PATHOLOGY & LABORATORY MEDICINE SERVICE

RETENTION OF RECORDS version 3
General Procedure # GEN00014

Principle:

This policy is to ensure that necessary records and documents of VAMHCS –P&LMS are adequately protected and maintained and to ensure that records that are no longer needed by VAMHCS-P&LMS or are of no value are discarded at the proper time.

Procedure:

1. Attached as Appendix A are The Record Retention Guidelines for Pathology & Laboratory Medicine- National Enforcement Program.
2. All records and materials must be maintained according to VA mandates unless otherwise required by accrediting agency (i.e. College of American Pathologists, CAP), Federal/State/Local regulations.
3. Should the laboratory cease testing, all records, slides, blocks, and tissues will be available at a local or remote storage site where that scope of service is offered.

Attachment(s):

Appendix A- Record Retention Guidelines for Pathology & Laboratory Medicine

References:

1. College of American Pathologists- General Checklist, August 17, 2016.
2. Pathology and Laboratory Medicine Service (P&LMS) Procedures-VHA HANDBOOK 1106.01, January 29, 2016.

DATE ADOPTED	*Author of Procedure/Policy*	Chief of Service
01/22/1996	Paul D. Gruver, MT	Signature: Dong H. Lee M.D.

Policy/Procedure(s) Retired:		Date retired:

Review Date	Version Number	Signature of reviewer
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Record Retention Guidelines for Pathology & Laboratory Medicine

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GENERAL/CLINICAL LABORATORY (Transfusion Medicine, Anatomic Pathology and Cytogenetic specific requirements listed separately)		
ITEM	**DISPOSITION**	**REFERENCE**
Miscellany		
Test requisition/Test Orders/Accession log	2 years	RCS 10-1;7100.12, CAP GEN.20377, TJC DC.02.04.01 & AXA, 42CFR493.1105
Shipping manifests/packing lists (see Note 11)	3 months	GEN.40530
Test records (results, dates and names of testing personnel)	2 years	RCS 10-1;7100.13, CAP GEN.20377, TJC DC.02.04.01& WT.05.01.01 & AXA, 42CFR493.1105
Test report (Preliminary, Final and Corrected, including reference lab reports) (See Note 2)	2 years	RCS 10-1;7100-14, CAP GEN.20377, TJC DC.02.04.01 & AXA, 42CFR493.1105
Direct To Consumer test results and reference ranges	10 years	CAP GEN.41497, GEN.20377
Bone marrow reports	10 years	CAP HEM.36270 & TJC AXA
Quality control records • Reagents • Instruments • Temperatures and other function checks	2 years	RCS 10-1;7100.16, CAP GEN.20377, TJC DC.02.04.01 &EC.02.04.03 & WT.05.01.01 & AXA, 42CFR493.1105

Microbiology: If streamlined QC is used, documentation of test system verification and historical QC review	As long as streamlined QC is used but at least 2 years	CAP MIC.21626 (An individualized quality control plan (IQCP) including all required elements of IQCP, may be implemented by the laboratory to allow for the use of streamlined QC for commercial microbial identification systems (MIS))
Copies of the completed APHIS/CDC Forms, used to report identification of HHS select agents to CDC	3 years	42 CFR 73.6 (b) (3)
Flow Cytometry: Gated dot plots and histograms (See Note 10)	10 years	CAP FLO.23706 (Paper or electronic format is acceptable) &FLO.30605
Forensic records (see CAP checklist for listing of records)	At least 2 years or as long as legal action is pending	CAP CHM.38500
Proficiency test records/applicable corrective action (See Note 6)	2 years	RCS 10-1;7100.16 & 7100.19, CAP GEN.20377 & COM.01700, TJC QSA.01.02.01 & AXA, 42CFR493.1105
Quality Management Records/Quality system assessments	2 years	RCS 10-1;7100.16, CAP GEN.20377, TJC DC.02.04.01, 42CRF493.1105
IQCP documents: risk assessment, validation data, and approved quality control plan.	2 years following discontinuation of the plan	CAP Gen.20375
Discontinued test procedures (paper or electronic) with initial date of use and retirement dates	2 years (not blood bank or tissue)	RCS 10-1;7100.17, CAP COM.10500 & GEN.20375, TJC DC.02.01.01 & AXA, 42CFR493.1105
Instrument printouts and worksheets (See Note 1)	2 years	CAP GEN.20377, TJC DC 02.04.01 & AXA, 42CFR493.1105
Instrument preventative maintenance records: (daily/weekly/monthly/quarterly/semiannual)	2 years	RCS 10-1;7100.20, CAP GEN.20377, TJC EC.02.04.03, WT.05.01.01, AXA, 42CFR493.1105
Instrument/Method validation, records of method performance specifications (including validation of electronic/procedure/built-in QC)	2 years after discontinuation of the test	RCS 10-1; 7100.16 (2 years), CAP GEN.20377 (Life+2yrs), 42CFR493.1105 (life of instrument but no less than 2 years)
Instrument repair records (major repairs, parts and replacement) and annual preventive maintenance (PM's)	Life of instrument	RCS-10;7100.21 & TJC EC.02.04.03 & AXA
MSDS Sheets or a record identifying the chemical/substance and where & when it was used (see Note 7)	30 years	29 CFR 1910.1020

Specimens		
Serum, heparinized and EDTA plasma, cerebrospinal fluid, body fluids	48 hours after results reported	RCS 10-1; 7100.23, TJC AXA, CAP GEN.20377 (does not include whole blood specimens such as blood gases)
Urine	24 hours	CAP GEN.20377, TJC AXA
Peripheral blood smears & body fluid smears	7 days	RCS 10-1; 7100.24, CAP GEN.20377, TJC AXA
Bone marrow smears	20 years	RCS-10; 7100.25 (20 years), CAP HEM.36270 (10 years)
Permanently stained slides for microbiology (e.g. Gram, Trichrome, etc	7 days	RCS 10-1; 7100.26, CAP GEN.20377, TJC AXA
Personnel		
Personnel records: qualifications, formal education, training, and competence, etc (As part of OPF)	30 years	RCS 10-1;7100.22
Initial training on an instrument/method	5 years	CAP GEN.20377 & GEN.55450 (2 years general lab 5 years blood bank), POC.06850 (2 years) RCS-10; 7100.22 (5 years)
Annual competency assessments	5 years	RCS 10-1;7100.22 (5 years), CAP GEN.20377 (2 years for clinical lab , 5 years for Blood Bank CAP considers these quality records)
Training records for Blood borne pathogens	3 years	29 CFR 1910.1030
Records of names, signatures, initials and codes used to identify which employee performed a test.	75 years	RCS 10-1;7100.29
Computer		
Computer preventative maintenance records: (daily/weekly/monthly)	2 years	CAP GEN.20377
Computer hardware/software installation, validation and updates	2 years after retirement of system	CAP GEN.43022, GEN. 20377

TRANSFUSION MEDICINE

ITEM	DISPOSITION	NOTES
Donor Records		
Donor Testing: • ABO/Rh type, difficulty in typing • Allogeneic donor testing to detect unexpected antibodies to red cell antigens	10 years	RCS 10-1; 7100.31 (5 years), TJC DC 02.04.01, CAP TRM.32250 & AABB 6.2A (10 years)
Control systems for donor testing	10 years	CAP TRM.32250, AABB 6.2A

Donor identifying information, address, medical history and exam, informed consent, receipt of educational materials, infectious disease marker tests	75 years	RCS 10-1; 7100.28 (75 years) CAP TRM.32250 & AABB 6.2A (10 years)
Donor Deferral: • Permanent deferral of donors • Donors placed under surveillance or indefinite deferral (for recipient protection)	Indefinite	RCS 10-1; 7100.34 (75 years) CAP TRM.32250, TJC QSA.05.23.01, AXA & AABB 6.2A (indefinite)
Severe adverse reaction to donation	10 years	AABB 6.2A
Notification to Donor of significant findings	10 years	CAP TRM.32250, AABB 6.2A
Identification of individuals performing each significant step in collection process, processing, compatibility testing and transportation of blood and components.	10 years	CAP TRM.32250, AABB 6.2A
Blood and Blood Components		
Results of inspection of blood and components incoming, during storage and prior to release.	10 years	RCS 10-1;7100.4, CAP TRM.32250 (5 years), & AABB 6.2A & 6.2B (10 years)
Serologic confirmation of donor blood ABO/Rh	10 years	TJC QSA.05.22.01 (5 years), CAP TRM.32250 & AABB 6.2A (10 years)
Irradiation of cellular components	10 years	CAP TRM.32250, AABB 6.2B
Source/receipt to final disposition of unit, unique identification of each unit and ID of recipient if applicable	10 years	RCS 10-1; 7100.5 CAP TRM.32250, TJC QSA.05.22.01, AXA & AABB 6.2A
Look back notification and records that track components subsequently identified as infectious, includes records related to quarantined blood and components.	75 years	RCS 10-1; 7100.35 (75 years), CAP TRM.32250 & AABB 6.2A & (10 years)
Look back to identify recipients who may have been infected with HCV or HIV/disease reporting	10 years	CAP TRM.32250 & AABB & 6.2B (10 years)
Patient Records		
Specimens from blood donors (units) and recipients	7 days post-transfusion or 10 days after crossmatch	RCS 10-1; 7100.27, CAP Reference 1, AABB 5.11.4, TJC QSA.05.12.01 & AXA
Requests for blood and blood components & order for blood, component, tests and derivatives	5 years	AABB 6.2B, RCS 10-1; 7100.6

Emergency release of blood, including, signed statement from the requesting physician indicating that the clinical situation was sufficiently urgent to require release of blood before completion of compatibility testing	10 years	AABB 6.2B, CAP.32250
Difficulty in blood typing, significant antibodies, significant adverse events to transfusion (transfusion reactions), and special transfusion requirements	Indefinite	RCS 10-1; 7100.28 (75 years), CAP TRM.32250 & TJC AXA (indefinite), AABB 6.2B (indefinite)
Patient Testing • ABO/Rh type testing and interpretation • Testing to detect unexpected antibodies to red cell antigens and interpretation • Testing and interpretation of serologic and computer crossmatch • Immediate evaluation/interpretation of transfusion reaction	10 years	RCS 10-1; 7100.31 (5 years); TJC DC 02.04.01, CAP TRM.32250 & AABB 6.2B (10 years)
Test Reports including preliminary, final and corrected (See Note 2)	10 years	TJC DC 02.04.01&AXA
Transfusion Record • Verification of patient identification prior to transfusion • Recipient Informed Consent • Transfusion record indicating ABO/Rh and compatibility testing, date/time of transfusion, transfusionist, vitals, component, unit#, amount given and adverse reactions if applicable	75 years	RCS 10-1; 7100.28 (75 years), CAP TRM.32250 (10 years), AABB 6.2B & TJC DC.02.04.01(10 years)
Apheresis or therapeutic phlebotomy records	10 years	CAP TRM.32250 (10 years), AABB 6.2B (5 yrs)
Final Inspection of blood and blood components before issue (if container in not intact or components are abnormal in appearance, maintain medical director approval)	10 years	AABB 6.2B
Verification process at time of issue of all recipient and blood component information, special transfusion requirements, crossmatch interpretation, date/time of issue and personnel issuing and accepting blood component.	10 years	AABB 6.2B (See standards for more details)
Verification at time of transfusion of all recipient and blood component information, special transfusion requirements & crossmatch interpretation,	5 years	AABB 6.2B (see standards for more details)
Quality Records		
Superseded procedures (paper or electronic), manuals and publications	5 years	RCS 10-1;7100.30, CAP GEN.20375 & COM.10500, AABB

with initial and retirement dates plus records of reviews; also includes labels, circulars, product inserts and computer manuals		6.2C, TJC AXA
Exceptions to policies, processes, and procedures	10 years	AABB 6.2C
Quality control records for: • Reagents, blood and blood products, critical materials/supplies • Instruments,/equipment/methods • Irradiation dose delivery	10 years	AABB 6.2A , 6.2B & 6.2C (10 years), RCS 10-1; 7100.32 & 7100.33, CAP TRM.32250, & TJC AXA (5 years)
Proficiency testing and corrective action as applicable	5 years	RCS 10-1; 7100.32, CAP TRM.32250, CAP COM.01700 & AABB 6.2C (5 years), TJC QSA.01.02.01 & AXA (2 years)
Container (i.e. portable coolers used to transport blood) qualifications and process validation records.	10 years	AABB 6.2C
Temperature monitoring of refrigerator, freezer and platelet incubators temperatures, ambient temperature (Blood and component storage temperatures)	10 years	AABB 6.2C (10 years), RCS 10-1; 7100.32 & 7100.33, CAP TRM.32250 &
Description and evaluation of nonconforming blood, blood components, tissue, derivatives, critical materials, and services including any corrective actions and acceptance for use. Disposition of nonconforming units	10 years	AABB 6.2C
Instrument validation, records of method performance specifications	10 years after retirement of the equipment	CAP GEN.20377 (Life+2yrs), AABB 6.2C (10 years after retirement of the equipment), RCS 10-1;7100.16 (2 years)
Instrument preventative maintenance records: (daily/weekly/monthly/)	10 years	AABB 6.2C (10 years , considered QC records), CAP TRM.32250 (5 years), RCS 10-1;7100.20 & TJC EC.02.04.03 (2 years)
Instrument repair records (major repairs, parts and replacement) and annual maintenance	10 years after retirement of the equipment	RCS-10;7100.21 & TJC EC.02.04.03&AXA (life of instrument), AABB 6.2C (10 years after retirement of the equipment
Validation of new or changed process and procedures	5 years	AABB 6.2C
Computer system (hardware and software) documentation/validation	2 years after retirement of system	CAP GEN.43022 & TRM.22000, AABB 6.2C
Quality system and self-assessment audits (Quality management reviews)	5 years	CAP TRM.32250 & AABB 6.2C (5 years), RCS 10-1;7100.16

		& TJC DC.02.04.01 (2 years)
Fatality Reports	10 years	AABB 6.2C
Testing of emergency management plan at defined intervals	2 years	AABB 6.2C
Personnel		
Staff qualifications, training and competency (as part of OPF)	30 years	RCS 10-1;7100.22 (30 years), AABB 6.2C (5 years)
Initial training on instrument/method	5 years	CAP GEN.20377 & GEN.55450, RCS-10;7100.22 & AABB 6.2C (5 years)
Annual Competency assessments	5 years	RCS 10-1;7100.22, AABB 6.2C & CAP TRM.32250 (CAP considers this a quality record)
Records of employee names, signatures, initials, and identification codes, and inclusive dates of employment for personnel who perform or review critical tasks	75 years	RCS 10-1;7100.29 (75 years), CAP TRM.32250 & AABB 6.2C (10 years)
Tissue Banking		
• Quality Control	5 years	TJC AXA
• Superseded procedures, manuals and publications • Storage temperatures.	10 years	TJC TS.03.02.01(10 years), TJC AXA; CAP TRM.32250 & TRM.45190 & COM.10500; RCS 10-1; 7100.36 & AABB 6.2C (5 years)
• Source facility/tissue supplier • Original donor or lot identification (numeric or alphanumeric) • All recipients • Date of transplantation or other final disposition	75 years	RCS 10;7100.54 (75 years), CAP TRM.32250 & TRM.45190, TJC AXA, TS.03.02.01 (10 years post disposition or expiration date whichever is longer) & AABB 6.2D (10 years)
Patient's medical record to include: type of tissue, the numeric or alphanumeric identifier, the quantity, expiration date, and date of use	10 years post disposition or expiration date whichever is longer	AABB 6.2D (Same for Derivatives see AABB 6.2E), TJC TS.03.02.01,
Collection, transportation, processing, issuing	10 years post disposition or expiration date whichever is longer	TRM.32250 & TJC TS.03.02.01 (10 years), AABB 6.2D (10 years - Same for Derivatives see AABB 6.2E)
Tissue Records including inspection of incoming tissue, requests, and adverse effects (see AABB standards for complete listing of required elements)	10 years	AABB 6.2D (Same for Derivatives see AABB 6.2E), TJC TS.03.02.01, CAP TRM.45190

Traceability of tissue to final disposition	10 Years	AABB 6.2D (Same for Derivatives see AABB 6.2E), CAP TRM.45190, TJC TS.03.02.01
ANATOMIC PATHOLOGY		
ITEM	**DISPOSITION**	**NOTES**
Surgical Pathology		
Wet tissue	2 weeks after date of the final report	RCS 10-1;7100.39 & CAP ANP.12500 (2 weeks after date of the final report), TJC QSA.13.07.01 & AXA (7 days after report), 42CFR493.1105 (until diagnosis is made)
Paraffin blocks (See Note 8)	10 years from date of the exam	RCS 10-1;7100.38 & CAP ANP.12500 (10 years), TJC QSA.13.07.01 & AXA, 42CFR493.1105 (2 years from examination date)
Histopathology microscopic slides, including stained slides	25 years	RCS 10-1; 7100.37 (25 years), CAP ANP.12500, TJC QSA.13.07.01 & AXA, 42CFR493.1105 (10 years) slides must remain readable
Surgical Pathology Control Slides	10 years	CAP ANP.12500 slides must remain readable for this period
Immunohistochemistry batch control slide records	2 years	CAP ANP.22660
Flurochrome stained slides	At discretion of the Lab Director	CAP ANP.12500
Images of ISH studies – for neoplastic disorders (See Note 3)	10 years	CAP ANP.12500 & ANP.22965, TJC AXA
Images of ISH studies – for constitutional disorders (See Note 3)	20 years	CAP ANP.12500 & ANP.22965
Digital images used for primary diagnosis	10 years if original glass slides are not available	CAP ANP.12500
Datasets from In-Vivo Microscopy (IVM) or Ex Vivo Microscopy (EVM) systems used to aid in interpretation or diagnosis (See Note 12)	10 years - data must be retrievable for this period	CAP ANP.12500 & ANP.57850
Reports (Final, Modified) (See Note 4)	25 years	RCS 10-1;113-40 (25 years), CAP ANP.12500 & TJC DC.02.04.01&AXA (10 years), 42CFR493.1105 (10 years)
Reports of outside consultations on laboratory cases (whether or not	10 years after the date	CAP ANP.12500

requested by the laboratory)	that the original report was issued	
Accession log records	5 years	RCS 10-1;7100.41 (5 years), CAP ANP.12500 (2 years)
Cytopathology		
Cell Blocks	10 years (suspicious cell blocks 25 years)	VHA Handbook 1106.01 (10 years) CAP CYP.06900 (Same as slides)
Slides (negative, unsatisfactory)	5 years	RCS 10-1; 7100.43, CAP CYP.06900, TJC AXA & QSA.08.09.01, 42CFR493.1105
Slides (suspicious, positive)	25 years	RCS 10-1;7100.44 (25 years), CAP CYP.06900 & TJC AXA & QSA 08.09.01, 42CFR493.1105 (5 years)
Fine Needle Aspiration Slides	25 years	RCS 10-1;7100.45 (25 years), CAP CYP.06900 & TJC AXA (10 years)
Reports (Final, Modified) (See Note 4)	25 years	RCS 10-1;7100.46 (25 years), CAP CYP.06600 (at least 10 years), TJC DC 02.04.01& AXA (10 years)
Accession log reports	5 years	RCS 10-1;7100.47 (5 years), CAP & CYP.06600 (5 years newly identified abnormality in cervical cytopathology)
Records of intra and extra-departmental consultations	10 years	CYP.02100
Molecular Pathology		
Images of ISH assays slides or images for neoplastic disorders (See Note 3)	10 years	CAP MOL.39288
Images of ISH assays slides or images for constitutional disorders (See Note 3)	20 years	CAP MOL.39288
Test Reports for neoplastic conditions - (A copy of each final report, all records of results, membranes, autoradiographs, gel photographs, and *in situ* hybridization slides)	10 years	CAP MOL.49640
Test Reports for constitutional disorders - (A copy of each final report, all records of results, membranes, autoradiographs, gel photographs, and *in situ* hybridization slides)	20 years	CAP MOL.49640
Next Generation Sequencing (NGS) data necessary to support primary results generated and re-analysis	2 years	CAP MOL.35870

Autopsy		
Wet tissue	6 months after date of final report	RCS 10-1; 7100.48 (6 months from final report), CAP ANP.33500 (3 months from final report)
Paraffin blocks (See Note 9)	10 years after date of final report	RCS 10-1; 7100.49 (10 years after date of final report), CAP ANP.33500 (10 years)
Slides	25 years after date of final report	RCS 10-1; 7100.50 (25 years after date of final report), CAP ANP.33500 (10 years)
Reports (Provisional, Final , Modified)	25 years after date of final report	RCS 10-1;7100.51 (25 years after date of final report), CAP ANP.33500 &CAP "Retention of Laboratory Records and Materials" & TJC DC 02.04.01&AXA (10 years)
Accession log records	5 years after date of final report	RCS 10-1;7100.52 (5 years after date of final report), CAP ANP.33500 (2 years)
CYTOGENETICS		
ITEM	**DISPOSITION**	**NOTES**
Original specimens and cultures	Until release of final report	CAP CYG.32700 (until release of final report), TJC QSA.09.06.01(Until adequate metaphase cells are available)
Processed specimens or cell pellets	2 weeks after release of final report	CAP CYG.32700 & TJC QSA.09.06.01(2 weeks after release of final report)
Permanently stained slides	3 years	CAP CYG.32700, TJC QSA.09.06.01
Flurochrome stained slides & Cytogenomic array slides	At discretion of lab director	CAP CYG.32700
Cytogenomic array data- original scan	2 weeks after report complete	CAP CYG.32700
Cytogenomic array data- sufficient original data to support the final report	20 years	CAP CYG.32700
Negatives, prints or digitized images	20 years	, TJC QSA.09.06.01
Slides, negatives, prints or magnetic media of abnormal cases	indefinite	TJC QSA.09.06.01
Images or permanent slides of ISH studies - (hard copy negatives or prints) and/or in retrievable digitized formats- non-neoplastic/constitutional disorders (See Note 5)	20 years	CAP CYG.32700

Images or permanent slides of ISH studies - (hard copy negatives or prints) and/or in retrievable digitized formats- neoplastic disorders (See Note 5)	10 years	CAP CYG.32700
Final Report	20 years	CAP CYG.32700 (10 years neoplastic conditions, 20 years constitutional/genetic conditions), TJC QSA.09.06.01(20 years) & AXA (25 years suggested)
ELECTRON MICROSCOPY		
ITEM	**DISPOSITION**	**NOTES**
Written Accession log records	5 years	CAP ANP.55100 (2 years), VHA Handbook 1106.01 (5 years)
Electronic Accession log (Vista)	25 years after specimen receipt	VHA Handbook 1106.01
Wet tissue	2 weeks after final report	CAP ANP.55100, VHA Handbook 1106.01
Resin/plastic blocks	25 years from date of exam	CAP ANP.55100 (10 years) , VHA Handbook 1106.01 (25 years from date of exam)
EM grids	10 years	CAP ANP.55100 (10 years), VHA Handbook 1106.01 (1 year)
Negatives, or electronic images (all images, local EM Unit archive with optical or other media back-up), which are part of the report and written reports	25 years after final report	CAP ANP.55100 (10 years), VHA Handbook 1106.01 (25 years after final report)
Digital Images which are part of the reports and electronic reports (VistA, CPRS)	Retained within patient electronic record 75 years after last episode of care	VHA Handbook 1106.01
Prints from negatives included with report	10 years along with the report	VHA Handbook 1106.01
Remaining prints from negatives	1 year after final report	VHA Handbook 1106.01
Maintenance records	2 calendar years	VHA Handbook 1106.01
Semi-thin section (glass slides)	25 year from date of exam	VHA Handbook 1106.01

NOTE 1: *For data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), it is not necessary to retain paper worksheets, printouts, etc., so long as the computer retains the data for at least two years. Manual computer entry of patient result data from worksheets, print-outs, etc. requires retention of all worksheets, printouts, etc. for at least two years. For results that are manually entered into the computer from 1) observation of an electronic display, with no paper print-out available, or 2) manually performed test methods without worksheets, the two-year retention requirement applies to the data within the computer (CAP:GEN.20377). 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. (TJC:DC.02.04.01)*

NOTE 2: *Original test report or an exact copy. 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. (TJC:DC.02.04.01)*

NOTE 3: *There is no retention requirement for images of slide preparations when the source slides remain readable for the required retention period. For an ISH assay with a normal result, retain an image of at least one cell illustrating the normal probe signal pattern. For an ISH assay with an abnormal result, retain images of at least two cells illustrating each relevant abnormal probe signal pattern (CAP ANP.12500 & ANP.22965)*

NOTE 4: *Pathology reports may be retained in either paper or electronic format. If retained in electronic format alone, the reports must include a secure pathologist electronic signature. Images of paper reports, such as microfiche or PDF files are acceptable (CAP ANP.12500)*

NOTE 5: *For an ISH assay with a normal result, retain an image of at least one cell illustrating the normal probe signal pattern. For an ISH assay with an abnormal result, retain images of at least two cells illustrating each relevant abnormal probe signal pattern. There is no retention requirement for images of slide preparations when the source slides remain readable for the required retention period. (CAP CYG.32700)*

NOTE 6: *Records Retention for Proficiency Testing, TJC Q&A, March 21, 2011*
How long should we keep proficiency testing records?
A. For non-waived testing, the minimum retention requirement is two years for both Joint Commission standards and regulatory compliance. However, non-waived proficiency testing performance is monitored for subsequent unsuccessful status for up to a five year period. In rare instances, a laboratory could be required to provide a Plan of Action for a current unsuccessful event that also addresses any unsuccessful events that occurred in the prior five year period. For this reason, it is recommended that laboratories retain non-waived proficiency testing records by specialty and subspecialty for a five year period, particularly if there has been unsatisfactory or unsuccessful status within that timeframe. If all proficiency testing performance was satisfactory beyond the minimum two year regulatory retention period, then there is probably little value in retaining it longer than the required two years.

Note that this recommendation is specifically intended for non-waived testing. Participation in proficiency testing for waived testing is voluntary. Thus the value of retaining waived proficiency testing records beyond two years is at the determination of the laboratory director.

NOTE 7: Material safety data sheets and paragraph (c) (5) (iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years;

Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g). (29 CFR 1910.1020)

NOTE 8: Paraffin blocks used for patient diagnostic purposes must be kept for at least 10 years and be stored in a manner that preserves their integrity. Given that patient survival rates are increasing and the continued emergence of treatment based on biomarker testing, which at times may be required on the original tissue, it is recommended that, whenever feasible, tissue block retention from patients with diagnosed malignancies be retained beyond the 10 year requirement. (CAP ANP.12500)

NOTE 9: For autopsy paraffin blocks, the CAP recommends extending the required retention period to indefinitely or for at least a generation (approximately 20 years); however, it is not a requirement of accreditation. These blocks represent the last opportunity for tissue-based biomarker, genetic, and other testing in the interest of family members and public health. Strategies, such as retaining even a select number of blocks from each case permanently or partnering with a regional biorepository for permanent storage may be considered. (CAP ANP.33500)

NOTE 10: The intent of this checklist requirement is retention of gated dot plots and histograms of hematolymphoid neoplasias, CD34 stem cell records, and congenital immunodeficiency evaluations for 10 years. Paper copies of gated dot plots and histograms are not required as long as the information is available electronically (e.g., .pdf, .tiff, .jpeg files). (CAP FLO.23706)

NOTE 11: E-mail Response from Marian Briggs at CAP: "Thank you for your patience in awaiting my response regarding the retention of packing lists. As stated during our phone conversation this morning, this issue was discussed at our February 10, 2014 staff meeting. As a result of our discussion, it was agreed that packing lists are NOT considered quality control records. However, the laboratory does need to define a minimum retention time for the packing lists that is reasonable and based on good lab practice."

NOTE 12: In Vivo Microscopy (IVM) and Ex Vivo Microscopy (EVM) systems include confocal microscopy, optical coherence tomography, multiphoton microscopy, optical spectroscopy/spectroscopic imaging, and similar technologies. These systems may be used by physicians during procedures (IVM) or by the laboratory in the evaluation of specimens that have been removed from the patient (EVM). The dataset refers to digitized or analog video or still images or other data (e.g. spectroscopic data) generated by an IVM or EVM system. If such data is used to aid in interpretation or diagnosis, record retention requirements apply. Stored data should include, at a minimum, the data used to aid in interpretation or diagnosis. (CAP ANP.12500) IVM datasets are stored as digital files. Storage of the entire original data is not required. Stored data should include, at a minimum, the critical data elements(original data or derived data) used for interpretation or diagnosis (CAP ANP.57850)

References:

1. "Retention of Laboratory Records and Materials", CAP Website, Revised June 2013
2. CAP Checklists, 8/17/2016
3. "Standards for Blood Banks and Transfusion Services" AABB 30th edition
4. Record Control Schedule (RCS-10), May 2016
5. "Comprehensive Accreditation Manual for Laboratory and Point of Care Testing", The Joint Commission, 7/1/2016
6. "Appendix A: Retention Times for Records, Reports, and Specimens (AXA)", The Joint Commission, 7/1/2016
7. Electronic Code of Federal Regulations, Title 42-Public Health, e-CFR Data current as of 10/17/2016
8. Electronic Code of Federal Regulations, Title 21-Food and Drugs, e-CFR Data current as of 10/17/2016
9. Electronic Code of Federal Regulations, Title 29-Labor, e-CFR Data current as of 10/17/2016
10. VHA Handbook 1106.01, 1/29/2016

Document Revisions

Date of Revision	Description of Revision	New Version Number
10/18/2016	CAP MIC.21626 (An individualized quality control plan (IQCP) including all required elements of IQCP, may be implemented by the laboratory to allow for the use of streamlined QC for commercial microbial identification systems (MIS)	V 3.0
10/18/2016	Instrument/Method validation, records of method performance specifications (including validation of electronic/procedure/built-in QC) 2 years after discontinuation of the test	V 3.0
10/18/2016	Initial training on an instrument/method 5 years	V 3.0
10/18/2016	Tissue Banking: Collection, transportation, processing, issuing or expiration date whichever is longer 10 years post disposition	V 3.0