Istituto Superiore di Sanità

Department of Infectious Diseases

Unit of Foodborne and Neglected Parasitic Diseases

European Union Laboratory for Parasites

Final report PT-09: Tr 1/2026

PT-09: "Detection of anti-*Trichinella* IgG in swine serum samples"

Design

Purpose	Evaluation of laboratories competence in detection anti Trichinella IgG in swine serum	
Timetable	Invitation mail: 27/01/2026 Website updates: within 27/01/2026 Registration deadline: 20/02/2026 PT items production: 10/03/2026 Shipping: 16/03/2026 Results submission deadline: 17/04/2026 Publication of the Final PT Report: 29/05/2026	
Participants	National Reference Laboratories for parasites, Public and private, national and international institution	
Number of participants	Depending on requests	
PT items	Matrix	EURL-P reference sera collected from pigs infected with *Trichinella* and from pigs free of *Trichinella*
	Item	Anti-*Trichinella* IgG present in the serum of infected pigs
	Number of PT items	3 per each participant
	Panel composition	3 items: 2 positive and 1 negative sera
	Number of surplus items	n.a.
Activities provided by external providers	Shipping	
Provider name	DHL	
Results evaluation	Qualitative evaluation	

Implementation

PT staff: Celani Francesco, Di Grazia Antonio, Tartarelli Irene

Compliance with planned timelines: YES ■ NO ☐

Participant number and type: 5 public institution

0 private institution

Acquisition of matrix and analyte:

The EURL-P reference sera, which constitute the objects of PVI, are tested using the EURL-P internal methods accredited according to ISO stanadard 17025: MI-01 "Detection of anti-Trichinella antibodies in pig serum by indirect ELISA" and MI-13 "Identification of Trichinella proteins presumably recognized by specific IgG present in the serum of infected pigs by western blotting".

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Production of PT items:

The PVI objects consist of swine sera that tested positive or negative in a test for the detection of anti-Trichinella IgG. The sera are preserved with merthiolate (sodium ethylmercurithiosalicylate) and maintained at a temperature between 4 and 15 °C, distributed in 100 µL aliquots in 1.5 mL tubes. The tubes thus prepared are sealed with parafilm and labeled with a unique alphanumeric code. The labels, printed on adhesive paper, are applied to the tubes and then protected with transparent tape to ensure their integrity and legibility. The sealed and labeled tubes are then placed in a 50 mL tube, on which the participant's identification code is indicated. Information available on the PTP website and in the "Instructions" form MO/POPVI-09/02 rev. 2.

Activities provided by external providers:

The PT provider (PTP) entrusted the shipment of PT items to a qualified transport company. The company that provided the shipping service was DHL.

Homogeneity and stability of PT items:

The same sample preparation method ensures the homogeneity of the PVI objects.

Based on the experience of the EURL-P, it has been possible to establish that sera containing merthiolate, stored at 4-15°C, remain stable for at least one month after the preparation date.

Distribution of PT items:

The PT items were shipped on 16/03/2026, the deadline for submission of results was set for 17/04/2026. Each set of PT items consisted of three serum samples (2 positive and 1 negative)

Instructions for participants:

Participants were informed of the shipment date via email on 27/01/2026. The email also contained a link for submitting results, which was active from 16/03/2026 (coinciding with shipment) to 17/04/2026. Participant instructions were made available on the PTP website from 27/01/2026.These instructions also contained information for sending feedback and submitting results. This information was sent to participants along with the PT announcement email and also remarked in the email sent on 16/03/2026 (shipment date).

Data analysis:

Feedback and participant's results were collected via the online Forms application and transferred from the PTP to an Excel file used for data processing, and further used to generate the tables with the participant results contained in this PT report.

Assigned value:

2 positive sera with optical density (OD) values respectively high and intermediate; 1 negative serum, characterized by an OD value below the cut-off of the MI-01 method "Detection of anti-Trichinella Antibodies in pig serum by indirect ELISA" established at 0.338 OD.

Criteria for results evaluation:

The evaluation of the results is qualitative. The result is considered correct if positive and negative PVI items are correctly identified; otherwise, it is considered incorrect. The evaluation is considered positive if all PVI items have been correctly identified, and negative otherwise. Information is available on the PTP website and in the MO/POPVI 09/02 rev 2 form.

Confidentiality of results:

The confidentiality of this report is guarantee using a unique code that allows the anonymity of participants. The identity of participants is kept confidential and subject to professional secrecy. PT provider reserves the right to provide the results of participation in the PT scheme to the competent authorities upon request. The participant will be notified in writing if a competent legislative authority requests the provision of the PT results.

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Results provided by participants and performance EVALUATION

Participant code	Applied method	PT item code	Result	Assigned value	Outcome	Final evaluation
A	ID SCREEN TRICHINELLA INDIRECT MULTI-SPECIES OF ID.VET	Sample 1	Positive	Positive	Correct	Positive
		Sample 2	Positive	Positive	Correct	
		Sample 3	Negative	Negative	Correct	
B	ID Screen ID.vet Trichinella indirect multi-species TRICHIS-MS ver 0117 EN	Sample 1	Positive	Positive	Correct	Positive
		Sample 2	Positive	Positive	Correct	
		Sample 3	Negative	Negative	Correct	
C	In-house ELISA	Sample 1	Positive	Positive	Correct	Positive
		Sample 2	Positive	Positive	Correct	
		Sample 3	Negative	Negative	Correct	
D	Indirect ELISA: Priocheck Porcine Trichinella Ab (Batch number: 241001L)	Sample 1	Positive	Positive	Correct	Positive
		Sample 2	Positive	Positive	Correct	
		Sample 3	Negative	Negative	Correct	
E	Trichinella antibody (Pigtype Indical)	Sample 1	Positive	Positive	Correct	Positive
		Sample 2	Positive	Positive	Correct	
		Sample 3	Negative	Negative	Correct	

Summary of results:

Total number of PT panels	5
Number of participant	5
Number of participants that passed the PT	5
Number of participants that failed the PT	0

Overtime comparison of results

Laboratory code 2026	2025	2026
A	NP	POS
B	NP	POS
C	POS	POS
D	POS	POS
E	POS	POS

NP= no participation. **POS**= positive. **NEG**= negative.

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Comments on participants' performance: the consistently reliable laboratory results demonstrate both the robustness of the assays and the high level of staff expertise.

Performance evaluation if different methods are applied: Not applicable. This year no different analytical methods were applied; all participating laboratories used commercial ELISA methods for Trichinella antibody detection. NA

Comments and recommendations based on the outcomes of PT: The PT outcomes indicate a high level of analytical accuracy and inter-laboratory consistency among participants. It is recommended to maintain the current quality assurance practices, continue regular staff training, and ensure ongoing monitoring of assay performance to preserve the high standards achieved.

Possible sources of error:

- Improper sample handling or storage conditions
- Pipetting inaccuracies or dilution errors
- Instrument calibration or maintenance issues
- Variability in reagent quality or lot-to-lot differences
- Deviations from standard operating procedures (SOPs)
- Inadequate staff training or human error during analysis
- Contamination of samples or reagents
- Data transcription or reporting errors
- Environmental factors affecting assay performance (e.g., temperature fluctuations)
- Delays in sample processing or testing

Written and elaborated by
PTP person in charge

Dr. A. Ludovisi

Verified and issued by
The Director

Dr. A. Casulli

Date 11/05/2026

Notes:

1. Personal data are processed in compliance with the regulatory provisions referred to in EU Regulation 2016/679 and Privacy Code, as reported in Legislative Decree no. 101/2018. The data controller of personal data is the Istituto Superiore di Sanità with registered office in Viale Regina Elena n. 299 - 00161 Rome, in the person of its President. In addition, the ISS has appointed its own Data Protection Officer (D.P.O.), e-mail address:

responsabile.protezionedati@iss.it. Data are processed exclusively for carrying out the PT activities, for this purpose adequate physical, technical and organizational security measures have been set up to prevent and avoid their destruction and/or loss of integrity, as well as their illicit or incorrect use. Data is accessible only to authorized personnel who has their own credentials and their own operating station. The participant has the rights referred to in art. 15 GDPR et seq., more precisely right of access, right of rectification, right of treatment limitation, right to data portability, right of opposition, as well as the right to lodge a complaint with the Guarantor Authority (art. 77 GDPR and 141 Privacy Code, as reported by Legislative Decree 101/2018). The ISS, in its capacity as Data Controller, undertakes to keep the records of processing activities correctly pursuant to art. 30 GDPR.

2. The original raw data and a copy of Final PT Report are kept for 10 years at the PTP site.

End of the report

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