TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/2/2019
Department:	All staff	**Due Date:**	4/30/2019
		Implementation:	**4/17/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Retention of Records and Materials SGAH.L13 v9

Description of change(s):

This SOP is assigned to all lab staff to review to

- re-inforce awareness that items are retained for specific time frames
- remind you of its usefulness as a resource

Header: updated facility

Section 5: changed onsite competency period to 2 years, increased BB offsite competency to 10 years; update transmittal form completion steps

Section 6: updated BB SOP title

Section 9: removed Iron Mtn form

This revised SOP will be implemented on April 17, 2019

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	Robert SanLuis	Date: 2/16/2017

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**

Form revised 3/31/00

TABLE OF CONTENTS

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 (EDCS)]
Instrument printouts	2 years
Instrument maintenance records	For the life of the instrument
Instrument/method performance specifications	while in use, plus 2 years
Individualized Quality Control Plan (IQCP)	while in use, plus 2 years
IQCP quality assessments	2 years (Maintained on EDCS)
TRAINING & COMPETENCY MATERIALS	
Competency Materials	~~3~~ 2 years onsite in Competency File Offsite storage for Active staff + 3yrs; Active + ~~5~~ 10yrs for Blood Bank
Training Documents for a. Specific Job Assignments b. Other general training	 a. Onsite for active employee b. 3 years onsite in Training File Offsite storage for Active staff + 3yrs; Active + 5yrs for Blood Bank
Inactive employee (personnel, training and competency files)	Onsite for 1 year, offsite storage for 3years; 10 years for Blood Bank
BLOOD BANK	
Refer to Blood Bank Procedure, "Record Management Process, Blood Bank."	
SPECIMENS	
CSF / Body Fluid / Tissue	1 month
Serum / Plasma / Urine	7 days
Urine specimens in cups	8-24 hours (until next QC performed)
Micro raw specimens (swab, stool, nasal wash, aspirate)	8-24 hours
Specimens for Blood Bank Recipients	7 days post transfusion (or 10 days post cross match)
Peripheral blood/body fluid smears	7 days

Form revised 3/31/00

MATERIAL/RECORD	PERIOD OF RETENTION
Gram stain slides	7 days
Malaria slides, negative	1 month
Malaria slides, positive	Indefinitely
Zika hold specimens	6 weeks frozen, minimum

LABORATORY INFORMATION SYSTEM

Transave tapes (transactions)	Indefinitely (see Transave Search SOP)

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. • 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. • 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. **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. **Note**: The ability to retrieve records one or more years in the future may depend on the description.
3	Complete the Iron Mountain Transmittal Sheet, one form per every 5 boxes. ~~The person who initially prepares the box will complete the form.~~ Include the following information: a. Customer ID (WAH = V057 or SGMC = V056) b. Customer name c. Customer box number – place small barcode label d. Record Code (from Appendix or Quest Diagnostics Intranet) e. Date range / FROM f. Date range / TO (information to be added when box is full) ~~g. 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~~ ~~• BB records – BB manager's name~~ ~~• LIS / IT records – IT project manager's name~~ ~~• All other Lab records – Operations manager or Core lab supervisor's name~~ h. Major description (same as that written on the outside end of the box)

Form revised 3/31/00

	i. Minor description may be used if major description does not provide enough detail. j. Preparer's name k. Date l. 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: WAH – inside the core lab SGMC – 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 a photocopy of transmittal form and file in department.
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, Blood Bank; Blood Bank procedure
Transave Search, IT 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. Section 5 - • added Discontinued/Revised Procedures to Clinical Laboratory Records • specified active and inactive records for Training & Competency Materials • deleted Bone Marrow reports • added Note describing cease of Lab operation	L. Barrett	L. Loffredo
001	6/1/2010	Section 5 – Deleted PKU results and Bone Marrow slides from item A. Added off-site storage process Section 9 - added addenda	L. Barrett	L. Loffredo
002	8/13/2010	Section 5 – • revised retention of training documents • added Reference #1 completion (item B.3.e) Section 9 – updated A, added B	L. Barrett	L. Loffredo
003	9/21/2011	Section 5 – • revised retention of QM records • removed trichrome stain Section 9 – updated A	L Loffredo	L. Loffredo
004	10/18/12	Section 5 – revised retention of UA specimens Section 9 – updated A	L. Barrett	L. Loffredo
005	3/11/13	Section 5A – Removed Blood Bank retention information Section 5 – added Blood Bank SOP 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 Section 6 – add LIS SOP Footer – version # leading zero's dropped due to new EDCS in use as of 10/7/13	L. Barrett M. Sabonis	L. Loffredo
7	2/16/17	Updated owner Header: added other sites Section 5: add IQCP, BB competency, revise specimen retention Section 9: update addendum A	L Barrett	R SanLuis
8	3/21/19	Section 5: changed onsite competency period to 2 years, increased BB offsite competency to 10 years; update transmittal form completion steps Section 6: update BB SOP title Section 9: removed form	L Barrett	R SanLuis

Form revised 3/31/00

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
Workforce Central logs	ACC 110	8 Years
Competency and Training Materials, Inactive Personnel files	HRE 160	Active + 3
Competency and Training Materials, Transfusion Medicine (Immunohematology)	HRE 270	Active + 5
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
IQCP	LAB 265	Active + 2
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