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# Organization

## Policy

GENETWORx has clearly defined and documented the parties responsible for the provision of services and the relationship of individuals responsible for key quality functions.

## Purpose

This policy provides direction for the processes and procedures to organize, maintain, and monitor the Laboratory quality system.

## Responsibility

### Laboratory Leadership has the authority and is responsible for laboratory operations, compliance with all standards and applicable laws and regulations and management review of the quality system.

### The Laboratory Director has the authority and is ultimately responsible for all medical and technical policies procedures, and consultative and support services that relate to the safety and care of patients.

### The Laboratory Supervisors and staff are responsible for reporting to the authorities defined in the facility’s structure, and following all policies, processes, and procedures as written.

## Emergency Operations Plan

The Laboratory maintains emergency operations plans to respond to the effects of disasters.

## Quality System

The Laboratory maintains a defined, documented, and implemented quality system and trains all personnel in its application.

## Quality Representative

The Laboratory has designated supervisors, who report to executive management, to supervise the quality system.

## Management Reviews

The Laboratory management assesses the effectiveness of the quality system through scheduled management reviews.

# Quality Management System Overview

## Responsibility

### Laboratory Leadership has the authority and is responsible for laboratory operations, compliance with all standards and applicable laws and regulations and management review of the quality system.

### The Laboratory Director has the authority and is ultimately responsible for all medical and technical policies procedures, and consultative and support services that relate to the safety and care of patients.

### The Laboratory Supervisors and staff are responsible for reporting to the authorities defined in the facility’s structure, and following all policies, processes, and procedures as written.

### Emergency Operations Plans

#### The Laboratory maintains emergency operations plans to respond to the effects of disasters.

### Quality System

#### The Laboratory maintains a defined, documented, and implemented quality system and trains all personnel in its application.

### Quality Representative

#### The Laboratory has designated supervisors, who report to executive management, to supervise the quality system.

### Annual Management Reviews

#### The Laboratory management assesses the effectiveness of the quality system through scheduled management reviews on an annual basis. The laboratory Director or designee performs the annual management review and the results are reviewed by the Laboratory Director and Chief Executive Officer.

## Quality Management Plan Overview

### Objective

### The objective of the Quality Assurance plan is to ensure that clinical sample testing performed at GENETWORx adhered to its applicable federal and state regulations, the College of American Pathologists (CAP) guidelines and all relevant GENETWORx policies and procedures. The Quality Management Plan consists of nine major components that are summarized in Table 1.

|  |  |
| --- | --- |
| Table 1. Major Components of the GENETWORx Quality Management Plan. | |
| QP 100 | Quality System |
| QP 200 | Personnel |
| QP 300 | Equipment |
| QP 400 | Reference lab |
| QP 500 | Quality Controls |
| QP 600 | Document Control |
| QP 700 | Reporting and Classification of Incidents |
| QP 900 | Quality Assurance |
| QP 1000 | Facilities and Safety |

### Overview of Specific Quality Plan Components

#### QP 100 Quality System

The Quality System details the organization, policies of our compliance plan, critical values, scope of authority and services, reporting of quality concerns, and the terms of the laboratory accreditiation. Additional documentation regarding emergency procedures and the flow of patient quality information is also detailed.

#### QP 200 Personnel

This section of the Quality Management Plan provides direction for the processes and procedures to effectively manage laboratory personnel. This includes the scope of responsibility for hiring of personnel, policies for the maintenance of personnel files, policies for the provision and documentation of continuing education, competence assessment, and policies for private health information.

#### QP 300 Equipment

This section of the Quality Management Plan provides details on the installation, validation, and reporting of instrument malfunction to maintain the highest quality of results for the patient.

#### QP 400 Reference Laboratory Policy.

This section of the Quality Management Plan details the policy of GENETWORx regarding the criteria for determination of accreditation of laboratories used as reference laboratories.

#### QP 500 Quality Control

This section of the Quality Management Plan outlines the analytical systems of all departments to ensure the quality and correctness of data, the processes of clinical assay validation, and the conditions under which sample testing may be cancelled.

#### QP 600 Document Control

This section of the Quality Management Plan insures compliance with existing GENETWORx SOPs and recording any deviations from good laboratory practices. The creation and revision of SOPs as well as the retention of records are detailed. The ability of appropriate personnel to perform quality control or other operations or procedures in lieu of Laboratory Director.

#### QP 700 Reporting and Classification of incidents

This section of the Quality Management Plan details the steps required to report, categorize, investigate, analyze, track and summarize occurrences involving the lab.

#### QP 900 Quality Assurance

This section of the Quality Management Plan details the Molecular Quality Assurance plan and continuous Quality Improvement Plan. The QA program is designed to optimize performance and render accurate diagnoses through continual analysis of practices as well as ensure continuous monitoring of patient safety. Continuous quality indicators (Pre-Analytical, Analytical, and Post analytical) are established to help achieve the goal and are described.

#### QP 1000 Facilities and Safety

This section of the Quality Management Plan details the procedures required to provide adequate facilities for clinical testing and insuring safe and comfortable assay performance. Chemical Hygiene, Fire Safety and emergency procedures, Blood-Borne Pathogen Safety and Biohazard Waste Handling are discussed.

# Critical Value Policy:

## Critical Value Definition

### Any value reported to a caregiver that may require rapid clinical attention to avert significant patient morbidity or mortality. GENETWORx’s Policy, Critical Values Results, defines these values.

### The Laboratory maintains a list of critical laboratory values that is approved by the Laboratory Director of the facility. The Laboratory notifies appropriate personnel when a critical value is obtained during testing. The Laboratory ensures that the results are accurately conveyed by asking the caregiver to repeat the information back and documenting this callback in the GENETWORx LIMS.

Reference: College of American Pathologists, Laboratory General Checklist, GEN.20316

# Scope of Authority and Responsibility

## Laboratory Director

1. Exercises authority in matters related to compliance with federal, state and local regulations including, but not limited to CAP, AABB, JCAHO, CLIA, OSHA, MOSH, and FDA.
2. Reviews quality summary from appropriate sections of the laboratory.
3. Ensures that the laboratory quality improvement program is coordinated with the hospital-wide quality improvement program through the Department of Quality & Patient Safety.
4. Consults with physicians and/or medical staff, patients, administration, government and other agencies as needed concerning laboratory testing.
5. Ensures the service Quality System Plan is implemented and sustained.
6. Reviews and approves Laboratory policies.
7. Reviews and approves systems that support the operations of the lab, i.e. courier system, reference laboratories and computer system.
8. Ensures interpretation, correlation, and communication of laboratory data.
9. Ensures performance of anatomic pathology procedures.
10. Ensures provision of consultations regarding the medical significance of laboratory data.
11. Monitors standards of performance, quality control, and quality management, including tests referred to outside laboratories.
12. Ensures the provision of educational programs, planning, research, and development appropriate to the needs of the laboratory.
13. Ensures sufficient personnel with adequate documented training and experience are available to meet the needs of the laboratory.
14. Ensures implementation of a safe laboratory environment.
15. Has primary decision responsibility in the selection of all laboratory equipment and supplies.
16. Reviews and approves the content and format of all patient reports at least annually

## Chief Executive Officer

1. May act as the Laboratory Director’s designee in matters of review of proficiency testing, QC data, annual review of procedure manuals, and other tasks as deemed necessary.
2. Approves Quality Manuals in conjunction with the Laboratory Director

## Laboratory Manager

1. Exercises authority in matters related to compliance and local, state, and federal regulations;
2. Review laboratory error/variance reports, investigates, and follows up as appropriate.
3. In conjunction with laboratory medical director, reviews and analyzes quality summary to identify trends or recurring variances.
4. Approves hiring of qualified personnel.
5. Acts as the Laboratory Director’s designee in matters of review of proficiency testing, QC data, annual review of procedure manuals, reports and other tasks as deemed necessary.

## Laboratory Supervisor

1. Prepares/reviews policy, process and procedure documents;
2. In conjunction with laboratory staff, review laboratory error/variance reports, investigates system failures that may impact patient care and participates in corrective actions.
3. Compiles reports for tracking and trending.
4. Interviews and participates in hiring of qualified personnel.
5. Prepares and maintains the Quality Plan.
6. Performs audits of major systems.
7. Review Quality Control and analyzes statistics for trends or recurring variances.
8. Documents and participates in training and competency of personnel.
9. Acts as the Laboratory Director’s designee in matters of review of proficiency testing, QC data, monthly maintenance and QC and safety checks and other tasks as deemed necessary.

## Technical Staff

1. May prepare procedures.
2. Participates in training and competency assessment of employees.
3. Reviews Quality Control to identify and monitor trends and deviations.
4. Identifies errors/variances as they occur and reports them appropriately.

## Support Staff

1. Ensures proper paperwork supports medical necessity of laboratory testing ordered on outpatients.
2. Identifies errors/variances as they occur and reports to supervisor.

# Laboratory Goals

## Policy

### The goal of GENETWORx is to produce accurate, timely, and clinically relevant laboratory reports by:

#### Detecting and preventing errors in laboratory processes;

#### Reducing process variations that can cause errors;

#### Improving effectiveness and efficiency of processes;

#### Responding to customer needs in providing laboratory services;

#### Developing and maintaining a competent staff; and

#### Complying with all required regulations and accreditation standards.

# Scope of Services

## Policy

Our organizational relationships are shown in the attached organizational charts. (See Quality Manual Attachment 1, Organizational Chart). The laboratory is accredited by the College of American Pathologists as a high complexity clinical laboratory and the American Association of Blood Banks (AABB) for relationship testing.

The Laboratory provides laboratory services including. Major sections within the Laboratory include:

#### Genetic Testing

#### Women’s Health Testing

#### GI pathogen testing

#### Clinical Chemistry

#### Toxicology (Screen and Confirmation of Drugs of Abuse)

#### Next Generation Sequencing

The Laboratory provides services six (6) days a week, from 8:30 AM to 5:00 PM as determined by workflow. The Laboratory may change staffing patterns to facilitate the delivery of services as needed.

# Reporting of Concerns

## Policy

### GENETWORx promotes an environment for providing quality patient testing. Staff is expected to report issues or conditions that would interfere with quality results. Management is expected to respond to quality concerns by performing a thorough investigation and implementing any remedies.

### GENETWORx’s Management encourages every employee to communicate any concerns regarding test quality or laboratory safety to management. Please report all the concerns to your immediate Supervisor. If no action was takes, please bring your concerns to Laboratory Manager, Safety Committee or QA/QC/QI Committee to rectify the situation immediately.

### If GENETWORx as an employer took no action regarding your concerns and problems persist, please notify College of American Pathologists if needs be. CAP holds such communications in strict confidence (see below).

### GENETWORx is committed to patient safety and safety of its employees. If any unsatisfactory processes noted, please bring them to management for review and further action.

### Any harassment or punitive action against an employee in response to a complaint or concern reported to CAP or other regulatory agency regarding laboratory quality or safety is strictly prohibited. The Laboratory ensures that there is no harassment or punitive action taken against employees who report patient testing concerns to either the organization or other regulatory agencies.

### The College of American Pathology, CAP, also provides a confidential hotline for reporting quality or safety concerns. It is (866-236-7212). Unsafe laboratory equipment or products should be reported to The Laboratory Director.

# Terms of Accreditation

## Policy

1. GENETWORx will report to its accreditation agency (CAP) any investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than 2 working days after the laboratory learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. CMS, State Department of Health, The Joint Commission, FDA, OSHA).
2. GENETWORx will report to its accreditation agency (CAP) any discovery of actions by laboratory personnel that violate national, state or local regulations. Refer to Section VII for information on reporting Quality Concern issues.
3. GENETWORx will report to its accreditation agency (CAP) of any change in laboratory test menu (notification must occur prior to starting new patient testing).
4. GENETWORx will report to its accreditation agency (CAP) any change in location, ownership or directorship of the laboratory; notification must occur no later than 30 days prior to the change(s); or, in the case of unexpected changes, no later than 2 working days afterwards
5. GENETWORx will accommodate the provision of an inspection team comparable in size and scope if requested by CAP.
6. GENETWORx will cooperate with CAP when the laboratory is subject to a CAP investigation or inspection.
7. GENETWORx will adhere to the Terms of Use for the CAP Certification Mark of accreditation.

# Management Review Workflow

## Purpose:

To illustrate the flow of patient quality information within GENETWORx.

## Process:

Laboratory patient quality information flows as demonstrated in the following chart.

Chief Executive Officer

Laboratory Director

QA Committee

Laboratory Supervisors

Lab Manager

Laboratory Staff

**Reporting documents include:**

|  |  |  |  |
| --- | --- | --- | --- |
| Name | **Frequency** | **Definition** | **Reported to** |
| Corrective Action Reports | Quarterly | Monitors that have been selected by the department to monitor the quality of testing. | QA Committee or Safety Committee |
| Quarterly QA Report by Dept. | Quarterly | Provides the opportunity for the department to report additions or changes to their service that will impact patient care. | QA Committee or Safety Committee |
| Case Review | As needed | The Laboratory Director or Safety Committee will facilitate investigation of any particular patient case in order to improve patient care. This is performed upon request. | QA Committee or Safety Committee |
| Process Review | As needed | The Laboratory Director or Safety Committee will facilitate investigation of any particular patient case in order to improve patient care. This is performed upon request. | QA Committee or Safety Committee |
| Quality Plan Review | Annually | An internal assessment of the Quality Plan will be performed annually by qualified personnel | QA committee and Safety Committee |

## Urgent Information:

|  |  |
| --- | --- |
| Number | Notes |
| **1** | Urgent information regarding the quality of patient care may be communicated directly to the CEO, Laboratory Director and/or the Laboratory Manager. They will determine the method and manner for disseminating the information. |

# Quality Plan Review

## Internal Audit Schedule

1. The Quality Manager is responsible for scheduling and planning the internal audits of the laboratory on an annual basis.
2. Scheduling is done in consultation with the Laboratory Director.
3. The Quality Manager will take into consideration the schedule and availability of laboratory associates prior to agreeing to a date.
4. Audits are generally scheduled in the third quarter of the year.
5. The Quality Manager selects auditors to ensure that an audit team is qualified as per the requirements for each type of audit.

## The general process for any internal audit is as follows:

1. The Quality Manager notifies the laboratory that an internal audit will be conducted, the general scope of the audit, and provides an approximate timeframe.
2. The Quality Manager schedules an opening conference with the auditors to discuss the audit objectives, assignments, timing, and report format

and distribution.

1. The auditors perform their audit activities to assess the soundness of the quality system, management system, and technical operations.
2. The audit teams provide the Quality Manager with their audit findings, including potential non-conformities and observations.
3. The Quality Manager discusses preliminary observations (if any) with management.

1) Non-conformities that are non-systemic, are easily corrected, and do not indicate serious deficiencies in the management

system can be corrected prior to the completion of the audit.

2) The correction is documented in the audit records, but is not

included in the final audit report.

1. The Quality Manager, Director, and other associates(s) as requested by the Quality Manager to review the audit results submitted by the audit teams and verify the findings that are true non-conformities supported by objective evidence.
2. The Quality Manager finalizes the audit report and notifies the appropriate GENETWORx associates.
3. A quality incident review is used for follow-up on any audit non-conformities identified in the audit report.

i. If audit non-conformities show that laboratory results may have been affected, the laboratory must notify its customers and accreditation agency of the results, in writing, within thirty (30) days of discovery.

j. The internal audit assessment report, findings and follow-up documentation will be retained according to the procedure for Retention (SOP 604.038).

## Management Review

### The annual quality system review will be conducted by the Quality Manager under the direction of the Laboratory Director. The review will cover the Quality Manual, the procedures (SOPs), continuing education, proficiency testing, validation records, corrective and preventive actions, annual audit findings, safety program, annual equipment checklist, monthly QA checklist, customer feedback and testimony monitoring. Each element will be reviewed for completeness and accuracy. The Quality Manager will also review these elements for any changes that should be made and/or opportunities for improvement or corrective/preventative actions, and for adherence to the SOP. This annual review will be retained in Quality Assurance according to the procedure for Retention (QP 600 Document Control).

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision History** | | | |
| Revision Number | Reason for Revision | Author | Effective Date |
| 0 | Original SOP | Bill Miller | Upon Signature |
| 1 | Reformat Quality System, Add CEO signature Line | Sarah Jacobs-Helber | 07/21/2017 |
| 2 | Addition of Clinical Chemistry and Toxicology | Sarah Jacobs-Helber | 08/15/2017 |
| 3 | Addition of Quality Plan Review information. | Sarah Jacobs-Helber | 10/19/2017 |
| 4 | Addition of Next Generation Sequencing Quality Plan | Sarah Jacobs-Helber | 05/23/2018 |

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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 |  |  |

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