

**The College of
Veterinarians of Ontario**

Guideline

Ordering, Performing and Interpreting Laboratory Tests in Veterinary Clinical Practice

Guideline

Ordering, Performing and Interpreting Laboratory Tests in Veterinary Clinical Practice

Approved by Council: January 31, 2007

Publication Date: Update March 2007 – Website February 2007

To Be Reviewed by: January 2012

Key Words: laboratory tests, diagnosis, quality assurance,
unlawful practice

Related Topics:

Legislative References: Ontario Regulation 1093 Sections: 17. (1) 2, 7 &
7.1, 18, 19, 33(1), 40(2)(a)

College Contact: Registrar

Reference Materials: Ontario Regulation 1093

TABLE OF CONTENTS

	Page #
PURPOSE	1
SCOPE	1
THE LEGISLATION.....	1
COLLEGE POSITION	2
APPENDIX 1 – SAMPLE CORRESPONDENCE FOR USE BY PRACTITIONERS IN ASSESSING EXTERNAL DIAGNOSTIC LABORATORIES	4
APPENDIX 2 - NOTES TO PRACTITIONERS ON INTERPRETATION OF THE RESULTS OF THE LABORATORY QUESTIONNAIRE	6

Purpose

This guideline has been developed to help members understand the College's expectations related to ordering, performing and interpreting laboratory tests. This guideline is intended to address the interpretation of test results, the appropriateness of tests ordered or conducted. "Laboratory tests" include but are not limited to fecal flotation and smears, biochemical profiles, histopathology, complete blood counts (CBC's) and microbiology. Tests may be performed by a laboratory within a clinical practice ("in-house laboratory") or by a laboratory outside of the member's practice ("external laboratory").

Scope

This guideline applies to members who order, perform or interpret laboratory tests through in-house or external laboratories.

The Legislation

The *Veterinarians Act 1989*, is the profession-specific Act which governs the practice of veterinarians in Ontario. O. Reg. 1093 is the regulation under that Act.

O. Reg. 1093 Section 17. (1) describes situations in which a member would be found guilty of professional misconduct:

2. *Failing to maintain the standard of practice of the profession.*
7. *Providing, or attempting or offering to provide, services that are not reasonably useful or needed.*
 - 7.1 *Recommending, referring, ordering or requisitioning laboratory tests, technical procedures or professional services that are not reasonably useful or needed.*

O. Reg. 1093 Sections 18 and 19 require veterinarians to maintain appropriate standards of practice including procedures done by their auxiliaries:

18. *A member shall exercise generally accepted standards of practice and procedures in the performance of veterinary services.*
19. (1) *A member is responsible for the conduct of his or her auxiliaries and for the suitability and quality of the performance of their acts.*
 - (2) *A member is guilty of professional misconduct if an auxiliary of the member does or omits to do anything that, if done or omitted by a member, would constitute professional misconduct.*

O. Reg. 1093 Section 33 (1) (a) – (b) contains a definition of a valid Veterinarian-Client-Patient Relationship (VCPR) considered relevant to laboratory testing:

- (a) *the member has assumed the responsibility for making medical judgements regarding the health of the animal or group of animals and the need for medical treatment and the custodian of the animal or group of animals had indicated a willingness to accept the advice of the member;*
- (b) *the member has sufficient knowledge of the animal or group of animals by virtue of a history and inquiry and either physical examination of the animal or group of animals or medically appropriate and timely visits to the premises where the animal or group of animals is kept to reach at least a general or preliminary diagnosis;*

O. Reg. 1093 Section 40. (2)(a) defines a regular client:

A person is a regular client of a member if,

- i) the person uses the professional services of the member regularly and with reasonable frequency, and*
- ii) the person has not requested the transfer of the records for the person's animal to another member;*

College Position

Laboratory testing can be a critical component in the diagnostic process of veterinary medicine. However, there are limitations associated with laboratory tests that must be recognized and understood. Members have a professional responsibility to ensure that these limitations are appropriately mitigated through continuous quality assurance and critical evaluation.

An awareness and understanding of the limitations of laboratory testing will allow members to interpret results appropriately. Limitations might include sensitivity, specificity, predictive value of a positive test, confidence intervals and any other statistical concepts which potentially influence the reliability of results. Members are encouraged to make increased familiarity with the details of these concepts as they apply to their own practice as part of their ongoing self-study and continuing education activities.

Quality laboratory testing is a component of professional care that is expected of all members for their patients. If a member fails to ensure a high standard, that member could be found to be practicing below acceptable standards.

Ensuring quality testing should include a reliable Quality Assurance (QA) program for all in-house diagnostic testing and equipment. QA should include internal and external monitoring systems, with documentation of external audits and internal trials maintained in a QA log. Protocols for all laboratory procedures should be documented for reference and meet the current best practice or standard.

Maintenance of laboratory equipment should at least be in accordance with the manufacturers' recommendations. This maintenance should be clearly documented and maintained along with all operators' manuals.

Members should take steps to ensure that the external laboratories that they use have acceptable QA standards in place. This could include a requirement for documented QA programs or external accreditation or recognition. Members should also expect to see evidence of accreditation of the laboratory for the relevant test where available.

The College has developed sample correspondence (Appendix 1) and a questionnaire (Appendix 2) to assist veterinarians in evaluating the QA protocols for the laboratories it uses or is considering. Members may use this information to guide their choice of which laboratory to use. For example, members may use this questionnaire to compare laboratories or to determine if a particular laboratory has sufficient QA. It may also form the basis for discussion with a laboratory prior to using it for a particular test. As with any decision related to any professional service, it is the member's professional judgement weighing all factors including QA that determines which laboratory they will use for a particular test.

Members should only order diagnostic tests which are relevant to the patient's situation. Laboratory tests should only be ordered by a veterinarian for patients for whom there exists a proper VCPR.

It is inappropriate for a laboratory to offer interpretation, including a diagnosis, or to provide test results directly to an owner – this should be provided to the treating veterinarian who is in the best position to interpret the results and their significance for the owner and advise on therapeutic options. It is not in the public interest for a laboratory to accept samples directly from an owner or to provide the results directly to an owner.

Any non-member, or any person not supervised by a CVO member, who provides diagnostic laboratory test results directly to an owner would be considered by the College to be practising veterinary medicine without a licence.

APPENDIX 1 – SAMPLE CORRESPONDENCE FOR USE BY PRACTITIONERS IN ASSESSING EXTERNAL DIAGNOSTIC LABORATORIES

Date:

Name of Laboratory
Address
Address
City, Province Postal Code

Dear laboratory director:

In order to assist our practice in assessing the appropriateness of your services to our testing needs, we ask that you complete the attached questionnaire and return it to us promptly.

In the questionnaire we ask for your input under four column headings that are described in detail below. Please indicate **Y** (yes), **N** (no), or **ND** (not done) for each category.

Quality program:

Indicate if your laboratory has a formal externally validated program in place for each category. Examples would include external accreditation/registration entities such as independent auditor for ISO 9001:2000, Standards Council of Canada for ISO 17025, Canadian Food Inspection Agency (CFIA), American Association of Veterinary Laboratory Diagnosticians (AAVLD), Thyroid Registry of the Orthopedic Foundation for Animals Inc. (OFA), etc.

Test development and validation:

Indicate if your laboratory has qualified veterinary input into test development and validation.

On-site veterinary expertise:

Indicate if there is a qualified veterinarian available on-site or on-contract to assist practitioners with the interpretation of test results.

Referred testing:

Indicate if you send these tests to another laboratory.

We look forward to receiving your response via fax (123-456-7890) or mail.

Yours sincerely,

Dr. Practitioner

In each box in the table below, please circle your answer **Y** (yes), **N** (no), or **ND** (not done) for each category.

Discipline	Sub-discipline	Quality program			Test development and validation			On-site veterinary expertise			Referred testing		
		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Anatomic pathology	Gross pathology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Histopathology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Immunohistochemistry	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Bacteriology	Bacteriology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Mycology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Mycoplasmology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Clinical pathology	Biochemistry	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Cytology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Endocrinology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Hematology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Pharmacology	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
	Urinalysis	Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Immunology/serology		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Molecular biology		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Parasitology		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Toxicology		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
Virology		Y	N	ND	Y	N	ND	Y	N	ND	Y	N	ND
To which standard(s) is your laboratory registered, accredited, or certified, and who is your auditor?													
If you refer testing to other laboratories, do you only use those with verified quality programs?											yes	no	
Laboratory Name:													
Name:						Date:							
Title:													

Appendix 2 - Notes to Practitioners on Interpretation of the Results of the Laboratory Questionnaire

Quality Program

In order to provide credible results, a veterinary diagnostic laboratory is expected to have in place a **formal, written quality program**. Such a program includes a Quality Manual with: Vision and Mission statements; Quality Policy and Objectives; protocols for written standard operating procedures (SOP's); internal quality control procedures; staff selection (credentials and qualifications) and training requirements; test validation procedures; mechanisms for preventing the reporting of erroneous laboratory results to clients; rules for subcontracting work to other laboratories; a means of tracking client satisfaction with laboratory services; means of detecting, reporting, and preventing errors in testing. Such a program leads to continuous improvement in testing and in client service.

The basis of a quality system is that you “say what you do, do what you say, and prove it”. The “prove it” component is assessed by a variety of **external accreditation or registration bodies**, such as specialized auditors for ISO 9001:2000, Standards Council of Canada for ISO 17025, Canadian Food Inspection Agency (CFIA), American Association of Veterinary Laboratory Diagnosticians (AAVLD), Thyroid Registry of the Orthopedic Foundation for Animals Inc. (OFA), etc.

In order to ensure continuing competence in testing, reputable laboratories also participate in **external proficiency testing** services or programs, such as those offered by the Veterinary Laboratory Association (VLA), Randox RIQAS, Michigan State University, National Veterinary Services Laboratory (NVSL, USDA), etc.

Test Development and Validation

Selection of appropriate veterinary tests and validation of tests as fit-for-use requires that veterinary expertise be involved in order to establish the suitability of the test for the analyte in question, in the matrix involved (blood, tissue, feces, etc.), and for the purpose intended. Many veterinary tests and most laboratory equipment are adapted from human testing methods/equipment, but must be adapted successfully to the diversity of veterinary species and applications to be useful to clients.

On-Site Expertise

Once a suitable test is in place, it is important that qualified veterinarians are available to assist in interpretation of test results. There is no perfect test, and all results must be interpreted in the context of the clinical situation. Positive results from highly sensitive tests could be ‘false-positive’, e.g., a positive heartworm ELISA result in a cat living in an area in which heartworm disease is rare could well be a false positive that does not require treatment or, certainly, euthanasia. Questionable results should be questioned, repeated if necessary, or supported by an alternative test type. Laboratories should have established reference intervals for numerical results, preferably generated in-house on their own equipment with their own procedures.

Referred Testing

Referral of tests is necessary as no laboratory is able to offer all possible tests in-house. However, when referring tests to other laboratories, the originating laboratory must have confidence in the quality system of the referral lab, and should document their assessment of the other laboratory's quality.