

# History Tracking Report: 2010 to 2009 Requirements

## Accreditation Program: Laboratory 2010 Chapter: Document and Process Control

### Standard DC.01.01.01

#### 2010 Standard Text:

The laboratory establishes procedures for collecting specimens.

**2010 Standard:** DC.01.01.01

**2010 EP:** 1

#### 2010 EP Text:

The laboratory has written procedures for collecting specimens that address the following:

- Patient identification
- Patient preparation
- Specimen collection
- Precautions for specimen collection
- Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy
- Specimen storage; preservation, including organism viability for microbiology specimens; and transport
- Specimen receipt and processing
- Specimen rejection criteria
- Collection of reference laboratory specimens

Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten.

### Standard IM.6.180

#### 2009 Standard Text:

Written procedures are developed for collecting specimens to ensure that they are satisfactory for the tests to be performed.

**2009 Standard:** IM.6.180

**2009 EP:** 1

#### 2009 EP Text:

**Revision Code:** Split

The written procedures relate to the following: Ordering of tests Standard and special methods for preparing {jc}patients{/6} and specimen collection, as well as precautions to be taken for special procedures Proper identification, specimen labeling (including specimen source, when appropriate), specimen storage, specimen preservation, conditions for specimen transportation, receipt of specimens, and specimen processing Laboratory policy for handling improperly collected or preserved specimens that states criteria for handling or rejection of unacceptable specimens

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**2010 Standard:** DC.01.01.01**2010 EP:** 1**2010 EP Text:**

The laboratory has written procedures for collecting specimens that address the following:

- Patient identification
- Patient preparation
- Specimen collection
- Precautions for specimen collection
- Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy
- Specimen storage; preservation, including organism viability for microbiology specimens; and transport
- Specimen receipt and processing
- Specimen rejection criteria
- Collection of reference laboratory specimens

Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten.

**2009 Standard:** IM.6.180**2009 EP:** 5**2009 EP Text:****Revision Code:** Consolidate

Written procedures for reference laboratory testing are included in the procedure manual. These may be obtained from the reference laboratory and need not be rewritten.

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**2010 Standard:** DC.01.01.01**2010 EP:** 1**2010 EP Text:**

The laboratory has written procedures for collecting specimens that address the following:

- Patient identification
- Patient preparation
- Specimen collection
- Precautions for specimen collection
- Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy
- Specimen storage; preservation, including organism viability for microbiology specimens; and transport
- Specimen receipt and processing
- Specimen rejection criteria
- Collection of reference laboratory specimens

Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten.

**2009 Standard:** QC.2.20**2009 EP:** 3**2009 EP Text:****Revision Code:** Consolidate

The specimen label also includes the specimen source identification and other information required by laboratory policy. Note: Such sites include operating rooms, physician office examination and treatment rooms, or other areas where specimens are obtained.

**2010 Standard:** DC.01.01.01**2010 EP:** 1**2010 EP Text:**

The laboratory has written procedures for collecting specimens that address the following:

- Patient identification
- Patient preparation
- Specimen collection
- Precautions for specimen collection
- Specimen labeling, including the source, when pertinent to the test being ordered, and other labeling information required by laboratory policy
- Specimen storage; preservation, including organism viability for microbiology specimens; and transport
- Specimen receipt and processing
- Specimen rejection criteria
- Collection of reference laboratory specimens

Note: The laboratory may use a reference laboratory's procedures—they need not be rewritten.

**2009 Standard:** QC.8.50**2009 EP:** 3**2009 EP Text:**

Appropriate conditions are maintained during specimen storage and transportation to preserve the viability of organisms.

**Revision Code:** Consolidate**2010 Standard:** DC.01.01.01**2010 EP:** 2**2010 EP Text:**

Current specimen collection procedures are made available to laboratory staff, nonlaboratory staff, and external providers who collect specimens for laboratory testing.

Note: Electronic specimen collection procedure manuals may be used if they are accessible to staff.

**2009 Standard:** IM.6.180**2009 EP:** 4**2009 EP Text:**

Electronic specimen collection procedure manuals are acceptable if available to staff.

**Revision Code:** Consolidate**2010 Standard:** DC.01.01.01**2010 EP:** 2**2010 EP Text:**

Current specimen collection procedures are made available to laboratory staff, nonlaboratory staff, and external providers who collect specimens for laboratory testing.

Note: Electronic specimen collection procedure manuals may be used if they are accessible to staff.

**2009 Standard:** IM.6.180**2009 EP:** 2**2009 EP Text:**

Specimen collection procedures apply to laboratory and non-laboratory staff; are readily available to staff (including laboratory's clients when the laboratory accepts a referral specimen) collecting specimens; and are current and followed.

**Revision Code:** Split

**2010 Standard:** DC.01.01.01**2010 EP:** 3**2010 EP Text:**

Staff follow the laboratory's procedures for specimen collection.

**2009 Standard:** IM.6.180**2009 EP:** 2**2009 EP Text:****Revision Code:** Split

Specimen collection procedures apply to laboratory and non-laboratory staff; are readily available to staff (including laboratory's clients when the laboratory accepts a referral specimen) collecting specimens; and are current and followed.

**Standard DC.01.02.01****2010 Standard Text:**

The laboratory performs testing based on written laboratory test orders.

**2010 Standard:** DC.01.02.01

**2010 EP:** 1

**2010 EP Text:**

The laboratory has written procedures for ordering tests.

**2010 Standard:** DC.01.02.01

**2010 EP:** 2

**2010 EP Text:**

Individuals who order laboratory tests or receive laboratory test results are authorized to do so in accordance with law and regulation.

**2010 Standard:** DC.01.02.01

**2010 EP:** 3

**2010 EP Text:**

Laboratory test orders are made in writing (paper or electronic).  
Note: The test order may be located in the clinical record.

**2010 Standard:** DC.01.02.01

**2010 EP:** 3

**2010 EP Text:**

Laboratory test orders are made in writing (paper or electronic).  
Note: The test order may be located in the clinical record.

**2010 Standard:** DC.01.02.01

**2010 EP:** 4

**2010 EP Text:**

Laboratory test orders for laboratory tests are legible.

**Standard IM.6.180****2009 Standard Text:**

Written procedures are developed for collecting specimens to ensure that they are satisfactory for the tests to be performed.

**2009 Standard:** IM.6.180

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Split

The written procedures relate to the following: Ordering of tests Standard and special methods for preparing {jc}patients{/6} and specimen collection, as well as precautions to be taken for special procedures Proper identification, specimen labeling (including specimen source, when appropriate), specimen storage, specimen preservation, conditions for specimen transportation, receipt of specimens, and specimen processing Laboratory policy for handling improperly collected or preserved specimens that states criteria for handling or rejection of unacceptable specimens

**2009 Standard:** IM.6.190

**2009 EP:** 9

**2009 EP Text:**

**Revision Code:** Retain

Requests are made by individuals authorized in accordance with law or regulation regarding ordering tests or receiving tests.

**2009 Standard:** IM.6.190

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Consolidate

Requests for laboratory tests are made in writing or electronically.

**2009 Standard:** IM.6.190

**2009 EP:** 8

**2009 EP Text:**

**Revision Code:** Consolidate

If the clinical record is used as the request, it meets the requirements of a written or electronic request.

**2009 Standard:** IM.6.190

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Split

Information is legible and complete.

**2010 Standard:** DC.01.02.01

**2010 EP:** 5

**2010 EP Text:**

Laboratory test orders are complete and include the following:

- Patient's first and last name
- Patient's gender
- Patient's age or date of birth
- Name of the individual who requested the test
- Name of the individual to contact (which may be the individual requesting the test) concerning potentially life-threatening laboratory results
- Name of the test(s) ordered
- Any special handling required
- Date and, when pertinent to the test being ordered, time the specimen was collected
- Date and time the specimen arrived at the laboratory
- The specimen source, when pertinent to the test being ordered
- Additional information required by the laboratory to support accurate test interpretation and reporting of results, such as race, ethnicity, or family history

**2010 Standard:** DC.01.02.01

**2010 EP:** 5

**2010 EP Text:**

Laboratory test orders are complete and include the following:

- Patient's first and last name
- Patient's gender
- Patient's age or date of birth
- Name of the individual who requested the test
- Name of the individual to contact (which may be the individual requesting the test) concerning potentially life-threatening laboratory results
- Name of the test(s) ordered
- Any special handling required
- Date and, when pertinent to the test being ordered, time the specimen was collected
- Date and time the specimen arrived at the laboratory
- The specimen source, when pertinent to the test being ordered
- Additional information required by the laboratory to support accurate test interpretation and reporting of results, such as race, ethnicity, or family history

**2009 Standard:** IM.6.190

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Consolidate

Orders or requisitions for services clearly identify the following: Patient's name  
 Patient's gender Patient's age or date of birth Requesting individual, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results including panic or alert values Test(s) required  
 Special handling required Date and, when relevant, the time the specimen was collected Date and time the specimen and requisition arrived at the laboratory The specimen source, when appropriate Additional information required to select appropriate tests and to ensure accurate test interpretation and reporting of results (e.g., race/ethnicity, family history, pedigree).

**2009 Standard:** IM.6.190

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Split

Information is legible and complete.

**2010 Standard:** DC.01.02.01

**2010 EP:** 6

**2010 EP Text:**

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.

**2010 Standard:** DC.01.02.01

**2010 EP:** 8

**2010 EP Text:**

Laboratory test orders for interpretation of Pap smears include the following:  
 - The date of the woman's last menstrual period  
 - Information on previous abnormal reports, treatments, or biopsies

**2009 Standard:** IM.6.190

**2009 EP:** 4

**2009 EP Text:**

Verbal requests are permitted if the laboratory obtains written or electronic authorization for testing in accordance with its own policy (but within 30 days), or documentation exists of attempts to obtain authorization. If law or regulation is more restrictive, then that law or regulation applies.

**Revision Code:** Retain

**2009 Standard:** IM.6.190

**2009 EP:** 6

**2009 EP Text:**

Requests for Pap smears include the date of the woman's last menstrual period, age or date of birth, and information on previous abnormal reports, treatments, or biopsies.

**Revision Code:** Retain

**Standard DC.01.03.01**

**2010 Standard Text:**

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

**2010 Standard:** DC.01.03.01

**2010 EP:** 1

**2010 EP Text:**

The laboratory has a system for uniquely identifying each specimen collected or received by the laboratory.

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.

**2010 Standard:** DC.01.03.01

**2010 EP:** 2

**2010 EP Text:**

The unique identification for each specimen has the following characteristics:

- It is included in the labeling of each specimen.
- It is an identifier in the analytical phases of patient testing.
- It is part of the laboratory record for the specimen.

**2010 Standard:** DC.01.03.01

**2010 EP:** 3

**2010 EP Text:**

The laboratory maintains specimen identity throughout all testing phases.

**2010 Standard:** DC.01.03.01

**2010 EP:** 4

**2010 EP Text:**

The laboratory is able to retrieve specimens it collects, receives, or tests by date, patient name, or unique identifier within a regular working day.

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 IM.6.240**

**2009 Standard Text:**

The pathology and clinical laboratory services maintain a record of daily specimen accession and a system for identifying each specimen.

**2009 Standard:** IM.6.240

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Retain

The laboratory has a system for identifying\* each specimen collected or received by the laboratory. \*This is accomplished by providing each specimen with an individual accession number or any other method that identifies each specimen in a unique way.

**2009 Standard:** IM.6.240

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Retain

The identification is used to label the individual specimen, is a part of the accession record, and is used in patient testing.

**2009 Standard:** QC.1.83

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Retain

The laboratory develops procedures to maintain the integrity of the specimens throughout all testing phases.

**2009 Standard:** IM.6.240

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Split

An audit trail\* permits convenient and timely retrieval by date, individual name, or identification of the following: Specimens collected, received, or tested Data required to be on the test request and report as specified by the standards in this manual \*This information does not need to be kept in one place or on a single log in the laboratory. Copies of the request and report may be a part of this audit trail. A combination of the work logs and test reports can satisfy this requirement.

**2010 Standard:** DC.01.03.01

**2010 EP:** 4

**2010 EP Text:**

The laboratory is able to retrieve specimens it collects, receives, or tests by date, patient name, or unique identifier within a regular working day.

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.

**2009 Standard:** IM.6.240

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

Required information is accessible in an organized form and is available within a normal working day.

**2010 Standard:** DC.01.03.01

**2010 EP:** 5

**2010 EP Text:**

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)

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.

**2009 Standard:** IM.6.240

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

Required information is accessible in an organized form and is available within a normal working day.

**2010 Standard:** DC.01.03.01

**2010 EP:** 5

**2010 EP Text:**

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)

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.

**2009 Standard:** IM.6.240

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Split

An audit trail\* permits convenient and timely retrieval by date, individual name, or identification of the following: Specimens collected, received, or tested Data required to be on the test request and report as specified by the standards in this manual \*This information does not need to be kept in one place or on a single log in the laboratory. Copies of the request and report may be a part of this audit trail. A combination of the work logs and test reports can satisfy this requirement.

**Standard DC.02.01.01****2010 Standard Text:**

The laboratory has procedures for each laboratory test.

**2010 Standard:** DC.02.01.01

**2010 EP:** 1

**2010 EP Text:**

Written laboratory procedures for each test meet the following requirements:

- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory's current practice.
- They are readily available to staff performing the testing.

Note 1: Test procedures include, but are not limited to, the following:

- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Pertinent literature references

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.

(See also LD.04.05.09, EPs 1, 2, and 10)

**Standard IM.6.260****2009 Standard Text:**

The laboratory has current written descriptions of and instructions for test methods and procedures.

**2009 Standard:** IM.6.260

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Split

Current descriptions and instructions meet the following requirements: A complete written description of test procedures exists\*Documentation shows annual review and evaluation by the laboratory services director or by the supervisor of the organized laboratory component The laboratory director or designee signs and dates written procedures and changes in written procedures before they are put into useTest procedures for pre-analytical, analytical and post-analytical phases of testing follow manufacturers' instructions. Note: An exception to this requirement is when the laboratory establishes the manufacturer's performance specifications for test procedures with modifications to the manufacturer's instructions. This would be scored at QC.1.70, Element of Performance # 3. \*Test procedures include, but are not limited, to step-by-step performance of the procedure, including test calculations and interpretation of results, microscopic examination including the detection of inadequately prepared slides, result entry in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results, or panic, or alert values; control and calibration procedures, reference intervals (normal values), reportable range special precautions, limitations in the test methodology including interfering factors, and pertinent literature references

**2010 Standard:** DC.02.01.01**2010 EP:** 1**2009 Standard:** IM.6.260**2009 EP:** 2**2010 EP Text:**

Written laboratory procedures for each test meet the following requirements:

- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory's current practice.
- They are readily available to staff performing the testing.

Note 1: Test procedures include, but are not limited to, the following:

- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Pertinent literature references

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.

(See also LD.04.05.09, EPs 1, 2, and 10)

**2009 EP Text:**

Written procedures are readily available for consultation by the technical staff performing the testing.

**Revision Code:** Consolidate

**2010 Standard:** DC.02.01.01**2010 EP:** 1**2010 EP Text:**

Written laboratory procedures for each test meet the following requirements:

- They contain a complete description of the test.
- They include detailed instructions for performing the test.
- They adhere to manufacturers' instructions (preanalytical, analytical, and postanalytical phases of testing).
- They include the date of implementation.
- They reflect the laboratory's current practice.
- They are readily available to staff performing the testing.

Note 1: Test procedures include, but are not limited to, the following:

- A step-by-step description of the performance of the procedure, including test calculations and interpretation of results
- Microscopic examination, including the detection of inadequately prepared slides
- Result entry in the patient clinical record
- Reporting patient results, including, when appropriate, the process for reporting imminent life-threatening results, or panic or alert values
- Control and calibration procedures
- Reference intervals (normal values)
- Reportable range
- Special precautions
- Limitations in the test methodology, including interfering factors
- Pertinent literature references

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.

(See also LD.04.05.09, EPs 1, 2, and 10)

**2010 Standard:** DC.02.01.01**2010 EP:** 2**2010 EP Text:**

Discontinued procedures are retained for at least two years and include the implementation and discontinuation dates.

**2009 Standard:** IM.6.260**2009 EP:** 3**2009 EP Text:**

There is documentation of the date of implementation and the date of discontinuance for each procedure.

**Revision Code:** Consolidate**2009 Standard:** IM.6.260**2009 EP:** 4**2009 EP Text:**

Discontinued procedures, along with the implementation and discontinuance dates, are retained for at least two years.

**Revision Code:** Retain

**2010 Standard:** DC.02.01.01

**2010 EP:** 3

**2010 EP Text:**

If manufacturers' manuals or package inserts are used as procedures, they are modified to include specific laboratory operational policies.

Note: These may include detailed quality control protocols, calibration protocols, and other institution-specific procedures regarding the test or instrument.

**2009 Standard:** IM.6.260

**2009 EP:** 5

**2009 EP Text:**

If manufacturers' manuals or package inserts are used, they are enhanced to include specific operational policies (for example, detailed quality control protocols, calibration protocols, and other institution-specific procedures regarding the test or instrument).

**Revision Code:** Retain

**2010 Standard:** DC.02.01.01

**2010 EP:** 4

**2010 EP Text:**

Staff follow the laboratory's procedures for each test.

**2009 Standard:** IM.6.260

**2009 EP:** 6

**2009 EP Text:**

Laboratory procedures are followed.

**Revision Code:** Retain

**Standard DC.02.02.01**

**2010 Standard Text:**

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

**2010 Standard:** DC.02.02.01

**2010 EP:** 1

**2010 EP Text:**

The laboratory is able to identify the individual(s) performing and reporting the laboratory procedure including the preanalytical, analytical, and postanalytical phases of testing.

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.

**2010 Standard:** DC.02.02.01

**2010 EP:** 1

**2010 EP Text:**

The laboratory is able to identify the individual(s) performing and reporting the laboratory procedure including the preanalytical, analytical, and postanalytical phases of testing.

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.

**2010 Standard:** DC.02.02.01

**2010 EP:** 2

**2010 EP Text:**

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.

**Standard IM.6.210**

**2009 Standard Text:**

A system exists to identify the individual responsible for performing or completing laboratory procedures.

**2009 Standard:** IM.6.210

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Consolidate

The laboratory has a system (either manual or electronic) to identify the individual responsible for performing or completing the laboratory procedure.

**2009 Standard:** IM.6.210

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Consolidate

The laboratory has a method to trace the identity of the person performing the test for computerized reports whose format does not allow space for identifying the staff members who performed the test. Note: The Joint Commission does not require identification to be on the report filed in the patient record. Exceptions to this policy include reports that require specific interpretation, such as surgical pathology reports (See standard IM.6.220).

**2009 Standard:** IM.6.210

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Retain

If initials are used, a list identifies the names and employment dates for those staff members.

**Standard DC.02.03.01****2010 Standard Text:**

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

**2010 Standard:** DC.02.03.01

**2010 EP:** 1

**2010 EP Text:**

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

**2010 Standard:** DC.02.03.01

**2010 EP:** 2

**2010 EP Text:**

The laboratory report includes the following information: The name and address of the laboratory performing the test.

**2010 Standard:** DC.02.03.01

**2010 EP:** 3

**2010 EP Text:**

The laboratory report includes the following information: The patient's first and last name.

**2010 Standard:** DC.02.03.01

**2010 EP:** 4

**2010 EP Text:**

The laboratory report includes the following information: The patient identifier, which cannot be the patient's room number or physical location.

**2010 Standard:** DC.02.03.01

**2010 EP:** 5

**2010 EP Text:**

The laboratory report includes the following information: The specimen collection date (and time, when pertinent to the test performed).

**2010 Standard:** DC.02.03.01

**2010 EP:** 6

**2010 EP Text:**

The laboratory report includes the following information: The specimen source, when pertinent to the test performed.

**Standard IM.6.220****2009 Standard Text:**

Required records and reports are maintained and, as appropriate, filed in the patient's clinical record and with the laboratory services.

**2009 Standard:** IM.6.220

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Split

The patient's clinical record includes authenticated, dated reports of examinations and tests performed by the laboratory services.

**2009 Standard:** IM.6.220

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Retain

The report in the patient's clinical record includes the name and address of the laboratory performing the test.

**2009 Standard:** IM.6.220

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

The report identifies the {jc}patient{/1} by name and identification number; and the specimen by source, when appropriate, and date (and time, if applicable).

**2009 Standard:** IM.6.220

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

The report identifies the {jc}patient{/1} by name and identification number; and the specimen by source, when appropriate, and date (and time, if applicable).

**2009 Standard:** IM.6.220

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

The report identifies the {jc}patient{/1} by name and identification number; and the specimen by source, when appropriate, and date (and time, if applicable).

**2009 Standard:** IM.6.220

**2009 EP:** 4

**2009 EP Text:**

**Revision Code:** Split

The report identifies the {jc}patient{/1} by name and identification number; and the specimen by source, when appropriate, and date (and time, if applicable).

<p><b>2010 Standard:</b> DC.02.03.01                      <b>2010 EP:</b> 7</p> <p><b>2010 EP Text:</b></p> <p>The laboratory report includes the following information: The condition of unsatisfactory specimens.</p>	<p><b>2009 Standard:</b> IM.6.200                      <b>2009 EP:</b> 2</p> <p><b>2009 EP Text:</b></p> <p>The laboratory implements a policy for reporting the condition of unsatisfactory specimens.</p>
<p><b>2010 Standard:</b> DC.02.03.01                      <b>2010 EP:</b> 8</p> <p><b>2010 EP Text:</b></p> <p>The laboratory report includes the following information: The results of examinations and tests performed.</p>	<p><b>2009 Standard:</b> IM.6.220                      <b>2009 EP:</b> 1</p> <p><b>2009 EP Text:</b></p> <p>The patient's clinical record includes authenticated, dated reports of examinations and tests performed by the laboratory services.</p>
<p><b>2010 Standard:</b> DC.02.03.01                      <b>2010 EP:</b> 9</p> <p><b>2010 EP Text:</b></p> <p>The laboratory report includes the following information: The authentication of interpretive reports, such as surgical pathology reports.</p>	<p><b>2009 Standard:</b> IM.6.220                      <b>2009 EP:</b> 5</p> <p><b>2009 EP Text:</b></p> <p>Reports filed in the patient record that require specific interpretation, such as surgical pathology reports and reports of some clinical tests, are authenticated by the individual making the interpretation. (See standard IM.6.210 for other means of identification of testing personnel.)</p>
<p><b>2010 Standard:</b> DC.02.03.01                      <b>2010 EP:</b> 10</p> <p><b>2010 EP Text:</b></p> <p>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.</p>	<p><b>2009 Standard:</b> IM.6.200                      <b>2009 EP:</b> 1</p> <p><b>2009 EP Text:</b></p> <p>The laboratory report includes the date and time of reporting.</p>
<p><b>2010 Standard:</b> DC.02.03.01                      <b>2010 EP:</b> 11</p> <p><b>2010 EP Text:</b></p> <p>The laboratory report includes the following information: The result units (that is, concentration or activity) for quantitative analytes.</p>	<p><b>2009 Standard:</b> IM.6.230                      <b>2009 EP:</b> 3</p> <p><b>2009 EP Text:</b></p> <p>Quantitative analysis reports include units of concentration or activity.</p>

**2010 Standard:** DC.02.03.01**2010 EP:** 12**2010 EP Text:**

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)

Note 1: This requirement also applies to reference laboratory reports.

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.

**2010 Standard:** DC.02.03.01**2010 EP:** 12**2010 EP Text:**

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)

Note 1: This requirement also applies to reference laboratory reports.

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.

**2010 Standard:** DC.02.03.01**2010 EP:** 12**2010 EP Text:**

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)

Note 1: This requirement also applies to reference laboratory reports.

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.

**2010 Standard:** DC.02.03.01**2010 EP:** 13**2010 EP Text:**

The laboratory does not revise results or information related to the interpretation of results in a reference laboratory's report.

**2009 Standard:** IM.6.230**2009 EP:** 2**2009 EP Text:**

The laboratory's reference intervals (normal values) for each test performed are included in the clinical record, either as part of the report or by including a current listing of such values.

**Revision Code:** Consolidate**2009 Standard:** IM.6.230**2009 EP:** 5**2009 EP Text:**

Reference intervals (normal values) are also furnished for test results received from a referral laboratory.

**Revision Code:** Consolidate**2009 Standard:** IM.6.230**2009 EP:** 7**2009 EP Text:**

The reference intervals (normal values) are appropriate to the population served.

**Revision Code:** Consolidate**2009 Standard:** IM.6.220**2009 EP:** 3**2009 EP Text:**

Results (or information related to the interpretation of results) in a reference laboratory's report are not revised by the referring laboratory.

**Revision Code:** Retain

**2010 Standard:** DC.02.03.01

**2010 EP:** 14

**2010 EP Text:**

For interpretive reports, the qualified individual providing the interpretation authenticates the results.

Note: Authentication can be verified through electronic signatures, written signatures or initials, rubber-stamp signatures, or computer key.

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 <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

**2010 Standard:** DC.02.03.01

**2010 EP:** 15

**2010 EP Text:**

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.

**2009 Standard:** IM.6.220

**2009 EP:** 6

**2009 EP Text:**

**Revision Code:** Split

Reports are authenticated\* the individual performing the test and by identifying the individual who evaluated the results.\*Authentication can be by written signatures or initials, rubber-stamp signatures, or computer key. Authorized users of signature stamps or computer keys sign a statement assuring that they alone will use the stamp or key. The authorized user for cytology is the individual qualified as a technical supervisor. The authorized user for histopathology is the individual qualified as a technical supervisor.

**2009 Standard:** IM.6.220

**2009 EP:** 6

**2009 EP Text:**

**Revision Code:** Split

Reports are authenticated\* the individual performing the test and by identifying the individual who evaluated the results.\*Authentication can be by written signatures or initials, rubber-stamp signatures, or computer key. Authorized users of signature stamps or computer keys sign a statement assuring that they alone will use the stamp or key. The authorized user for cytology is the individual qualified as a technical supervisor. The authorized user for histopathology is the individual qualified as a technical supervisor.

**Standard DC.02.04.01****2010 Standard Text:**

The laboratory retains records as required by law and regulation.

**2010 Standard:** DC.02.04.01

**2010 EP:** 1

**2010 EP Text:**

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.

**2010 Standard:** DC.02.04.01

**2010 EP:** 1

**2010 EP Text:**

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.

**2010 Standard:** DC.02.04.01

**2010 EP:** 2

**2010 EP Text:**

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.

Note: For immunohematology: When there is no expiration date, records shall be retained indefinitely.

**2010 Standard:** DC.02.04.01

**2010 EP:** 2

**2010 EP Text:**

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.

Note: For immunohematology: When there is no expiration date, records shall be retained indefinitely.

**Standard QC.1.150****2009 Standard Text:**

The laboratory retains quality control records as required by law or regulation.

**2009 Standard:** QC.1.150

**2009 EP:** 1

**2009 EP Text:**

**Revision Code:** Consolidate

The laboratory retains all quality control records for at least two years including test system performance specifications that the laboratory establishes and verifies, and quality system assessments.

**2009 Standard:** QC.1.150

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Split

In instances where state or local regulations require longer retention periods, the laboratory abides by them.

**2009 Standard:** QC.1.150

**2009 EP:** 2

**2009 EP Text:**

**Revision Code:** Consolidate

All immunohematology (including blood and blood product records and transfusion records) and histocompatibility records are retained for at least five years. (See Appendix XX for retention times.)

**2009 Standard:** QC.1.150

**2009 EP:** 3

**2009 EP Text:**

**Revision Code:** Split

In instances where state or local regulations require longer retention periods, the laboratory abides by them.

**2010 Standard:** DC.02.04.01**2010 EP:** 3**2010 EP Text:**

The laboratory retains test orders for at least two years, or longer if required by law and regulation.

Note: This includes the patient's clinical record, if it is used as the test order.

**2009 Standard:** IM.6.190**2009 EP:** 7**2009 EP Text:****Revision Code:** Retain

Test requisitions and test authorizations are retained for at least two years. Note: The patient chart or clinical record, if used as the test requisition or test authorization, is retained for at least two years and is available to the laboratory at the time of testing and for two years thereafter.

**2010 Standard:** DC.02.04.01**2010 EP:** 4**2010 EP Text:**

The testing laboratory retains instrument printouts for at least two years, or longer if required by law and regulation.

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.

**2009 Standard:** IM.6.250**2009 EP:** 1**2009 EP Text:****Revision Code:** Split

The testing laboratory retains the original report or an exact duplicate\* of each test report, including instrument printouts, preliminary and final reports, reference laboratory reports\*\*, and corrected reports for the following periods (See Appendix E for retention times): Immunohematology and histocompatibility reports--at least 5 years Histopathology and cytology reports--at least 10 years All other reports--at least 2 years \*An "exact duplicate" is an exact copy of the information reported. It includes the name and address of the laboratory performing the test. The copy does not need to be on paper, but can be retrieved from a computer system, microfilm, or microfiche record, provided that it contains the exact information sent to the individual ordering the test. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing identifiers, the duplicate includes the signature or identifiers.\*\*The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

**2010 Standard:** DC.02.04.01**2010 EP:** 5**2010 EP Text:**

The testing laboratory retains an original test report or an exact copy, including preliminary, final, corrected, and reference laboratory reports, for the following periods:

- 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.

**2010 Standard:** DC.02.04.01**2010 EP:** 6**2010 EP Text:**

For all other laboratory records, the laboratory complies with law and regulation for record retention.

**2010 Standard:** DC.02.04.01**2010 EP:** 7**2010 EP Text:**

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)

**2009 Standard:** IM.6.250**2009 EP:** 1**2009 EP Text:****Revision Code:** Split

The testing laboratory retains the original report or an exact duplicate\* of each test report, including instrument printouts, preliminary and final reports, reference laboratory reports\*\*, and corrected reports for the following periods (See Appendix E for retention times): Immunohematology and histocompatibility reports--at least 5 years Histopathology and cytology reports--at least 10 years All other reports--at least 2 years \*An "exact duplicate" is an exact copy of the information reported. It includes the name and address of the laboratory performing the test. The copy does not need to be on paper, but can be retrieved from a computer system, microfilm, or microfiche record, provided that it contains the exact information sent to the individual ordering the test. A manual log containing duplicate information is also acceptable. For tests requiring an authorized signature or containing identifiers, the duplicate includes the signature or identifiers.\*\*The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

**2009 Standard:** IM.6.250**2009 EP:** 2**2009 EP Text:****Revision Code:** Retain

While record retention requirements are determined by law or regulation, as well as by local needs, records are retained for at least two years. (See Appendix E for retention times.)

**2009 Standard:** IM.6.250**2009 EP:** 3**2009 EP Text:****Revision Code:** Retain

All reports are readily retrievable.

**2010 Standard:** DC.02.04.01**2010 EP:** 8**2010 EP Text:**

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.

**2009 Standard:** IM.3.10**2009 EP:** 16**2009 EP Text:**

Records, slides, blocks, and tissues are maintained and available for the time frames specified in Appendix E in the event that the laboratory has ceased to operate.

**Revision Code:** Retain