Quality Management for In-Clinic Laboratories

The total quality management system and quality plan

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All human clinical laboratory testing in the United States is regulated by the Clinical Laboratory Improvement Amendments of the US FDA, and other countries have similar regulations. Failure of such laboratories to correct issues of noncompliance with legislation results in lack of accreditation and termination of laboratory services. In contrast, veterinary laboratories are not uniformly regulated by government entities. Laboratory accreditation is offered by the American Association of Veterinary Laboratory Diagnosticians and is optional. This accreditation is “restricted to publicly funded, full-service laboratories, full service being defined as offering necropsy, histopathology, bacteriology, and virology or equivalent services on site.” The International Organization for Standardization offers certification for veterinary laboratories, but such certification is also voluntary in that it represents a commitment statement from the laboratory, without enforcement, with respect to adherence to the QA principles and procedures that are outlined in their standards for medical laboratories and general requirements for the competence of testing and calibration laboratories. Both the American Animal Hospital Association and the UK Royal College of Veterinary Surgeons have a laboratory quality section as a component of their overall veterinary hospital accreditation programs.

Just as measures for QA in the surgical suite (eg, autoclaving of instruments and sterile draping) are widely accepted standards of best practice, QA and continuous quality improvement are imperative in veterinary clinical diagnostic medicine. Lack of understanding of the magnitudes and causes of the statistical uncertainties that are inherent in all biological measurements can lead to misdiagnosis and poor patient outcomes. Preventive and corrective measures pertaining to statistical and nonstatistical QC in the laboratory are risk-management safeguards against the production of inaccurate data, which may carry ethical, financial, professional, and legal ramifications.

This is the first installment in a series of 5 articles intended to help veterinary practitioners and staff provide quality management for in-clinic laboratory testing. Please watch for additional articles in the series in future issues of the JAVMA.

The TQMS

According to the brain-to-brain loop concept in human clinical diagnostic medicine, the generation of any laboratory test result consists of 10 steps, beginning with test ordering and ending with patient outcome (Table 1). The ends of the loop, which consist of the preanalytic and postanalytic phases of laboratory testing, have historically been less thoroughly evaluated and monitored than the analytic (instrument measurement) phase but are equally important.

Table 1—Stages and phases of laboratory testing according to the brain-to-brain loop concept in human clinical laboratory medicine.

<table>
<thead>
<tr>
<th>Testing phase</th>
<th>Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preanalytic</td>
<td>Test ordering</td>
</tr>
<tr>
<td></td>
<td>Sample collection</td>
</tr>
<tr>
<td></td>
<td>Sample identification</td>
</tr>
<tr>
<td></td>
<td>Sample transportation</td>
</tr>
<tr>
<td></td>
<td>Sample preparation</td>
</tr>
<tr>
<td>Analytic</td>
<td>Sample analysis</td>
</tr>
<tr>
<td></td>
<td>Results reporting</td>
</tr>
<tr>
<td></td>
<td>Results interpretation</td>
</tr>
<tr>
<td>Postanalytic</td>
<td>Clinical decision-making</td>
</tr>
<tr>
<td></td>
<td>Patient outcome</td>
</tr>
</tbody>
</table>

ABBREVIATIONS

KQI  Key quality indicator
QA  Quality assurance
QC  Quality control
SOP  Standard operating procedure
TQMS  Total quality management system

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Planning for quality

The in-clinic laboratory should be organized as a separate cost center within the veterinary clinic, with its own budget, inventory control, and document control. A TQMS should begin with identifying personnel to serve as quality managers—ideally a veterinarian and technician who have an interest in laboratory testing and who are dedicated to motivating the staff to participate in a culture of in-clinic laboratory quality. Veterinary medical expertise is needed in the development of a TQMS to ensure that the intended uses of laboratory results (ie, diagnosis and treatment decisions) are integrated into the related processes. Veterinary reference laboratories have highly trained staff who run daily QC testing on technologically advanced instruments, but still regularly identify problems requiring correction. It follows that in-clinic laboratories would also have testing-related errors and, therefore, the need for quality improvement.

Once instituted, the quality plan should be reviewed periodically (every other year if no substantial infrastructure changes are made), updated as necessary, and easily accessible to all clinic personnel. The plan should be used for new personnel training and continuing education, and management may consider including among the clinic’s client-facing informational and public relations materials a brief introduction or summary of the plan, notice of its existence, or a general statement of the clinic’s intent for organized laboratory quality planning (Appendix 1; Supplementary Appendix S1, available at: avmajournals.avma.org/doi/suppl/10.2460/javma.258.1.55). Major categories within the plan include the laboratory environment, personnel, equipment, and working practices.

Information regarding the laboratory environment should include the following:

- Name and location of the clinic.
- Statement on the values, vision, and mission of the laboratory.
- Statement on the clinic’s commitment to a TQMS with continuous quality improvement.
- Description of clientele and patients.
- General description of the types of laboratory services provided.
- Description of dedicated laboratory facilities, such as where the laboratory is located within the clinic; whether there are different personnel shifts within a day; whether lockers, bathroom, and breakroom facilities are available for personnel; and whether access to reference materials and instruction manuals is provided.

Information regarding personnel should include the following:

- Defined personnel laboratory roles and their respective training and ongoing competency requirements.
- Health and safety practices, with a stated commitment to compliance with all federal and local requirements and training for prevention of zoonotic disease transmission.

Information about laboratory equipment should include the following:

- Statement on commitment to appropriate selection and evaluation of instruments and analytical methods.
- Statement on commitment to selection and design of routine QC procedures.
- Statement on commitment to regular instrument and equipment maintenance.
- Outline of required materials and their storage.

Important. Research in human medicine has pinpointed errors during preanalytic phases as most common, and anyone who has interpreted a confusing laboratory report has encountered potential postanalytic error. Similar to this systems concept, it is useful to think of the veterinary diagnostic laboratory as operating within a framework of a formalized, planned TQMS, which operates as a systematic cycle or loop of components for continuous improvement (Figure 1).

Design and implementation of such a system require a top-down commitment that engages all staff. Veterinary reference laboratories have highly trained staff who run daily QC testing on technologically advanced instruments, yet still regularly identify problems requiring correction. It follows that in-clinic laboratories would also have testing-related errors and, therefore, the need for quality improvement.

Figure 1—Diagram of the components comprising the TQMS loop in clinical laboratory medicine. Reprinted with permission from Westgard QC. Lesson QP 2: assuring quality through total quality management. Available at: www.westgard.com/lesson50.htm.
Quality goals and standards

The core purpose of a TQMS is to support attainment of specified quality goals, which represent the laboratory accuracy requirements or standards that must be achieved to satisfy the needs of clinicians and that ensure patient safety (Figure 1). For the preanalytic and postanalytic phases, predefined goals are used to maximize sample stability and quality prior to analysis and to ensure accuracy in result reporting and interpretive support, respectively. For the analytic phase, the requirement is to provide test results that are correct (ie, represent the true result for the patient within stated limits of measurement error), can reliably provide information that differentiates health from disease, and can therefore inform appropriate clinical decision-making. A detailed discussion of statistical goal setting for analytic quality is beyond the scope of this article, and interested readers are advised to consult other resources.10–13 Examples of goals for preanalytic, analytic, and postanalytic phases of in-clinic laboratory testing may include (but are not limited to) the following:

• All sample tubes, slides, and reports are labeled with a unique patient identifier (use of 2 identifiers is ideal because patients may have the same or similar names).
• All samples have adequate substrate for testing (adequate volume for fluid phase samples).
• All samples are visually inspected prior to analysis for any gross evidence of potential interfering properties (eg, hemolysis, lipemia, or icterus).
• All samples are analyzed within a specified time limit as appropriate for sample stability.
• If a QC failure is noted for an automated instrument, analysis of patient samples on that instrument ceases until the failure is remedied (note: the concept of statistical QC, including QC failure, will be discussed in the fifth article in this series).
• Routine maintenance of instruments, microscopes, refractometers, and automated pipettes is performed in accordance with manufacturer instructions.
• Any critical (potentially life-threatening) results are verified and immediately reported.
• All results are relayed to clients within specified turnaround times.
• All detected laboratory errors or indications for repeated testing due to error flags are documented and analyzed for root causes to guide appropriate corrective and preventive actions.

Quality laboratory processes and procedures

An SOP is a set of instructions that describes how to perform a laboratory procedure and ensures consistency and optimal quality for that procedure. Standard operating procedures describe the “how” of laboratory functions within the larger framework of the TQMS, which addresses both how and how well the work is being done. Each SOP should be of uniform format; an SOP template (ie, an SOP for how to write SOPs) should be developed and used to standardize the information presented. It should be detailed and clearly understandable, such that a staff member unaccustomed to the procedure would be able to perform it after reading the SOP. An SOP should be written for each and every laboratory function, including functions such as specimen accessioning and biological waste disposal. Importantly, SOPs do not solely pertain to the operation of more sophisticated instruments, such as those used for CBC and biochemical analyses. Veterinary personnel may want to consider the use of SOPs for all workflows, from the in-clinic laboratory to other clinic functions. Like the quality plan, SOPs are an integral and necessary component for providing adequate staff training, continuing education, and efficient, uniform laboratory operations. Because procedural changes are typically made more frequently than alterations of the more high-level topics in the quality plan, laboratory operating procedures and protocols should be kept in a distinct SOP manual. Creation of SOPs will be covered in more detail in the third article in this series.

QC and QA

The QC and QA components of a TQMS consist of monitoring daily laboratory work processes. Quality assurance is a generic term that refers to the monitoring and assessment of testing processes to allow identification and correction of problems to maintain performance. Although the terms can be used interchangeably, traditionally, QC refers to statistical and nonstatistical analyses performed during the analytic phase of testing, whereas QA refers to the broader monitoring of all dimensions and characteristics of quality, including during the pre- and postanalytic phases, instrument maintenance (including centrifuges, microscopes, and other nonautomated equipment), accurate record keeping (for instrument maintenance, QC assay results, reagent and calibrator logs, and patient reports), any external audits or accreditation requirements, and monitoring of turnaround time. Participation in an external quality assessment program or comparative testing with the clinic’s reference laboratory for various types of instruments is recommended as part of ongoing quality assessment. This topic is outside the scope of this series of articles and is discussed in other resources.14–17

Quality control can be statistical or nonstatistical in nature. Statistical QC refers to the use of statistical methods to monitor and maintain the quality...
of products and services, whereas nonstatistical QC includes other checks and methods to ensure that accurate and reliable results are reported. Nonstatistical methods are used heavily in the pre- and postanalytic phases and also are an essential component for analytic tests with known limitations (eg, blood smear examination for leukocyte differential cell counts and evaluation of RBC morphology and any platelet clumping). Concordance of test results with clinical signs, results of other laboratory tests, and review of previous patient data are other examples of nonstatistical QC that may be used to evaluate test results. A useful concept for QA and QC is that of establishing KQIs (synonymous with key performance indicators or KPIs), which are selected to track current performance in key areas of laboratory function (Table 2). Measurement of KQIs will help to monitor successes and shortfalls in achieving the quality goals of the in-clinic laboratory and can highlight areas for improvement and future goal setting.

The term QA is occasionally used synonymously with quality assessment. Strictly speaking, quality assessment refers to a collection of monitoring systems as just described, whereas QA more correctly refers to the broad outcome of a TQMS and is not a component.

Quality improvement

Quality improvement is the final component of the TQMS feedback loop, whereby the information gained from QC and QA directly informs more planning (eg, modification of staff duties or training, SOPs, or quality plans) or specific actions in a cycle of continuous quality improvement. Problems, nonconformities, or failure to achieve desired laboratory quality goals can be identified in several ways, including the following:

- Review of QC statistical data (instrument performance).
- Implementation of improvement opportunity forms, which are simple forms placed at each laboratory workstation that enable staff to record issues and suggestions for better laboratory function.
- Monitoring of KQIs.
- Checking of consumable materials for any obvious defects, proper storage, expiry dates, proper disposal, and adequate stock supply.
- Examination of groups of patient reports to identify possible trends or data shifts.
- Review of staff and client feedback.
- Management review of the TQMS and its components, including the laboratory budget and inventory control.
- Monitoring and follow-up of any implemented preventive and corrective actions.
- Monitoring and follow-up of any changes in the use of human or material resources.

Inherent to this list are recommended planned timelines for evaluation of the relative success of any implemented changes, evaluation of the TQMS itself by the quality manager or team, and periodic rereview of SOPs by staff (eg, after changes or every other year if no change has been made).

Clinical Bottom Line

Similar to other aspects of veterinary medicine, such as physical examination, surgery, diagnostic im-

### Table 2—Examples of KQIs that may be used for monitoring and assessing QC and QA of in-clinic laboratories, organized by phase of laboratory testing.

<table>
<thead>
<tr>
<th>Preanalytic</th>
<th>Analytic</th>
<th>Postanalytic</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%) of laboratory samples insufficiently labeled with unique patient identifiers</td>
<td>No. (%) of tests indicating hypercalcemia*</td>
<td>No. (%) of laboratory results reported to clients beyond specified turnaround times†</td>
</tr>
<tr>
<td>No. (%) of blood or urine samples with an insufficient volume for testing</td>
<td>No. (%) of positive benchtop serologic test results for an infectious disease, compared with the known prevalence in the geographic area or any confirmatory test results</td>
<td>No. (%) of critical (life-threatening) values reported to the clinician on an immediate basis</td>
</tr>
<tr>
<td>No. (%) of EDTA- or heparin-treated blood samples for CBC with grossly visible clots</td>
<td>No. (%) of control-run failures (outside of specified acceptable control limits)</td>
<td>Mean time between sample collection and results reporting (particularly for critical values)</td>
</tr>
<tr>
<td>No. (%) of samples with visible hemolysis, lipemia, or icterus</td>
<td>No. (%) of tests with instrument alerts or error flags</td>
<td>No. (%) of corrected or amended reports</td>
</tr>
<tr>
<td>No. (%) of samples undergoing delayed analysis (beyond the recommendation for the specified test per stability of the sample)</td>
<td>No. (%) of blood smear preparations for CBC with measured thrombocytopenia, abnormal differential counts, and atypical scattergram plots (if available)</td>
<td>No. (%) of laboratory reports appropriately incorporated into patient medical records</td>
</tr>
</tbody>
</table>

*Analytic tests chosen for KQIs should have the lowest margin of error because the results are used for clinical treatment decisions, additional diagnostic investigations, and patient monitoring. If a QC problem has been identified for a particular measurand or measurands (ie, substances to be measured), such as instrument flags or data drifts in, for example, aggregate albumin data, these tests may be chosen to ensure that corrective and preventive actions have been effective. †Although typically classified as pertaining to the postanalytic phase, turnaround time is affected by all phases of the total testing process.
aging, and medication protocols for specific diseases, the laboratory testing process should proceed in accordance with defined practices that can be tailored to the needs of the veterinary clinic and its patient base. From the veterinarian’s decision to order a test, through to the patient’s outcome following any diagnostic or treatment decisions made on the basis of that test, veterinary personnel have the responsibility to take necessary steps to help ensure that laboratory test results are reliable and acted upon appropriately to provide for the best possible patient care. A checklist is suggested as a launching point for implementation of the recommendations in this article (Appendix 2; Supplementary Appendix S2, available at: avmajournals.avma.org/doi/suppl/10.2460/javma.258.1.55). Board-certified veterinary clinical pathologists (eg, members of the American College of Veterinary Pathologists or European College of Veterinary Clinical Pathology), veterinary clinical laboratory directors, and laboratory professionals in industry, commercial diagnostic reference laboratories, and government-run diagnostic reference laboratories are available for further consultation on these matters; various other resources are also available.18–20 Additionally, voluntary laboratory accreditation options exist for veterinary clinics, typically as a component of a hospital accreditation program.21,22

Acknowledgments

No third-party funding or support was received in connection with this study or the writing or publication of the manuscript. The authors declare that there were no conflicts of interest.

References


Appendices continued on next page.
Appendix 1
Hypothetical example of a quality plan for an in-clinic laboratory.

Quality Plan for Laboratory Services

1. Name and Location
The laboratory operates within a mixed-animal practice known as [practice name]. The laboratory is located in [city], [state].

2. Laboratory Vision and Mission Statement
The [practice name] aims to provide, in a timely manner, high-quality veterinary laboratory testing that is perceived to represent good value for money. The highest priority is to do this in a caring way, with consideration for staff, clients, and patients, to support the highest quality of veterinary care. We value integrity, honesty, communication, and ongoing education about laboratory testing and its applications. All staff and management are expected to participate in a continuous quality improvement effort within the laboratory and help promote a culture of ongoing improvement. All feedback and ideas from staff as well as identification of nonconformities and complaints from clients will be considered and addressed through the continuing improvement opportunity process.

3. Environment
The [practice name] is located in [neighborhood] of [city] and provides service to hospital clients that include pet owners, local animal shelters, and local farms. The laboratory provides hematochemical, biochemical, fecal, and urinalysis as well as benchtop serologic testing for selected infectious diseases and selected cytotologic and microbiological testing for dermatologic diseases. Laboratory samples may be sent for analysis at a contracted reference laboratory. Mammalian samples can be analyzed in the laboratory; avian and reptilian samples will be referred for testing to a contracted reference laboratory.

4. Facilities
The [practice name] is situated in a _____ square foot section of the northwest area of the treatment room of the hospital. The hospital has ample parking for staff and any clients delivering specimens to the laboratory. The laboratory is operational during all working hours of the hospital, with employees suitable for the caseload present for each shift. There is room for expansion within the existing grounds as well as a _____ square foot adjacent yard for patient exercise and canine urine or fecal sample collection. Lockers are present for employees, with padlocked locker space available for each employee’s coats and other belongings. The laboratory area contains a bookshelf with various reference books and journals as well as several computers with laboratory information software and internet access. Online access is available to various publications, including the option to purchase articles for a fee.

5. Personnel
Hiring of trained staff with experience in veterinary diagnostic testing will be given the highest priority. If trained staff are not identified among the applicants, all persons will be given training appropriate for the job for which they have been hired. Veterinary technicians with appropriate qualifications (registered or licensed veterinary technicians with certification by the Academy of Veterinary Clinical Pathology Technicians) will be sought as needed. Other qualified support staff will be hired or trained to support the laboratory services processes.

6. Equipment
The laboratory contains modern instruments and equipment appropriate to meet the requirements for analysis and turnaround time to meet the needs of clients. All instruments will undergo method or instrument validation studies appropriate for the instrumentation prior to initiation of routine testing (see fourth article in this series). All tests have defined quality requirements and appropriate methods of statistical and nonstatistical QC. Routine maintenance and calibration of equipment will be performed in accordance with manufacturers’ recommendations. Reagents and other necessary materials will be stored according to specification and properly disposed of on their expiration date. A state-of-the-art hospital and laboratory information system (H-LIS) will be used to facilitate the laboratory processes and reporting, with password-based security and regular backup to ensure the security and integrity of the data. Automatic transfer of hematochemical and biochemistry results from the instruments to the H-LIS ensures accuracy of data transmission.

7. Health and Safety
All local, state, and federal regulations applying to health and safety will be observed. All employees will receive training regarding potential zoonoses associated with laboratory testing during their initial orientation and periodic continuing education thereafter. A health and safety plan will be in place and described in a health and safety manual.

8. Working Practices
The processes of the laboratory will be conducted in accordance with written procedures and policies that are subject to document control (the latter encompasses review, modification, distribution, and accessibility of current documents and removal of older versions from circulation). Clients will be informed, prior to testing, about testing options and associated costs. Continuing education will be provided for staff and clients. All laboratory-related waste will be recycled when possible, or disposed of safely, to include dedicated sharps and biohazardous waste disposal systems. Submitted samples are the property of the laboratory once received, and written policies are available regarding specimen retention and use for ongoing internal QA and QC. All sample submissions are subject to client confidentiality, and results are not released to or discussed with other veterinarians or owners unless the client specifically gives permission or requests this.
## Appendix 2

**Checklist for development of a TQMS for in-clinic laboratories.**

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Compliant?</th>
<th>Additional comments by auditor</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 1 quality manager or team leader is identified who has a special interest in laboratory testing and who can educate and motivate the entire staff to participate in a culture of laboratory quality and continuous improvement.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>A quality plan is drafted that includes descriptions of the laboratory environment, personnel, equipment, and working practices.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>Quality goals are drafted for preanalytic, analytic, and postanalytic phases of testing.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>SOPs are developed for all laboratory functions.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>QC data are assessed for automated instruments per manufacturer instructions or more frequently. If QC failure occurs, the protocol is to cease patient sample analysis and troubleshoot until laboratory instruments are operating within QC specifications.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>Laboratory spaces and equipment are clean and well maintained, with logs for recording cleaning and maintenance activities.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>Reagents and other supplies are stored and disposed of properly. An inventory list is maintained with preferred and backup suppliers.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>Key quality indicators for the preanalytic, analytic, and postanalytic testing phases have been identified and are tracked, with number and percentage of errors and nonconformities evaluated at routine intervals against predefined goals. Smaller laboratories may choose to keep an incident log.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>Preventive and corrective actions are taken as appropriate to decrease errors, with scheduled periodic review to assess the effectiveness of these actions.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
<tr>
<td>SOPs and the TQMS are reviewed for potential updates or improvements at predetermined intervals. Such reviews will include staff and client feedback and evaluation of any changes implemented since the previous review.</td>
<td>☐ Yes ☐ No</td>
<td></td>
</tr>
</tbody>
</table>