

TRAINING UPDATE

Lab Location:

All – Supervisors and TIC

Date Distributed:

1/16/23

Department:

Core Lab

Due Date:

2/15/23

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Title: Retention of Records and Materials (AHC.L14)
Description of change(s):
<p>Added Addendum B:</p> <p>Addendum B When results are filed in Sunquest, it is generally not necessary to save hard copies of results. The exceptions are listed below and must be retained per policy:</p> <ol style="list-style-type: none">1. Path Reviews2. CBC printouts with histograms3. PCR printouts4. Any manual worksheets, including downtime5. QLS printouts and requisitions <p>This revised SOP was implemented 10th of January, 2023</p>

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

AHC.L13 Retention of Records and Materials

Copy of version 13.0 (approved and current)

Last Approval or
Periodic Review Completed 1/10/2023

Uncontrolled Copy printed on 1/16/2023 2:52 PM

Next Periodic Review
Needed On or Before 1/10/2025

Printed By Demetra Collier (110199)

Effective Date 1/10/2023

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/10/2023	13.0	<i>Nicolas Cacciabeve MD</i> Nicolas Cacciabeve	
Approval	Lab Director	12/14/2021	12.0	Nicolas Cacciabeve	
Approval	Lab Service director	12/13/2021	12.0	<i>Robert SanLuis</i> Robert SanLuis	
Approval	QA approval	12/9/2021	12.0	Leslie Barrett (104977)	
Approval	Lab Director	3/9/2021	11.0	Nicolas Cacciabeve	
Approval	Lab Service director	3/9/2021	11.0	<i>Robert SanLuis</i> Robert SanLuis	
Approval	QA approval	2/26/2021	11.0	Leslie Barrett	
Approval	Lab Director	11/2/2020	10.0	Nicolas Cacciabeve	
Approval	QA approval	10/27/2020	10.0	Leslie Barrett	
Approval	Lab Director	4/1/2019	9.0	Nicolas Cacciabeve	
Approval	Core lab approvals	4/1/2019	9.0	<i>Robert SanLuis</i> Robert SanLuis	
Approval	QA approval	3/27/2019	9.0	Leslie Barrett	
Periodic review	Lab Service director	1/25/2019	8.0	<i>Robert SanLuis</i> Robert SanLuis	
Approval Captured outside MediaLab	Lab Director	3/1/2017	8.0	Nicolas Cacciabeve	Recorded on 12/21/2018 by Leslie Barrett (104977) when document added to MediaLab
Periodic review	Designated Reviewer	3/1/2017	8.0	Nicolas Cacciabeve	Recorded on 12/21/2018 by Leslie Barrett (104977) when document added to MediaLab

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Prior History

Updated prefix 12/20/21

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
13.0	Approved and Current	Major revision	1/10/2023	1/10/2023	Indefinite
12.0	Retired	Major revision	12/9/2021	12/20/2021	1/10/2023
11.0	Retired	Major revision	2/25/2021	3/9/2021	12/20/2021
10.0	Retired	Major revision	10/26/2020	11/2/2020	3/9/2021
9.0	Retired	Major revision	3/25/2019	4/17/2019	11/2/2020
8.0	Retired	First version in Document Control	12/21/2018	3/21/2017	4/17/2019

Uncontrolled copy
Current as of 1/16/2023 2:52 PM

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
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

TABLE OF CONTENTS

1. PURPOSE..... 1

2. SCOPE..... 1

3. RESPONSIBILITY 1

4. DEFINITIONS 1

5. PROCEDURE..... 2

6. RELATED DOCUMENTS 8

7. REFERENCES 8

8. REVISION HISTORY 8

9. ADDENDA AND APPENDICES..... 9

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 (see Addendum B)
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	2 years onsite in Competency File Offsite storage for Active staff + 3yrs; Active + 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 / Samples in VCM/UTM	7 days
Urine specimens in cups	8-24 hours (until next QC performed)
Micro raw specimens (swab, stool, nasal wash, aspirate)	1 month
Positive blood culture bottles	1 month
Specimens for Blood Bank Recipients	7 days post transfusion (or 10 days post cross match)
Peripheral blood/body fluid smears	7 days
Gram stain slides	7 days

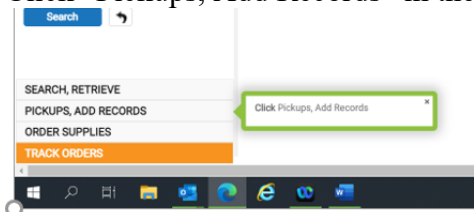
MATERIAL/RECORD	PERIOD OF RETENTION
Malaria slides, negative	1 month
Malaria slides, positive	Indefinitely
Zika hold specimens	6 weeks frozen, minimum

LABORATORY INFORMATION SYSTEM

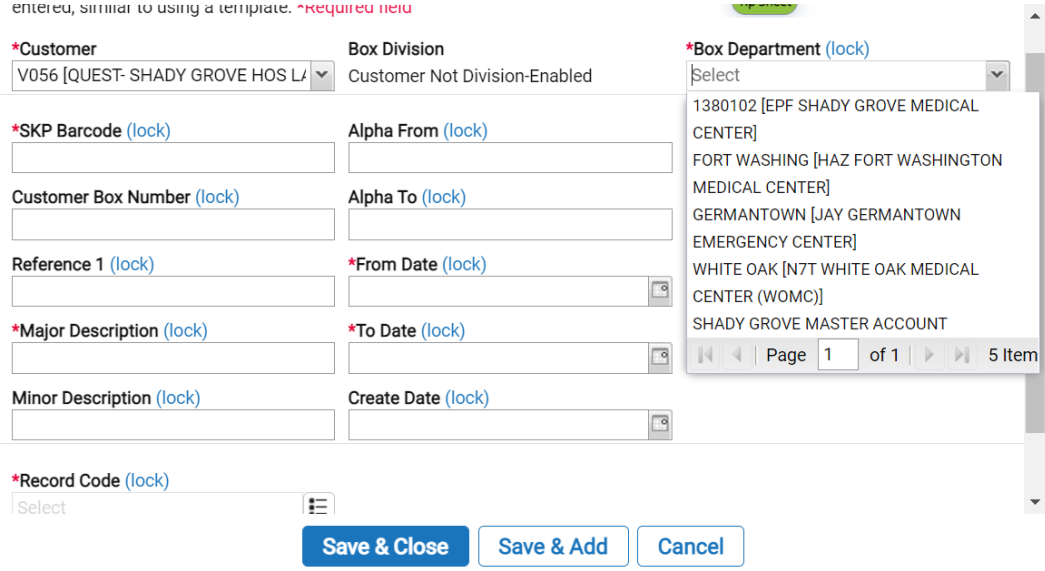
Transave tapes (transactions) Indefinitely (see Transave Search SOP)

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.

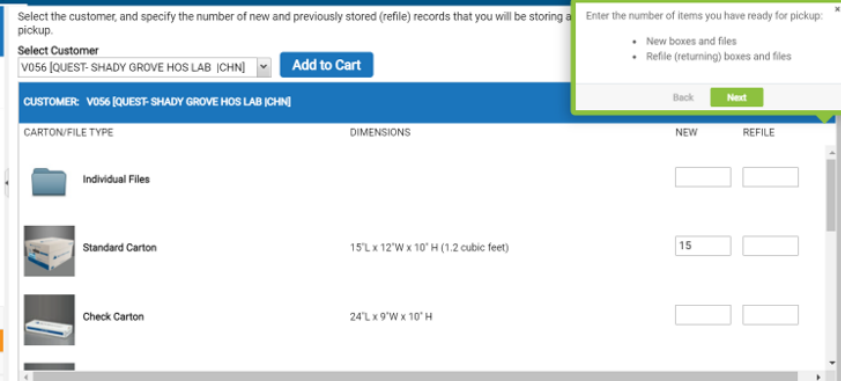
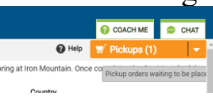
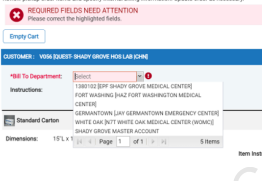
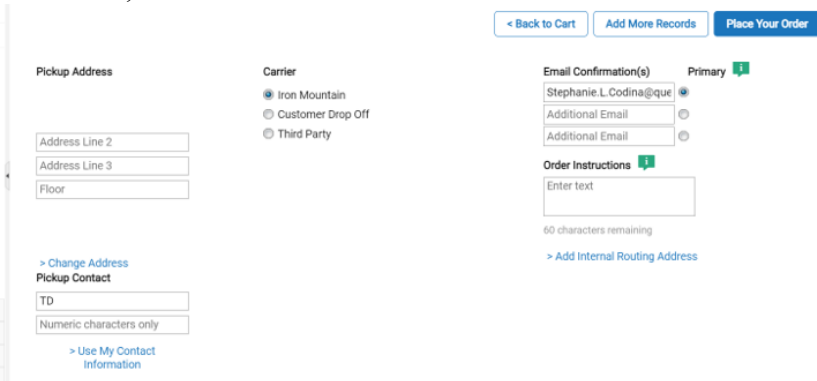
B. Sending Records for Off-Site Storage

Step	Action
1	<p>Documents must be separated into appropriate Record Class Code and placed into storage boxes. Do not mix Record types.</p> <ul style="list-style-type: none"> 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 biennially for accuracy and updated as necessary. <p>Note: Do not overfill boxes.</p>
2	<p>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.</p> <p>Note: The ability to retrieve records one or more years in the future may depend on the description.</p>
3	<p>Log into Iron Mountain via the ourQuest online using the following link: https://questdiagnostics.sharepoint.com/sites/DW-COMMUNITY/Records-Management/Pages/default.aspx</p> <p>You can also access via the following pathway:</p> <ul style="list-style-type: none"> Access ourQuest online Click “My Communities” Click “All Communities” Set the filter to the “Legal & Compliance” functional group Search for “Records Management”
4	<p>Click “Pickups, Add Records” in the lower, left area of the screen.</p> 

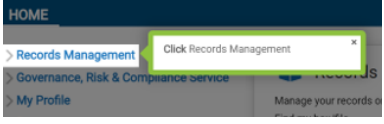
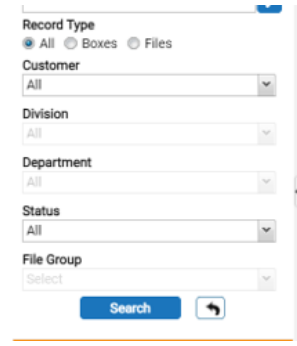

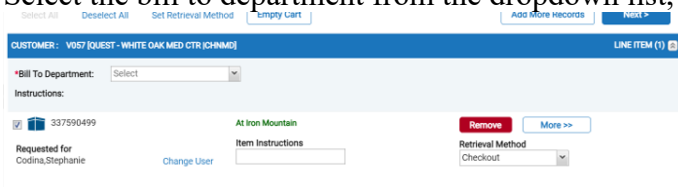
Step	Action
5	<p>Click “Pickup List (Add Records).”</p>
6	<p>Click “Add Box.”</p>
7	<p>Select “standard carton” from the pop-up menu.</p>
8	<p>Select the customer from the menu. All Adventist Healthcare sites will use customer V056 beginning November 2021. Shady Grove is the primary site on our account. You will be able to select a different hospital site in a future prompt.</p>

Step	Action
9	<p>Complete the screen prompts then click save.</p> <ul style="list-style-type: none"> • Box Department = the sites at which the records were created • SKP Barcode = the barcode from the box in which the records are stored • Alpha From and To = used if the records are alphabetized such as patient last name • From Date and To Date = the date range of the records contained in the box • Major Description = same as that written on the outside end of the box • Minor Description = may be used if major description does not provide enough detail. • Record Code = comes from Appendix or Quest Diagnostics Intranet <p>entered, similar to using a template. *required field</p> 
10	<p>Store full, labeled box in a designated central location:</p> <ul style="list-style-type: none"> WOMC – inside the core lab SGMC – storage area across from time clock FWMC – office or other available space GEC – within the lab

C. Scheduling a Pickup of Records

Step	Action
1	Arrange a pickup when 10 or more boxes have been prepared.
2	Access the Iron Mountain site per instructions above.
3	Click “Pickups, Add Records.”
4	<p>Enter the number of each type of box ready for pickup (most will be “standard carton.”).</p> <ul style="list-style-type: none"> Type the number of new boxes for pickup. Type the number of refilled boxes for pickup. <p>Click “Add to Cart” when done.</p> 
5	<p>Click the orange “Pickups” prompt.</p> 
6	<p>Select the department location for the pickup from the dropdown menu.</p> 
7	<p>Enter the pickup address, contact, and order instructions into the designated fields then click, “Place Your Order.”</p> 

D. Retrieval of Records from Off-Site Storage

Step	Action
1	Access the Iron Mountain site per instructions above.
2	Click "Records Management." 
3	Fill in the applicable fields using the dropdown menus to identify the box needed and click "Search." Note: Prior to November 2021, White Oak Medical Center was using account V057. 
4	Identify the box needed from the list that appears and click the truck icon to have the box physically returned to the site. Prior to November 2021, you can use retained copies of the transmittal lists to locate a box barcode number. 
5	Select the bill to department from the dropdown list, then click the "Next" button. 
6	Enter the address to which the box should be delivered and the contact person to complete the transaction.

E. 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, *Record Retention Schedule*, questdiagnostics.sharepoint.com
Records Management Process, Blood Bank; Blood Bank procedure
Transave Search, IT procedure

7. REFERENCES

- Standards for Blood Banks and Transfusion Services, AABB, Current Edition.
- College of American Pathologists, Laboratory Accreditation Manual, Laboratory General Checklist, current version.
- 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 - <ul style="list-style-type: none"> 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 and Section 9 – added addenda	L. Barrett	L. Loffredo
002	8/13/2010	Section 5 – <ul style="list-style-type: none"> 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 – <ul style="list-style-type: none"> 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

Version	Date	Reason for Revision	Revised By	Approved By
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 zeros 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 (addendum B)	L Barrett	R SanLuis
9	10/23/20	Header: changed WAH to WOMC Section 5: changed micro samples to 1 month Section 6: updated QD website Add. A: added interview & recruitment	L Barrett	R SanLuis
10	2/25/21	Section 5A: added samples in VCM/UTM	L Barrett	R SanLuis
11	12/7/21	Header: deleted site names, added All Labs Section 5: Updated accounts and added instructions for electronic creation, retrieval, and pickup of boxes. Add. A: Updated retention time for ADM180 Footer: updated prefix to AHC	SCodina	RSanLuis
12	1/10/23	Added Addendum B	D Collier	RSanLuis

9. ADDENDA AND APPENDICES

A. Record Class Codes and Schedules

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 + 8
Workforce Central logs	ACC 110	8 Years
Interview Checklists, Employee recruitment	HRE 100	3 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
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

Addendum B

When results are filed in Sunquest, it is generally not necessary to save hard copies of results. The exceptions are listed below and **must** be retained per policy:

1. Path Reviews
2. CBC printouts with histograms
3. PCR printouts
4. Any manual worksheets, including downtime
5. QLS printouts and requisitions

Uncontrolled copy
Current as of 1/16/2023 2:52 PM