**TRAINING UPDATE**

| | | | |
|---|---|---|---|
| **Lab Location:** | GEC, SGMC & WAH | **Date Distributed:** | 3/27/2015 |
| **Department:** | QA & Mgmt | **Due Date:** | 4/30/2015 |
| | | **Implementation:** | **5/1/2015** |

**DESCRIPTION OF PROCEDURE REVISION**

| **Name of procedure:** |
|---|
| **Retention of Records and Materials GEC.L11, SGAH/WAH.L13v7** |
| **Description of change(s):** |
| Section 5A – updated retention time for procedures and inactive employee files, remove microfiche records<br>Section 6 – add LIS SOP<br><br>This revised SOP will be implemented on May 1, 2015 |

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

| | | |
|---|---|---|
| **Title** | **Retention of Records and Materials** | |
| **Prepared by** | Leslie Barrett | Date: 1/22/2009 |
| **Owner** | Lori Loffredo | Date: 1/22/2009 |

| **Laboratory Approval** | | |
|---|---|---|
| **Print Name and Title** | **Signature** | **Date** |
| *Refer to the electronic signature page for approval and approval dates.* | | |
| | | |
| | | |
| Local Issue Date: | Local Effective Date: | |

| **Review:** | | |
|---|---|---|
| **Print Name** | **Signature** | **Date** |
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## 1. PURPOSE

Federal, state and local laws and regulations set forth specific retention periods for records and materials. This procedure describes the minimum retention time and process for off-site storage.

## 2. SCOPE

Laboratory records and materials will be retained for at least the minimum time frame required by the College of American Pathologists (CAP) and AABB (formerly the American Association of Blood Banks), and in accordance with the Quest Diagnostics Record Management Program.

## 3. RESPONSIBILITY

All Laboratory staff must comply with this procedure.

## 4. DEFINITIONS

Record Class Codes – numbering sequence that categorizes similar records with the same retention time frame.

## 5. PROCEDURE

### A. Retention Guidelines

| MATERIAL/RECORD | PERIOD OF RETENTION |
|---|---|
| **CLINICAL LABORATORY RECORDS** | |
| Patient test results | 11 years |
| Accession records | 2 years |
| Specimen requisitions (downtime/manual) | 11 years |
| Quality control records | 2 years |
| Proficiency Testing | 2 years |
| Quality Management records | 3 years |
| Discontinued/Revised Procedures | 2 years (maintained on electronic document control system) |
| Instrument printouts | 2 years |
| Instrument maintenance records | For the life of the instrument |
| Instrument/method performance specifications | while in use, plus 2 years |
| **TRAINING & COMPETENCY MATERIALS** | |
| Competency Materials | 3 years onsite in Competency File<br>Offsite storage for Active staff + 3yrs |
| Training Documents for | |
| a. Specific Job Assignments | a. Onsite for active employee |
| b. Other general training | b. 3 years onsite in Training File<br>Offsite storage for Active staff + 3yrs |
| Inactive employee (personnel, training and competency files) | Onsite for 1 year, offsite storage for 3years<br>~~Records sent to Employee Services~~ |
| **BLOOD BANK** | |
| Refer to Blood Bank Procedure, "Record Management Process, Transfusion Service." | |
| **SPECIMENS** | |
| CSF | 1 month |
| Serum/Plasma/Body Fluid | 7 days |
| Urine specimens | 8-24 hours (until next QC performed) |
| Specimens for Blood Bank Recipients | 7 days post transfusion (or 10 days post cross match) |
| Peripheral blood/body fluid smears | 7 days |
| Permanently stained slides - microbiology (gram) | 7 days |
| **LABORATORY INFORMATION SYSTEM** | |
| Transave tapes (transactions) | Indefinitely (see Transave Search SOP) |
| ~~Patient laboratory reports (microfiche)~~ | ~~Indefinitely~~ |

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**Note:** In the event the Laboratory should cease operation, all records and materials will be removed to offsite storage and maintained for at least the minimum period of retention.

### B. Sending Records for Off-Site Storage

| Step | Action |
|---|---|
| 1 | Documents must be separated into appropriate Record Class Code and placed into storage box(es). Do **not** mix Record types.<br>• Refer to Appendix for a list of commonly used codes. The complete list of codes is available on Quest Diagnostics Intranet, refer to Related Documents section.<br>• The Record Class Codes and Schedule are maintained by the QD Legal / Compliance department. At a minimum, the Addendum is reviewed annually for accuracy and updated as necessary.<br>**Note**: Do not overfill boxes. |
| 2 | Record a description of the box contents in the appropriate space on one end of the box. The description must be complete, concise and accurate.<br>**Note**: The ability to retrieve records one or more years in the future may depend on the description. |
| 3 | Complete the Iron Mountain Transmittal Form (Addenda B), one form per box. The person who initially prepares the box will complete the form. Include the following information:<br><br>a. Customer ID (WAH = V057 or SGAH=V056)<br>b. Record Code (from Appendix or Quest Diagnostics Intranet)<br>c. Date range / FROM<br>d. Date range / TO (information to be added when box is full)<br>e. Reference #1 – the name of the owner of the records. If records do not specifically belong to a person (ie, lab records), document as follows<br>• BB records – BB manager's name<br>• LIS / IT records – IT project manager's name<br>• All other Lab records – Operations manager or Core lab supervisor's name<br>f. Major description (same as that written on the outside end of the box)<br>g. Minor description may be used if major description does not provide enough detail.<br>h. Preparer's name<br>i. Date<br>j. Phone number |
| 4 | Record customer ID # on barcode box label. Affix label to end of box. Place pink copy of transmittal form inside box. |
| 5 | Store full, labeled box in a designated central location:<br>WAH – inside the lab conference room<br>SGAH – hallway across from time clock |
| 6 | Arrange for pickup weekly or when 10 boxes are complete via website www.ironmountainconnect.com or phone 1-800-FastFile. |
| 7 | Retain yellow copy of transmittal form and file in department. |

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|---|---|
| 8 | White copy of form is given to driver upon pick-up. |

### C. Retrieval of Records from Off-Site Storage

| Step | Action |
|---|---|
| 1 | Records may be retrieved via request from the website www.ironmountainconnect.com or phone 1-800-FastFile or fax 1-800-934-5384. |
| 2 | Via the website refer to the customer handbook for specific instructions on retrievals. The Inventory Report and Supplemental Reports are utilized to determine carton number(s). |
| 3 | The retained copy of the Transmittal form can be used to determine carton (box) number. |

### D. Should this laboratory cease to exist

| Step | Action |
|---|---|
| 1 | All records currently in storage would be managed by the Corporate Records Management Department |

## 6. RELATED DOCUMENTS

Records Management Program, *our*Quest *on*line *homepage*, (Units and Functions/Legal and Compliance)
Records Management Process, Transfusion Service; Blood Bank procedure
Transave Search, LIS procedure

## 7. REFERENCES

1. Standards for Blood Banks and Transfusion Services, AABB, Current Edition.
2. College of American Pathologists, Laboratory Accreditation Manual, Laboratory General Checklist, current version.
3. Customer Handbook, Iron Mountain, Inc., Collegeville, PA, 2004.

## 8. REVISION HISTORY

| Version | Date | Reason for Revision | Revised By | Approved By |
|---|---|---|---|---|
| | | Supersedes SOP L032.01 | | |
| 000 | 2/1/2010 | Updated owner.<br>Section 5 -<br>• added Discontinued/Revised Procedures to Clinical Laboratory Records<br>• specified active and inactive records for Training & Competency Materials<br>• deleted Bone Marrow reports<br>• added Note describing cease of Lab operation | L. Barrett | L. Loffredo |
| 001 | 6/1/2010 | Deleted PKU results and Bone Marrow slides from item A.<br>Added off-site storage process and addenda | L. Barrett | L. Loffredo |

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| 002 | 8/13/2010 | Section 5 –<br>• revised retention of training documents<br>• added Reference #1 completion (item B.3.e)<br>Section 9 – updated A, added B | L. Barrett | L. Loffredo |
| 003 | 9/21/2011 | Section 5 –<br>• revised retention of QM records<br>• removed trichrome stain<br>Section 9 – updated A | L Loffredo | L. Loffredo |
| 004 | 10/18/12 | Section 5 – revised retention of UA specimens<br>Section 9 – updated A | L. Barrett | L. Loffredo |
| 005 | 3/11/13 | Section 5A – Removed Blood Bank retention information<br>Section 5 – added Blood Bank SOP<br>Section 9 – updated Addendum A to remove Blood Bank retention information | S. Codina | L. Loffredo |
| 006 | 3/16/15 | Section 5A – updated retention time for procedures and inactive employee files, remove microfiche records<br>Section 6 – add LIS SOP<br>Footer – version # leading zero's dropped due to new EDCS in use as of 10/7/13 | L. Barrett<br>M. Sabonis | L. Loffredo |

## 9. ADDENDA AND APPENDICES

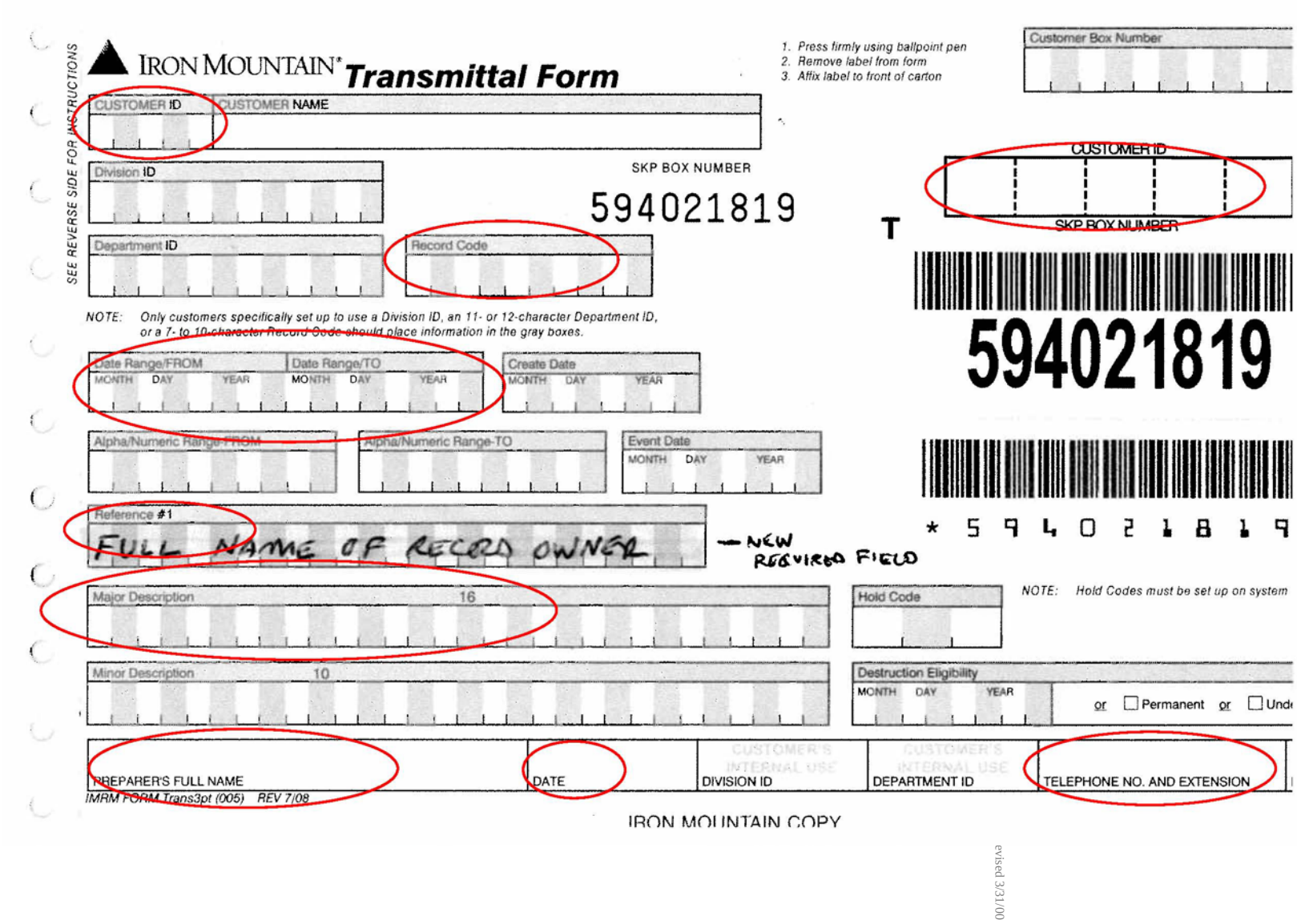
A. Record Class Codes and Schedules
B. Iron Mountain Transmittal Form

## Addenda A

### Record Class Codes and Schedules

| Record Type Name | Customer Record Class Code | Retention |
|---|---|---|
| LIS Logs (Performance Monitoring) | ADM 100 | 3 Years |
| Disaster Recovery Plans | ADM 170 | Active + 10 |
| Application Documentation, Source Code, Version Changes | ADM 180 | Active + 3 |
| Competency and Training Materials, Inactive Personnel files | HRE 160 | Active + 3 |
| Medical Director Consultations | LAB 200 | 3 Years |
| Laboratory Operations Management Records | LAB 200 | 3 Years |
| Research and Development Records | LAB 220 | Active + 10 |
| Equipment/Instrument User Manuals | LAB 240 | Active |
| Equipment/Instrument Maintenance, Calibration, Quality Control Records, Reagent Logs, Temperature Monitoring Logs, Audits | LAB 260 | 2 Years |
| Validation | LAB 290 | Active + 2 |
| Patient Test Results | LAB 310 | 11 Years |
| Discontinued/Revised Procedures | LAB 350 | 2 Years |
| Lab Worksheets and Instrument Printouts | LAB 350 | 2 Years |
| Database Control / New Test Signoff Records | LAB 380 | 7 Years |
| Specimen Requisitions (Downtime/Manual/Standing Orders) | LAB 470 | 11 Years |
| Send Out Test Results | LAB 480 | 11 Years |
| Proficiency Testing | LAB 500 | 2 Years |
| Accession Records | LAB 640 | 2 Years |
| Quality Management Records | LEG 550 | 3 Years |
| Quality Improvement Plans, Metrics, Quality Measures | LEG 550 | 3 Years |
| HIPAA Patient Requests | LOS 140 | 6 Years |
| Supply Packing Lists | LOS 180 | 1 Year |

## Addenda B


IRON MOUNTAIN® Transmittal Form
SEE REVERSE SIDE FOR INSTRUCTIONS
1. Press firmly using ballpoint pen
2. Remove label from form
3. Affix label to front of carton
Customer Box Number
CUSTOMER ID
CUSTOMER NAME
SKP BOX NUMBER
594021819
Division ID
Department ID
Record Code
NOTE: Only customers specifically set up to use a Division ID, an 11- or 12-character Department ID, or a 7- to 10-character Record Code should place information in the gray boxes.
Date Range/FROM
MONTH DAY YEAR
Date Range/TO
MONTH DAY YEAR
Create Date
MONTH DAY YEAR
Alpha/Numeric Range-FROM
Alpha/Numeric Range-TO
Event Date
MONTH DAY YEAR
Reference #1
FULL NAME OF RECORD OWNER
NEW REQUIRED FIELD
Major Description 16
Hold Code
NOTE: Hold Codes must be set up on system
Minor Description 10
Destruction Eligibility
MONTH DAY YEAR
or Permanent or Unde
PREPARER'S FULL NAME
DATE
CUSTOMER'S INTERNAL USE
DIVISION ID
CUSTOMER'S INTERNAL USE
DEPARTMENT ID
TELEPHONE NO. AND EXTENSION
IMRM FORM Trans3pt (005) REV 7/08
IRON MOUNTAIN COPY
CUSTOMER ID
SKP BOX NUMBER
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