Veterinary Clinical Pathology
An International Journal of Laboratory Medicine

Guidelines for Resident Training in Veterinary Clinical Pathology. IV: Laboratory Quality Management – Teaching Domains, Competencies, and Suggested Learning Outcomes

Journal:	*Veterinary Clinical Pathology*
Manuscript ID	Draft
Manuscript Type:	ASVCP Special Report
Date Submitted by the Author:	n/a
Complete List of Authors:	Flatland, Bente; University of Tennessee, Biomedical and Diagnostic Sciences Dehghanpir, Shannon; Louisiana State University School of Veterinary Medicine, Pathobiological Sciences Freeman, Kathleen ; Veterinary Information Network Grimes, Carolyn; Zoetis Reference Laboratories Hancock, Tamara; University of Missouri System, Department of Veterinary Pathobiology Hollinger, Charlotte; Charles River Laboratories Inc Mattawan Hooijberg, Emma; University of Pretoria, Department of Companion Animal Clinical Studies Korchia, Jeremie; Colorado State University System, Department of Microbiology, Immunology and Pathology Lawson, Cheryl; Iowa State University, Veterinary Pathology Matlow, Jennifer; IDEX Corp Sample, Saundra; Zoetis Reference Laboratories Viall, Austin; University of California Davis, Department of Veterinary Pathology, Microbiology, and Immunology
Key Words:	competency-based, entrustable professional activity, EPA, QA, QC, quality assessment, quality assurance, quality control

Guidelines for Resident Training in Veterinary Clinical Pathology. IV: Laboratory Quality Management – Teaching Domains, Competencies, and Suggested Learning Outcomes

Bente Flatland[1], Shannon D. Dehghanpir[2], Samantha J. M. Evans[3], Kathleen P. Freeman[4], Carolyn Grimes[5], Tamara Hancock[6], Charlotte Hollinger[7], Emma Hooijberg[8], Jeremie Korchia[9], Cheryl Lawson[10], Jennifer R. Matlow[11], Saundra Sample[12], Austin Viall[13]

[1]Department of Biomedical and Diagnostic Sciences, College of Veterinary Medicine, University of Tennessee, Knoxville, TN, USA.

[2] Department of Veterinary Clinical Sciences, School of Veterinary Medicine, Louisiana State University, Baton Rouge, LA, USA.

[3] Department of Veterinary Biosciences, College of Veterinary Medicine, The Ohio State University, Columbus, OH, USA.

[4] Veterinary Information Network, United Kingdom

[5] Zoetis Reference Laboratories, Zoetis, Inc., Parsipanny, NJ, USA.

[6] Department of Veterinary Pathobiology, College of Veterinary Medicine, University of Missouri, Columbia, MO, USA.

[7] Charles River Laboratories, Mattawan, MI, USA.

[8] Department of Companion Animal Clinical Studies, Faculty of Veterinary Science, University of Pretoria, Pretoria, South Africa.

[9] Department of Microbiology, Immunology and Pathology, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, CO, USA.

[10] Department of Veterinary Pathology, College of Veterinary Medicine, Iowa State University, Ames, IA, USA.

[11] Idexx, Inc., Bloomfield, MI, USA.

[12] Zoetis Reference Laboratories, Zoetis, Inc., Parsipanny, NJ, USA.

[13] Department of Veterinary Pathology, Microbiology, and Immunology, School of Veterinary Medicine, University of California Davis, Davis, CA.

Short Running Header Title

Laboratory Quality Management Training Guidelines

Correspondence

Bente Flatland

University of Tennessee

College of Veterinary Medicine

bflatlan@utk.edu

Disclosures

Bente Flatland and Kathy Freeman serve on the advisory committee for Vetbiologicalvariation.org, a not-for-profit veterinary biological variation database. Dr. Freeman is also a Director of CustomClinPath, a partnership involved with developing applications and calculators intended to make biological variation-based tools available to clinicians and clinical pathologists. Dr. Freeman and Dr. Korchia are co-editing a planned textbook about laboratory quality management, to which Drs. Flatland, Hooijberg, and Matlow will contribute. No other authors have potential conflicts of interest.

Abstract

Background: The 2019 ASVCP Education Committee Forum for Discussion, presented at the annual ASVCP/ACVP meeting, identified a need to develop recommendations for teaching laboratory quality management principles in veterinary clinical pathology residency training programs.

Objectives: To present a competency-based framework for teaching laboratory quality management principles in veterinary clinical pathology residency training programs, including entrustable professional activities (EPA), domains of competence, individual competencies, and learning outcomes.

Methods: A joint subcommittee of the ASVCP Quality Assurance and Laboratory Standards (QALS) and Education Committees executed this project. A draft guideline version was reviewed by ASVCP membership and shared with selected ACVP committees in early 2022, and a final version was voted upon by the full QALS and Education Committees in late 2022.

Results: Eleven domains of competence with relevant individual competencies were identified. In addition, suggested learning outcomes and resource lists were developed. Domains and individual competencies were mapped to six EPA.

Conclusions: This guideline presents a framework for teaching principles of laboratory quality management in veterinary clinical pathology residency training programs and was designed to be comprehensive yet practical. Guidance on pedagogical terms and possible routes of implementation are included. Recommendations herein aim to improve and support resident training but may require gradual implementation, as programs phase in necessary expertise and resources. Future directions include development of learning milestones and assessments and consideration of how recommendations intersect with American College of Veterinary Pathologists training program accreditation and certifying examination.

Keywords

Competency-based, entrustable professional activity, EPA, QA, QC, quality assessment, quality assurance, quality control

Introduction

Guidelines for resident training in veterinary clinical pathology were developed by the ASVCP Education Committee in 2003 (clinical chemistry)[1], 2006 (hematology)[2], and 2009 (cytopathology and surgical pathology).[3] These documents presented learning outcomes organized into knowledge, abilities, and skills. Learning outcomes related to quality assessment/assurance (QA) and quality control (QC) were woven into all three documents, appearing most frequently in the clinical chemistry document[1], but laboratory quality management was not approached as a stand-alone entity.

At the 2019 American College of Veterinary Pathologists and American Society for Veterinary Clinical Pathology (ACVP/ASVCP) annual meeting in San Antonio, TX, the ASVCP Education Committee's Forum for Discussion addressed teaching practical QA/QC to clinical pathology residents. The need to revisit existing residency training guidelines and address laboratory quality management as an independent topic was identified. Subsequent to that meeting, the Education Committee, in cooperation with the Quality Assurance and Laboratory Standards (QALS) committee, formed a joint subcommittee to propose residency training guidelines focused on laboratory quality-related topics for the ASVCP.

The 2011 Roadmap for Veterinary Medical Education in the 21st Century[4] introduced formalized competency-based education in veterinary medicine in the USA. A competency-based framework for teaching veterinary clinical pathology in US veterinary student curricula has been published.[5] The Royal College of Pathologists also utilizes a competency-based framework to present its curriculum for veterinary clinical pathology specialty training in the United Kingdom.[6] In order to align with current

veterinary pedagogical documents, a competency-based framework was also chosen for ASVCP laboratory quality management residency training recommendations herein.

Veterinary laboratory quality management is a multifaceted topic that has historically not received as much emphasis in North American clinical pathology residency programs as patient data interpretation or diagnostic cytology – yet knowledge of QA/QC helps makes clinical pathology unique among veterinary specialties. Furthermore, laboratory testing is steadily increasing in complexity, with more distributed sites, advanced and varied instrumentation, a growing point-of-care sector, and more diverse operating personnel, among other changes. Laboratory quality consulting is also an emerging service area for veterinary clinical pathologists who advise practicing veterinarians, researchers, and industry. Within this expanding landscape of laboratory sophistication, the overall need for quality management expertise and experience is expected to grow.

Importantly, the scope of these guidelines is focused on laboratory quality. For broader clinical pathology resident competency recommendations, readers should refer to existing ASVCP training guideline documents.[1-3] The intended audiences for this document are clinical pathology residents, clinical pathology faculty, clinical pathology training program coordinators, and laboratory managers. This document also has potential to inform work done by the American Board of Veterinary Specialists, the ACVP Certifying Examination Board, and any person(s) or committee(s) vetting or accrediting clinical pathology residency training programs in the future.

Methods

To form the subcommittee, interested volunteers were solicited from the ASVCP Education Committee and the ASVCP Quality Assurance and Laboratory Standards (QALS) Committee. The subcommittee additionally recruited Dr. Tamara Hancock to serve as an advisor regarding use of pedagogical concepts and terms, given her qualifications in both pedagogy and clinical pathology.

Potential guideline formats were discussed, and a competency-based framework utilizing domains, competencies, outcomes, and entrustable professional activities (EPA) was decided upon.

The American Association of Veterinary Medical College (AAVMC) Competency-Based Veterinary Education (CBVE) framework defines "domain" as a broad, distinguishable area of competence – multiple domains, in aggregate, provide a descriptive framework for a profession.[7] In the context of this guideline, listed domains denote broad topics reflecting the work of laboratory quality management. "Competency" is defined by CBVE as an observable ability related to a specific, measurable, and assessable activity that integrates knowledge, skills, values, and attitudes. "Learning outcome" is defined as an observable and assessable achievement that a learner can perform at the end of a learning session or program.[7,8] In the context of this guideline, listed competencies and learning outcomes represent granular quality management skills and abilities that comprise each domain. "EPA" are defined by CBVE as essential tasks of a discipline that a learner can be trusted to perform with limited supervision in a given context, once sufficient competence has been demonstrated.[7] In the context of this guideline, listed EPA are complex tasks that clinical pathologists execute when performing their work. Identified EPA are not limited to laboratory quality management, but laboratory quality management is a component of all identified EPA (thereby allowing mapping of domains and competencies to these EPA).

Members first developed a list of domain topics within the larger domain of laboratory quality management. The committee was next subdivided into teams of 2 to 4 individuals per domain, and each team developed competencies and learning outcomes for each domain. All subcommittee members reviewed and discussed competencies and learning outcomes for all domains. Once domains, competencies, and learning outcomes were developed, EPA were identified, and competencies were mapped to these EPA. Resources (books, articles, and web-based resources) were included to support each domain.

Given the complexity of laboratory quality management as a topic area, the subcommittee focused on developing competencies and learning outcomes that, in the authors' opinions, could reasonably be addressed within a three-year training program. Optional learning outcomes for "advanced" learners (third-year residents, residents with a strong QA/QC interest, or learners post-residency) were included for selected competencies.

Draft domains, competencies, learning outcomes, and EPA were approved by the ASVCP Education and QALS committees, and the draft document was approved for ASVCP member review by the ASVCP Executive Board. An electronic version of the draft document was posted on-line at the ASVCP website for eight weeks in early 2022 for member review. Concurrently, feedback was sought via email from the ACVP Training Program Committee, ACVP Training Program Accreditation Task Force, and ACVP Exam Committee.

All feedback was considered by the authors, and revisions were made accordingly. The most substantive change post-review was re-categorization of learning outcomes as "Core Level 1", "Core Level 2", and "Advanced" based on author consensus, in acknowledgement of risk of that recommendations as a whole could be perceived as overwhelming, and with the hope that this change could better help residency program instructors incorporate recommendations into existing programs. Each competency does not necessarily contain learning outcomes from all three categories, and "Core Level" numerical designations (1 or 2) are not intended to correspond with particular program years, but to give a sense of expected learning sequence.

Core Level 1 learning outcomes are intended as suggested introductory core material suitable for residents earlier in their program (starting in the first year), reflecting a bare minimum of QA/QC knowledge that positions residents to master outcomes designated "Core Level 2" and, optionally, "Advanced". Core Level 2 learning outcomes are intended as suggested core material suitable for residents who have mastered relevant Core Level 1 outcomes, later in their residency program

(presumably predominantly in the second- and third-year). These guidelines recommend that clinical pathology residents attain proficiency in Core Level 1 and Core Level 2 learning outcomes by the completion of a residency program. Advanced learning outcomes are intended as suitable for residents with a strong QA/QC interest or clinical pathologists post-residency. Inclusion of Advanced competencies and learning outcomes into three-year residency training programs is encouraged, but these are considered beyond expectations of core training and may require time and resources that individual programs or supporting organizations (e.g., ASVCP and ACVP) independently or in collaboration will need to retool and/or develop. These guidelines represent cumulative current best recommendations but are expected to evolve over time and undergo future revisions addressing shifts in emphasis and approach.

Abbreviated List of Domains and Competencies

Domain 1: General Quality Management Principles

Competency 1.1: Develops a laboratory quality plan

Competency 1.2: Promotes laboratory occupational health and safety

Competency 1.3: Promotes continuous laboratory improvement

Competency 1.4: Describes laboratory test cost accounting

Domain 2: Basic Laboratory Statistics

Competency 2.1: Describes basic principles of classical statistics

Competency 2.2: Applies statistics in the medical laboratory

Competency 2.3: Applies significant figures

Domain 3: Instrument Selection and Analytical Assessment

Competency 3.1: Selects instrument or assay

Competency 3.2: Assesses analytical performance of instrument or assay

Domain 4: Quality Goals, Assay Development, and Analytical Validation

Competency 4.1: Describes and explains quality goals for pre-analytical, analytical, and post-analytical processes

Competency 4.2: Uses quality goals and performs assay validation

Domain 5: Statistical Quality Control (SQC), External Quality Assessment (EQA), and Proficiency Testing (PT)

Competency 5.1: Describes SQC principles

Competency 5.2: Interprets control data

Competency 5.3: Performs SQC validation

Competency 5.4: Describes structure and function of EQA/PT programs and interprets EQA/PT data

Optional Competency 5.5: Performs Repeat Patient Testing Quality Control (RPT-QC)

Optional Competency 5.6: Describes instrument or method harmonization

Domain 6: Non-statistical QC

Competency 6.1: Describes impact of sample and reagent handling on test results

Competency 6.2: Confirms quantitative data, whether expected or aberrant, with qualitative assessment and/or repeat results.

Competency 6.3: Maintains quality assurance in laboratory reports

Domain 7: Tests Yielding Ordinal and Nominal Data (Qualitative Tests)

Competency 7.1: Evaluates analytical and diagnostic performance of qualitative tests

Competency 7.2: Describes approaches to quality management of qualitative testing

Domain 8: Patient Data Interpretation Tools

Competency 8.1: Explains general principles of biological variation (BV)

Competency 8.2: Explains, generates, and evaluates population-based reference intervals (pRI)

Competency 8.3: Applies BV-based patient data interpretation tools appropriately

Competency 8.4: Explains clinical decision thresholds

Domain 9: Clinical Validation of Tests, Diagnostic Performance Evaluation

Competency 9.1: Describes considerations for and design of diagnostic accuracy studies

Domain 10: Microscopic Evaluation

Competency 10.1: Demonstrates use and proper care of light microscopic equipment and stains

Competency 10.2: Recognizes and controls pre-analytical error during microscopic examination

Competency 10.3: Recognizes and controls analytical error during microscopic examination

Competency 10.4: Recognizes and controls post-analytical error during microscopic examination

Competency 10.5: Describes procedures for archiving samples, documents, and reports

Domain 11: Point-of-Care Testing (POCT)

Competency 11.1: Identifies and uses POCT resources

Competency 11.2: Describes statistical and non-statistical QA/QC for POCT

Competency 11.3: Documents POCT QA/QC activities

Optional Competency 11.4: Designs a quality management program for owners/users of POCT

Detailed List of Domains and Competencies with Learning Outcomes

Domain 1: General Quality Management Principles

Competency 1.1: Develops a laboratory quality plan

Core Level 1

- Lists and explains components of laboratory quality culture and management: laboratory environment, health and safety, personnel, instrumentation, documents and documentation, and laboratory information management systems (LIMS).
- Describes and explains a global approach to quality planning, implementation, and improvement (e.g. Total Quality Management).
- Describes the purpose, importance, and components of a laboratory quality plan.
- Lists and explains the importance of maintaining manufacturer-supplied laboratory instrument operational documents, including:
    - Instrument purchase agreements
    - Instrument service agreements and other service documents
    - Instrument user manuals and quick-start guides
- Lists and explains components of other commonly used laboratory operational and QA/QC documents, including (listed alphabetically):
    - External quality assessment (EQA), proficiency testing (PT), or other comparison testing event documents
    - Error or adverse event logs or forms (“improvement opportunity” documentation), if not inherent to the laboratory information management system (LIMS)

- Instrument logs for QC and maintenance
- Patient result logs (e.g., if not archived in instrument software)
- Personnel training records
- Reagent logs (date of opening, expiration dates, lot numbers)
- Sample condition logs (e.g., whether hemolyzed or lipemic)
- Standard operating procedures (SOP)
- Temperature logs (e.g., for refrigerators and freezers), or other equipment maintenance logs (e.g., maintenance of centrifuges, pipettes, refractometers, etc.)
-

- Describes the importance of documenting occurrence and resolution of laboratory errors.
- Recognizes features of an effective document control system in the clinical laboratory.

Core Level 2

- Assists laboratory personnel in review and/or maintenance of laboratory quality plan documents
- Generates laboratory SOPs and assists laboratory personnel in review and/or maintenance of laboratory SOPs.
- Assists laboratory personnel in review and/or maintenance of laboratory personnel training records.
- Assists laboratory personnel in review and/or keeping of instrument maintenance logs or other laboratory operational logs.

Advanced

- Describes and explains considerations for choosing, maintaining and continuously improving the LIMS and information technology within a veterinary laboratory, including patient information confidentiality and data security.
- Recognizes elements common to various laboratory quality standards, as well as differences in structure and emphasis of various approaches (e.g., lean vs. six sigma vs. total quality management).

Competency 1.2: Promotes laboratory occupational health and safety

Core Level 1

- Describes and explains applicable biological, chemical, and physical safety risks and regulations associated with the various laboratory procedures and circumstances.
- Describes and explains example approaches to laboratory work environment risk reduction regarding zoonotic and reverse zoonotic diseases.

Core Level 2

- Generates a risk assessment for at least one laboratory process, procedure, or method within the veterinary laboratory and makes recommendations to reduce biological, chemical, and physical safety risks to acceptable levels.

Competency 1.3: Promotes continuous laboratory improvement

Core Level 1

- Lists and explains the categories of laboratory error (pre-analytical, analytical, and post-analytical).
- Aware of, able to describe, and able to give examples of laboratory quality assurance processes and procedures in all phases of testing (pre-analytical, analytical, and post-analytical).

Core Level 2

- Under supervision of laboratory personnel, participates in measurement of control material and interpretation of control data, including troubleshooting of a QC failure ("out-of-control" QC data) and monitoring of analytical error resolution or mitigation. Also see Domain 5.
- Under supervision of laboratory personnel, participates in identification, troubleshooting, and documentation of laboratory error (non-conforming event), including implementation, documentation, and monitoring of error resolution or mitigation (improvement opportunity) in pre- and/or post-analytical phases of testing.

Advanced

- Assists an experienced manager/auditor in designing and conducting a quality audit in a particular area of the laboratory
- Describes and explains the use of key quality indicators (a.k.a., key performance indicators) based on expert recommendations, identified problems, or known tests of high importance in the laboratory.
- Assists an experienced manager/auditor in the development of a summary quality audit report; implements recommendations based on audit findings.
- Assists a laboratory manager in creating a plan or reviewing an existing plan for both initial quality management training of new personnel and continuing education for all laboratory personnel.

Competency 1.4: Describes laboratory test cost accounting

Core Level 1

- Lists elements contributing to laboratory test costs. Explains direct (e.g., consumable supplies, technologist, and pathologist time) and indirect (e.g., utilities, administrative) cost elements.

Core Level 2

- Given cost analysis data, explains the contributions of each component to total test cost and calculates cost-per-test for a laboratory test.

Domain 2: Basic Laboratory Statistics

Competency 2.1: Describes basic principles of classical statistics

Core Level 1

- Recognizes data types (quantitative, ordinal, nominal) and data distributions (Gaussian, lognormal, skewed).
- For quantitative data, recognizes the difference between normal and non-normal distribution; knows the mathematical properties of normal distribution.
- Discusses the principle of a normality test and can interpret the resulting p-value.
- Explains the concept of the null hypothesis (H0) and alternative hypothesis (H1) of a statistical test.
- Correctly interprets the result of a statistical test by correctly accepting or rejecting H0.
- Defines type I and type II statistical error, and explains the relationship between these errors, statistical power, and significance level.
- Explains the relationship between effect size, sample size, variation, and statistical power.
- Explains the principle of confidence intervals.
- Describes the relationship between statistical tests, a resulting test statistic, and a p-value.
- Discusses differences between parametric and non-parametric statistical tests and between paired and non-paired statistical tests.

Competency 2.2: Applies statistics in the medical laboratory

The application of statistics in the medical laboratory overlaps statistical quality control. Also see Domain 5.

Core Level 1

- Describes a dataset using statistical graphical tools (e.g., histogram, scatterplot) and metrics of central tendency and dispersion (e.g., mean, median, mode, variance, standard deviation, standard error, coefficient of variation).
- Explains the role, benefits, and limitations of the t-test and f-test in method comparison data analysis.
- Defines the term *bias* in the context of diagnostic laboratory method comparison and explains how presence of bias affects use of diagnostic laboratory data.

Core Level 2

- Given analytical performance data, calculates the CV, bias, and total error (TE) associated with a laboratory measurand.
- Given method comparison data, identifies and characterizes bias.
    - Given method comparison data, carries out and interprets Bland-Altman data analysis, including mean difference, limits of agreement, and graphical representation of bias.
    - Given method comparison data, carries out and interprets regression analysis.
    - Calculates predicted results for a given method using results of regression analysis.
- Interprets whether bias for a specific laboratory test is clinically important, taking critical values and clinical decision limits into account.
- Given method comparison data, calculates and interprets correlation coefficients.
- Given analytical performance data and a quality goal, calculates the sigma metric for a particular test or process within the laboratory.

Competency 2.3: Applies significant figures

Core Level 1

- Defines *significant figure*. Given a numeric value, identifies the number of significant figures represented.
- Explains implications of significant figures for laboratory data interpretation (patient and control).

Core Level 2

- Given relevant instrument performance data, determines optimal number of significant figures for patient data reporting (determines best "reporting interval").

Domain 3: Instrument Selection and Analytical Assessment

Competency 3.1: Selects an instrument or assay

Core Level 1

- Lists and explains conditions under which instrument or assay analytical assessment studies (verification; more abbreviated than validation) can be performed.
- Lists and explains analytical (e.g., sample type, volume, and throughput; precision) and non-analytical (e.g., instrument size and cost, terms of service contract, reagent costs) considerations for selecting a diagnostic laboratory instrument or method.
- Lists and explains analytical (verification experiments, establishment of reference intervals) and non-analytical (e.g., establishing test costs) steps for implementing a new instrument or analytical method at a given testing site.

Competency 3.2: Assesses analytical performance of an instrument or assay

Core Level 1

- Outlines the basic design and explains the purpose and goals of the following analytical assessment experiments:
    - Short-term replication (repeatability or within-in run imprecision)
    - Long-term replication (reproducibility or between-run imprecision)
    - Linearity/ reportable range
    - Interference
    - Recovery
    - Detection limits
    - Method comparison
    - Carryover
    - Prozone effect
    - Assessment of patient sample stability and storage conditions

Core Level 2

- Given manufacturer-supplied analytical performance claims and performance data from an instrument or assay, interprets whether manufacturer's claims are achieved, particularly at measurand concentrations at or near clinical decision limits.
- Lists steps to be taken if performance claims are not achieved.
- Explains implications of identifying bias between a new instrument or assay and a comparative method.

Domain 4: Quality Goals, Assay Development, and Analytical Validation

Competency 4.1: Describes and explains quality goals for pre-analytical, analytical, and post-analytical processes

Core Level 1

- Defines the term "quality goal" (performance goal) and explains how quality goals are used in laboratory management, including instrument analytical performance assessment and statistical quality control.
- Describes and cites examples of quality goals and metrics for pre- and post-analytical testing phases.
- Lists sources of potential quality goals for the analytical phase of testing (e.g. allowable total error, biologic variation) and describes advantages and limitations of each.

Core Level 2

- Describes different types of quality goals, e.g., according to the hierarchy of analytical performance goals as defined by the European Federation of Clinical Chemistry and Laboratory Medicine consensus statement (cited in resources).
- Explains how ASVCP allowable total error goals were generated and identifies their position in the analytical goal hierarchy.
- Able to evaluate data from biological variation studies and calculate quality goals for imprecision, bias and total analytical error.
- Lists further steps to be taken if measured analytical error determined during method validation exceeds analytical performance goals.

- Lists further steps to be taken if observed pre-analytical or post-analytical performance falls short of quality goals or metrics.

Competency 4.2: Uses quality goals and performs assay validation

Core Level 1

- Lists and explains conditions under which comprehensive instrument or assay validation studies should be performed.

Core Level 2

- Given an assay or method and its proposed application in a given laboratory, chooses appropriate analytical assessment experiments from the list in Competency 3.2 that would provide a comprehensive analytical validation.
- Given a pre-determined quality goal, correctly assesses testing or other process performance in light of that goal. If performance does not meet goal, suggests appropriate corrective actions and method and timeline for reevaluation.
- Given instrument or assay validation data, performs calculations, data analysis, and interpretation for each of the analytical assessment experiments listed in Competency 3.2.

Domain 5: Statistical Quality Control (SQC), External Quality Assessment (EQA), and Proficiency Testing (PT)

Competency 5.1: Describes SQC principles

Core Level 1

- Defines the terms control material, control data, control rule, control limits, and control chart.
- Explains how SQC fits into daily laboratory operations.
- Explains the relationship between normal (Gaussian) distribution and control data from a stable test system.
- Explains the purpose of a control rule; explains what is meant by in-control data and out-of-control data.
- Given a control chart and candidate control rules, identifies both random and systematic error.
- Describes the rationale for documenting errors and corrective actions.

Core Level 2

- Given control data and one or more control rules, constructs a control chart.
- Lists and explains the benefits and limitations of various test materials for SQC, including commercial control material, stable patient sample pools, and repeat testing of patient samples

Competency 5.2: Interprets control data

Core Level 2

- Given unacceptable control data for a given instrument or method, formulates appropriate troubleshooting questions to help evaluate the testing process and test system.
- Given results of test system troubleshooting for a given instrument or method, determines appropriate corrective action(s) for that instrument or method.

Advanced

- Describes circumstances under which a multi-rule procedure may be used, preferred, or needed instead of simple QC rules.
- Interprets control data using multi-rule procedures.

Competency 5.3: Performs SQC validation

Core Level 1

- Defines and explains the terms QC validation, analytical quality goal, probability of error detection, probability of false rejection, and N.

Core Level 2

- Lists inputs needed for performing QC validation.
    - Justifies selected analytical quality goal(s). Explains how to obtain estimates of assay bias and imprecision.
- Given the needed inputs and a QC validation tool (e.g., an operating specifications [OpSpecs] chart), selects suitable control rule(s) and N.
- Explains options for monitoring assay analytical performance if no SQC solution is possible.
- Recognizes when non-statistical quality control is preferred or complements SQC.
- Calculates sigma metric and explains the role of sigma metric in SQC.

Advanced

- If asked to evaluate QC validation for a laboratory serving multiple species, selects and justifies QC validation inputs.
- Calculates, explains, and applies quality goal index.

Competency 5.4: Describes structure and function of EQA/PT programs and interprets EQA/PT data

Core Level 1

- Explains purpose, structure, and frequency of EQA/PT programs.
- Integrates EQA/PT program costs into cost-accounting of laboratory tests. Also see Competency 1.5.
- Explains various criteria used to judge acceptability of EQA/PT testing results.
- Explains, calculates, and applies standard deviation index.
- Calculates bias from EQA/PT data.
- Describes the rationale for documenting errors and corrective actions.

Core Level 2

- Given EQA/PT data, judges acceptability of laboratory performance.
- Given unacceptable laboratory performance for a given instrument or method, formulates appropriate troubleshooting questions to help evaluate the testing process and test system.
- Given results of test system troubleshooting for a given instrument or method, determines appropriate corrective action(s) for that instrument or method.

Advanced

- If a commercial EQA/PT program is not available for monitoring the instrument or assay in question (e.g., point-of-care [POCT], or in-clinic, instrument), designs a local or in-house proficiency testing program using central laboratory equipment to monitor analytical performance.

Optional Competency 5.5: Performs Repeat Patient Testing Quality Control (RPT-QC)

Advanced

- Describes appropriate patient sample storage conditions for RPT-QC for hematology and chemistry and/or other types of testing (endocrinology, etc.).
- Given a dataset of differences, able to compute RPT-QC control limits.
- Given a dataset of differences and RPT-QC limits, able to judge test system analytical performance.

Optional Competency 5.6: Describes instrument or method harmonization

Advanced

- Defines harmonization and explains challenges to achieving laboratory data harmonization across instruments and laboratories.
- Able to discuss different methods of determining bias (e.g., assayed quality control materials, well-characterized field method, true reference method) and advantages and limitations of each for purposes of QC validation and patient results interpretation.
- Outlines a protocol for harmonizing instruments of the same type within a single laboratory or laboratory network.

Domain 6: Non-statistical QC

SOPs, logs, improvement opportunity forms, and other laboratory process documents are important components of non-statistical QC. Also see Competency 1.1.

Competency 6.1: Describes impact of sample and reagent handling on test results

Core Level 1

- Describes the flow of specimens through the laboratory.
- Understands the rationale for, and can explain steps involved in, appropriate sample collection (e.g., anticoagulant selection) and handling (i.e., processing, storage, or shipping).
- Explains rationale for using two unique patient identifiers for labeling/sample identification and lists example identifiers.
- Describes appropriate storage and handling of patient samples and deleterious effects of delays sample handling.
- Describes appropriate storage and handling of reagents, quality control materials, and calibration materials.

Advanced

- Given example laboratory layouts and workflows, proposes improvements to streamline laboratory layout and workflow to minimize time between sample receipt and analysis.

Competency 6.2: Confirms quantitative data, whether expected or aberrant, with qualitative assessment and/or repeat results

Core Level 1

- Assesses blood smear or direct fluid smear to correlate with automated results.
- Evaluate leukocyte morphology for toxicity, dysplastic, and leukemic changes.

- Interprets hematologic scattergrams or graphs and correlates with automated results and microscopic findings.

Core Level 2

- Explains when alternative methods are needed for reporting hematology measurands (e.g., PCV vs. HCT, MCHC vs. CHCM) and under what circumstances, and for which measurands, automated hematology data should not be reported (e.g., erythrocyte agglutination, platelet clumping, camelid samples).
- Identifies plasma discolorations and potential interferences and can describe how interferents may affect individual measurands; explains and interprets “serum index” (or “plasma index”) values of H, L, and I generated by automated chemistry instruments.
- Defines “critical values” (a.k.a. “panic values”) and gives examples.
- Defines “repeat criteria” and “review criteria” and gives examples of each.
- Evaluates trends in individual patient data and can interpret patient data in light of total case information.

Advanced

- Under supervision of laboratory staff or an attending pathologist, monitors the number of corrected and amended patient reports to survey for potential sources of error.

Competency 6.3: Maintains quality assurance in laboratory reports

Core Level 1

- Explains the need for consultations for complicated microscopy cases (hematology, cytology, urine, etc).
- Reviews case follow up (e.g., histopathologic diagnosis, clinical follow-up).
- Describes the importance of double checking the accuracy of results entered from other areas of testing (whether through manual entry, scanning/electronic reporting or other means) or from other laboratories to which specimens are sent ("send outs").

Core Level 2

- Appropriately amends reports as necessary and alerts clients of amended change(s).

Domain 7: Tests Yielding Ordinal and Nominal Data (Qualitative Tests)

Competency 7.1: Evaluates analytical and diagnostic performance of qualitative tests

Core Level 2

- Determines an analytical quality goal for a test yielding ordinal or nominal data
- Describes how verification/validation of tests yielding ordinal and nominal data differs from verification/validation of tests yielding quantitative data.
- Describes how assessing agreement of tests yielding ordinal and nominal data differs from assessing agreement of tests yielding quantitative data.

Advanced

- Under supervision from an experienced laboratory manager or clinical pathologist, evaluates analytical and diagnostic performance of a test yielding ordinal or nominal data.

- Under supervision from an experienced laboratory manager or clinical pathologist, creates quality plan for managing tests yielding ordinal and nominal data, for example:
    - SNAP™ or other immunologic assay kits
    - Urinalysis testing (biochemical and cytologic)
    - Fecal testing
    - Blood typing and cross-matching tests
    - Serum and urine protein electrophoresis
    - Nucleic acid amplification tests

Optional Competency 7.2: Describes approaches to quality management of qualitative testing

Advanced

- Describes and discusses approaches for determining limit of the blank, limit of detection, and clinical cut-off value (medical decision limit).
- Describes and discusses analytical and diagnostic test performance concepts in light of qualitative testing, e.g.,
    - Precision as the uncertainty interval around a cut-off value (medical decision limit).
    - Accuracy as agreement with clinical classification
    - Percent positive agreement (PPA) as a reflection of diagnostic sensitivity
    - Percent negative agreement (PNA) as a reflection of diagnostic specificity
    - Predictive values for positive and negative results as a reflection of clinical usefulness of a qualitative test and the importance of prevalence in this consideration
- Describes and discusses strategies to confirm positive results for qualitative tests

- Describes and discusses considerations for selecting control patients or specimens when validating a qualitative test (e.g., the need for control data close to the cut-off value).

Domain 8: Patient Data Interpretation Tools

Competency 8.1: Explains general biological variation (BV)

Core Level 1

- Defines and explains biological variation (BV), intraindividual variation (CVI), interindividual variation (CVG), and analytical variation (CVA).

Core Level 2

- Able to interpret and apply index of individuality (II).
- Describes basic design of a BV study.
- Lists considerations for reporting results of a BV study.

Competency 8.2: Explains, generates, and evaluates population-based reference intervals (pRI)

Core Level 1

- Explains the statistical principles underlying pRI and describes benefits and limitations of pRI.
- Lists considerations for reporting results of a pRI study.
- Lists considerations for defining a reference sample population.
- Defines reference interval partitioning and explains indications for partitioning pRI.

Core Level 2

- For a given measurand, explains impact of II on utility of pRI.
- Given a pRI, transfers and validates the pRI for use in another laboratory.
    - Determines whether pRI transference is appropriate.
    - Given pRI verification data, determines if a pRI is validated/verified.
    - Explains next steps if pRI validation/verification fails.

Advanced

- Given data from a reference sample population and an appropriate software program, generates de novo pRI.
    - Defines outlier and states considerations for handling of outliers.
    - Identifies reference sample data distribution.
    - Given data and a distribution, identifies appropriate statistical methods to use for reference limit estimation.
    - Generates and interprets confidence intervals for upper and lower reference limits.
    - Justifies reference limit selection, based on statistical and clinical information.
- Given reference interval data, determines whether partitioning is required and valid. If required and valid, generates partitioned pRI.

Competency 8.3: Applies BV-based patient data interpretation tools appropriately

Core Level 2

Given patient data and biological variation data, defines, calculates, and applies the following quantities and concepts:

- Homeostatic set-point
- Critical number of samples
- Reference change value
- Critical difference
- Individualized reference interval (iRI), a.k.a. subject-based reference values
- Dispersion

Competency 8.4: Explains clinical decision thresholds

Core Level 2

- Explains difference between expert-based clinical decision thresholds and population-based reference intervals.
- Explains limitations of expert-based clinical decision thresholds.

Domain 9: Clinical Validation of Tests, Diagnostic Performance Evaluation

Competency 9.1: Describes considerations for and design of diagnostic accuracy studies

Core Level 1

- Recognizes and discusses factors affecting calculated diagnostic sensitivity, diagnostic specificity, and predictive values:
    - Impact of the selected control population characteristics (as healthy or suspect) on calculated test performance metrics and overall test diagnostic performance.

753 - Impact of the selected interpretation threshold (cut-off value, medical decision
754 threshold) on the sensitivity and the specificity, and on the use of the test as a test of
755 exclusion, confirmation, or both.
756 - Impact of prevalence and pre-test probability on predictive values.
757 • Explains inverse relationship of diagnostic sensitivity and specificity.
758 • Explains diagnostic test characteristics most suitable for screening tests vs. confirmatory tests.
759 Describes the pros and cons of using tests with better sensitivity vs better specificity in various
760 clinical scenarios.
761
762 ***Core Level 2***
763 • Explains how to choose a reference test ("gold standard") for a diagnostic test performance
764 study and describes potential limitations of using a selected gold standard test.
765 • Given paired results of an index test and a reference test, or given test results from two
766 populations, calculates diagnostic test performance metrics: diagnostic sensitivity, diagnostic
767 specificity, predictive values, and likelihood ratio.
768 • Describes Standards for Reporting of Diagnostic Accuracy (STARD) criteria for designing and
769 reporting diagnostic accuracy studies.
770 • Integrates diagnostic performance metrics, clinical decision thresholds, population-based
771 reference intervals, and biological variation data to advise clinicians on appropriate test
772 selection, interpretation of patient results, and sensible timelines for repeat testing.
773
774 ***Advanced***
775 • Given study data and appropriate software tools, prepares and interprets a receiver operating
776 characteristic (ROC) curve using appropriate calculations and statistics.

Domain 10: Microscopic Evaluation

Competency 10.1: Demonstrates use and proper care of light microscopic equipment and stains

Core Level 1

- Performs routine cleaning and maintenance of a light microscope, including ocular adjustment and Kohler illumination.
- Explains the importance of periodic professional servicing of laboratory microscopes.
- Describes and explains correct usage of common stains, including benefits and limitations
- Describes and can identify common artifacts associated with routine stains and other sources of potential stain-related error
- Describes and can identify common artifacts associated with various types of cytological preparation techniques.

Core Level 2

- Lists components of SOPs for proper stain/stainer usage
- Performs routine cleaning and maintenance of automated stainers under supervision or guided by SOP or user manual.
- Troubleshoots problems with stain quality
- Lists components of an SOP for proper cytocentrifuge usage.
- Describes routine cleaning and maintenance of a cytocentrifuge under supervision or guided by SOP or user manual.
- Explains advantages and limitations of digital microscopy, including

- Static digital microscopy (photomicrographs)
- Whole slide imaging (WSI)
- Region of interest imaging (ROI)
- Telecytology (live video imaging)

Advanced

- Lists the SOPs that are needed to operate and maintain digital microscopy systems
- Describes how to validate digital imaging systems
- Explains the common problems associated with static and scanned microscopy images; troubleshoots problems of static images and scanned slide quality

Competency 10.2: Recognizes and controls pre-analytical error during microscopic examination

Core Level 1

- Determines whether microscopy slides are of good quality/adequate for interpretation.
- Describes and explains proper specimen handling and shipping requirements (including adequate labeling, temperature, humidity, separation from formalin, packaging, shipping, etc.) and describes the deleterious effects of improper handling or delayed processing.

Core Level 2

- Able to troubleshoot poor quality cytology specimens and advise clinical personnel and laboratory staff about improving specimen quality and/or slide preparation for tissue aspirate and bone marrow samples.
  - Lists and explains artifacts or discrepancies due to various collection techniques.

825 - Lists and explains sample handling and preparation factors that may affect microscopic
826 interpretation.
827 • Lists and justifies the elements of a cytology submission form and microscope slide or sample
828 container label.
829
830 **Competency 10.3: Recognizes and controls analytical error during microscopic examination**
831
832 ***Core Level 1***
833 • Explains the steps of a standardized approach to microscopic slide examination when evaluating
834 blood smears and cytology samples.
835
836 ***Core Level 2***
837 • Lists and explains components of a quality assurance program for cytologic services, including, but
838 not limited to, the use of patient safety checklists, case rounds, cytology/histology correlates, formal
839 or informal second reviews, participation in an external quality assurance program, and
840 maintenance of certification/continuing education.
841 • Lists and explains quality metrics for cytology services and, where relevant, interprets metrics
842 against pre-determined quality goals, e.g., turn-around time (TAT) or cytology-histology correlation
843 rate, and correlation with clinical feedback or other types of testing (e.g., PARR, flow cytometry,
844 biochemistry, hematology, etc.).
845
846 **Competency 10.4: Recognizes and controls post-analytical error during microscopic examination**
847
848 ***Core Level 2***

- Provides standardized written reports for interpretation of blood smears and cytology samples that clearly communicate both sample description and interpretation; uses correct terminology, grammar, and syntax.
- Describes and can use the laboratory's mechanism(s) for verifying release of initial, amended, and addendum reports. Corrects and documents any detected reporting errors.
- Describes and can use the laboratory's mechanism(s) for notifying clinical personnel about urgent, amended, or addendum reports.
- Documents communications with laboratory clients.

Advanced

- Uses voice dictation systems for reporting:
    - Lists and explains potential limitations of voice dictation software.
    - Describes how to validate dictation software program function.
    - Able to preview and correct any dictation errors prior to report release.
- Uses image capture (photomicrographs):
    - Obtains high quality images using a microscope camera that accurately reflect the specimen.
    - Obtains and advises how to obtain photomicrographs using "smart" devices (e.g., smartphone or tablet camera).
    - Troubleshoots problems with microscopy image generation and transmission.

Competency 10.5: Describes procedures for archiving samples, documents, and reports

Core Level 1

- Describes and explains the laboratory's policy and biosafety regulations regarding storage and disposal of perishable blood, tissue, and fluid specimens.
- Describes the laboratory's policies and procedures for archiving non-perishable blood smear and cytology specimens.

Core Level 2

- Describes and explains the laboratory's policies and procedures for archiving microscopy images, patient reports, and SOPs.
    - Describes and uses the laboratory's document control systems and procedures
    - Able to use the laboratory's specimen and report filing systems for documents (paper and/or electronic) and digital images.
    - Describes and explains the laboratory's policies and procedures regarding back-up of and access to digital data, including patient data privacy, as applicable.
- Describes and explains the laboratory's policies and procedures for samples "lost to lab" (e.g. digital images taken of slides sent out for PCR, tracking system for samples leaving the laboratory for subcontracted testing).

Domain 11: Point-of-Care Testing (POCT)

Competency 11.1: Identifies and uses POCT resources

Core Level 2

- Given a POCT problem or issue, identifies appropriate published literature and/or manufacturer or supplier resources that can help troubleshoot POCT.

- Given a particular POCT problem or issue, under the supervision of laboratory personnel, applies information about the specific POCT methods, limitations/interferences, and analytical performance to troubleshoot a problem or issue.
- Refers POCT users to appropriate publications, checklists, templates, or other resources regarding POCT selection, operation, and QA/QC.

Competency 11.2: Describes statistical and non-statistical QA/QC for POCT

Core Level 2

- Discusses QA/QC challenges unique to POCT, including training of POCT operators and limited ability of POCT operators to manipulate instrument functionality.
- Discusses and gives examples of basic non-statistical and statistical QC procedures appropriate for use by clinical personnel operating POCT (veterinarians, technicians, students, etc.).
- Compares and contrasts QA/QC procedures needed for POCT intended for in-clinic use with QA/QC procedures of analogous central laboratory instruments, for example
    - Hematology analyzers
    - Biochemistry analyzers (including glucometers, lactate meters, and blood gas instruments)
    - Urinalysis analyzers
    - Coagulation analyzers
    - SNAP™ test kits and other colorimetric or immunologic rapid tests

Competency 11.3: Documents POCT QA/QC activities

Core Level 2

- Compares and contrasts how operational considerations for POCT maintenance and QA/QC differ from maintenance and QA/QC of centralized laboratory instruments.
- Using the list of forms and documents provided in Competency 1.1, discusses basic documentation and records required for management of POCT and in-clinic laboratories.

Optional Competency 11.4: Designs a quality management program for owners/users of POCT

Advanced

- In consultation with an experienced laboratory manager or clinical pathologist, identifies key components & subcomponents of a quality management program for owners/users of POCT, including (listed alphabetically):
    - Document management procedures
    - Immediate clinician notification criteria (“panic” values)
    - Inventory of consumable supplies
    - Key Performance Indicators (e.g., turn-around time [TAT], financial), if applicable
    - Logs (see list in Competency 1.1)
    - Plausibility review of patient results
    - Process and operator competency audits
    - Repeat and review criteria
    - Reagent and consumable supply storage conditions (including monitoring temperatures of fridges, etc.)
    - SOPs, including procedures for maintenance requirements and periodic analytical performance re-evaluation

- Sources of pre-analytical, analytical, and post-analytical errors
- Training needed for POCT operators
- Waste disposal considerations
- Written quality policy/plan

Discussion

Quality management of the veterinary laboratory is a broad knowledge area incorporating many different types of testing in various laboratory settings. Mastery of laboratory quality management topics, including knowledge of BV and how BV impacts test performance and patient data interpretation, makes clinical pathologists unique among veterinary specialists and enables them to contribute positively and materially to patient care and research activities in a variety of settings. Mastery of laboratory quality management principles also has potential to enhance career prospects for newly minted clinical pathologists entering a variety of career paths. Both points are justification for developing training recommendations specifically aimed at the discipline of laboratory quality management.

Embracing competency-based education requires a large investment on the part of participating programs. If adopted, this investment would optimally be supported by leading organizations in the field (i.e., ASVCP and ACVP) through development of training and assessment resources. The competency-based approach has potential to precipitate fundamental changes not just in how residents are taught and assessed, but also in the role they play within veterinary teaching hospitals (e.g., as the backbone of diagnostic cytology services). Adoption of competency-based training means that competencies, learning outcomes, milestones, and assessments will assume increasing importance in the structure and execution of residency training programs. Competency-based training may require increased formative and summative assessments, with documentation of competence at varying timepoints, as residents

968 progress through programs and milestones are met. Further discussion of implications and challenges of
969 competency-based training, with identification of needed resources, is encouraged at national (ASVCP,
970 ACVP) and individual program levels.

971 Not all clinical pathology training programs currently have faculty with expertise in QA/QC or
972 well-developed resources for teaching laboratory quality management. Provided resource lists and the
973 appendix are intended to help both instructors and trainees gain knowledge and master suggested
974 learning outcomes. It is expected that implementation of recommendations presented here will need to
975 be phased in over time and will require development of additional teaching resources (e.g., training data
976 sets, etc.) for both instructors and trainees by individual programs, as well as by ASVCP and ACVP. These
977 formal laboratory quality management domains and competencies also have potential to inform and
978 guide future ACVP certifying examinations and residency training program accreditations. With these
979 ramifications in mind, the committees focused on suggesting practical learning outcomes that advance
980 the specialty of clinical pathology but are also aimed at being realistic for gradual incorporation into
981 existing training programs.

982 A prior published veterinary competency-based guideline for teaching clinical pathology in
983 veterinary student curricula presented competencies and illustrative subcompetencies.[5] Per CBVE,
984 subcompetencies are more granular than competencies, used to more clearly define a competency, and
985 appropriate for use in developing course or rotation objectives and assessments.[8] Learning outcomes
986 are defined as individual achievements that learners are able “to do” at the end of a lesson or program.[8]
987 In practice, there may be overlap between illustrative subcompetencies and learning outcomes. These
988 guidelines present learning outcomes for each individual domain and competency, and authors credit
989 the Royal College of Pathologist’s Curriculum for Specialty Training in Veterinary Clinical Pathology,
990 which provides a similar level of detail, for inspiration.[6] If EPA’s, domains, and individual competencies
991 are relatively prescriptive and represent a trainee’s “learning destination”, then learning outcomes,

992 milestones, and assessments are generally considered to be less prescriptive and represent a trainee's
993 "learning journey" and the documentation thereof. Various journeys can lead to the same destination!
994 Given that laboratory quality management has historically not received as much emphasis in North
995 American clinical pathology residency programs as patient data interpretation or diagnostic cytology,
996 and given that not all clinical pathologists practicing today feel comfortable teaching this topic, the
997 committees hope that provision of suggested learning outcomes, together with suggested resources and
998 the appendix, can help programs implement the domains and individual competencies recommended by
999 this guideline.

1000 These guidelines deliberately did not address milestones or assessments. Development of
1001 appropriate milestones and assessments to monitor and document mastery of the presented domains
1002 and competencies is very important, but ultimately beyond the scope of this project and at discretion of
1003 individual training programs. An area for future discussion is whether, and how much, standardization of
1004 milestones for laboratory quality management training is needed, e.g., particularly in light of
1005 forthcoming residency program accreditation. Individual programs will likely benefit from examples of,
1006 and guidance regarding, development of milestones and assessments, but should retain flexibility to
1007 develop milestones and assessments that make sense for their program structure and resources.
1008 Consideration is also needed regarding how any future milestones and assessments intersect with the
1009 certification process – and, for selected topic areas deemed less easily "testable" in a standard certifying
1010 examination format, whether these have potential to be prerequisites for, or alternatives to, certifying
1011 examination.

1012 EPAs 1 and 6 in Table 1 are borrowed from the human pathology literature[9], but the remaining
1013 EPAs were developed based on author consensus. As acknowledged in the Introduction, EPA are not
1014 limited to laboratory quality management, but laboratory quality management is a component of all
1015 identified EPA (thereby allowing mapping of domains and competencies to these EPA).

Although EPA 2 (Provides consultations regarding selection and interpretation of diagnostic laboratory tests) implies recognition that appropriate laboratory test selection by clinicians is a critical first step in laboratory quality assurance[10-12], any broader role clinical pathologists have in advising clinicians about appropriate test selection, and explicit suggestions for how to reduce the proportion of inappropriate test orders in a given laboratory setting, are not addressed by this guideline. Given that appropriate test selection by clinical personnel impacts laboratory resources management, test interpretation, and patient management and outcomes, incorporating discussion of this issue within residency training programs is encouraged. Furthermore, development and incorporation of EPAs across guidelines for resident training in veterinary clinical pathology is recommended – some professional activities, such as advising clinical personnel on appropriate test selection or test interpretation, incorporate more than one knowledge domain.

Much discussion occurred during all phases of guideline development concerning domain organization. Although knowledge of basic statistics may be assumed upon entry into a residency training program, basic statistics (Domain 2) was included, since the basic principles of classical statistics are foundational for understanding analytical performance assessment and statistical quality control. Selection and implementation of a new laboratory instrument or method (Domain 3) was presented separately from assay development and method validation (Domain 4), given that instrument selection and implementation has both analytical and non-analytical aspects, and assay development and method validation predominantly focus on analytical performance. This resulted in some information overlap, because the scientific studies used for validation of a newly developed or modified assay (e.g., precision, linearity) can also be used during an instrument purchase evaluation and the verification of manufacturer analytical performance claims. In Domain 3, authors were purposefully careful using the term “verification”, given its potential varied connotations. JO Westgard describes method verification using the questions: “did you get what you paid for? does it live up to the label? does performance

match the claim?"[13] Practicing clinical pathologists may use this term broadly to denote the various less intensive (compared to validation) assessments of analytical performance that accompany new method selection and implementation (e.g., as when purchasing a commercial instrument). In Domain 3, use of this term is consist with these two connotations. In contrast, CLSI uses the term "verification" specifically to denote *statistical confirmation* of whether instrument performance claims are met.[14]

Statistical QC (Domain 5) and non-statistical QC (Domain 6) were presented separately in order to emphasize that these are two very different approaches to QC. Whereas SQC focuses on the analytical phase of testing and is most directly relevant for methods yielding quantitative data, non-statistical QC includes broader quality assessment/assurance processes relevant to all testing phases and that are also potentially applicable to methods yielding nominal and ordinal data. Finally, although doing so resulted in some information overlap across domains, considerations for nominal and ordinal tests ("qualitative testing", Domain 7) and POCT (Domain 11) were presented as independent domains in order to emphasize the unique approaches that these types of testing require, and in order to make this guideline as user-friendly as possible (e.g., allow readers specifically interested in POCT training to easily find relevant competencies).

In conclusion, this guideline presents a list of recommended domains of competence and individual competencies, as well as suggested learning outcomes and resources, for teaching laboratory quality management in veterinary clinical pathology training programs. The importance of laboratory quality management in veterinary medicine can only be expected to grow, given increasing complexity of diagnostic testing, rising expectations of laboratory diagnostic performance, and application of artificial intelligence and machine learning algorithms to medical information. As the specialty of veterinary clinical pathology gains experience with application of these domains and competencies, and as training approaches are refined, this guideline is also expected to evolve and change over time. Future directions include development of learning milestones and assessments that monitor and

document mastery of the domains and competencies presented here, and consideration of how recommended domains and competencies intersect with training program accreditation and certifying examination. Recommendations in this guideline are a first step towards ensuring that all veterinary clinical pathology trainees receive comprehensive instruction in this important and unique aspect of our specialty.

References

1. Christopher MM, Stokol T, Sharkey L. Guidelines for resident training in veterinary clinical pathology. I. Clinical chemistry. Vet Clin Pathol. 2003;32:202-208.
2. Sharkey L, Wellman M, Christopher MM. Guidelines for resident training in veterinary clinical pathology. II. Hematology. Vet Clin Pathol. 2006;35:382-387.
3. Kidney BA, Dial SM, Christopher MM. Guidelines for resident training in veterinary clinical pathology. III. Cytopathology and surgical pathology. Vet Clin Pathol. 2009;38:281-287.
4. North American Veterinary medical Education Consortium. Roadmap for Veterinary Medical Education in the 21st Century: Responsive, Collaborative, Flexible. NAVMEC report and recommendation. Washington, DC: NAVMEC; 2011.
5. Newman AW, Moller CA, Evans SJM, Viall A, Baker K, Schaefer DMW. American Society for Veterinary Clinical Pathology – recommended clinical pathology competencies for graduating veterinarians. J Vet Med Ed. 2021; DOI: 10.3138/jvme-2021-0004.
6. The Royal College of Pathologists. Curriculum for specialty training in veterinary clinical pathology. London, England: RCP; 2018.
7. Competency Based Veterinary Education: CBVE framework. Washington, DC; American Association of Veterinary Medical Colleges: 2018.
8. Competency Based Veterinary Education (CBVE). CBVE Terminology A Common Language for Developing the CBVE Shared Mental Model. Available at https://cbve.org/terminology. Accessed January 24, 2022.
9. McCloskey CB, et al. Entrustable professional activities for pathology: recommendations from the College of American Pathologists Graduate Medical Education Committee. Academic Pathology, 2017; 4:1-9. DOI: 10.1177/23742895177142.

10. Laposata M, Dighe A. “Pre-pre” and “post-post” analytical error: high incidence patient safety hazards involving the clinical laboratory. Clin Chem Lab Med. 2007;45:712-719. DOI: 10.1515/CCLM.2007.173.
11. Plebani M, Laposata M, Lundberg GD. The brain-to-brain loop concept for laboratory testing 40 years after its introduction. Am J Clin Pathol. 2011;136:829-833. DOI: 10.1309/AJCPR28HWHSSDNON.
12. Plebani M. Toward a new paradigm in laboratory medicine: the five rights. Clin Chem Lab Med. 2016;54:1881-1891. DOI: 10.1515/cclm-2016-0848.
13. Westgard JO. *Basic Method Validation and Verification Training in Analytical Quality Management for Healthcare Laboratories*. 4th ed. Madison, WI: Westgard QC; 2020:33.
14. Clinical and Laboratory Standards Institute (CLSI). EP15-A2 User Verification of Performance for Precision and Trueness; Approved Guideline. 2nd ed. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

Table 1

Individual competencies mapped to EPA

Domain		EPA 1[9] Composes a patient report for a laboratory test requiring pathologist interpretation	EPA 2 Provides consultations regarding selection and interpretation of diagnostic laboratory tests	EPA 3 Provides consultations regarding management of in-clinic laboratory testing	EPA 4 Creates, implements, and maintains a laboratory quality plan	EPA 5 Identifies and resolves laboratory errors in each phase of testing	EPA 6[9] Evaluates, selects, and implements a new instrument, method, or assay
1.	General Quality Management Principles		1.3	1.1, 1.2, 1.3,1.4	1.1, 1.2, 1.4	1.3	1.3
2.	Basic laboratory statistics	2.3	2.2	2.2			2.1 to 2.3
3.	Instrument selection and analytical verification			3.1, 3.2			3.1, 3.2
4.	Assay development and analytical validation			4.1, 4.2	4.1, 4.2		4.1, 4.2
5.	Statistical quality control and EQA/PT			5.1 to 5.6	5.1 to 5.6	5.2, 5.3, 5.4	5.1 to 5.6
6.	Non-statistical QA/QC	6.3	6.2	6.1, 6.2	6.1	6.1 to 6.3	6.1
7.	Ordinal and nominal (qualitative) tests		7.1	7.2	7.1, 7.2	7.1	7.1, 7.2
8.	Patient data interpretation	8.1 to 8.4	8.1 to 8.4	8.1 to 8.4		8.2, 8.4	8.2, 8.4
9.	Clinical validation of tests, diagnostic performance evaluation		9.1				9.1
10.	Microscopy	10.4,10.5	10.4		10.1 to 10.5	10.2 to 10.4	10.1, 10.5
11.	Point-of-care testing		11.1	11.1 to 11.4	11.4	11.1-11.4	

1110