| *POLICY AND PROCEDURE* | |
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| SUBJECT/TITLE: | Laboratory Quality Assessment and Assurance Policy |
| APPLICABILITY: | Laboratory Staff |
| CONTACT PERSON & DIVISION: | Christina R Henning Laboratory |
| ORIGINAL DATE ADOPTED: | 09/30/2016 |
| LATEST EFFECTIVE DATE: | 09/30/2016 |
| REVIEW FREQUENCY: | Every 5 years |
| BOARD APPROVAL DATE: | N/A |
| REFERENCE NUMBER: | 400-004-P |

## A. PURPOSE

The purpose of the Quality Assessment and Assurance Policy is to ensure that the Canton City Health District (CCHD) Laboratory provides high quality testing throughout the entire testing process.

## B. POLICY

The Canton City Health Department laboratory has established quality systems for all general laboratory systems and for all phases of the total testing process, including preanalytic, analytic, and post analytic phases. We will ensure continuous improvement of our performance through ongoing monitoring of each system to identify, evaluate and resolve problems with a goal of assuring accurate and reliable test results are obtained and reported to our providers in a timely manner.
Each of the systems in our laboratory will be evaluated as needed to be sure that it meets our quality goals. If a problem is identified, we will design and implement a solution that is approved by the laboratory director. To determine if our solution has worked, we will re-evaluate the system at a later time (e.g., 3 months later). We will keep written records of our review, findings, and actions.

## C. BACKGROUND

This Quality Assessment Plan was initially implemented on August 1, 2014, and will be reviewed and updated or revised as needed.

## D. GLOSSARY OF TERMS

N/A.

## E. PROCEDURES & STANDARD OPERATING GUIDELINES

### 1. Confidentiality of Patient Information

This laboratory will, to the best of our ability, comply with the patient privacy regulations included in the final CLIA regulations and in the Healthcare Insurance Portability and Accountability Act. We will limit access to patient information to those individuals who are authorized to access the information and will implement policies and procedures to prohibit unauthorized access. (See 800-016-P_HIPAA Policy for further details)

### 2. Specimen Identification and Integrity

This laboratory will follow written policies and procedures to ensure proper patient identification, specimen collection, labeling, accessioning, processing, and storage, specimen testing and reporting results. We will periodically evaluate our systems utilizing the Quarterly QA Review process to ensure that specimens are properly tracked throughout the testing process from collection to reporting. If an incident is identified the following practice will be implemented.

> An incident is an irregularity in the sample analysis process. It may occur in the pre-analytical, analytical, or post analytical phases. Whenever an irregularity is encountered the analyst needs to note all pertinent facts in the Lab Orders and Results Log (400-004-03-F), including date, irregularity, and contact information. If the incident involves the pre-analytical or post analytical phase the submitting/receiving entity needs to be notified and correct information obtained or transmitted.

### 3. Complaints

Any complaints about our laboratory, whether from providers, patients or staff, will be taken seriously and will be documented and evaluated promptly. Documentation of complaints will be maintained on the Lab Orders and Results Log which is used for all general issues and concerns. Corrective actions will be implemented to prevent recurrence. Complaints will be reviewed as part of the Quarterly QA review and issues and concerns will be documented on the form which is used to provide information to the laboratory director for review and to document any underlying cause of the complaint. This information will be documented and kept with our quality assessment records.

### 4. Communications

Effective communication between the laboratory and any authorized person who orders or receives test results is vital to the operation of this laboratory. This includes the laboratory test requisition, information needed concerning the patient or the specimen, and the test report. Every significant breakdown in communications will be documented and will be reviewed and if necessary corrective actions will be planned and implemented to prevent a repeat occurrence. Additionally, a communications log is established to maintain records of communications that are not patient specific.

Patient specific information is maintained in the patient's electronic medical file, usually through the use of a "To Do" or in the Lab Orders and Results log using the patients unique ID.

**5. Personnel Competency**

This laboratory will ensure that all testing personnel are properly trained and are competent prior to testing patient specimens. At least Semi-annually for new employees and annually thereafter, the laboratory director and/or technical consultant will review the performance of each employee working in the laboratory to assure employee competency. The written result of the review will be filed in the individual's personnel file. The director will ensure that laboratory personnel are provided with retraining or continuing education if indicated. (See 400-004-01-P_Personnel Competency Assessment Program for additional details)

**6. Proficiency Testing**

This laboratory will enroll in formal proficiency testing appropriate to the test menu and treats all proficiency test challenge specimens the same manner as patient specimens. We will forward the results of our proficiency testing (PT) to the laboratory director. The director will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort to identify the cause of failure. If a cause is found, we will take necessary corrective actions and re-evaluate the PT results after the next PT challenge. This information will be recorded and kept with our proficiency testing records. (See 400-004-02-P_Proficiency Testing Policy for additional details)

**7. Test Request**

This laboratory will ensure that there is a written or electronic request from an authorized person for each laboratory test performed. In order to provide optimal patient care, the laboratory will run tests ordered verbally by an authorized individual but will make a reasonable effort to obtain written or electronic orders by the end of the next business day. The test requisition must include all information necessary: patient's name and date of birth OR the patient's unique identifier, sex and test(s) to be performed, source of specimen if applicable, date of specimen collection, and additional information as required.

**8. Specimen Submission, Handling, and Referral**

This laboratory follows written policies and procedures to ensure specimen integrity. Instructions will include specimen identification, collection techniques, specimen labeling, storage, preservation, and processing. Our policies include criteria for acceptable specimens and procedures for rejecting specimens. For specimens to be referred to a reference laboratory, we follow that laboratory's instructions. We submit specimens only to laboratories that are CLIA certified or accredited.

**9. Procedure Manual**

This laboratory maintains a procedure manual that includes all tests performed. It refers to the manufacturer's instructions, if applicable. The Procedure Manual (400-001-P_Clinical Laboratory Testing Procedures) addresses site-specific information not included in the manufacturer's instructions, such as who is authorized to order tests, how test results are reported, and procedures to

be followed if the test system is inoperable. The laboratory director and all staff are a part of the review process. Following review periods and as needed the procedure manual will be approved with any subsequent additions or revisions.

**10. Test Systems**

We will ensure that our testing environment (temperature, humidity, water quality) meets the manufacturer's specifications and that we follow the manufacturer's instructions for maintenance and function checks. For new test systems, we will verify performance specifications, such as accuracy, precision, sensitivity, specificity, and reference intervals.

**11. Quality Control**

For each test system used, we follow the manufacturer's instructions and the CLIA regulations, to ensure accuracy and precision for our test results. Our quality control system is designed to help us detect errors due to the test system, environmental conditions or operator error. We use commercial assayed control materials developed to detect errors throughout the analytic phase and will use their statistics or will calculate our own parameters to evaluate our performance. We document the results of all controls and will take appropriate actions when the controls do not perform as expected.

For quantitative testing, we run a minimum of two controls each day of patient testing; for qualitative tests we run controls based on the manufacturer's instructions. If a test includes titration, we include a negative control and one with graded or titered reactivity. For culture media, disks and reagents, we follow the manufacturer's specifications.

The laboratory has developed a quality assurance log sheet for every test system it performs. These sheets document the response of pertinent reagents and responses. Laboratory staff is responsible for ensuring that testing is performed at appropriate intervals and results are entered in the appropriate quality assurance log. Any deviant responses must be responded to and brought to the attention of laboratory supervision, and steps taken to identify and remedy the reason for the response.

Quality assurance logs will be reviewed as part of the Quarterly QA review. Issues and concerns will be documented on the form, which is used to provide information to the laboratory director for review and to document any underlying cause of the complaint.

**12. Comparison of Test Results**

If a backup test system is available for use when the primary system is inoperable, we will evaluate the relationship of those results to the results from the primary system.

Anytime we get a result that is inconsistent with clinical data (patient's age, gender, diagnosis, other clinical data, or other test results), we will assess the inconsistency to determine appropriate actions. We will document our findings and actions and keep the documentation with our quality assessment records.

**13. Corrective Actions**

This laboratory will record all activities, quality assessment monitoring, errors, and problems. For each significant problem found, corrective actions will be implemented if possible and will be documented.

At a later time, we will review each problem to determine the effectiveness of our corrective actions and take additional actions if indicated. For significant incidents an Incident Investigation Report (IIR) (400-004-04-F_Incident Investigation Form) form is utilized. These forms will be reviewed by the Laboratory Director for completeness and to ensure a resolution is found to the error to prevent future reoccurrence. The form is detailed to capture the essence of the issue and provides for a review process to ensure corrective actions have been completed. The form is in a format that permits editing to fit the situation as needed. These forms are included in the Quarterly QA Review process to ensure trends are identified and can be addressed.

**14. Test Records**

This laboratory will maintain records that include positive identification of the specimen, date the specimen was processed in the laboratory, conditions and disposition of unacceptable specimens, dates and records of testing, identification of testing personnel, instrument printouts with patient results and patient test results in accordance with the Canton City Health District Records Retention Policy. Instrument printouts with patient results will be retained as well. All documents will be kept for a minimum of two years.

**15. Test Report**

Our laboratory test report system will ensure that test results are accurately and reliably relayed to the ordering individual. This will include calculations, transcribed and electronically transmitted information from our laboratory. The information will include patient identification (name and date of birth or chart number), name and address of the testing facility, the test performed, the specimen source if pertinent, the date of testing, the test result, and units of measure if applicable. Information concerning interpretation or reference (normal) ranges is available to the individual(s) using or interpreting the test result. We will document the condition and disposition of any unacceptable specimens and will immediately alert the proper personnel of any result that indicates a life-threatening situation or if the test cannot be run for any reason. Test reports will be released only to authorized individuals.

When errors are identified in the patient test reports, the ordering entity will be notified immediately and corrected reports will be provided. Errors such as this will be recorded in the Lab Orders and Results Log.

**16. Employee Safety**

The Laboratory Director will ensure that the laboratory is a safe working environment for all staff members. We maintain an effective OSHA program that includes all hazards to which laboratory personnel may be exposed. Safety includes but is not limited to the items described in the Safety Plan (400-003-P_Safety Policy). The Safety Policy specifically addresses general laboratory practices, personal protective equipment, laboratory ventilation, emergencies and accidents, monitoring and examination, training and information, record keeping, chemical and biological safety and electrical safety.

### 17. Quality assessment assurance

The Laboratory will assure quality assessment activities and requirements are completed, reviewed, and that follow-up actions have been taken through the use of the Incident Investigation Form (IIF) and the Quarterly QA Checklist. The IIF will be used to document all incidents of significance including but not limited to PT or analyte systems failure or other incident that directly affects patient care. Not all incidents will rise to the need for use of this form. For instance, receipt of an incomplete test requisition may only require contact to the requesting authority for correction of the form and documenting of said request in the Lab Orders and Results Log. These logs along with the IIF's will be monitored for trends utilizing the QA Checklist. The QA checklist is our primary means of laboratory systems quality assessment. The form is updated and revised as needed following each quarterly review.

## F. CITATIONS & REFERENCES

800-016-P_HIPAA Policy
400-001-P_Clinical Laboratory Testing Procedures
400-003-P_Safety Plan
CLIA Laws and Rules which can be found at http://wwwn.cdc.gov/clia/regulatory/default.aspx.

## G. CONTRIBUTORS

The following staff contributed to the authorship of this document:

1. Christina R Henning, Laboratory Manager

## H. APPENDICIES & ATTACHMENTS

400-004-01-P_Personnel Competency Assessment Program
400-004-02-P_Proficiency Testing Policy
400-004-08-A_Sample Personnel Competency Form

## I. REFERENCE FORMS

400-004-03-F_Lab Orders and Results Log
400-004-04-F_Incident Investigation Form
400-004-05-F_Quarterly QA Checklist
400-004-06-F_Policy Acknowledgement Signature Page
440-004-07-F_Laboratory Director Attestation Page

## J. REVISION & REVIEW HISTORY

| Revision Date | Review Date | Author | Notes |
|---|---|---|---|
| 09/30/2016 | | C Henning | Originally approved policy |

## K. APPROVAL

This document has been approved in accordance with the "800-001-P Standards for Writing and Approving PPSOGFs" procedure as of the effective date listed above.