

International Commission on Trichinellosis (ICT)

Recommendations for Quality Assurance in Digestion Testing Programs for Trichinella

ICT Quality Assurance Committee (Appendix 1)

Part 5

Recommendations on essential components and minimum requirements for a *Trichinella* testing laboratory certification program

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A. Introduction

This document provides a set of recommended essential components and minimum requirements for recognizing competence of a laboratory program for *Trichinella* digestion testing. Although certification is the term used in this document to denote this recognition, other designations may also be appropriate. For the purpose of this document, the competent authority granting this recognition is considered the Certifying Body, and Testing Laboratories are those certified under the program. The Certifying Body may designate a National Reference Laboratory or similarly qualified body to fulfill some or all of its responsibilities.

Laboratories conducting *Trichinella* testing must implement a quality management system (QMS) with policies and procedures which incorporate quality assurance (QA), quality control, analyst competence, suitable facilities, validated method(s), and sample identification and traceability. The World Organisation for Animal Health (OIE) and International Standards Organisation (ISO) provide extensive recommendations and standards, respectively, for quality management in veterinary testing laboratories. Based

on the same principles and guidelines, the following ten essential components, with minimum requirements to be met for each, are recommended by ICT for a *Trichinella* testing laboratory certification program:

1. Quality management system
2. Regulatory oversight
3. Structure of program
4. Standardized and validated assay
5. Laboratory facilities/equipment
6. Sample collection and handling
7. Traceability
8. Training
9. Proficiency assessment
10. Audits

Although some countries may not have sufficient veterinary infrastructure, regulatory oversight, or resources to fulfill all recommendations set forth here, this document should still serve as a useful reference.

References:

Forbes, L.B., Parker, S., & Scandrett, W.B. 2005 A program to accredit laboratories for reliable testing of pork and horse meat for *Trichinella*. *Veterinary Parasitology*, 132: 173-177.

International Organization for Standardization, 2005. ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories. International Organization for Standardization, Geneva, Switzerland.

World Organisation for Animal Health (2008). Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases, Second Edition. World Organisation for Animal Health (OIE: Office International des Epizooties), 12 rue de Prony, 75017 Paris, France, 1-25.

B. Components and Requirements

B.1 Quality management system

A QMS is the foundation of any certification program and includes all policies, procedures and associated documentation required by both the Certifying Body and Testing Laboratory to ensure that testing is reliable and fit for purpose. The specific policies and procedures should be described in a quality manual or supporting documents. Appendix 1 of Part 1 of this series includes a glossary of QA terms relevant to reliable *Trichinella* testing.

The Certifying Body should be third party accredited by the national accreditation body or other signatory of the International Laboratory Accreditation Cooperation (ILAC) in accordance with the ISO/IEC 17025 standard for quality assurance, with the *Trichinella* digestion assay included within its scope of accredited tests.

The Certifying Body should similarly implement QA in all prescribed policies, procedures and documentation pertaining to the delivery of the program, including training, proficiency sample provision, etc., as applicable.

It is also recommended that the Testing Laboratory be accredited to the ISO/IEC 17025 standard. The Testing Laboratory must, at a minimum, meet management and technical requirements based on the principles of ISO/IEC 17025, and have a quality management system approved by the Certifying Body.

The Certifying Body and Testing Laboratory must have a quality manual, standard operating procedures (SOPs), and records/reports to document fulfilment of respective responsibilities.

B.2 Regulatory oversight

The Certifying Body should have the legally empowered authority to oversee and/or govern the certification process and ultimately provides or approves all policies and procedures required for certified testing, including granting or revoking certification status of Testing Laboratories.

This role would typically be held by the Competent Authority, Veterinary Authority, or similar authority for a particular country, as defined by OIE and CODEX, which provide international guidelines for the control of *Trichinella*.

The extent of oversight required by the Certifying Body may vary based on the Testing Laboratory's level of QA recognition and the purpose of testing.

References:

World Organisation for Animal Health (2011). Glossary, *In: Terrestrial Animal Health Code*, Volume 1. World Organisation for Animal Health (OIE: Office International des Epizooties), 12 rue de Prony, 75017 Paris, France.

Codex Alimentarius Commission (2005) The Code of Hygienic Practice for Meat, Section 3. Codex Alimentarius Commission, Viale delle Terme di Caracalla, 00153 Rome, Italy.

B.3 Structure of program

A documented description of the certification program should be provided by the Certifying Body which clearly outlines the program organization and objectives (including purpose of testing) and respective roles and responsibilities of the Certifying Body and Testing Laboratory. This should include all requirements that must be met by the Testing Laboratory to achieve and maintain certification status, including any associated fees, legal agreements, reporting relationships, subcontracting, and regulatory obligations for suspect or positive test results.

Key information on the program can be compiled into an information package provided to candidate laboratories, including a checklist of important milestones in the certification process, with expected time frames and assigned responsibilities (Certifying Body and/or Testing Laboratory) for each.

It is important that any laboratory certification program remain current with changes in knowledge, technology, and QA requirements pertaining to the purpose of testing, so that test reliability is not compromised. In order to achieve this, a thorough review of the program should be conducted periodically by the Certifying Body.

B.4 Standardized and validated assay

An assay with statistically sound validation data to scientifically demonstrate its fitness for intended purpose should be used, and is a requirement for any testing conducted within the scope of ISO/IEC 17025 accreditation.

The magnetic stirrer method for pooled sample digestion has been extensively validated and is recommended by the ICT as the most reliable method for the detection of *Trichinella* larvae, and is also prescribed by the OIE and European Union (European Commission, 2005, and amendments). Essential QA standards for digestion testing to ensure accuracy and reliability when performing this assay are provided in Part 2 of this series.

Depending on the purpose of testing and client demands (for example, to meet *Trichinella* testing requirements of importing countries) an alternate method may be stipulated for certified testing which is not equivalent to the recommended or prescribed method and may not be validated. In such cases there may be a requirement for bilateral agreement between the Certifying Body and client that the method is fit for the intended purpose. However, in the absence of adequate supporting QA data, the results from such tests cannot be considered reliable for food safety purposes.

References:

European Community (2005). Regulation (EC) No 2075/2005 of the European Parliament and of the Council of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat. *Official Journal of the European Commission*, L 338/ 60-82

World Organisation for Animal Health (2011). Chapter 2.1.16. Trichinellosis (2008), In: Manual of Diagnostic Tests and Vaccines for Terrestrial Animals. World Organisation for Animal Health (OIE: Office International des Epizooties), 12 rue de Prony, 75017 Paris, France.

B.5 Laboratory facilities/equipment

The minimum physical standards and specifications for certified testing should be provided by the Certifying Body. Whenever possible, Biosafety Level 2 guidelines should be followed. Guidelines for facilities and equipment for basic (Biosafety Level 1 and 2) laboratories are provided in the Laboratory biosafety manual of the World Health Organization (WHO). The purpose of testing may also dictate other requirements such as situating the laboratory on the same premises as the slaughterhouse generating the carcasses for testing.

Recommended equipment with minimum specifications for performance of the digestion assay are included in Part 2 of this series. The amount of equipment required will vary

according to anticipated sample load, number of staff, work hours and other factors related to each laboratory site.

Reference:

World Health Organization. 2004. Laboratory biosafety manual, third edition. World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

B.6 Sample collection and handling

The Certifying Body should provide or approve all requirements for sampling, which may vary depending on purpose of testing, species tested, and client demands. Specific recommendations for sampling for the digestion assay are provided in Part 2 of this series.

A detailed prescriptive SOP for sample collection and handling should be provided or approved by the Certifying Body, including any stipulations for sample identification, fitness criteria, storage, and decontamination and disposal.

B.7 Traceability

The Certifying Body should provide or approve identification and traceability procedures and associated documentation to reliably and uniquely link samples, test results and carcasses of origin, as well as procedures required when positive results are obtained, including any subsequent sample collection and testing to determine affected carcass(es), and the decontamination and disposal of positive carcasses.

If testing is done for food safety, disease control, or export purposes, carcasses should not leave the premises until negative test results have been obtained. The Testing Laboratory should have procedures for detaining intact or processed carcasses, as well as for maintaining control of by-product and offal, pending negative test results, to prevent distribution of infected material.

For domestic surveillance purposes in non-endemic areas, the Certifying Body may lessen the above requirement based on assessment of risk, and the practicality and reliability of established procedures to enable traceability of any positive results to herd of origin.

The Certifying Body or other appropriate regulatory authority should have an effective mechanism, with requisite SOPs, for trace-back of any positive carcasses, using information provided by the slaughter facility and/or Testing Laboratory.

B.8 Training

Technical training is necessary to ensure competency of analysts and that accurate and repeatable results are achieved by the laboratory performing the assay. Specific recommendations for training and qualifying analysts, and for contents of a training manual, are found in Part 4 of this series. Training should be administered by a qualified provider, as determined by the Certifying Body. In addition to training in the performance of the digestion assay, analysts must be familiar with basic laboratory

procedures and equipment, and the quality management system and safety policies and procedures of the Testing Laboratory. It is recommended that eligible candidate analysts successfully complete a standardized and documented training session to demonstrate competence prior to conducting certified testing (see Part 4).

B.9 Proficiency assessment

A reliable, standardized, validated and quality assured system to prepare and provide *Trichinella* proficiency samples is required for training, and for the ongoing assessment of competency of analysts and the Testing Laboratory quality system. Examples of such proficiency sample systems for *Trichinella* used by National Reference Laboratories have been published. Proficiency testing providers should be ISO/IEC 17025-accredited and/or preferably accredited to the ISO/IEC 17043 standard specific to proficiency testing. Specific recommendations to ensure quality assurance in proficiency testing are provided in Part 3 of this series.

References:

Forbes LB, Rajic A, Gajadhar AA. 1998. Proficiency samples for quality assurance in *Trichinella* digestion tests. *Journal of Food Protection*, 61: 1396-1399.

Vallee I, Mace P, Forbes L, Scandrett B, Durand B, Gajadhar A, Boireau P. 2007. The use of proficiency samples to assess diagnostic laboratories in France performing a *Trichinella* digestion assay. *Journal of Food Protection*, 70: 1685-1690.

Marucci G, Pezzotti P, Pozio E. 2009. Ring trial among National Reference Laboratories for parasites to detect *Trichinella spiralis* larvae in pork samples according to the EU directive 2075/2005. *Veterinary Parasitology*, 159: 337-340.

International Organization for Standardization, 2010. ISO/IEC 17043, General requirements for the competence of testing and calibration laboratories. International Organization for Standardization, Geneva, Switzerland.

B.10 Audits

To ensure that all requirements of the certification program are met, a formal system of scheduled on-site audits of the Testing Laboratory is required to identify and document deficiencies in the quality management system for testing, specify corrective actions, and effect satisfactory resolution. Such on-site assessments are also an opportunity to foresee potential technical needs and problems and implement continual improvements.

Scheduled internal on-site audits, conducted at least once annually, should be part of the quality management system of the Testing Laboratory and required by the Certifying Body. Internal audits should be conducted by the Testing Laboratory's Quality Assurance Manager or qualified designate.

Scheduled external on-site audits should be conducted by the Certifying Body at least once biannually and/or by another third party such as the national accrediting body (for ISO 17025-accredited Testing Laboratories) at the prescribed frequency.

The Certifying Body must be kept informed of all internal or third party audit findings.

Audit frequency may be increased based on previous audit findings, operational changes, proficiency failures, and ongoing corrective actions.

A standardised audit checklist should be used to ensure all aspects of the quality management system for *Trichinella* testing are reviewed. Key elements should include facilities, personnel, training, equipment, quality manual, SOPs and record keeping.

The Certifying Body must have a standardized and transparent process for any corrective action requirements and commensurate deadlines to be met by the Testing Laboratory, and for the delay, suspension or revocation of certification status of the Testing Laboratory.