



# The Joint Commission

Accreditation Program: Laboratory  
Document and Process Control

**Standard DC.01.01.01**

The laboratory establishes procedures for collecting specimens.

**Rationale for DC.01.01.01**

A specimen that is properly timed, collected, identified, preserved, stored, received, and processed is the first step toward achieving an accurate result.

**Elements of Performance for DC.01.01.01**

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| 1. <b>D</b> | The laboratory has written procedures for collecting specimens that address the following:<br>- Patient identification<br>- Patient preparation<br>- Specimen collection<br>- Precautions for specimen collection<br>- Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy<br>- Specimen storage; preservation, including organism viability for microbiology specimens; and transport<br>- Specimen receipt and processing<br>- Specimen rejection criteria<br>- Collection of reference laboratory specimens<br>Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten. | <b>A</b> |
| 2.          | Current specimen collection procedures are made available to laboratory staff, nonlaboratory staff, and external providers who collect specimens for laboratory testing.<br>Note: Electronic specimen collection procedure manuals may be used if they are accessible to staff.  | <b>A</b> |
| 3.          | Staff follow the laboratory's procedures for specimen collection.  | <b>A</b> |

**Standard DC.01.02.01**

The laboratory performs testing based on written laboratory test orders.

**Elements of Performance for DC.01.02.01**

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| 1. <b>D</b> | The laboratory has written procedures for ordering tests.  | <b>A</b> |
| 2.          | Individuals who order laboratory tests or receive laboratory test results are authorized to do so in accordance with law and regulation. | <b>A</b> |
| 3. <b>D</b> | Laboratory test orders are made in writing (paper or electronic).<br>Note: The test order may be located in the clinical record.         | <b>A</b> |
| <b>M</b>    | 4. Laboratory test orders for laboratory tests are legible.  | <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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| <p><b>M</b> 5. Laboratory test orders are complete and include the following:</p> <ul style="list-style-type: none"> <li>- Patient's first and last name</li> <li>- Patient's gender</li> <li>- Patient's age or date of birth</li> <li>- Name of the individual who requested the test</li> <li>- Name of the individual to contact (which may be the individual requesting the test) concerning potentially life-threatening laboratory results</li> <li>- Name of the test(s) ordered</li> <li>- Any special handling required</li> <li>- Date and, when pertinent to the test being ordered, time the specimen was collected</li> <li>- Date and time the specimen arrived at the laboratory</li> <li>- The specimen source, when pertinent to the test being ordered</li> <li>- Additional information required by the laboratory to support accurate test interpretation and reporting of results, such as race, ethnicity, or family history</li> </ul> <p><b>M</b> 6. <b>D</b> If the laboratory permits verbal orders for laboratory testing, the laboratory requests written (paper or electronic) authorization within 30 days and retains the written authorization, or documentation of its attempts to obtain written authorization, in accordance with law and regulation.</p> <p><b>M</b> 7. Before taking action on a verbal order or verbal report of a test result, staff uses a record and "read back" process to verify the information.</p> <p><b>M</b> 8. Laboratory test orders for interpretation of Pap smears include the following:</p> <ul style="list-style-type: none"> <li>- The date of the woman's last menstrual period</li> <li>- Information on previous abnormal reports, treatments, or biopsies</li> </ul> | <p><b>C</b></p> <p><b>C</b></p> <p><b>3 C</b></p> <p><b>C</b></p> |
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### Standard DC.01.03.01

The laboratory has a system for maintaining the integrity of, uniquely identifying, and retrieving records for each specimen.

#### Elements of Performance for DC.01.03.01

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| <p>1. The laboratory has a system for uniquely identifying each specimen collected or received by the laboratory.<br/>Note: This is accomplished by providing each specimen with an individual accession number or any other method that identifies each specimen in a unique way.</p> <p><b>M</b> 2. <b>D</b> The unique identification for each specimen has the following characteristics:</p> <ul style="list-style-type: none"> <li>- It is included in the labeling of each specimen.</li> <li>- It is an identifier in the analytical phases of patient testing.</li> <li>- It is part of the laboratory record for the specimen.</li> </ul> <p>3. The laboratory maintains specimen identity throughout all testing phases.</p> | <p><b>A</b></p> <p><b>C</b></p> <p><b>A</b></p> |
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4. The laboratory is able to retrieve specimens it collects, receives, or tests by date, patient name, or unique identifier within a regular working day. **A**  
Note: This information does not need to be kept in one place or on a single log in the laboratory. A combination of work logs and test reports can satisfy this requirement.
5. The laboratory is able to retrieve data on the test order or test report by date, patient name, or unique identifier within a regular working day. (See also DC.02.04.01, EP 7) **A**  
Note: This information does not need to be kept in one place or on a single log in the laboratory. A combination of work logs and test reports can satisfy this requirement.

**Standard DC.02.01.01**

The laboratory has procedures for each laboratory test.

**Rationale for DC.02.01.01**

Written procedures play an important role in patient safety. They describe the work standards of the laboratory and the steps to be followed when conducting laboratory tests. When procedures are comprehensive and followed by staff, the laboratory can be confident that it will produce and report accurate test results.

**Elements of Performance for DC.02.01.01**

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| <p>1. <b>D</b> Written laboratory procedures for each test meet the following requirements:</p> <ul style="list-style-type: none"> <li>- They contain a complete description of the test.</li> <li>- They include detailed instructions for performing the test.</li> <li>- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).</li> <li>- They include the date of implementation.</li> <li>- They reflect the laboratory's current practice.</li> <li>- They are readily available to staff performing the testing.</li> </ul> <p>Note 1: Test procedures include, but are not limited to, the following:</p> <ul style="list-style-type: none"> <li>- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results</li> <li>- Microscopic examination, including the detection of inadequately prepared slides</li> <li>- Result entry in the patient clinical record</li> <li>- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values</li> <li>- Control and calibration procedures</li> <li>- Reference intervals (normal values)</li> <li>- Reportable range</li> <li>- Special precautions</li> <li>- Limitations in the test methodology, including interfering factors</li> <li>- Pertinent literature references</li> </ul> <p>Note 2: An exception to including manufacturers' instructions is allowed when the laboratory establishes the performance specifications for test procedures with modifications to the manufacturer's instructions.<br/>(See also LD.04.05.09, EPs 1, 2, and 10)</p> | <p><b>A</b></p> |
| <p>2. <b>D</b> Discontinued procedures are retained for at least two years and include the implementation and discontinuation dates.</p>  | <p><b>A</b></p> |
| <p>3. If manufacturers' manuals or package inserts are used as procedures, they are modified to include specific laboratory operational policies.<br/>Note: These may include detailed quality control protocols, calibration protocols, and other institution-specific procedures regarding the test or instrument.</p>  | <p><b>A</b></p> |
| <p><b>M</b> 4. Staff follow the laboratory's procedures for each test.</p>  | <p><b>C</b></p> |

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**Standard DC.02.02.01**

The laboratory identifies the individual(s) responsible for performing and reporting laboratory procedures.

**Elements of Performance for DC.02.02.01**

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| 1. | The laboratory is able to identify the individual(s) performing and reporting the laboratory procedure including the preanalytical, analytical, and postanalytical phases of testing.<br>Note: The individual(s) performing and reporting the laboratory procedure does not need to be identified in the report filed in the patient's clinical record. However, reports that require specific interpretation, such as surgical pathology reports, must identify the individual making the interpretation. | <b>A</b> |
| 2. | (D) When the laboratory uses initials or other unique identifiers to identify the individual(s) performing and reporting the laboratory procedure, a written list of names that includes the initials or other unique identifiers for the staff is maintained.   | <b>A</b> |

**Standard DC.02.03.01**

The laboratory report is complete and is in the patient's clinical record.

**Elements of Performance for DC.02.03.01**

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| 1.      | The laboratory report is maintained in the patient's clinical record.   | <b>A</b> |
| 2.      | (D) The laboratory report includes the following information: The name and address of the laboratory performing the test.   | <b>A</b> |
| 3.      | (D) The laboratory report includes the following information: The patient's first and last name.  | <b>A</b> |
| 4.      | (D) The laboratory report includes the following information: The patient identifier, which cannot be the patient's room number or physical location.   | <b>A</b> |
| 5.      | (D) The laboratory report includes the following information: The specimen collection date (and time, when pertinent to the test performed).  | <b>A</b> |
| 6.      | (D) The laboratory report includes the following information: The specimen source, when pertinent to the test performed.  | <b>A</b> |
| 7.      | (D) The laboratory report includes the following information: The condition of unsatisfactory specimens.  | <b>A</b> |
| 8.      | (D) The laboratory report includes the following information: The results of examinations and tests performed.  | <b>A</b> |
| (M) 9.  | (D) The laboratory report includes the following information: The authentication of interpretive reports, such as surgical pathology reports.   | <b>C</b> |
| (M) 10. | (D) The laboratory report includes the following information: The date and time the test results were generated as a final report. The date and time cannot be changed on copies of the report that are made at a later date. | <b>C</b> |
| (M) 11. | (D) The laboratory report includes the following information: The result units (that is, concentration or activity) for quantitative analytes.  | <b>C</b> |

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| <p><b>M</b> 12. <b>D</b> The laboratory report includes the following information: Test reports for nonwaived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (For waived testing, see also WT.05.01.01, EP 3)</p> <p>Note 1: This requirement also applies to reference laboratory reports.</p> <p>Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the laboratory result, there must be a notation directing the reader to their location.</p>  | <p><b>C</b></p> |
| <p>13. The laboratory does not revise results or information related to the interpretation of results in a reference laboratory's report.</p>   | <p><b>A</b></p> |
| <p><b>M</b> 14. <b>D</b> For interpretive reports, the qualified individual providing the interpretation authenticates the results.</p> <p>Note: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key.</p> <p>Footnote: Qualifications of the individual providing interpretations are described in 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 <a href="http://wwwn.cdc.gov/clia/regs/toc.aspx">http://wwwn.cdc.gov/clia/regs/toc.aspx</a>.</p> | <p><b>C</b></p> |
| <p>15. The individual identified by the electronic signature, written signature or initials, rubber-stamp signature, or computer key used for authentication is the only individual who uses it.</p>  | <p><b>A</b></p> |

### Standard DC.02.04.01

The laboratory retains records as required by law and regulation.

#### Elements of Performance for DC.02.04.01

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| <p>1. The laboratory retains quality control records, including test system performance specifications and quality system assessments, for at least two years, or longer if required by law and regulation.</p>   | <p><b>A</b></p> |
| <p>2. The laboratory retains immunohematology, including blood and blood component records and transfusion records, for at least 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date, and histocompatibility records for at least 5 years or longer if required by law and regulation.</p> <p>Note: For immunohematology: When there is no expiration date, records shall be retained indefinitely.</p> | <p><b>A</b></p> |
| <p>3. The laboratory retains test orders for at least two years, or longer if required by law and regulation.</p> <p>Note: This includes the patient's clinical record, if it is used as the test order.</p>  | <p><b>A</b></p> |
| <p>4. The testing laboratory retains instrument printouts for at least two years, or longer if required by law and regulation.</p> <p>Note: Retained records may be paper or electronic. Electronic systems must be able to retrieve all information printed on the original hard copy generated at the time of testing in order to be considered satisfactory for compliance.</p>  | <p><b>A</b></p> |

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- M** 5. The testing laboratory retains an original test report or an exact copy, including preliminary, final, corrected, and reference laboratory reports, for the following periods: **C**
- At least 5 years for histocompatibility reports
  - At least 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date for immunohematology reports
  - At least 10 years for histopathology and cytology reports
  - At least 2 years for all other reports
- Note 1: The exact copy includes the name and address of the laboratory performing the test. The copy may be on paper or maintained in a computer system, microfilm, or microfiche record. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing individual identifiers, the copy includes the signature or individual identifiers.
- Note 2: The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially ordered the test. The referring laboratory must retain or be able to produce an exact copy of each testing laboratory's test report.
- Note 3: For immunohematology: When there is no expiration date, records shall be retained indefinitely.
- M** 6. For all other laboratory records, the laboratory complies with law and regulation for record retention. **C**
7. The laboratory is able to retrieve reports in a timely manner to support patient care and other activities. (See also DC.01.03.01, EP 5) **A**
8. The laboratory maintains records, slides, blocks, and tissues and makes arrangements for their availability for the time frames required by law and regulation in the event that the laboratory ceases to operate. **A**

### Standard DC.03.01.01

The laboratory implements a standardized approach to hand-off communications.

#### Elements of Performance for DC.03.01.01

- M** 1. The laboratory's process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information. **3 C**
- Note: Such information may include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these.