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# Document and Sample Control System Overview

## Policy

### GENETWORx has very strict Document Control System in place. As part of the control system all the laboratory personnel and laboratory managers will follow rules sited below:

### All copies of policies and procedures in place should be current. Each laboratory department will have one folder with complete SOP’s at the workbench area. SOP binder is not to be removed by any employees.

### Copies of discontinued SOP’s will be saved per the record retention Policy (per QP 600). Discontinued SOP’s will be placed in a folder or binder. The date the discontinued SOP is archived will be indicated on the front page of the SOP along with a short reason why the SOP has been discontinued. The electronic version of the discontinued SOP stored on the shared drive will be annotated with the date archived (See #7 below).

### Laboratory Supervisors are responsible for ensuring that laboratory personnel have read the policies and procedures relevant to their job activities. All the written documentation of SOP’s been reviewed by laboratory personnel on the annual basis must be kept at the begging of the SOP binder.

### All the policies and procedures should be authorized by Laboratory Director or Designee **prior** to implementation. The Laboratory Manager is Medical Directors designee regarding updating, reviewing, and signing off on every policy and procedure **prior** to implementation. The Laboratory Director will review all the SOP’s and confirm authorization by signing off on the Opening page.

### All policies and procedures must be reviewed by Laboratory Director or Designee at least annually.

### The Laboratory Director and Laboratory Manager are the only members of laboratory team that have access to all SOP’s at any time. Access can be granted to Laboratory Supervisors or their Designee for a defined period if requested. All the requests should be address with the Laboratory Manager.

### All the SOP’s and forms should be saved on password multishare drive, folder Current SOP’s (with access limited to Managers and the Laboratory Director).

# Document and Sample Retention System

## Purpose

The purpose of this policy is to provide documentation of adequate medical care, quality control and compliance with all state and federal requirements. The following list details the retention of laboratory records and materials

## Security of document and sample retention storage

All documents must be stored on site in a secure area or a secure off-site location. GENETWORx stores is retained documents with Iron Mountain.

## Retention Policy

The following minimum record retention periods meet the College of American Pathologists recommendations for the minimum requirements for the retention of laboratory records and materials. They also meet or exceed the regulatory requirements specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). Records must be retained and available for these minimum times should the laboratory cease operation.

|  |  |
| --- | --- |
| **Materials/Record:**  | **Period of retention1** |
| **General laboratory** |
| Accession records | **2 years** |
| Instrument maintenance records | **2 years** |
| Quality control records | **2 years** |
| Quality management records | **2 years** |
| Specimen requisitions (including the patient chart or medical record only if used as the requisition) | **2 years** |
| Patient test results and reports (both original and corrected) | **2 years** |
| Instrument printouts | **2 years** |
| Policies and Procedures | **2 years** |
| Archived Policies/Procedures | **2 years** |
| Next Generation Sequencing data (FastQ, BAM, VCF files) | **2 years** |
| **Personnel Records** |
| Competency | **2 years** |
| Training records | **The time period in which the method/test system is in use or length of employment (whichever is shorter), plus 2 years** |
| Proficiency Records | **2 years** |
| **Sample Retention** |
| Serum/CSF/body fluids (except urine) | **48 hours** |
| Urine | **24 hours** |
| Peripheral blood smears/body fluid smears | **7 days** |
| Permanently stained slides-microbiology (gram, trichrome, etc.) | **7 days** |
| Buccal Swabs | **1 Month** |
| Nails | **1 Month** |

## Record Retention Requirements for New York

### The following record retentions are required specifically for the state of New York:2

### All records and reports of tests performed including the original or duplicates of original reports received from another laboratory shall be kept on the premises of both laboratories and shall be exhibited to representatives of the department on request. Records listed below shall be retained by the laboratory for at least the period specified. If other New York State or Federal regulations or statutes require retention for different periods of time, the laboratory shall retain the appropriate record for the longest period applicable. Records shall be retained in their original form for a period of three months and may thereafter be stored on microfilm, microfiche, or other photographic record, or as magnetic tapes or other media in an electronic data processing system. Such records shall be adequately protected against destruction, either by archival storage or duplicated photographic or electronic medium or by other suitable means providing equivalent protection. Records which are required to be retained for more than two years may, after two years, be stored off the immediate laboratory premises, provided they can be available to the laboratory staff or other authorized person in the laboratory within 24 hours of a request for records.

#### Requests for tests shall be retained for the same period of time as required for the test results or seven years, whichever is less, except that referral information for cytogenetic cases shall be retained for six years.

#### Accession records shall be retained for seven years.

#### Records of quality control results shall be retained for two years.

#### Preventative maintenance, service and repair records shall be

#### Retained for as long as the instrument remains in use, except that records of monitoring of temperature-controlled spaces shall be kept for one year.

#### The following types of laboratory reports shall be retained for at least

#### the period specified;

##### (i) tissue pathology including exfoliative cytology - 20 years;

##### (ii) syphilis serology - negative report - two years;

##### (iii) cytogenetics - 25 years; and

##### (iv) all others - 7 years.

#### Worksheets containing instrument readings and/or personal observations upon which the outcome is based shall be retained for one year.

### The following requirements shall apply to the retention and disposition of specimens:

#### Specimens shall be retained to be accessible to the laboratory within 24 hours for at least the period set forth below:

##### blood film - other than routine - 1 year;

##### blood film - routine - 6 months;

##### cytology slide showing any abnormality - 7 years;

##### cytology slide showing no abnormality - 3 years;

##### tissue block - 20 years;

##### recipient blood specimens - 1 week stoppered at 6 degrees Celsius.

## Reference

### CAP GENERAL Checklist GEN.20377 August 17, 2016

### PART 58-1 OF 10 NYCRR, CLINICAL LABORATORIES, Sec. 58.1-11, sec c. pages 18-20

# Policy and SOP Preparation

## Purpose

### Writing: The purpose of this procedure is to describe the steps necessary to correctly create a new Standard Operating Procedure (SOP) or policy for GENETWORx, and allow anyone to create a SOP with all the necessary information for it to be complete.

### Revising: All laboratory procedure manuals will be reviewed by the Laboratory Director or designee on an annual basis. All changes in procedure are documented and on the Revision number section at the bottom of the SOP/policy. The retention of these materials will be per the Record Retention policy (Section II of QP 600).

## Writing an SOP/Policy

### A new procedure or method is developed, which requires a SOP.

### Use the SOP/Policy Template (Quality Manual Attachment 20 (Molecular) or Attachment 25 (Clinical))

### If the document is a policy to be included in the Quality Manual, create a signature line for the Chief Executive Officer.

### If the SOP is an original, the block next to the “Revised by” Date will be annotated “original.”

### The SOP # is assigned by the Laboratory Manager. For a new SOP it should be the next number in the series, i.e., 200.002.0 if the previous number in the series is 200.001.0. For an original SOP the decimal should be .0,

### State the purpose of the SOP or policy. This should be a concise description of what the SOP is to accomplish.

### List all the reagents, equipment, and supplies necessary to complete the task (this may not be necessary in all SOP’s and is not necessary for policies).

### List all special safety precautions that should/must be followed during the task, if applicable.

### Describe the procedure. This should include every step used from the beginning to the end of the procedure. A trained employee should be able to read the SOP, complete the task, and obtain the desired results.

### List all special notations that are of any importance to the task.

### The following are suggested headers for main sections of the SOP’s. SOP’s are not limited to, and may not contain all of the following (suggested list from CLSI GP2-A4 Vol. 22 No. 5 p.

#### Purpose/Policy

#### Reagents

#### Equipment

#### Supplies

#### Specimen

#### Special Safety Precautions

#### Quality Control

#### Procedure

#### Interpretation/Results

#### Calculations

#### Expected Values

#### Method Limitations

#### Procedure notes

#### References

#### Related Documents

#### Appendixes(forms, labels, tags, tables)

### Prior to implementation an SOP must be approved by the Laboratory Director or designee who must sign the SOP header.

### Policies should be reviewed and approved by the Chief Executive officer prior to final approval by the Laboratory Director.

### The SOP is forwarded in electronic format to the Laboratory Manager for inclusion on the shared SOP drive

### A copy of the current, signed SOP must be kept in the department for access by all employees.

## Revising an SOP

### The SOP is rewritten or edited to incorporate new techniques and changes.

### Document the changes made in the version history section of the procedure.

### The SOP is approved by the supervisor.

### The SOP takes on the next consecutive revision number 600.001.1, 600.001.2 etc.(note the original SOP for this subject would be 600.001.0, 600 series = Laboratory Operations, .001 = first SOP, .0 = original SOP.

### The Revision is approved by the Laboratory Director.

### The Revision is forwarded to the Laboratory Manager for inclusion on the shared SOP drive. The previous version is placed in the archived folder.

### Employees are responsible for reviewing all changes to the SOP as soon as it is effective. Review is documented on each individual SOP in the “Reviewed by” table:

### The previous version of the SOP is archived for a minimum of 2 years. Annotate on the SOP the date of archival and by whom.

## Annual SOP Review: All SOP’s are reviewed on an annual basis by the Laboratory Director or Designee.

## Director Designee Policy

### The Laboratory Director may train and designate individuals to perform the following tasks:

|  |  |
| --- | --- |
| **Task** | **Designee** |
| Monthly Control QC Review | Manager, General Supervisor, Senior Medical Technologist, |
| Training and Competency Assessment | Manager, General Supervisor, Senior Medical Technologist, Medical Technologist, Technical Assistant with appropriate training |
| Temperature Check Review | Manager, General Supervisor, Senior Medical Technologist, |
| QC Deviation Reports | Manager, General Supervisor, Senior Medical Technologist, |
| Monthly Maintenance Log Review | Manager, General Supervisor, Senior Medical Technologist, |
| Inventory Check | Manager, General Supervisor or Senior Medical Technologist |
| Reagent QC Cross Check Review | Manager, General Supervisor, Senior Medical Technologist, |
| Monthly Safety Check | Manager, Director of Operations, General Supervisor |
| Fire Drill Organization | Manager, Director of Operations |
| Initial Safety Tour | Director of Operations, Safety Officer |
| Minor changes to SOPs (ie typographical errors) | Manager, Manager, General Supervisor |
| Approving Proficiency Results | Manager, General Supervisor |

# Policy for Management and Correction of Laboratory Records

## Purpose

### The purpose of this policy is to describe the policy for the correction of laboratory records.

## Scope

### This policy refers to correction of the following documents

#### Quality control data

#### Temperature logs

#### Worksheets

#### Maintenance logs

## Policy

### All laboratory records and changes to such records must be legible and indelible.

### All entries must be visible; Correction fluid should never be used

### In a paper record, draw a line through the erroneous information in the document in a fashion that makes it clear it is an error but does not obliterate or reduce the ability to read the erroneous information. Sign or initial and date the entry. If only initials are used, there must be a corresponding entry on the Signature Identification sheet available in the record for reference.

### Write in the corrected information as close to the original entry as possible, maximizing the likelihood that a user accessing the record will see the correction and locate the correct information.

# Policy for Storage and Destruction of Documents

## Purpose

### The Health Insurance Portability and Accountability Act (HIPAA) requires healthcare providers to regularly shred documents containing information on patient’s medical histories. This is one of the most explicitly outlined requirements in the 1996 law, and it’s all to prevent identity theft. It is imperative that any company collecting or holding medical records ensure that spare copies of those records are destroyed regularly.

### The Privacy Rule requires a covered entity to implement “appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.” This general obligation is the same for hardcopy and electronic information, and encompasses the disposal of protected health information, or PHI.

## Scope

This policy applies to all employees handling any documents containing laboratory data or personal health information (PHI).

## Policy

### What kinds of materials are covered under HIPAA shredding regulations? How do you know whether a piece of paperwork goes into the “to-be-shredded” pile or whether it’s okay to just toss in the trash? The general takeaway from HIPAA enforcement action is simple: be vigilant about everything that contains patient data.

### It is important to shred all documents that contain any of this confidential information. Locked shredding containers are located in strategic locations throughout the buildings. Documents to be shredded should be place in the appropriate container and should not be left to accumulate in offices.

### It is the responsibility of all employees to:

#### Ensure the security and confidentiality of patient and employee records and information.

#### Protect against anticipated threats to the security and/or integrity of such patient and employee records and information.

#### Guard against unauthorized access to or use of such records or information that could result in substantial harm or inconvenience to any patient or employee.

### The reasons for shredding documents are:

#### To ensure that personal information relating to patients and employees including social security numbers, credit card numbers, addresses, phone numbers, e-mail addresses, and date of birth is safeguarded and not accessed by unauthorized individuals and

#### To encourage the efficient recycling of all printed materials.

### The following PHI should be shredded

#### Anything with a social security number (SSN)

This is good practice not just for HIPAA, but as a general rule. SSNs are like gold to identity thieves — if you see a nine-digit number on a form, toss it in the shredder.

#### Anything with a name and address

This might seem strange, since it’s just about the most easily accessible information out there. But what’s important here is keeping in compliance with HIPAA shredding rules — which dictate that anything with a name and address is considered “private information.”

#### Anything with a birthdate

If it has a birthdate on it, chances are it’s got a name on it too, making it easy for identity thieves to match up someone’s name and birthday. Always assume that if a document features a name and at least one other piece of identifying information, it’s covered by HIPAA shredding rules.

#### Photographs and X-rays

Many times, identity thieves will “steal” health care by pretending to be someone who is eligible for better insurance or free care. Often, photographs and x-rays won’t include faces, so it can be relatively easy for an identity thief to pretend to be the patient in question.

#### Electronically stored information-including voicemails.

HIPAA shredding rules include parameters for destroying information stored on hard drives and other digital media. Destruction must be by degaussing or total destruction, such as hard drive shredding. Often, this information is easier to access than paperwork, simply because protecting data on a computer is more complicated than tossing an insurance form in a shredding machine.

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| **Revision History** |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Change company name and SOP number, reformat Quality System, Add CEO signature Line, clarification of record retention policy | Sarah Jacobs-Helber | 07/21/2017 |
| 1 | Addition of Director Designee Policy | Sarah Jacobs-Helber | 09/11/2017 |
| 2 | Addition of Retention Requirements for Next Generation Sequencing | Sarah Jacobs-Helber | 02/13/2018 |
| 3 | Addition of Retention policy for nails | Sarah Jacobs-Helber | 03/28/2019 |
| 4 | Addition of Policy for Management and Correction of Laboratory Records, addition of Clinical SOP template | Sarah Jacobs-Helber | 04/19/2019 |
| 5 | Addition of record destruction policy. | Sarah Jacobs-Helber | 0902/2020 |

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| **Review & Approval History** |
| **Printed Name** | **Signature** | **Date** |
| Sarah Jacobs-Helber, PhD HCLD(ABB), Laboratory Director |  |  |
| William Miller, HTL, MBA Chief Executive Officer |  |  |

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| **Reviewed by** |
| **Printed Name** | **Signature** | **Date** |
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