A Comprehensive On-site Diagnostic Program for the Detection of *Trichinella*

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Purpose for Testing

• Surveillance
  - for control management
  - for status declaration

• Food safety

• Export requirement

• Import verification

• Disease outbreak investigation
Testing Locations

I. Off-site (samples collected elsewhere)
   - most diagnostic labs
   - reference labs

II. On-site (samples collected on premises)
    - abattoirs/packing plants
    - field labs
Oversight of Testing Laboratories

[Diagram showing interconnection between National Reference and Diagnostic Laboratory and Diagnostic Laboratories (Off-Site)]
Oversight of Testing Laboratories

- National Reference and Diagnostic Laboratory
  - Diagnostic Laboratories (Off-Site)
  - Diagnostic Laboratories (On-Site)
Oversight of Testing Laboratories

Reference and Diagnostic Laboratory (International)

National Reference and Diagnostic Laboratories

Diagnostic Laboratories (Off-Site)
Diagnostic Laboratories (On-Site)
Requirements for off-site and on-site testing are similar

- QA system and manual
- Purpose of laboratory
- Purpose of testing
- Appropriate test method (fit for purpose)
- Standardized and validated method
- Trained and competent analysts
- Suitable facilities
- Proficiency testing
- External audits for lab accreditation/certification
Key Elements of On-site QA Program

- Quality Goals – measurable
- Defined Test Method - suitable, reliable
- Samples - suitable, stable
- Internal Quality Control - CCP
- External Quality Procedures - PT, accreditation
- Record keeping - sample tracking and traceback
- Documented results
- Procedures (SOP’s) and Documentation
- QA Manual
All Tests are Not Equal

- Non-validated tests
- Validated tests (a validation continuum)
Validated Test Method

- Based on documented evidence that the method does what it is intended to do

- The robustness, repeatability, and reproducibility of the method under certain conditions have been evaluated and documented

- An important element of quality control and provides an assurance of reliability
All Tests are Not Equal

- Non-validated tests
- Validated tests (a validation continuum)
- Harmonized tests
- Equivalent tests
- Prescribed tests
- Alternative tests
- Ad-hoc tests
An Experience

- Six persons with food poisoning in city hospitalized
- All suspect food confiscated for testing
- Wild boar meat tested for *Trichinella* at local lab
- Meat released to owners for consumption
- Number of cases increased to 24
- Cooked sausage and roast submitted to reference lab
- Method available was not fit for purpose, but …
- Roast: no larvae recovered
- Sausage: motile larvae recovered
- > 40 cases of confirmed trichinellosis
QA Manual is a Documented Plan to Meet Management and Technical Goals

- Reproducibility and reliability of results
- Permanent record of sample handling
- Identification and elimination of errors due to poor performance of media, reagents, equipment, etc.
- Permanent record of equipment performance
- Equipment maintenance and calibration procedures
- Test procedures and results
- Analyst training and competence
- Problem solving and corrective action
A National Program for *Trichinella* Testing of Pork and Horsemeat by On-site Industry Laboratories

- Developed and implemented by CFAP
- In operation for 11 years, since 1997
- 14 laboratories accredited, 90 analysts trained and certified
Background

- CFIA Centre for Food-borne and Animal Parasitology (CFAP) accredited for diagnostic testing as per ISO/IEC Standard 17025


- based on this standard, a national program was developed to accredit industry on-site laboratories

Accreditation for On-site Testing

- provides testing capacity to meet export demands
- meets internationally acceptable QA standards
- provides documentation of compliance with acceptable testing standards
- Accreditation and oversight provided by a national reference laboratory
Oversight of Testing Laboratories
Main Criteria for Accreditation

1. Defined Quality Assurance System
2. Suitable Laboratory Facilities
3. Standardized and Validated Method
4. Certified Analysts
5. External Audit

Consistent with ICT Recommendations Appendix 2. Quality assurance program for *Trichinella* testing

CFAP provides information package on the accreditation process to interested parties
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<th>Step in the Accreditation Process for On-site Testing</th>
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<td>Review of application</td>
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<td>Preparation of proficiency samples (scheduling required)</td>
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<td>Candidate arranges with CFIA Vet-in-Charge for export certification</td>
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Quality Assurance Manual

- It is a statement of the laboratory’s policies and good laboratory management practices
- Describes the quality assurance system used in a testing laboratory
- Documents plans to meet management and technical goals of the quality assurance system
Contents of a QA Manual

- Who (titles and responsibilities)
- What (scope and activities)
- When (frequency)
- Where (location)
- How (methodology and mechanisms)
- Why (purpose)
Example Quality Assurance Manual

1. Table of Contents
2. Laboratory Information
3. Test Methods and Procedures
4. Equipment and Supplies
5. Quality Control Activities
6. Sample Handling
7. Record Keeping Procedures
8. Staff Training
9. Proficiency Testing Program
10. Problem Solving and Corrective Actions
11. Mechanism for Handling Complaints
12. Proprietary Rights and Confidential Information
13. Sub-contracting
14. References
15. Appendices
Suitable Laboratory Facilities

- Controlled, clean environment for testing
- Equipment and consumable supplies must meet required specifications of the test method
- Must comply with local safety regulations
Standardized/Validated Method

- Magnetic stirrer method for pooled sample digestion
  EU Directive EC No 20705/2005

- Double separatory funnel procedure for pooled sample digestion
  Gajadhar, Forbes, and Rajic, 1996

- Digestion assay more sensitive than trichinoscopy

- Validation of double separatory method
Analyst Certification

• 5-day training course conducted at CFAP
• training manual provided
• Candidates must pass a practical examination at CFAP and at on-site laboratory
• A total of 90 analysts comprising 14 different laboratories have been certified since 1997
External Audit

• Initial on-site audit conducted by CFAP to verify key criteria are met
• Major and minor non-conformances must be addressed within specified time frame before accreditation is recommended
• Biannual audits conducted thereafter
Proficiency Testing

- Proficiency panels performed 2-4 times per yr
- Required to ensure competence of analysts and quality system of testing
- Prepared from experimentally infected rats


Vallée, Macé, Forbes, Scandrett, Durand, Gajadhar, Boireau. 2007. *Use of Proficiency Samples To Assess Diagnostic Laboratories in France Performing a Trichinella Digestion Assay*. J Food Prot 70, 1685-1690(6)
Proficiency Testing (cont’d)

• Encapsulated larvae recovered from semi-digested infected meat
• Meat-balls prepared from ground-beef
• Three levels of larval loads in panels (L,M,H)
• Proficiency panels validated prior to distribution
• Proficiency testing conducted according to pre-established guidelines
Proficiency Testing Results

- Evaluation of system and analysts
- Interpretation according to purpose for testing
- Positive/negative versus quantitative
- Goal of $\geq 75\%$ larval recovery from each proficiency sample
- Food safety goal of $\leq 1$ LPG of meat
- Corrective actions may be required
- Need for establishing reasonable and achievable guidelines
Questions/Comments?