laboratory services.

Elements of Performance for HR.01.02.03

- | | | |
|----|---|--|
| 1. | The qualifications of the laboratory director of record meet the requirements set forth in federal and state law and regulation. (See also QSA.03.01.01, EP 1)
Footnote: Qualifications of the laboratory director are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . |  A |
| 2. | The laboratory director possesses effective management skills.
Note: An example of effective management is the ability of the laboratory director to delegate responsibility to others in the department or laboratory who have the qualifications to perform those responsibilities. (See also LD.04.05.01, EP 7) | A |
| 3. | A qualified individual provides clinical consultation.
Note: In hospitals, it is preferable to have a pathologist providing clinical consultation.
Footnote: Qualifications of the individual providing clinical consultation are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . |  A |
| 4. | A qualified individual directs clinical laboratory services.
Footnote: Qualifications of the individual directing clinical laboratory services are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . |  A |
| 5. | A pathologist directs anatomic pathology services. |  A |
| 6. | A pathologist or another physician qualified in cytology directs cytology services. |  A |

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

- | | | |
|----|--|----------|
| 7. | A pathologist or another physician qualified in immunohematology, hemotherapy, and blood banking directs blood-transfusion services. (See also LD.04.05.01, EP 7) | A |
| 8. | A pathologist, doctoral scientist, or other qualified physician with specialized training or experience in molecular pathology directs molecular pathology services. | A |
| 9. | A qualified individual directs embryology services. The director of the embryology laboratory has the following qualifications:
- A doctoral degree and sufficient training and experience in biology, biochemistry, the physiology of reproduction, as well as clinical laboratory sciences and their operation
- Two years of documented experience in a laboratory performing in vitro fertilization and assisted reproductive-technology procedures.
Note: The director of the embryology laboratory who is not a physician or doctoral scientist, but who was functioning as the director on or before July 20, 1999, is considered qualified. | A |

Standard HR.01.02.05

The laboratory verifies staff qualifications.

Elements of Performance for HR.01.02.05

- | | | |
|----|--|----------|
| 1. | <p> When law or regulation requires laboratory service providers to be currently licensed, certified, or registered to practice their professions, the laboratory both verifies these credentials with the primary source and documents this verification when a provider is hired and when his or her credentials are renewed. (See also HR.01.02.07, EP 2)</p> <p>Note 1: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented.</p> <p>Note 2: A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source.</p> <p>Note 3: An external organization (for example, a credentials verification organization (CVO)) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.</p> | A |
| | 2. When the laboratory requires licensure, registration, or certification not required by law and regulation, the laboratory both verifies these credentials and documents this verification at time of hire and when credentials are renewed. (See also HR.01.02.07, EP 2) | C |
| | 3. The laboratory verifies and documents that the applicant has the education and experience required by the job responsibilities. Footnote: Education and experience requirements are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | C |
| 6. | The laboratory uses the following information to make decisions about staff job responsibilities:
- Verified licensure, certification, or registration required by law or regulation or the laboratory
- Verified education and experience | A |

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 HR.01.02.07

The laboratory determines how staff function within the organization.

Elements of Performance for HR.01.02.07

- | | | |
|---|--|------------------|
| | 1. All staff who provide laboratory services possess a current license, certification, or registration, in accordance with law and regulation. | ▲ ² A |
| | 2. Staff who provide laboratory services practice within the scope of their license, certification, or registration and as required by law and regulation. (See also HR.01.02.05, EPs 1 and 2) | ▲ ² A |
| M | 5. Staff supervise and observe students when they are performing laboratory procedures. | C |

Standard HR.01.03.01

Staff are supervised effectively.

Elements of Performance for HR.01.03.01

- | | | |
|---|---|---|
| M | 3. Supervisory staff have training and experience to supervise. | C |
|---|---|---|

Standard HR.01.04.01

The laboratory provides orientation to staff.

Elements of Performance for HR.01.04.01

- | | | |
|---|--|---|
| | 1. The laboratory determines the key safety content of orientation provided to staff. (See also EC.03.01.01, EPs 1-3)
Note: Key safety content may include specific processes and procedures related to the provision of laboratory services, the environment of care, and infection control. | A |
| M | 2. D The laboratory orients its staff to the key safety content before staff provides laboratory services. Completion of this orientation is documented. (See also IC.01.05.01, EP 6) | C |
| M | 3. D The laboratory orients staff on the following: Organization-wide and laboratory-specific policies and procedures related to job duties and responsibilities. Completion of this orientation is documented. | C |
| M | 4. D The laboratory orients staff on the following: Their specific job duties and responsibilities, including those related to infection prevention and control. Completion of this orientation is documented. (See also IC.01.05.01, EP 6; IC.02.01.01, EP 7) | C |
| M | 5. D The laboratory orients staff on the following: Sensitivity to cultural diversity based on their job duties and responsibilities. Completion of this orientation is documented. | C |
| M | 6. D The laboratory orients staff on the following: Patient rights, including ethical aspects of laboratory services and the process used to address ethical issues based on their job duties and responsibilities. Completion of this orientation is documented. | C |

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

- | | |
|---|---|
| <p>M 9. Staff is oriented to each preanalytic, analytic, and postanalytic activity he or she will be expected to perform.
 Note 1: Preanalytic activity includes patient identification and preparation; specimen collection, labeling, handling, processing or preparation, preservation, and fixation; transportation and storage; instrument preventive maintenance, troubleshooting and calibration procedures; and quality control and documentation of all quality control activities, including instrument and procedural calibrations and maintenance.
 Note 2: Analytic activity includes test performance and knowledge of reagent stability and storage.
 Note 3: Postanalytic activity includes results reporting (including assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results), identifying factors that may adversely affect test performance, correcting identified problems, or notifying the supervisor when problems arise.</p> <p>10. D Prior to performing laboratory duties, the laboratory director or supervisor documents that staff have completed orientation and have demonstrated competence in performing their required duties.</p> <p>12. D Prior to performing laboratory duties, the staff member affirms, in writing, that he or she can perform the duties for which orientation was provided.</p> | <p>C</p> <p>C</p> <p>C</p> |
|---|---|

Standard HR.01.05.03

Staff participate in education and training.

Elements of Performance for HR.01.05.03

- | | |
|---|---|
| <p>M 1. D Staff participate in education and training to maintain or increase their competency. Staff participation is documented.</p> <p>M 4. D Staff participate in education and training whenever staff responsibilities change, including when a test, methodology, or instrumentation changes. Staff participation is documented. (See also HR.01.06.01, EP 21)</p> <p>M 5. D Staff participate in education and training that is specific to the needs of the patient population served by the organization. Staff participation is documented.</p> <p>M 6. D Staff participate in education and training that incorporates the skills of team communication, collaboration, and coordination of services. Staff participation is documented.</p> <p>M 7. D Staff participate in education and training that includes information about the need to report unanticipated adverse events and how to report these events. Staff participation is documented.</p> | <p>C</p> <p>C</p> <p>C</p> <p>C</p> <p>C</p> |
|---|---|

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 HR.01.06.01

Staff are competent to perform their responsibilities.

Elements of Performance for HR.01.06.01

- | | | |
|------------------------------|--|-----------------|
| <p>M 3.</p> | <p>An individual qualified by education, experience, and knowledge related to the skill being reviewed assesses staff competence.
Footnote: Qualifications for this individual are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx.</p> | <p>C</p> |
| <p>M 18.</p> | <p>The staff member's competency assessment includes the following:</p> <ul style="list-style-type: none"> - Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing - Monitoring, recording, and reporting of test results - Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance - Direct observation of performance of instrument maintenance function checks and calibration - Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples) - Problem-solving skills as appropriate to the job <p>(See also WT.03.01.01, EP 6)</p> | <p>C</p> |
| <p>M 19. D</p> | <p>During the first year of employment, each staff member's competence is assessed at least semiannually for all laboratory tests he or she performs. This assessment is documented.
Note: For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter.</p> | <p>C</p> |
| <p>M 20. D</p> | <p>After the first year of employment, each staff member's competence is assessed on an annual basis for all laboratory tests he or she performs. This assessment is documented.
Note: For waived testing competency requirements, refer to the "Waived Testing" (WT) chapter.</p> | <p>C</p> |
| <p>M 21. D</p> | <p>If a test, methodology, or instrumentation changes, or the individual's duties change, his or her competence to perform these new skills or duties is assessed. This assessment is documented. (See also HR.01.05.03, EP 4)</p> | <p>C</p> |
| <p>22.</p> | <p>For histocompatibility testing, the competency assessment process includes the following:</p> <ul style="list-style-type: none"> - A defined system to confirm testing competence - A previously tested specimen is given to each individual as an unknown in order to verify his or her ability to reproduce test results at least monthly - Established acceptable performance criteria - Documented performance levels - Documented corrective action | <p>A</p> |

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