Quality Assessment Plan

Purpose

- Quality assurance is broadly defined as the adherence to well prescribed procedures designed to assure an accurate and reliable product. The Quality Assessment (QA) Plan for the North Dakota Department of Health, Division of Microbiology is based on Continuous Quality Improvement (CQI). The QA plan encompasses:
    - Satisfaction (Quality) as defined by our customers.
    - Quality as defined by high scores on internal and external proficiency testing.
    - Decision making by use of data and scientific methods.
    - Interdepartmental communication and cooperation through employee teams.
    - Emphasis on processes rather than individual components.
    - Review and improvement of all processes through continuous assessment.
    - A quality assessment team will meet monthly or as needed to discuss and implement any necessary changes.

Quality Assurance Objectives

- Monitor and evaluate quality.
- Identify and correct problems.
- Assure accurate, reliable and prompt reporting of test results.
- Assure adequacy and competency of team members.
- Improve quality of laboratory services to our customers on a continuous basis.

Responsibility

- The laboratory director, medical director, and management team are responsible for the overall quality of all laboratory services. Responsibility for the daily quality of work performed in each department within the division is delegated to the general supervisor of each area.

Scope of Services

- The NDDoH, Division of Microbiology is a part of North Dakota's public and environmental health laboratory. It functions as a testing and reference laboratory for customers in the State of North Dakota. The Division of Microbiology performs testing in the following areas: bacteriology, immunology, mycobacteriology, mycology, parasitology, serology, and virology as well as dairy, water, and bioterrorism testing.

Quality Assessment Procedures

Analytic Procedures	
Technical Procedures	The Technical Procedures in ipassport are updated when needed and reviewed annually by the testing personnel performing the tests, lead analyst, QA coordinator, microbiology and/or division director. The procedures in ipassport contain: • Step-by-step performance of the procedure, interpretations of results, and testing performance criteria. • Calibration and calibration verification procedures. • Quality control procedures and remedial action if control results fail to meet the laboratory's criteria for acceptability. • Limitations in methodologies, including interfering substances. • Literature references. • Description of action to be taken if test system becomes inoperable.
Bioterrorism– LRN Procedure Manual	Procedures for testing of suspected select agents/bioterrorism agents are provided by and updated by the Laboratory Response Network.

Validation of Tests	A comparative study is performed on each new procedure to verify the acceptability of test results. This study is reviewed and approved by the technical supervisor, QA coordinator, and director before instituting the procedure in the laboratory.
Quality Control	Good quality control practices ensure accurate and reliable outcomes to laboratory testing by determining the proper performance of a test, procedure, and/or laboratory personnel. Quality control recommendations and the quality control program for each test procedure are described in the division's Technical Procedures in ipassport. Accurate records are maintained in the appropriate quality control log books located in each unit laboratory. The information recorded is used to determine the quality of the test being monitored. QC Logs are dated, initialed, and contain corrective actions needed to comply with our QC program. All team members must participate in the Division's Quality Control Program. Records are monitored daily by the microbiologist and general supervisor of each unit laboratory and reviewed quarterly by the division's QA coordinator. QC summaries are included in the QA report submitted to the technical supervisor.
IQCP	The "Individualized Quality Control Plan" (IQCP) is the Clinical Laboratory Improvement Amendments (CLIA) Quality Control (QC) procedure for an alternate QC option allowed by 42CFR493.1250. The guidance and concepts for IQCP are a formal representation and compilation of many things laboratories already do to ensure quality test results. IQCP permits the laboratory to customize its QC plan according to test method and use, environment, and personnel competency while providing for equivalent quality testing. The IQCP includes: Risk Assessment, Quality Control Plan (QCP), and Quality Assessment (QA). The IQCP will address the potential failures and errors identified in the entire testing process: preanalytic, analytic and postanalytic phases of testing. • A Risk Assessment is the process of identifying and evaluating the potential failures and errors that could occur during the **preanalytical** (before testing), **analytical** (testing), and **postanalytical** (after testing) phases of testing. ▪ At a minimum, it will evaluate the following five components of the testing process for potential failures and errors: o Specimen, test system, reagent, environment, testing personnel • A Quality Control Plan (QCP) will describe practices, procedures and resources needed by your laboratory to ensure the quality of a testing process. The QCP includes measures to assure the accuracy and reliability of test results, and that the quality of testing is adequate for patient care. ▪ At a minimum, the QCP includes the number, type, and frequency of testing control materials, as well as criteria for acceptable quality control. • Quality Assessment (QA) can be described as a multi-part activity. ▪ Monitor and Assess The laboratory must establish and follow written policies and procedures to monitor and assess, and when indicated, correct problems identified. The monitoring should include, but is not limited to, the following risk assessment components: specimen, test system, reagents, environment, and testing personnel. ▪ Corrective Action The QA must also include a review of the effectiveness of corrective actions taken to resolve problems identified. The

	laboratory must update the risk assessment and modify the QCP, as necessary based on the information obtained from the QA. The QA coordinator performs an evaluation for each IQCP annually to ensure it continues to provide accurate and reliable test results. If necessary, any portion of the risk assessment will be updated with new information as needed along with any modifications to the QCP. The annual evaluation will be submitted to the CLIA director for review.
Instrument Maintenance and Calibrations	The care and service of laboratory equipment is a team effort and must be performed at different levels. The general supervisor assumes the responsibility for establishing a maintenance schedule for each unit laboratory. Schematic diagrams and operating manuals are accessible to laboratory personnel. Equipment is monitored and maintained on a daily basis. To detect malfunctions, a maintenance log for each piece of equipment is located in each unit laboratory. The logs contain the date, type of service, measurement, comments, corrective action, and analyst initials.
Personnel Competency	Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to: • Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. In addition, direct observations will include performance of instrument maintenance and function checks. • Monitoring the recording and reporting of test results • Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records • Direct observations of performance of instrument maintenance and function checks • Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples • Assessment of problem solving skills
Proficiency Testing (PT)	Our Proficiency Testing Program aids in determining the quality of the performance of laboratory personnel, detects technical and procedural deficiencies, and ensures appropriate corrective action. The division participates in the following external proficiency testing programs: • Centers for Disease Control • CDC LRN Proficiency Program • The College of American Pathologists • FDA Milk Split Samples • FDA Food Split Samples • EPA Water Coliform Proficiency • FERN Water Coliform Proficiency • Tri-State Milk Split • North Dakota/Minnesota Challenge Set – BT • South Dakota State Laboratory Inter- Laboratory Exchange • Wisconsin State Laboratory of Hygiene Proficiency Testing • Western States Proficiency Test

	Internal proficiency testing is conducted on tests not included in the external proficiency testing challenges. Non-commercially available proficiency testing material may be obtained by inter-laboratory exchange with other states. All testing samples are handled and processed in the same manner as patient specimens. The results are not shared between other laboratories. Tests are repeated when: • Results are not consistent with case history. • Results are out of acceptable range. • Controls fail to meet laboratory's criteria for acceptability. Upon receipt from the proficiency testing provider, results are reviewed by the QA coordinator. The QA coordinator will hold a meeting with the technical supervisor and testing personnel involved to review the specific proficiency. In the event of unsatisfactory results, corrective action is taken to avoid future discrepancies. Samples are retested and a "Corrective Action Form" is completed. The form includes our result, intended result, repeat result, description of procedure used to obtain result, other tests which could or should have been run, other aids which could have been used, evaluation of test method and possible changes, and evaluation of our protocol and possible changes. A corrective action is filled out when the answer we gave is not the intended answer and is filled out whether the specimen is graded or not and even when a consensus agreement was not reached. The summary is reviewed by the technical supervisor who reviews it with the unit personnel. It is then forwarded to the QA coordinator and CLIA director for final review.

Safety

It is the policy of the North Dakota Department of Health to protect the safety and health of our employees. No job should be considered so important that it cannot be done safely. The laboratory's goal is to reduce accidents and health hazards by planning for and implementing hazard control. The laboratory has established and maintains an active safety program and management performance.

Enforcing and reevaluating the safety program is ultimately the responsibility of the laboratory director. Management provides incentive for and full support of all safety procedures, training and hazard elimination practices. Management will keep fully informed on all health and safety issues throughout the lab.

The general supervisors are directly responsible for training employees on the proper procedures and safe methods to be used in their jobs. They must take immediate steps to correct hazardous conditions and/or practices. Supervisors will not permit safety to be sacrificed for any reason and will enforce the established safety program.

The success of a safety program depends on the employees' willingness to keep them informed and follow established safety policies. It is the employees' responsibility to cooperate in every respect with the laboratory's safety program. Some of the major points of the division's safety program require that:

- All injuries and accidents must be reported immediately to your general supervisor and a lab incident report must be completed and given to the lab director.
- Personal protection equipment, where required, must be worn by all employees. There will be no exceptions to this requirement.
- Hazardous conditions and other safety concerns must be reported immediately to your supervisor.
- Every employee must read and understand the Safety Manual and sign the "Employee Training Information Verification Form".

Patient Test Management

Specimen Acceptability	Specimen receipt and handling is discussed in detail in the 'Specimen Receipt and Handling' procedure.

	The following criteria is used for specimen rejection: • Recommended transport/hold time exceeded • Specimen damaged (leaked, broken, etc.) • Improper specimen (contaminated, inadequate collection, wrong body site, duplicate sample) • Unsuitable for request • Specimens of insufficient amount (QNS) • Mislabeled or unlabeled specimens Action on rejected specimens includes one or more of the following: • Alert physician and/or institution • Request a repeat • Hold specimen until contacted • Send report stating reason for rejection • Specimens that are irreplaceable may be run with a written disclaimer added to the report with approval of the lead analyst
Specimen Referral	The Centers for Disease Control, Atlanta, GA, is the reference laboratory for the NDDoH, Division of Microbiology
Testing Accountability	Each specimen received is logged onto the unit laboratory bench sheet. The bench sheet includes appropriate comments on progress and completion of testing. Rejected specimens are also documented in the same manner.
Analytic Time	Analytic time, also known as "turnaround time", is defined as the amount of time after receipt of the specimen until test results are issued to the requesting facility. If testing is delayed, the requesting facility is notified by telephone. All communications are documented in the telephone log. The analytic time is indicated for each test in the Directory of Services or in the procedure manual. The general supervisors document any situation out of compliance and submit an internal Corrective Action to the QA coordinator or director.
Timeliness of Result Reporting	All completed test results are reported within 24 hours of test completion. Emergency values, i.e., positive test and culture results, are phoned to the requesting facility the day the test is completed or at the beginning of the next day. The general supervisors document any reporting failures and submit an Internal Corrective Action Report to the QA coordinator or director.
Accuracy of Results Validation	The validity of the test results are determined by the microbiologist who compares patient information with the patient's test results and checks the quality control outcomes. The general supervisor is consulted when information does not correlate with the patient's test results or test controls are unacceptable. Patient test results are not reported until all discrepancies are resolved. If an incorrect test result has been reported, the general supervisor immediately notifies the requesting institution and/or physician by telephone. A Corrected Report is sent within 24 hours of verification of the corrected test result. The general supervisor checks that all records clearly state the corrections to assure that the incorrect original result is not reissued verbally or in writing. The general supervisors complete an Internal Corrective Action Form. A copy of both the original and corrected report is attached to the form and submitted to the technical supervisor for review.
Customer Satisfaction	
Customer satisfaction is our primary goal. To attain this, we assess the outcome of our Quality Assurance Plan by monitoring customer verbal and written responses.	
Services Provided	See Directory of Services for a complete list of services provided.

Communication Log	Each unit laboratory has a telephone log book to record incoming calls and laboratory originated calls for giving out reports and other information. In addition, calls can be recorded in StarLims. Laboratory designed logs contain the following: • Institution/Customer Code • Time • Date • Specimen number or subject • Contact person • Phone number • Disposition • Initials of lab employee
Customer Feedback	A customer satisfaction survey is included with the Directory of Services issued every other year. The survey is conducted online. Management reviews the completed forms and appropriate action is taken when necessary.
Records and Data Management	Records need to be managed in an efficient manner to serve the purpose for which they were created. Our records and data management system is a plan for the organization, use, retention, disposal, and selective preservation of records.
Records Retention	A records retention schedule has been established for all computerized and written records in the division. Records are reviewed annually. Refer to the North Dakota Department of Health's Personnel Policy Manual for more detail.
Data Management Responsibilities	The data input operator or office assistant is responsible for accurate data entry of patient demographics. Patient demographic logs are reviewed by the office staff daily to ensure accurate data entry. Test results are entered manually or through instrument interfacing with the laboratory information management system (LIMS). The microbiologist (or designee) is responsible for accurate results and verifies accuracy through two results validations steps in the LIMS workflow.
Resource Management	
Workload	The workload units for each task have been established from historical data and are reviewed annually by the division director.
Positon Standards	Each employee's position standards combine the job description responsibilities, workload units per task, and performance standards as they relate to each assigned task. The position standards serve to: • Accurately measure performance based on job knowledge, initiative, quality of work, quantity of work, competency, and attitude; • Specify what constitutes meeting standards, not meeting standards, and exceeding standards; • Provide a positive approach for personnel who are meeting requirements but would like to exceed them.
Proficiency Testing	The division's policy of maintaining a high quality of performance is reflected in the scores received in the proficiency testing program. Remedial training is instituted when an unsatisfactory response has been traced to a technical error or procedural failure. The general supervisor and/or the technical supervisor will assist in all patient testing and PT challenges involving the procedure in question until the employee has satisfactorily completed an internal proficiency test
Performance Review	The performance of each individual is evaluated and documented annually by the general supervisors and reviewed by the technical supervisors and lab director

	during the first year of employment and when changes in procedures occur. Performance reviews are conducted every 6 months for 1 year. The technical and general supervisor document acceptable performance before the laboratory analyst can report patient results.
Personnel Policies	Personnel policies and procedures are reviewed for effectiveness when necessary and at least annually by the management. The division personnel are notified of any revisions at the monthly staff meeting. Minutes of the staff meeting are distributed via e-mail to all personnel within 48 hours of the meeting.
Quality Assessment Review	A QA coordinator monitors the division's records and policies for compliance of each laboratory area to the overall QA plan. A QA committee assists the coordinator in these monitoring activities. This committee that meets on an as needed basis consists of the QA coordinator and three to four staff members appointed by the director for a two year term. A QA Report is compiled by the QA coordinator and presented to the lab director for review. Outcomes from the QA review are shared with the appropriate departments and staff. General information for the entire division is discussed at the next division meeting.
Problem Identification	Quality assurance includes incident reports of problems brought to the attention of the technical supervisors, QA coordinator, or division director through the internal complaint process. The ability to define a problem, propose changes, implement action, and monitor follow-up is the basis of the QA program. When reporting a laboratory problem an "Internal QA Remedial Action Form" is submitted. Management reviews the problem and determines if an investigation is required. All investigations of complaints are documented and corrective actions instituted. The QA coordinator monitors the corrective actions using the problem status log and makes recommendations to the division director and CLIA laboratory director. The technical supervisors, division director and CLIA laboratory director review the progress of the corrective actions as updated in the QA report.
QA Audit Reports	A QA Audit Report is a focused monitor that evaluates the total outcome of the QA plan. Several QA Audit Reports are included in the regularly review to monitor the overall QA program. Deficiencies are discussed with the lab director, a corrective action form completed, and presented in the biannually QA report.
Quality Indicator	Quality indicators are used to map the review processes for the QA Plan. Refer to the quality indicators table for more information.

References

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8. *Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.* U.S. Department of Commerce, National Technical Information Service, Springfield, VA 22161.

9. https://www.cms.gov/regulations-and-guidance/legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

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Quality Indicators

ASPECT	INDICATOR	THRESHOLD	SCANNING MONITORS	LOCATION OF RECORDS	FREQUENCY	RESPONSIBILITY	ACTIONS
Analytical Procedures	Quality Control	100% within Acceptable Limits	QC Logs	Unit Laboratories	Daily	Microbiologist; General Supervisor	Corrective Action in QC Logs
	IQCP	100% within Acceptable Limits	Reviewed and Approved	QA Coordinator Office	Annually	QA Coordinator	Reviewed by Lab Director
	Proficiency Testing	100% within Acceptable Limits	QC Logs	Unit Laboratories	Quarterly	QA Coordinator	Report to Technical Supervisor
	Technical Procedure Manual	100% NCCLS Format	Reviewed and Approved	Unit Laboratories	Annually	Technical Supervisor; QA Coordinator	Compliance
	Test Validation Files	100% of Tests Developed	Reviewed and Approved	QA Coordinator Office	As Received	Technical Supervisor	Compliance
Customer Satisfaction	Telephone Communications	100% Recorded in Communications Log	Communications Log; LIMS	Administrative Office	Daily	Technical Supervisor	Internal Corrective Action Report
	Written Communications	100% Duplicated for Records	Communications File	Administrative Office	As Received	Technical Supervisor	Internal Corrective Action Report
	Customer Feedback	100% Satisfaction	Customer Feedback Forms	Administrative Office	Biennially	Technical Supervisor	Internal Corrective Action Report
Patient Test Management	Analytic Time	100% within Acceptable Limits	Bench Sheets	Unit Laboratories	Monthly	General Supervisor	Internal Corrective Action Report
			QA Audit Reports		Biannually	QA Coordinator	Report to Technical Supervisor
	Accountability	100% of Specimens Accounted For	Bench Sheets	Unit Laboratories	Monthly	General Supervisor	Internal Corrective Action Report
			QA Audit Reports		Biannually	QA Coordinator	Report to Technical Supervisor
	Timeliness of Result Reporting	Reported within 24 Hours of Completed Testing	LIMS; QA Audit Reports	Data Processing	Monthly	General Supervisor QA Coordinator	Internal Corrective Action Report
	Accuracy of Results Validation	100% Accuracy	QA Audit Reports	Unit Laboratories	Daily	Microbiologist; General Supervisor	Reviewed by Technical Supervisor
	Specimen Acceptability	Specific for Each Procedure	Directory/ ipassport	Unit Laboratories	Daily	General Supervisor	Communications Log
Records/Data Management	Records Retainment	Specific for Each Record	Policy Manual Guidelines	Adm Offices and Unit Labs	Annually	Administrative Secretary; QA Coordinator	Compliance Report to Technical Supervisor
Resource Management	Workload	Meets Standards	Monthly Reports	Administrative Files	Monthly	General (Area) Supervisor	Reviewed by Lab Director
	Position Standards	Meets Standards	Productivity Analysis	Administrative Office Files	Annually	General (Area) Supervisor; Director	Reviewed by Lab Director
	Performance Review	Satisfactory Performance	Planning Session Form	Personnel File	Annually *Semi-Annually	General Supervisor	Reviewed by Lab Director
	Proficiency Testing	Acceptable Scores	PT Reports	QA Coordinator Office; PT Files	Tri-annually	QA Coordinator	Documented Remedial Training

*Performance of individuals responsible for high complexity testing must be evaluated and documented at least semiannually during the first year and annually thereafter unless test methodology or instrumentation changes, in which case, performance must be reevaluated to include the new changes prior to reporting patient test results.