

Best Practice Guidance: Specimen and Specimen-Product Storage and Retention

Each laboratory should have in place a written plan for the retention of “Original Specimens,” “Specimen Product (isolates),” and “Specimens with Unusual Results.” This is valuable to the laboratory so that specimens can be retained for repeat or additional testing when needed, for further investigation for public health purposes, for quality control purposes and new test validation. An inventory system of retained specimens and isolates should be in place for the biosafety and biosecurity of the laboratory. The lab must consider the needs of the patient, the storage capacity for the laboratory and the needs of the laboratory for development of future tests.

Before establishing a specimen and specimen product storage/retention plan it is important to consult the guidelines of your accrediting agency:

1. CLIA- Clinical Laboratory Improvement Act
2. CAP- College of American Pathologists
3. TJC- The Joint Commission
4. AABB- American Association of Blood Banks

The plan should be overseen by the designated “Curator.” The plan must state how long and under what conditions specimens and/or their products are stored. The plan must differentiate between the “Original Specimens” (specified as a clinical source that is normally the original submission) and the “Specimen Product” (isolates obtained from culturing clinical specimens, DNA extracts, etc.) and “Specimens with Unusual Results.” Always record the owner of the specimens and/or their products. The plan must call for the routine destruction of specimens and isolates that are no longer needed.

Stored samples should be monitored and not kept for longer than necessary since refrigerator and freezer space may be limited. Sample freeze/thaw cycles must be monitored, as samples may deteriorate with these conditions. Each laboratory section must also describe proper disposal of specimens including any treatment necessary prior to disposal (autoclaving, chemical inactivation, etc.). Laboratories should consider software options for curating specimens and/or their products. Chain of custody must be maintained for forensic specimens.

PROTOCOL

The following guidelines are suggested for the retention of original specimens, specimen product and specimens with unusual results:

1. Any original specimens and specimen products from studies must comply with the study agreement and must be determined with the collaborators. Agreements or contracts for special projects should address specimen/sample storage at the beginning of the project.
2. An inventory system for each collection must be in place. It should allow for capture of the following information at a minimum:
 - a. Lab/Section
 - b. Accession #
 - c. Specimen type (this should be the original clinical or environmental source regardless of whether we received the original or the retained item was a referred product of testing)
 - d. Date archived
 - e. Archived item designation
 - i. original specimen/sample
 - ii. specimen/sample product-isolate, extract, smear, etc)
 - f. Archive temperature
 - g. Archive location (items i, ii at a minimum with another more specific location as appropriate)
 - i. room
 - ii. unit ID
 - iii. shelf
 - iv. box #/name
 - v. slot #
 - h. date of destruction
 - i. destruction method
3. Conducting inventory on a regularly scheduled basis will be described per section in the SOP that pertains to the inventory items.
4. The process for retrieving those items to be destroyed and performing destruction will be described in the SOP that pertains to the inventory items.

Table 1. Suggested Storage Guidelines by Laboratory Section

Laboratory Section	Original Specimens stored from date testing completed	Specimen Product stored from date testing completed	Specimens with Unusual Results (examples)
Blood Lead	One Week refrigerated (2-8°C).	Not Applicable	1 year frozen if >20 ug/ml at minus 80 degrees C.
Mycobacteriology	One Week refrigerated (2-8°C)	Positive TB cultures 3 Years at minus 80 degrees C.	MDR TB stored indefinitely at minus 80 degrees C. Unusual MALDI ToF results stored indefinitely at minus 80 degrees C.
Microbiology Reference	One Week refrigerated (2-8°C)	Pathogens 3 Years at minus 80 degrees C.	At minus 80 degrees C: Resistant <i>N. gonorrhoeae</i> 10 years, <i>N. gonorrhoeae</i> in children, 10 years, <i>B. pertussis</i> 10 years, <i>Legionella</i> sp. 10 years, Vancomycin resistant <i>S. aureus</i> 10 years. Unusual, emerging and novel resistance mechanisms 10 years
Syphilis Serology	One Week refrigerated (2-8°C)	Positive RPR and TPPA frozen at minus 20 degrees C, 6 months	High titer >1:32 frozen for three years at minus 80 degree C. Positive Syphilis in children, 10 years
Chlamydia/Gonorrhea	One Week refrigerated (2-8°C)	Not Applicable	Positives from extra-genital sources minus 80 degrees C 5 years
HIV/HCV	One Week refrigerated (2-8°C)	Positive HIV and HCV, stored for 5 year at minus 80 degrees C. Indeterminate confirmatory results stored for 5 years at minus 80 degrees. Negative retain 5 per month stored for 5 years at minus 80 degrees C.	HIV-2 stored indefinitely at minus 80 degrees C.

Laboratory Section	Original Specimens stored from date testing completed	Specimen Product stored from date testing completed	Specimens with Unusual Results (examples)
Rabies - Cerebellum or hippocampus, and brain stem	Cerebellum or hippocampus, and brain stem stored for 2 months refrigerated (2-8°C).	Smears stored for one month refrigerated (2-8°C).	<p>Positive specimens stored 3 years at minus 80 degrees C.</p> <p>10% of positive raccoon, skunk and bat specimens; ensure geographic diversity of specimens by species. 20 years at minus 80 degrees C.</p> <p>Any positives from unusual animal types stored for 20 years at minus 80 degrees C.</p>
Viral Serology	One Week refrigerated (2-8°C)	All positives stored for 3 years at minus 80 degrees C.	Unusual or Rare Positives stored 5 years at minus 80 degrees.
Virus Isolation	One Week refrigerated (2-8°C)	All positives stored for 3 years at minus 80 degrees C.	Unusual Positives stored indefinitely at minus 80 degrees.
Molecular	One Week refrigerated (2-8°C)	<p>Respiratory specimens (positive and negative) 2 years at minus 80 degrees C.</p> <p>Mosquito pools 5 years at minus 80 degrees.</p> <p>Positive animal serum 3 years at minus 80 degrees C.</p> <p>RNA 5 years at minus 80 degrees C.</p>	<p>Human specimens positive for arboviruses store indefinitely at minus 80 degrees.</p> <p>Positive mosquito pools stored indefinitely at minus 80 degrees.</p>
PFGE	Not Applicable	<p>DNA extracted for serotyping stored for 1 year at minus 80 degrees C.</p> <p>Pathogens stored for 3 years at minus 80 degrees C.</p> <p>Plugs stored for 3 years refrigerated (2-8°C).</p>	Stored electronically

Laboratory Section	Original Specimens stored from date testing completed	Specimen Product stored from date testing completed	Specimens with Unusual Results (examples)
Environmental Chemistry	Clinical samples = 1 year Unknown samples = 30 days at minus 80 degrees C. Drinking water = 30 days at minus 80 degrees C. Environmental = 60 days at minus 80 degrees C.	Not applicable	Not applicable
Biomonitoring	Clinical samples = 1 year at minus 80 degrees C.	Not applicable	Not applicable
Biothreat	Clinical samples = 1 year at minus 80 degrees C.	All positive isolates stored indefinitely at minus 80 degrees C.	All positive isolates stored indefinitely at minus 80 degrees C.
Chemical Threat	Clinical and environmental samples = 1 year at minus 80 degrees C.	All positives stored for 10 years at minus 80 degrees C.	Not applicable
Food Microbiology	Food samples stored for 1 month refrigerated (2-8°C).	All pathogens stored for 3 years at minus 80 degrees.	Not applicable

RESOURCES:

1. College of America Pathologist (CAP) Retention Laboratory Records and Materials; 2010 Mar [cited 2015 July 22]. Available from <http://www.ncleg.net/documentsites/committees/PMC-LRC2011/December%205,%202012/College%20of%20American%20Pathologist%20Retention%20Policy.pdf>
2. Infectious Disease Laboratory: Specimen Retention Schedule. Minnesota Department of Health; 2013 Jul [cited 2015 July 22]. Available from http://www.health.state.mn.us/divs/phl/clin/spec_retention.html#retention
3. Guidelines for the Retention of Laboratory Records and Materials. Ontario Association of Medical Laboratories; 2006 Jun [cited 2015 July 22]. Report No.: CLP020-002. Available from <http://www.oaml.com/documents/GuidelinefortheRetentionofRecordsMaterialsJune06.pdf>
4. Content Sheet 5-1: Overview of Sample Management. World Health Organization; 2005 [cited 2015 July 22]. Available from http://www.who.int/ihr/training/laboratory_quality/5_b_content_sample_mgmt.pdf

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National Center for Immunization and Respiratory Diseases (IP)

Office of Surveillance, Epidemiology and Laboratory Services (OSELs)

National Center for HIV, Viral Hepatitis, STDs and TB Prevention (PS)

National Center for Zoonotic, Vector-borne, and Enteric Diseases (CK)

National Center for Environmental Health (NCEH)

Coordinating Office for Terrorism Preparedness and Emergency Response (CTPER))



8515 Georgia Avenue, Suite 700

Silver Spring, MD 20910

Phone: 240.485.2745

Fax: 240.485.2700

Web: www.aphl.org