The Joint Commission

History Tracking Report: 2009 to 2010 Requirements

Accreditation Program: Laboratory

2009 Chapter: Management of Information

Standard IM.1.10	**Standard IM.01.01.01**
2009 Standard Text:	**2010 Standard Text:**
The {jc}organization{/2} plans and designs information management processes to meet internal and external information needs.	The laboratory plans for managing information.

2009 Standard: IM.1.10	**2009 EP:** 1	**2010 Standard:** IM.01.01.01	**2010 EP:** 1
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
The {jc}organization{/2} bases its information management processes on an assessment of internal and external information needs. The assessment identifies the flow of information throughout {jc}an organization{/5}, including information storage and feedback mechanisms. The assessment identifies the data and information needed: within and among departments, services, or programs; within and among the staff, the administration, and the governance for supporting relationships with outside services and contractors; with licensing, accrediting, and regulatory bodies; with purchasers, payers, and employers; for supporting informational needs between the {jc}organization{/2} and the {jc}patients{/6}; and for participating in research and databases.		The laboratory identifies the internal and external information needed to provide safe, quality laboratory services.	

2009 Standard: IM.1.10	**2009 EP:** 1	**2010 Standard:** IM.01.01.01	**2010 EP:** 2
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
The {jc}organization{/2} bases its information management processes on an assessment of internal and external information needs. The assessment identifies the flow of information throughout {jc}an organization{/5}, including information storage and feedback mechanisms. The assessment identifies the data and information needed: within and among departments, services, or programs; within and among the staff, the administration, and the governance for supporting relationships with outside services and contractors; with licensing, accrediting, and regulatory bodies; with purchasers, payers, and employers; for supporting informational needs between the {jc}organization{/2} and the {jc}patients{/6}; and for participating in research and databases.		The laboratory identifies how data and information enter, flow within, and leave the laboratory.	

2009 Standard: IM.1.10 **2009 EP:** 2 **2010 Standard:** IM.01.01.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

To guide development of processes for managing information used internally and externally, the {jc}organization{/2} assesses its information management needs based on the following: Its missionIts goalsIts servicesStaff{jc}Patient{/1} safety considerationsQuality of care, treatment, and services Mode(s) of service deliveryResourcesAccess to affordable technologyIdentification of barriers to effective communication among caregivers

The laboratory uses the identified information to guide development of processes to manage information.

2009 Standard: IM.1.10 **2009 EP:** 3 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

The {jc}organization{/2} bases its management, staffing, and material resource allocations for information management on the scope and complexity of care, treatment, and services provided.

No EP

2009 Standard: IM.1.10 **2009 EP:** 4 **2010 Standard:** IM.01.01.01 **2010 EP:** 4

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Identified staff participates in assessment, selection, integration, and use of information management systems for clinical/service and {jc}organization{/2} information.

The laboratory selects staff and licensed independent practitioners to participate in the assessment, selection, integration, and use of information management systems for the delivery of laboratory services.

2009 Standard: IM.1.10 **2009 EP:** 5 **2010 Standard:** IM.03.01.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The {jc}organization{/2} has an ongoing process to assess the needs of the {jc}organization{/2}, departments, and individuals for knowledge-based information.

The laboratory has an ongoing process to assess the knowledge-based information needs of the laboratory and its staff.

2009 Standard: IM.1.10 **2009 EP:** 6 **2010 Standard:** IM.03.01.01 **2010 EP:** 4

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The {jc}organization{/2} uses the assessment for knowledge-based information as a basis for planning.

The laboratory uses the assessment of knowledge-based information as a basis for planning access to knowledge-based information resources.

Standard IM.2.10

2009 Standard Text:

Information privacy and confidentiality are maintained.

Standard IM.02.01.01

2010 Standard Text:

The laboratory protects the privacy of health information.

2009 Standard: IM.2.10 **2009 EP:** 1

2009 EP Text: **Revision Type:** Split

The {jc}organization{/2} has a written policy(ies) for addressing the privacy* and confidentiality** of information, that is based on and consistent with law or regulation.Note 1: The laboratory has a process to ensure confidentiality of patient information throughout all phases of the testing process that is under the laboratory's control.Note2: Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.*Privacy An individual's right to limit the disclosure of personal information.**Confidentiality The safekeeping of data/information so as to restrict access to individuals who have need, reason, and permission for such access.

2010 Standard: IM.02.01.01 **2010 EP:** 1

2010 EP Text:

The laboratory has a written policy addressing the privacy of health information.

2009 Standard: IM.2.10 **2009 EP:** 1

2009 EP Text: **Revision Type:** Split

The {jc}organization{/2} has a written policy(ies) for addressing the privacy* and confidentiality** of information, that is based on and consistent with law or regulation.Note 1: The laboratory has a process to ensure confidentiality of patient information throughout all phases of the testing process that is under the laboratory's control.Note2: Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.*Privacy An individual's right to limit the disclosure of personal information.**Confidentiality The safekeeping of data/information so as to restrict access to individuals who have need, reason, and permission for such access.

2010 Standard: IM.02.01.03 **2010 EP:** 5

2010 EP Text:

The laboratory protects against unauthorized access, use, and disclosure of health information.
Note 1: This protection includes confidentiality of patient information throughout all phases of the testing process that is under the laboratory's control.
Note 2: Test results are released only to authorized persons, the individual responsible for using the test results, and/or the laboratory that initially requested the test.

2009 Standard: IM.2.10 **2009 EP:** 2

2009 EP Text: **Revision Type:** Delete:NE

The {jc}organization{/2}'s policy, including changes to the policy, has been communicated to staff.

2010 Standard: N/A

2010 EP Text:

No EP

2009 Standard: IM.2.10 **2009 EP:** 3

2009 EP Text: **Revision Type:** Retain

The {jc}organization{/2} implements the policy.

2010 Standard: IM.02.01.01 **2010 EP:** 2

2010 EP Text:

The laboratory implements its policy on the privacy of health information.

2009 Standard: IM.2.10 **2009 EP:** 4 **2010 Standard:** IM.02.01.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The {jc}organization{/2} monitors compliance with the policy.

The laboratory monitors compliance with its policy on the privacy of health information.

2009 Standard: IM.2.10 **2009 EP:** 5 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

The {jc}organization{/2} improves privacy and confidentiality of information by monitoring information and developments in technology

No EP

2009 Standard: IM.2.10 **2009 EP:** 6 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

Individuals for whom identifiable health data and information are maintained or collected are made aware of how the data will be used and whether it will be disclosed.

No EP

2009 Standard: IM.2.10 **2009 EP:** 7 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

Personal identifiers are removed to the extent possible for uses and disclosures of health information, consistent with maintaining the usefulness of the information.

No EP

2009 Standard: IM.2.10 **2009 EP:** 8 **2010 Standard:** IM.02.01.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Protected health information* is used for the purposes identified or as required by law or regulation and not further disclosed without {jc}patient{/1} authorization.*Protected health information Health information that contains information such that an individual person can be identified as the subject of that information.

The laboratory uses health information only for purposes permitted by law and regulation or as further limited by its policy on privacy.

2009 Standard: IM.2.10 **2009 EP:** 8 **2010 Standard:** IM.02.01.01 **2010 EP:** 4

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Protected health information* is used for the purposes identified or as required by law or regulation and not further disclosed without {jc}patient{/1} authorization.*Protected health information Health information that contains information such that an individual person can be identified as the subject of that information.

The laboratory discloses health information only as authorized by the patient or as otherwise consistent with law and regulation.

2009 Standard: IM.2.10 **2009 EP:** 9 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

The {jc}organization{/2} preserves the privacy and confidentiality of data and information identified as sensitive.

No EP

Standard IM.2.20

2009 Standard Text:

Information security, including data integrity, is maintained.

Standard IM.02.01.03

2010 Standard Text:

The laboratory maintains the security and integrity of health information.

2009 Standard: IM.2.20 **2009 EP:** 1

2009 EP Text: **Revision Type:** Split

The {jc}organization{/2} has a written policy(ies) for addressing information security, including data integrity* that is based on and consistent with law or regulation. *Integrity In the context of data security, data integrity means the protection of data from accidental or unauthorized intentional change.

2010 Standard: IM.02.01.03 **2010 EP:** 1

2010 EP Text:

The laboratory has a written policy that addresses the security of health information, including access, use, and disclosure.

2009 Standard: IM.2.20 **2009 EP:** 1

2009 EP Text: **Revision Type:** Split

The {jc}organization{/2} has a written policy(ies) for addressing information security, including data integrity* that is based on and consistent with law or regulation. *Integrity In the context of data security, data integrity means the protection of data from accidental or unauthorized intentional change.

2010 Standard: IM.02.01.03 **2010 EP:** 2

2010 EP Text:

The laboratory has a written policy addressing the integrity of health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

2009 Standard: IM.2.20 **2009 EP:** 2

2009 EP Text: **Revision Type:** Delete:NE

The {jc}organization{/2}'s policy, including changes to the policy, has been communicated to staff.

2010 Standard: N/A

2010 EP Text:

No EP

2009 Standard: IM.2.20 **2009 EP:** 3

2009 EP Text: **Revision Type:** Consolidate

The {jc}organization{/2} implements the policy.

2010 Standard: IM.02.01.03 **2010 EP:** 5

2010 EP Text:

The laboratory protects against unauthorized access, use, and disclosure of health information.
Note 1: This protection includes confidentiality of patient information throughout all phases of the testing process that is under the laboratory's control.
Note 2: Test results are released only to authorized persons, the individual responsible for using the test results, and/or the laboratory that initially requested the test.

2009 Standard: IM.2.20 **2009 EP:** 4 **2010 Standard:** IM.02.01.03 **2010 EP:** 8

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The {jc}organization{/2} monitors compliance with the policy.

The laboratory monitors compliance with its policies on the security and integrity of health information.

2009 Standard: IM.2.20 **2009 EP:** 5 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

The {jc}organization{/2} improves information security, including data integrity, by monitoring information and developments in technology.

No EP

2009 Standard: IM.2.20 **2009 EP:** 6 **2010 Standard:** IM.02.01.03 **2010 EP:** 6

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The {jc}organization{/2} develops and implements controls to safeguard data and information, including the clinical record, against loss, destruction, and tampering.

The laboratory protects health information against loss, damage, unauthorized alteration, unintentional change, and accidental destruction.

2009 Standard: IM.2.20 **2009 EP:** 7 **2010 Standard:** IM.02.01.03 **2010 EP:** 3

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Controls to safeguard data and information include the following:Policies indicating when the removal of records is permittedProtection against unauthorized intrusion, corruption, or damageMinimization of the risk of falsification of data and informationGuidelines (including storage conditions for ensuring proper preservation) for preventing the loss and destruction of recordsGuidelines for destroying copies of recordsProtection of records in a manner that minimizes the possibility of damage from fire and water

The laboratory has a written policy addressing the intentional destruction of health information.

2009 Standard: IM.2.20 **2009 EP:** 7 **2010 Standard:** IM.02.01.03 **2010 EP:** 4

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Controls to safeguard data and information include the following:Policies indicating when the removal of records is permittedProtection against unauthorized intrusion, corruption, or damageMinimization of the risk of falsification of data and informationGuidelines (including storage conditions for ensuring proper preservation) for preventing the loss and destruction of recordsGuidelines for destroying copies of recordsProtection of records in a manner that minimizes the possibility of damage from fire and water

The laboratory has a written policy that defines when and by whom the removal of health information is permitted.
Note: Removal refers to those actions that place health information outside the laboratory's control.

2009 Standard: IM.2.20 **2009 EP:** 7 **2010 Standard:** IM.02.01.03 **2010 EP:** 7

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Controls to safeguard data and information include the following:Policies indicating when the removal of records is permittedProtection against unauthorized intrusion, corruption, or damageMinimization of the risk of falsification of data and informationGuidelines (including storage conditions for ensuring proper preservation) for preventing the loss and destruction of recordsGuidelines for destroying copies of recordsProtection of records in a manner that minimizes the possibility of damage from fire and water

The laboratory controls the intentional destruction of health information.

2009 Standard: IM.2.20 **2009 EP:** 8 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

Policies and procedures, including plans for implementation, for electronic information systems address the following: data integrity, authentication*, non-repudiation**, encryption*** as warranted, and auditability,**** as appropriate to the system and types of information, for example, {jc}patient{/1} information and billing information.*Authentication The validation of correctness for both the information itself and the person who is the author or user of information.**Non-repudiation The inability to dispute a document’s content or authorship.***Encryption The process of transforming plain text (readable) into cipher text that is unreadable without a special software key.****Auditability The ability to do a methodical examination and verification of all information activities such as entering and accessing.

No EP

Standard IM.2.30

2009 Standard Text:

Continuity of information is maintained.

Standard IM.01.01.03

2010 Standard Text:

The laboratory plans for continuity of its information management processes.

2009 Standard: IM.2.30 **2009 EP:** 1

2009 EP Text:

The {jc}organization{/2} has a business continuity/disaster recovery plan for its information systems.

Revision Type: Retain

2010 Standard: IM.01.01.03 **2010 EP:** 1

2010 EP Text:

The laboratory has a written plan for managing interruptions to its information processes (paper-based, electronic, or a mix of paper-based and electronic). (See also EM.01.01.01, EP 6)

2009 Standard: IM.2.30 **2009 EP:** 2

2009 EP Text:

For electronic systems, the business continuity/disaster recovery plan includes the following: Plans for scheduled and unscheduled interruptions, which includes end-user training with the downtime proceduresContingency plans for operational interruptions (hardware, software, or other systems failure)Plans for minimal interruptions as a result of scheduled downtimeAn emergency service plan A back-up system (electronic or manual) Data retrieval, including retrieval from storage and information presently in the operating system, retrieval of data in the event of system interruption, and back up of data

Revision Type: Split

2010 Standard: IM.01.01.03 **2010 EP:** 2

2010 EP Text:

The laboratory's plan for managing interruptions to information processes addresses the following: Scheduled and unscheduled interruptions of electronic information systems. (See also IM.03.01.01, EP 1; EM.01.01.01, EP 6)

2009 Standard: IM.2.30 **2009 EP:** 2

2009 EP Text:

For electronic systems, the business continuity/disaster recovery plan includes the following: Plans for scheduled and unscheduled interruptions, which includes end-user training with the downtime proceduresContingency plans for operational interruptions (hardware, software, or other systems failure)Plans for minimal interruptions as a result of scheduled downtimeAn emergency service plan A back-up system (electronic or manual) Data retrieval, including retrieval from storage and information presently in the operating system, retrieval of data in the event of system interruption, and back up of data

Revision Type: Split

2010 Standard: IM.01.01.03 **2010 EP:** 3

2010 EP Text:

The laboratory's plan for managing interruptions to information processes addresses the following: Training for staff and licensed independent practitioners on alternative procedures to follow when electronic information systems are unavailable. (See also EM.01.01.01, EP 6)

2009 Standard: IM.2.30 **2009 EP:** 2 **2010 Standard:** IM.01.01.03 **2010 EP:** 4

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

For electronic systems, the business continuity/disaster recovery plan includes the following: Plans for scheduled and unscheduled interruptions, which includes end-user training with the downtime proceduresContingency plans for operational interruptions (hardware, software, or other systems failure)Plans for minimal interruptions as a result of scheduled downtimeAn emergency service plan A back-up system (electronic or manual) Data retrieval, including retrieval from storage and information presently in the operating system, retrieval of data in the event of system interruption, and back up of data

The laboratory's plan for managing interruptions to information processes addresses the following: Backup of electronic information systems. (See also EM.01.01.01, EP 6)

2009 Standard: IM.2.30 **2009 EP:** 3 **2010 Standard:** IM.01.01.03 **2010 EP:** 5

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The plan is tested periodically as defined by the {jc}organization{/2} (or in accordance with law or regulation) to ensure that the business interruption back-up techniques are effective.

The laboratory's plan for managing interruptions to electronic information systems is tested for effectiveness according to time frames defined by the laboratory.

2009 Standard: IM.2.30 **2009 EP:** 4 **2010 Standard:** IM.01.01.03 **2010 EP:** 6

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

The business continuity/disaster recovery plan is implemented when information systems are interrupted.

The laboratory implements its plan for managing interruptions to information processes to provide laboratory results needed for patient care. (See also IM.03.01.01, EP 1)

Standard IM.3.10

2009 Standard Text:

The {jc}organization{/2} has processes in place to effectively manage information, including the capturing, reporting, processing, storing, retrieving, disseminating, and displaying of clinical/service and non-clinical data and information.

Standard IM.02.02.03

2010 Standard Text:

The laboratory retrieves, disseminates, and transmits health information in useful formats.

2009 Standard: IM.3.10 **2009 EP:** 1 **2010 Standard:** IM.02.02.03 **2010 EP:** 1

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Information technology industry standards or {jc}organization{/2} policies are used and address the following:Uniform data definitionsData capture Data displayData transmission

The laboratory has written policies addressing data capture, display, transmission, and retention.

2009 Standard: IM.3.10 **2009 EP:** 3 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Minimum data sets, terminology, definitions, classifications, vocabulary, and nomenclature, including abbreviations, acronyms, symbols, and dose designations are standardized throughout the {jc}organization{/2}.

No EP

2009 Standard: IM.3.10 **2009 EP:** 3 **2010 Standard:** IM.02.02.01 **2010 EP:** 1

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

Minimum data sets, terminology, definitions, classifications, vocabulary, and nomenclature, including abbreviations, acronyms, symbols, and dose designations are standardized throughout the {jc}organization{/2}.

The laboratory uses uniform data sets to standardize data collection throughout the laboratory.

2009 Standard: IM.3.10 **2009 EP:** 4 **2010 Standard:** IM.04.01.01 **2010 EP:** 1

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Quality control systems are used to monitor data content and collection activities. The method used provides for timely and economical data collection with the degree of accuracy, completeness, and discrimination necessary for their intended use.The method used minimizes bias in the data and regularly assesses the data's reliability, validity, and accuracy. Those responsible for collecting and reviewing the data are accountable for information accuracy and completeness.

The laboratory has processes to check the accuracy of laboratory-related health information.
Note: The laboratory has the flexibility to determine what health information needs to be checked for accuracy and the frequency with which it will be checked.

2009 Standard: IM.3.10 **2009 EP:** 5 **2010 Standard:** IM.02.02.03 **2010 EP:** 2

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Storage and retrieval systems are designed to support {jc}organization{/2} needs for clinical/service and {jc}organization{/2}-specific information. Storage and retrieval systems are designed to balance the ability to retrieve data and information with the intended use for the data and information. Storage and retrieval systems are designed to balance security and confidentiality issues with accessibility.Systems for paper and electronic records are designed to reduce disruption or inaccessibility during such times as diminished staffing and scheduled and unscheduled downtimes of electronic information systems.

The laboratory's storage and retrieval systems make health information accessible when needed for laboratory services. (See also IC.01.02.01, EP 1)

2009 Standard: IM.3.10 **2009 EP:** 6 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

Data and information are retained for sufficient time to comply with law or regulation.

No EP

2009 Standard: IM.3.10 **2009 EP:** 7 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

Knowledgeable staff and tools are available for collecting, retrieving, and analyzing data and their transformation into information.

No EP

2009 Standard: IM.3.10 **2009 EP:** 8 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

Data are organized and transformed into information in formats useful to decision makers.

No EP

2009 Standard: IM.3.10 **2009 EP:** 9 **2010 Standard:** IM.02.02.03 **2010 EP:** 3

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Dissemination of data and information is timely* and accurate.*Timely Defined by organization policy and based on the intended use of the information.

The laboratory disseminates data and information in useful formats within time frames that are defined by the laboratory and consistent with law and regulation.

2009 Standard: IM.3.10 **2009 EP:** 10 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

Data and information are disseminated in standard formats and methods to meet user needs and provide for retrievability and interpretation.

No EP

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

2009 EP Text: **Revision Type:** Retain

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.

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.

Standard IM.4.10

2009 Standard Text:

The information management system provides information for use in decision making.

2010 Standard Text:

No Standard

2009 Standard: IM.4.10 **2009 EP:** 1 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

The {jc}organization{/2} has the ability to collect and aggregate data and information to support care, treatment, and service delivery and operations, including the following: Individual care, treatment, and services and care, treatment, and service delivery Decision makingManagement and operationsAnalysis of trends Performance comparisons over time throughout the {jc}organization{/2} and with other organizations Performance improvement Infection control{jc}Patient{/1} safety

No EP

2009 Standard: IM.4.10 **2009 EP:** 2 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

To support clinical decision making, information found in the {jc}patient{/1} record is: Readily accessibleAccurateCompleteOrganized for retrieval of dataTimely**Timely Defined by organization policy and based on the intended use of the information.

No EP

2009 Standard: IM.4.10 **2009 EP:** 3 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

Comparative performance data and information are used for decision making, when available.

No EP

Standard IM.5.10

2009 Standard Text:

Knowledge-based information resources are readily available, current, and authoritative.

Standard IM.03.01.01

2010 Standard Text:

Knowledge-based information resources are available, current, and authoritative.

2009 Standard: IM.5.10 **2009 EP:** 2 **2010 Standard:** IM.03.01.01 **2010 EP:** 1

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

The {jc}organization{/2} provides access to knowledge-based information resources* needed by staff in any of the following forms: print, electronic, Internet, or audio. *Examples of knowledge-based information resources include current texts; periodicals; indexes; abstracts; reports; documents; databases; directories; discussion lists; successful practices; equipment and maintenance user manuals; standards; protocols; practice guidelines; clinical trials and other resources.

The laboratory provides access to knowledge-based information resources during hours of operation. (See also IM.01.01.03, EPs 2 and 6)

2009 Standard: IM.5.10 **2009 EP:** 3 **2010 Standard:** IM.03.01.01 **2010 EP:** 1

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

Knowledge-based information resources are available to clinical/service staff, through electronic means, after-hours access to an in-house collection, or other methods.

The laboratory provides access to knowledge-based information resources during hours of operation. (See also IM.01.01.03, EPs 2 and 6)

2009 Standard: IM.5.10 **2009 EP:** 4 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:Redun **2010 EP Text:**

The {jc}organization{/2} has a process for providing access to knowledge-based information resources when electronic systems are unavailable.

No EP

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.

Standard DC.01.01.01

2010 Standard Text:

The laboratory establishes procedures for collecting specimens.

2009 Standard: IM.6.180 **2009 EP:** 1

2009 EP Text: **Revision Type:** 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

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:** 1

2009 EP Text: **Revision Type:** 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

2010 Standard: DC.01.02.01 **2010 EP:** 1

2010 EP Text:

The laboratory has written procedures for ordering tests.

2009 Standard: IM.6.180 **2009 EP:** 2 **2010 Standard:** DC.01.01.01 **2010 EP:** 2

2009 EP Text: **Revision Type:** Split **2010 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.

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

2009 EP Text: **Revision Type:** Split **2010 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.

Staff follow the laboratory's procedures for specimen collection.

2009 Standard: IM.6.180 **2009 EP:** 3 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

The laboratory director or a qualified, specifically identified designee approves procedures.

No EP

2009 Standard: IM.6.180 **2009 EP:** 4 **2010 Standard:** DC.01.01.01 **2010 EP:** 2

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

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

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:** 5

2009 EP Text: **Revision Type:** 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.

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.6.190	Standard DC.01.02.01
2009 Standard Text:	**2010 Standard Text:**
Requests for laboratory tests are made in writing or electronically.	The laboratory performs testing based on written laboratory test orders.

2009 Standard: IM.6.190	**2009 EP:** 1	**2010 Standard:** DC.01.02.01	**2010 EP:** 3
2009 EP Text:	**Revision Type:** Consolidate	**2010 EP Text:**	
Requests for laboratory tests are made in writing or electronically.		Laboratory test orders are made in writing (paper or electronic). Note: The test order may be located in the clinical record.	
2009 Standard: IM.6.190	**2009 EP:** 2	**2010 Standard:** DC.01.02.01	**2010 EP:** 4
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
Information is legible and complete.		Laboratory test orders for laboratory tests are legible.	
2009 Standard: IM.6.190	**2009 EP:** 2	**2010 Standard:** DC.01.02.01	**2010 EP:** 5
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
Information is legible and complete.		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 **2010 Standard:** DC.01.02.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

Orders or requisitions for services clearly identify the following:Patient's name Patient's genderPatient's age or date of birthRequesting 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 laboratoryThe specimen source, when appropriateAdditional information required to select appropriate tests and to ensure accurate test interpretation and reporting of results (e.g., race/ethnicity, family history, pedigree).

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

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2009 Standard: IM.6.190 **2009 EP:** 4 **2010 Standard:** DC.01.02.01 **2010 EP:** 6

2009 EP Text: **Revision Type:** Retain **2010 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.

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.

2009 Standard: IM.6.190 **2009 EP:** 5 **2010 Standard:** N/A

2009 EP Text: **Revision Type:** Delete:NE **2010 EP Text:**

A system exists to ensure correct identification of the patient and specimen from the time of requesting to the time of reporting.

No EP

2009 Standard: IM.6.190 **2009 EP:** 6 **2010 Standard:** DC.01.02.01 **2010 EP:** 8

2009 EP Text: **Revision Type:** Retain **2010 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.

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:** 7 **2010 Standard:** DC.02.04.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

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.

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:** 8 **2010 Standard:** DC.01.02.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

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

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

2009 Standard: IM.6.190 **2009 EP:** 9 **2010 Standard:** DC.01.02.01 **2010 EP:** 2

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

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

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

Standard IM.6.200

2009 Standard Text:

The laboratory report includes the date and time of reporting and the condition of unsatisfactory specimens.

Standard DC.02.03.01

2010 Standard Text:

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

2009 Standard: IM.6.200 **2009 EP:** 1

2009 EP Text: **Revision Type:** Retain

The laboratory report includes the date and time of reporting.

2010 Standard: DC.02.03.01 **2010 EP:** 10

2010 EP Text:

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.

2009 Standard: IM.6.200 **2009 EP:** 2

2009 EP Text: **Revision Type:** Retain

The laboratory implements a policy for reporting the condition of unsatisfactory specimens.

2010 Standard: DC.02.03.01 **2010 EP:** 7

2010 EP Text:

The laboratory report includes the following information: The condition of unsatisfactory specimens.

Standard IM.6.210

2009 Standard Text:

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

Standard DC.02.02.01

2010 Standard Text:

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

2009 Standard: IM.6.210 **2009 EP:** 1

2009 EP Text: **Revision Type:** Consolidate

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

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.

2009 Standard: IM.6.210 **2009 EP:** 2

2009 EP Text: **Revision Type:** Retain

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

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.

2009 Standard: IM.6.210 **2009 EP:** 3

2009 EP Text: **Revision Type:** 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).

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.

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.

Standard DC.02.03.01

2010 Standard Text:

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

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	1	DC.02.03.01	1
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
The patient's clinical record includes authenticated, dated reports of examinations and tests performed by the laboratory services.		The laboratory report is maintained in the patient's clinical record.	

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	1	DC.02.03.01	8
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
The patient's clinical record includes authenticated, dated reports of examinations and tests performed by the laboratory services.		The laboratory report includes the following information: The results of examinations and tests performed.	

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	2	DC.02.03.01	2
2009 EP Text:	**Revision Type:** Retain	**2010 EP Text:**	
The report in the patient's clinical record includes the name and address of the laboratory performing the test.		The laboratory report includes the following information: The name and address of the laboratory performing the test.	

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	3	DC.02.03.01	13
2009 EP Text:	**Revision Type:** Retain	**2010 EP Text:**	
Results (or information related to the interpretation of results) in a reference laboratory's report are not revised by the referring laboratory.		The laboratory does not revise results or information related to the interpretation of results in a reference laboratory's report.	

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	4	DC.02.03.01	3
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
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).		The laboratory report includes the following information: The patient's first and last name.	

2009 Standard:	2009 EP:	2010 Standard:	2010 EP:
IM.6.220	4	DC.02.03.01	4
2009 EP Text:	**Revision Type:** Split	**2010 EP Text:**	
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).		The laboratory report includes the following information: The patient identifier, which cannot be the patient's room number or physical location.	

2009 Standard: IM.6.220 **2009 EP:** 4 **2010 Standard:** DC.02.03.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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).

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

2009 Standard: IM.6.220 **2009 EP:** 4 **2010 Standard:** DC.02.03.01 **2010 EP:** 6

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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).

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

2009 Standard: IM.6.220 **2009 EP:** 5 **2010 Standard:** DC.02.03.01 **2010 EP:** 9

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

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.)

The laboratory report includes the following information: The authentication of interpretive reports, such as surgical pathology reports.

2009 Standard: IM.6.220 **2009 EP:** 6 **2010 Standard:** DC.02.03.01 **2010 EP:** 14

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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.

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.

2009 Standard: IM.6.220 **2009 EP:** 6 **2010 Standard:** DC.02.03.01 **2010 EP:** 15

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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.

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.

Standard IM.6.230

2009 Standard Text:

The clinical record includes current reference intervals (normal values) approved by the laboratory director when test results are reported.

Standard LD.04.05.01

2010 Standard Text:

Laboratory leadership is effective.

2009 Standard: IM.6.230	**2009 EP:** 1	**2010 Standard:** LD.04.05.01	**2010 EP:** 8
2009 EP Text:	**Revision Type:** Retain	**2010 EP Text:**	
The laboratory director approves current reference intervals (normal values).		The laboratory director approves current reference intervals (normal values).	
2009 Standard: IM.6.230	**2009 EP:** 2	**2010 Standard:** DC.02.03.01	**2010 EP:** 12
2009 EP Text:	**Revision Type:** Consolidate	**2010 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.		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.	
2009 Standard: IM.6.230	**2009 EP:** 3	**2010 Standard:** DC.02.03.01	**2010 EP:** 11
2009 EP Text:	**Revision Type:** Retain	**2010 EP Text:**	
Quantitative analysis reports include units of concentration or activity.		The laboratory report includes the following information: The result units (that is, concentration or activity) for quantitative analytes.	
2009 Standard: IM.6.230	**2009 EP:** 4	**2010 Standard:** N/A	
2009 EP Text:	**Revision Type:** Delete:NE	**2010 EP Text:**	
Reference intervals (normal values) are updated as methods change.		No EP	

2009 Standard: IM.6.230 **2009 EP:** 5 **2010 Standard:** DC.02.03.01 **2010 EP:** 12

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

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

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.

2009 Standard: IM.6.230 **2009 EP:** 6 **2010 Standard:** LD.04.05.01 **2010 EP:** 9

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Documentation is available in the laboratory showing the basis of the reference intervals (normal values) and is available to the staff if requested.

The laboratory director makes the documentation for the basis of reference intervals (normal values) available to staff upon request.

2009 Standard: IM.6.230 **2009 EP:** 7 **2010 Standard:** DC.02.03.01 **2010 EP:** 12

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

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

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.

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.

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.

2009 Standard: IM.6.240 **2009 EP:** 1

2009 EP Text: **Revision Type:** 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.

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.

2009 Standard: IM.6.240 **2009 EP:** 2

2009 EP Text: **Revision Type:** Retain

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

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.

2009 Standard: IM.6.240 **2009 EP:** 3

2009 EP Text: **Revision Type:** 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:** 3 **2010 Standard:** DC.01.03.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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.

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 **2010 Standard:** DC.01.03.01 **2010 EP:** 4

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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

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 **2010 Standard:** DC.01.03.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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

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.

Standard IM.6.250

2009 Standard Text:

The laboratory retains a copy of all reports of anatomic and clinical laboratory tests and examinations, which are readily retrievable.

Standard DC.02.04.01

2010 Standard Text:

The laboratory retains records as required by law and regulation.

2009 Standard: IM.6.250 **2009 EP:** 1

2009 EP Text: **Revision Type:** 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:** 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 **2010 Standard:** DC.02.04.01 **2010 EP:** 5

2009 EP Text: **Revision Type:** Split **2010 EP Text:**

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.

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.

2009 Standard: IM.6.250 **2009 EP:** 2 **2010 Standard:** DC.02.04.01 **2010 EP:** 6

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

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.)

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

2009 Standard: IM.6.250 **2009 EP:** 3 **2010 Standard:** DC.02.04.01 **2010 EP:** 7

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

All reports are readily retrievable.

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)

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 Type:** 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

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)

2009 Standard: IM.6.260 **2009 EP:** 1

2009 EP Text: **Revision Type:** 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: LD.04.05.09 **2010 EP:** 2

2010 EP Text:

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)

2009 Standard: IM.6.260 **2009 EP:** 1

2009 EP Text: **Revision Type:** 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: LD.04.05.09 **2010 EP:** 10

2010 EP Text:

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)

2009 Standard: IM.6.260 **2009 EP:** 2

2009 EP Text: **Revision Type:** Consolidate

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

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)

2009 Standard: IM.6.260 **2009 EP:** 3 **2010 Standard:** DC.02.01.01 **2010 EP:** 1

2009 EP Text: **Revision Type:** Consolidate **2010 EP Text:**

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

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:
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- 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 Standard: IM.6.260 **2009 EP:** 4 **2010 Standard:** DC.02.01.01 **2010 EP:** 2

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

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

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

2009 Standard: IM.6.260 **2009 EP:** 5 **2010 Standard:** DC.02.01.01 **2010 EP:** 3

2009 EP Text: **Revision Type:** Retain **2010 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).

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:** 6 **2010 Standard:** DC.02.01.01 **2010 EP:** 4

2009 EP Text: **Revision Type:** Retain **2010 EP Text:**

Laboratory procedures are followed.

Staff follow the laboratory's procedures for each test.