| SOP for writing a Quality Plan | | European College of Veterinary Clinical Pathology |
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| Document #: 2.3. | Version: V1 | |
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1. Title

SOP for writing a Quality Plan for the Laboratory Certification Application, see Appendix 1.

2. Section

Diplomates applying for the Laboratory Certification Process.

3. Scope

To provide guidance and an example from the Laboratory Standard Committee (LSC) about how to write a quality plan for a veterinary clinical pathology laboratory.

4. Equipment list

This document, PC.

5. Procedure Instructions

The following points should be considered to include in a Quality Plan:

a. LAB INFORMATION
   i. Name and Location
      Name of the laboratory and relevant school/institution if applicable
      Address of the laboratory.
      Website.
      Contact name (email/ phone number).
   ii. Scope of services / Customers
      Core areas for which the laboratory provides services.
      Main customers of the lab services.
   iii. Mission statement / Ethics
      Summary of the aims and values of the lab.
      Ethics, privacy rules and the use of data.

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b. RESOURCES

i. Facilities / Equipment
A floor plan of the lab facilities and the description of each area.
List of equipment used for analyses.

ii. Personnel
Organization Chart.
Managers and clinical pathologist responsibilities.
Qualifications of the technical staff.
Continuing Education policy.

iii. Health and Safety Policy

c. ACTIVITIES

i. Description Process mappings from sample reception to sending results.

ii. Assurance Quality Programs IQC and EQA.
Name of the programs for EQA.
Which measurands/analytes are controlled (IQC and EQA) / how many levels / frequency

iii. LIMS (Laboratory Information Management System)
Description of the LIMS and methods used to ensure the integrity, accuracy and security of the data.

d. QUALITY MANAGEMENT

i. Quality Policy
Main goals and resources.

ii. Document Management
Description of document control for SOPs, documents and records.
Management of the validation, communication and archiving.

iii. Non-conforming events management
What are the actions implemented in case of non-conforming events.

iv. Review / assessment / improvement
Review information: technical review, cases review, direction review.
Assessment = internal audit, external assessment.
Implementation of actions for improvement.

v. External accreditations / inspections
List of additional accreditations or another assessment.

6. Interpretation
The Quality Plan is evaluated together with the Recertification Application. The evaluation process is carried out according to 2.2 SOP Process of Initial+Recertification for Laboratories. If the evaluation is satisfactory, the Chair of LSC will email the final report and letter to the ECVCP Secretariat for final formatting and archiving.
For laboratories which gain initial full approval as ECVCP training laboratory, a certificate will be prepared by the Chair of the LSC and sent to the ECVCP Secretariat.

7. Quality management information
Relevant Documentation on QM processes of the ECVCP.

8. Terms and conditions
After approval all applicable documents are archived and stored in the Evaluation Log.
Evaluation log corresponds to:
   a. Timeline in LSC Google table.
   b. Folder for each lab in Google ECVCP Documents archive.
   c. The Laboratory Standard Archivist (if not nominated, the chair) should ensure that the Evaluation Log is updated with the information (sent in applications, comments on application from reviewers, final letter of approval/ decline, final formatted letter from the ECVCP Administrator, Certificate), status of the application and is responsible for ethics, privacy rules and the use of data.

9. References
Applicable ECVCP documents.

Appendix 1

**Example of a Quality Plan:**

**The Ideal Veterinary Laboratory**
**Ewetopia, Footrotflats-shire, Somewhere in Scotland**

**LABORATORY VISION AND MISSION STATEMENT**

The *Ideal Veterinary Laboratory* aims to provide high quality veterinary laboratory testing in a timely manner and is perceived to represent good value for money. The highest priority is to do this in a caring way, with consideration for clients, owners and patients. We value integrity, honesty, communication and ongoing education about laboratory testing and its applications. The laboratory should make a profit for all share-holders in order to ensure its ongoing operation and continued ability to provide services to the veterinary community.

All staff and management individuals 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 nonconformities and complaints from clients will be considered and addressed through the improvement opportunity process.

**ENVIRONMENT**

The *Ideal Veterinary Laboratory* is located in Ewetopia, a suburb of Glasgow, providing a large metropolitan base for veterinary laboratory testing, with courier pickup and deliveries in the metropolitan area provided from one to three times per day, depending on the practice location. Additional potential clients include researchers associated with the University of Glasgow and pharmaceutical testing. The laboratory provides a range of haematologic, biochemical and endocrine testing, with additional esoteric tests offered inhouse and by send out to other laboratories. All waste is recycled, when possible, or disposed of by a dedicated biohazardous waste disposal team.

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**FACILITIES**

The *Ideal Veterinary Laboratory* has a 2,400 square meter facility with ample parking for staff and any clients delivering specimens to the laboratory. There are three shifts of working (night, day, evening), with employees suitable for the caseload present for each shift. There is room for expansion within the existing grounds, as well as 10 acres of surrounding park with a 12-stop fitness course and 3 miles jogging/walking pathways. A day care facility for employees' preschool-age children is provided in a separate building with adjacent outdoor play area and covered outdoor classroom. Afterschool care is also possible, by special arrangement.

There are locker rooms for male and female employees with padlocked locker space for each employee's coats, purses or other belongings that can be stored on a daily basis. There are showers and toilets in the locker rooms and convenient to the laboratories.

There is a reading room and library containing various reference books and journals, as well as several computers for internet access. The laboratory provides access to various current articles and purchases of articles based on membership in organizations providing these services.

**EQUIPMENT**

The laboratory contains modern instruments and equipment appropriate to meet the requirements for analysis and turn-around-time to meet the needs of submitting veterinary clients. All instruments are subject to method/instrument validation studies appropriate for the instrumentation prior to initiation of routine commercial testing. All tests have defined quality requirements in order to help determine appropriate statistical and nonstatistical quality control. All tests for which statistical QC is appropriate undergo QC Validation in order to provide for a high probability of error detection and low probability of false rejection.

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Haematologic and biochemistry tests also undergo periodic External Quality Assessment (EQA). For those tests for which there are no appropriate commercial EQA scheme, a schedule of comparative testing or other types of assessments are applied.

A state-of-the-art Laboratory Information System is used to facilitate the laboratory processes and reporting, with password-based security and periodic backup to ensure the security and integrity of the data.

**PERSONNEL**

Hiring of trained staff with experience in veterinary testing is given the highest priority. If trained staff are not identified amongst the applicants, all persons are given training appropriate for the job for which they have been hired. Veterinary Clinical Pathologists with appropriate qualifications (DipACVP, DipECVCP, DipECVP, DipRCPath, FRCPath) are hired, as needed. If no qualified pathologists with these credentials are available amongst applicants, trainee pathologists may be considered (i.e, board-eligible residents) and trained inhouse. Other qualified support staff are hired or trained in order to support the laboratory services processes.

**HEALTH AND SAFETY**

All local, state and federal regulations applying to Health and Safety are observed. All employees receive training regarding potential zoonoses associated with laboratory testing during their initiation and periodic 'refreshers' thereafter. Personal protective equipment and hoods or other appliances essential for the safe handling and processing of samples are provided.

**WORKING PRACTICES**

The processes of the laboratory are conducted according to written procedures and policies, which are subject to document control. A Directory of Services is provided for clients and updated periodically in order to provide information about tests, specimen requirements

and cost of testing. Continuing education is provided for staff and external clients periodically, in accordance with ongoing licensing requirements and industry practices.

Submitted samples are the property of the laboratory once received and there are written policies regarding specimen retention and use for ongoing internal quality control/quality assurance evaluations.

All submissions are subject to client confidentiality and are not released to or discussed with other veterinarians or owners unless the submitting practice specifically gives permission or requests this.

**SUMMARY**


This quality statement provides a written basis for the intent to conduct a high-quality laboratory testing service and to ensure that reasonable practices and profit are maintained in order to ensure the ongoing provision of care and support for our employees, submitting veterinary practices and their patients.