PREPARED BY:	**Name:** Monica Gonzalez **Title:** Laboratory Quality Manager	**Signature:** Monica Gonzalez **Date:** 09/26/2023
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Annual Review

Date	Signature	Date	Signature

PURPOSE:

Accreditation agencies NYSDOH, CMS, JCAHO, CAP, and ISO require that pertinent patient records, i.e.; glass slides, tissue blocks, request slips, completed worksheets, QC records, and instrument printouts be stored in an accessible area which allows for relatively easy retrieval. These records are used for education purposes, possible legal challenges, re-evaluation of pertinent patient records as deemed necessary by the clinician, recreation of the test process and to substantiate test report findings. In addition, the time frames that these records are archived vary according to the type of record, which must be stored.

Records which are required to be retained for more than 2 years, may be stored off the immediate laboratory premises, provided they can be available to the laboratory staff or other authorized personnel in the laboratory within 24 hours of request for records.

Data directly transmitted from instruments to the laboratory computer system via an interface (on-line system), 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, printouts, etc. requires retention of all worksheets, printouts, etc. for at least two years (digitized or photographic images are acceptable). 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.

POLICY:

Records shall be retained for at least as follows (as applicable):

Type	Item	Retention Period
Quality Assurance Records	All manuals, standard operating procedures, policies and documents related to the laboratory's Quality Management System (QMS) and quality assurance activities. Documentation that must be retained includes, but is notlimited to:	
	a) internal systems and process audits, and external inspection documents, including: i. who conducted the audit; ii. the dates of the audit; iii. audit findings and any actions taken;	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	b) complaints, investigations related to complaints and, if applicable, corrective action(s) associated with complaint investigation and resolution, including: i. ER	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)

Type	Item	Retention Period
	c) non-conformances and related documents associated with procedures and documentation of nonconformities.	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	d) corrective action documents associated with corrective action procedure and documentation, including: RCA's. i. corrective action documents associated with corrective action procedure and documentation for the category of forensic identity.	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials) Three (3) Years
	e) review of the effectiveness of corrective actions associated with corrective action effectiveness.	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	f) Quality Improvement Records - QI plan, PI monitors	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	g) Quality Management Records - As appropriate	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	h) Quality Management Records - Test Approval Form – New or Revised (Clinical Utility)	At least Ten (10) Years after the Laboratory stops offering the test that is under review.
	i) Management Review Records, including: Management Checklists, Audit Reviews, Management Rounding, Pt Safety Rounding, Management and Performance Improvement Meeting Minutes, Annual Evaluation of Effectiveness for Performance Improvement and Safety, Method Validations, Business Reviews, Reference Lab Quality Reports, etc.	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	j) Supply Inventory - Inventory of external services, supplies and purchased products records. This includes the recording of lot numbers of reagents, controls, calibrators, the date of receipt in the lab and the date the material was placed in service	As required by NYSDOH, CAP and ISO. Must be available for Management Review and retained for at least Two (2) Years.
	k) Purchasing Records - PO Requisitions, Packing Slips, Invoice Copies.	As per Wyckoff Heights Medical Center policies

Type	Item	Retention Period
	l) Safety - Incident/Accident Records	Two (2) Years - (At Least Fifteen (15) Years for Clinical Trials)
	m) Transfusion Medicine Records - All records pertaining to Transfusion Medicine	At least Ten (10) Years or as required by NYSDOH, CAP and ISO
	n) NYSDOH Permits and CAP Permits - Expired permits	Five (5) Years At Least Fifteen (15) Years for Clinical Trials
Human Resources, Training and Competency Records	Human resources, training and competency records	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	a) relevant licensure;	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	b) educational and professional qualifications;	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	c) dates of employment;	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	d) job descriptions;	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years

Type	Item	Retention Period
	e) training:	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	i. with the exception of safety training.	Three (3) Years.
	f) competency assessments; and	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
	g) continuing education	Duration of employment and Six (6) Years thereafter Staff performing Clinical Trials for at least Fifteen (15) Years
Controlled Document Retention	Controlled documents, including test procedures	Duration of use and Two (2) Years after discontinuation or archival.
	Transfusion and blood services controlled documents, including test procedures	Duration of use and Seven (7) Years after discontinuation or archival.
Laboratory Information System Records Retention	Laboratory Information System (LIS)records including records related to:	
	a) validation of system changes, including new or revised software and/or hardware, the test library, and major functions of laboratory information systems prior to their use for specimen testing, reporting and record keeping functions; and	Two (2) Years beyond the life of the system
	b) system maintenance required by the LIS manufacturer, or established and validated by the laboratory, including the environmental and operating conditions necessary to maintain the integrity of data.	Two (2) Years
	c) ongoing computer system checks (e.g. calculation verification)	Two (2) Years

Type	Item	Retention Period
	d) pending worksheets	1 Month
	e) VER (verified results)	1 Month
	f) critical value management reports	1 Month
Verification Records	Records on verification of supplies,equipment and instruments, and reagents and media (including initial validations and calibrations).	Duration of use and Two (2) Years after discontinuation. (The minimum retention period for the supplies inventory records is Two (2) Years; the laboratory management may define any length of storage greater than Two (2) Years.)
Monitoring, Maintenance and Preventive Maintenance Records	Monitoring, Maintenance and Preventive Maintenance Records:	
	a) environmental monitoring performed on cleanliness, monitoring and controlling the laboratory environment including monitoring of temperature-controlled spaces; and	Two (2) Years
	b) maintenance and preventive maintenance records generated from separation of incompatible activities, including service and repair records	For as long as the instrument remains in use and Two (2) Years following discontinuation of use.
	c) Instruments performing Clinical Trials testing Preventative Maintenance records, service and repair records.	At Least Fifteen (15) Years for Clinical Trials
Test Request and Specimen Processing Documents	The following records must be retained for at least the period specified or retain the appropriate record for the longest period applicable.	
	a) test request documentation – outreach requisitions including nursing homes referral information for cytogenetic cases	Seven (7) Years Six (6) Years
	b) accessioning records / test requisitions	Seven (7) Years

Type	Item	Retention Period
Analytic System Records Retention	Analytic system records must be retained by the laboratory, as follows:	
	a) performance specification data and records of acceptability criteria that the laboratory establishes or verifies from manufactures instructions or laboratory developed tests	Must be retained for as long as the laboratory uses the test process, plus Two (2) Years after discontinuation.
	b) testing records, including but not limited to worksheets containing instrument readings, the identity of staff who performed the test(s), and raw patient results	Must be retained for Two (2) Years
	c) result review records, including acceptability of quality control and calibration materials:	Two (2) Years
	• Quality Control Reports	Two (2) Years (Five (5) Years for Transfusion Medicine)
	• Exception Reports	Two (2) Years
	• Error Correction Review Reports	Two (2) Years
	• Intra-Laboratory Comparison	Two (2) Years
	• Individual Quality Control Plan (IQCP) (Including Risk Assessment and Supporting Data, and Approval of Quality Control Plan)	Two (2) Years following discontinuation of IQCP.
	• Ongoing Quality Assessment Data	Two (2) Years
	d) histogram of an automated differential result	Two (2) Years
Report Retention	All reports of tests performed, including the original or duplicates of original reports received from another laboratory,must be kept on the premises of both laboratories. Off-site or electronic storage systems are acceptable, provided the laboratory can produce records within twenty-four (24) hours of a request. Original electronic data must be maintained as long as the case file and must be protected from loss or modification. Reports must be produced for the Department upon request and be retained by the laboratory for:	

Type	Item	Retention Period
	a) tissue pathology including exfoliative cytology (cytopathology reports)	Twenty (20) Years
	b) syphilis serology negative report	Two (2) Years
	c) cytogenetics	Twenty Five (25) Years
	d) reference laboratory reports	Seven (7) Years
	e) all others – patient test results and reports, including original and corrected reports	Seven (7) Years
Specimen Retention	The Laboratory must be able to retrieve specimens within twenty-four (24) hours. Specimens must be retained, as follows:	
	a) blood films: i. routine ii. other than routine A routine blood film is one where no abnormal cells or cell counts are observed, or where a blood disorder is not indicated. A routine histogram of an automated differential is one that results as "normal" or "negative" and does not imply the need for further analysis. Histograms are considered to be an instrument printout and must therefore be retained, electronically or as hard copy. It is not required for a laboratory to create or maintain routine blood films if such films are not routinely generated in accordance with the laboratory's approved procedures.	 Six (6) Months One (1) Year Two (2) Years
	b) Permanently stained body fluid slides	Seven (7) Days
	c) bacteriology slide on which a diagnosis depends (slide received only)	One (1) Year
	d) Permanently stained microbiology slides from clinical specimens (including blood culture bottles)	At Least Seven (7) Days or until the final culture report has been issued

Type	Item	Retention Period
	e) cytology slide showing: i. no abnormality ii. any abnormality Include gynecological, non-gynecological, and fine needle aspirate (FNA) for cytopathology.	 Five (5) Years Ten (10) Years Ten (10) Years
	f) tissue block	Twenty (20) Years
	g) pathology tissue remnants	Until a diagnosis is made
	h) histopathology: i. block ii. slide Slides or electronic images that allow re-evaluation of the entire slide(s) used for reported results	 Twenty (20) Years Twenty (20) Years
	i) bone marrow biopsy	Twenty (20) Years
	j) photographic slides of cytogenetic karyotype	Twenty-Five (25) Years
	k) cytogenetic slide	Six (6) Years
	l) fluorochrome-stained slides	Discretion of Lab Director
	m) images of FISH studies	Ten (10) Years
	n) recipient blood specimens Recipient refers to any person receiving blood or bloodcomponents.	One (1) Week (Stoppered at One (1°) to Six (6°) Degrees Celsius
	o) samples of each unit of transfused blood	Seven (7) Days for further testing in the event of a transfusion Reaction

Type	Item	Retention Period
	p) mycobacteriology i. all original and subsequent *M. tuberculosis* complex isolates from all patients ii. stained slides of direct smears from primary specimens	One (1) Year until the final culture report has been issued
	q) serum and plasma	At least Forty-Eight (48) Hours Six (6) Days at Core Lab
	r) citrated plasma (frozen)	At least Forty-Eight (48) Hours Six (6) Days at Core Lab
	s) CSF and body fluids (except urine)	At least Forty-Eight (48) Hours Six (6) Days at Core Lab
	t) whole blood specimens, including blood gas specimens	At least Forty-Eight (48) Hours
	u) urine (refrigerated)	At least Forty-Eight (48) Hours
	v) records of blood, blood compounds and derivatives released for allogeneic or autogeneic transfusion - source to final disposition of each unit of blood or blood component and, if issued by the facility for transfusion, identification of the recipient	Ten (10) Years or Six (6) months after expiration date of the individual product whichever is later by the blood bank preparing the product and by institution using the product.
Proficiency Testing Records Retention	The laboratory must maintain all records generated during the test process for proficiency testing samples, including test reports. All documentation of review, investigation, corrective action, nonconformance, or other documentation related to proficiency testing, must also be retained. Records must be retained:	
	a) all categories;	Two (2) Years from the date of the proficiency test

Type	Item	Retention Period
	b) immunohematology category	Five (5) Years from the date of the proficiency test
Laboratory Closure	In the event that the Laboratory will cease operation, the Laboratory Director and Owner will notify the NYS Department of Health, and all records, slides, blocks and tissue cited above will be transferred and retained for the indicated times. The NYS Department of Health and former clients will be informed as to the new storage location(s).	

VERIFICATION OF COPIES OF RECORDS PRIOR TO DESTRUCTION:

If Applicable, laboratory records (e.g., patient reports, worksheets, quality control records) being converted onto another medium for storage and retention are verified for accuracy, legibility, and completeness before the original record is destroyed. See departmental specific procedures.

REFERENCES:

NYSDOH Regulations: Clinical Laboratory Standard of Practice, DSR FS, S1, S2, S3, S4, S5, S6, S7, S8, S9, S10, S11, S12

CAP General Checklist: 20377, 20425, 20430

More specific requirements for certain laboratory records are found in the Anatomic Pathology, (ANP.12500), Cytopathology, (CYP.06600), Cytogenetics, (CYG.32700), Molecular Pathology, (MOL.49640), Reproductive Laboratory Medicine, (RLM.12466), and Transfusion Medicine (TRM.32250) Checklists.

AABB

ICH-GCP (Good Clinical Practice)

RELATED DOCUMENTS:

Technical SOPs

Quality Records

DISTRIBUTION LIST:

Laboratory Management

Revision/Version No.	Date	Additions/Amendments
1	09/27/2023	• Changed format • Changed numbering
1		
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