

Final report PT-07: AnMol 1/2026

PT-07: “Molecular identification of Anisakid nematodes at the species level”

Design

Purpose	Evaluation of laboratories competence in molecular identification of Anisakid nematodes species	
Timetable	Invitation mail: 27/01/2026 Website updates: 31/01/2026 Registration deadline: 20/02/2026 PT items production: 16/03/2026 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	Ethanol (larvae) and saline buffer (DNA)
	Item	Anisakid nematodes (DNAs or larva fragments)
	Number of PT items	Based on request
	Panel composition	4 per participant (2 larva fragments and 2 DNA items)
	Number of surplus items	n.a.
Activities provided by external providers	Shipping	
Provider name	DHL	
Results evaluation	Qualitative evaluation	

Implementation

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

Compliance with planned timelines: YES NO

Participant number and type: **16** public institution

Acquisition of matrix and analyte: L3 larvae items stored in 96% ethanol were obtained by qualified providers: *A. pegreffii* larvae were provided by EURL-P, and *A. simplex* ss larvae were provided by Institute of Marine Research, Bergen, Norway. Both DNA items [*Hysterothilacium* spp (*H. aduncum*) and *A. simplex/A. pegreffii* hybrid genotype] were provided by EURL-P. DNAs were extracted from a single L3 larva. For typing of larva items the DNAs were extracted from a fragment of L3 larva. Characterization at species level was done by accredited EURL-P internal method (MI-04: Identification of Anisakidae larvae at the species level by PCR/RFLP) from 03/03/2026 to 09/03/2026.

PT Provider
 Unit of Foodborne and Neglected Parasitic Diseases
 Istituto Superiore di Sanità

viale Regina Elena, 299 – 00161 Rome, Italy



00629

Person in charge of PT: Dr. Marco Lalle
 e-mail: marco.lalle@iss.it;
 tel: +39 0649902670

Production of PT items: The PT items were produced on 11/03/2026 and consists of single fragment (in ethanol) and 10 µl of Anisakidae L3 larvae DNA. The PT panel consisted of four 1.5 ml tubes: two containing a single fragment of Anisakidae L3 larva of different species and two containing DNA extracted from a single Anisakidae L3 larva belonging to different species.

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: All larvae and DNAs were individually identified at species level analysing one of their fragments by the EURL-P internal method, accredited according to ISO 17025 "Identification at species level of parasites of the family Anisakidae by PCR/RFLP". Homogeneity was further ensured by providing all participants aliquots of the same DNA preparations. The stability of the PT items was evaluated by *ad hoc* experiments carried out by EURL-P. Larvae preserved in 96% ethanol and stored at a temperature between -20°C e +20°C maintain their stability for up to five years. DNAs stored at a temperature ≤ -15°C maintain their stability for up to 10 years. DNAs may also be stored refrigerated (temperature between +4°C e +8°C) for up to six months. Quality control required that PTP's staff analyse PT items before distribution.

Distribution of PT items: The PT items were shipped on 16/03/2026, with the deadline for submitting results set for 17/04/2026. Each set of PT items consisted of 50 ml vial marked with the participant's identification code. Each set contained four 1.5 ml vials identified with the code assigned by PTP to the PT items. The packaging consisted of a polystyrene and cardboard container containing an adequate number of cooling bricks to ensure that a temperature between 4°C and 15°C was maintained inside the package.

Instructions for participants: Participants were informed of the shipment date via email on 16/03/2026. 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. This document also contained information for sending feedback and submitting results. This information was sent to participants along with the PT announcement email and remarked in the email sent on 16/03/2026 (shipment date).

Data analysis: Feedback and participant results were collected via the online Forms application and transferred 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: The assigned value was determined by the competence of the staff involved in the analysis and production of the PT items.

Criteria for results evaluation: For each PT item, the result was evaluated by comparing the result reported by the participant with the expected value. Result evaluation in qualitative. Result was considered "correct" if larvae and DNAs of the PT item are properly identified at species level, and "incorrect" in case of wrong identification. Results have to be expressed reporting the species assigned to each PT item. PTP evaluated the result of the participant according to the sensitivity of the method applied. The participant was asked to correctly identify at least the species, for hybrid genomes (i.e. *Anisakis simplex*/*Anisakis pegreffii* hybrid genotype) the result was evaluated based on the genetic marker used (i.e. mitochondrial vs nuclear markers). Likewise, the correct identification of the subspecies was evaluated according to the resolution of the method applied. Due to the nature of PT items, no statistical parameters were applied for result evaluation. The final evaluation was "positive" if all PT items were correctly identified, otherwise it was "negative".

Confidentiality of results: The confidentiality of this report is guaranteed using a unique code that allows the anonymity of participants. The identity of participants is kept confidential and subject to professional secrecy. The EURL-P 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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viale Regina Elena, 299 – 00161 Rome, Italy



00629

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tel: +39 0649902670

Results provided by participants and performance EVALUATION

Participant code	Applied method	Item code	Result	Assigned value	Outcome	Final evaluation
AMM01	In house method (PCR Cox2 and sequencing)	AM1000	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	POSITIVE
		AM1001	<i>Anisakis simplex</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1002	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1003	<i>Anisakis berlandi</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	CORRECT	
AMM02	EURLP method MI-10 (multiplex PCR)	AM1004	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1005	<i>Anisakis simplex sensu lato</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1006	Negative	<i>Hysterothylacium spp</i>	INCORRECT	
		AM1007	<i>Anisakis pegreffii</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM03	EURLP method MI-10 (multiplex PCR)	AM1008	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1009	<i>Anisakis simplex</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1010	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1011	<i>Anisakis pegreffii</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM04	EURLP method MI-10 (multiplex PCR)	AM1012	<i>A. pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1013	<i>A. simplex s.l. e A. simplex/pegreffii ibrido</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1014	<i>Contracaecum osculatum</i>	<i>Hysterothylacium spp</i>	INCORRECT	
		AM1015	<i>A. pegreffii</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM05	EURLP method MI-04 (PCR_RFLP); + sequencing	AM1016	<i>A. pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1017	<i>A. simplex</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1018	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1019	<i>A. pegreffii</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM06	In-house method according the EURLP method (PCR-RFLP) + sequencing	AM1020	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1021	<i>Anisakis simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1022	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1023	<i>Anisakis sp.</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM07	EURLP method MI-04 (PCR_RFLP)	AM1024	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	POSITIVE
		AM1025	<i>Anisakis simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1026	<i>Hysterothylacium spp (H. aduncum)</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1027	<i>Anisakis simplex / pegreffii hybrid</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	CORRECT	
AMM08	EURLP method MI-04 (PCR_RFLP); EURLP method MI-10 (multiplex PCR); In house method (CO1 plus Sanger sequencing);	AM1028	<i>A. pergreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1029	<i>A. pergreffii</i>	<i>Anisakis simplex ss</i>	INCORRECT	
		AM1030	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1031	<i>A. pergreffii</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	INCORRECT	
AMM09	EURLP method MI-04 (PCR_RFLP); EURLP method MI-10 (multiplex PCR);	AM1032	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	POSITIVE
		AM1033	<i>Anisakis simplex</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1034	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1035	<i>A. simplex/A. pegreffii hybrid</i>	<i>A. simplex/A. pegreffii</i> hybrid genotype	CORRECT	

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00629

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 tel: +39 0649902670

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Participant code	Applied method	Item code	Result	Assigned value	Outcome	Final evaluation
AMM10	In house method POS CRENA 02 Rev. 11 (PCR-RFLP) and POS CRENA 11 Rev. 2 (PCR-Multiplex)	AM1036	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1037	<i>Anisakis simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1038	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1039	<i>Anisakis simplex s.s.</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	INCORRECT	
AMM11	EURLP method MI-04 (PCR_RFLP); EURLP method MI-10 (multiplex PCR);	AM1040	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	POSITIVE
		AM1041	<i>Anisakis simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1042	<i>Hysterothylacium spp (H. aduncum)</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1043	<i>A. simplex/pegreffii hybrid</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	CORRECT	
AMM12	EURLP method MI-04 (PCR_RFLP);	AM1044	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	POSITIVE
		AM1045	<i>Anisakis simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1046	<i>Hysterothylacium spp.</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1047	<i>hybrid Anisakis simplex/Anisakis pegreffii</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	CORRECT	
AMM13	EURLP method MI-10 (multiplex PCR)	AM1048	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1049	<i>Anisakis simplex s.l.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1050	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1051	<i>Anisakis pegreffii</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	INCORRECT	
AMM14	EURLP method MI-10 (multiplex PCR)	AM1052	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1053	<i>Anisakis simplex s.l. or A. simplex/pegreffii hybrid</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1054	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1055	<i>Anisakis pegreffii</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	INCORRECT	
AMM15	Published method (PCR and sequencing)	AM1056	<i>Anisakis pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1057	<i>Anisakis simplex sensu stricto</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1058	<i>Hysterothylacium aduncum</i>	<i>Hysterothylacium spp</i>	CORRECT	
		AM1059	<i>Anisakis simplex C (Anisakis berlandi)</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	INCORRECT	
AMM16	EURLP method MI-04 (PCR_RFLP); Published method; EURLP method and Sequencing	AM1060	<i>A. pegreffii</i>	<i>Anisakis pegreffii</i>	CORRECT	NEGATIVE
		AM1061	<i>A. simplex s.s.</i>	<i>Anisakis simplex ss</i>	CORRECT	
		AM1062	negative	<i>Hysterothylacium spp</i>	INCORRECT	
		AM1063	<i>A. simplex/ A. pegreffii hybrid</i>	<i>A. simplex/A. pegreffii hybrid genotype</i>	CORRECT	

Legenda:

- Laboratories that failed the PT are marked in bold.

Summary of results:

Total number of PT panels	16
Number of participants	16
Number of participants that passed the PT	5
Number of participants that failed the PT	11

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00629

Overtime comparison of results

Laboratory code 2026	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
AMM01	NP	NP	POS	NP	POS	POS	POS	POS	POS	POS
AMM02	NP	NP	NP	NP	NP	NP	NP	NP	POS	NEG
AMM03	POS	POS	NEG	POS	POS	POS	POS	POS	POS	NEG
AMM04	NP	POS	NP	NP	NP	NP	NEG	POS	POS	NEG
AMM05	POS	POS	POS	NEG	POS	POS	NEG	POS	NEG	NEG
AMM06	NP	NP	NP	POS	POS	POS	NEG	POS	NEG	NEG
AMM07	POS	POS	POS	POS	POS	POS	POS	POS	NP	POS
AMM08	NP	POS	NP	NEG	POS	NEG	NEG	POS	POS	NEG
AMM09	POS	NP	NP	NP	POS	POS	NEG	POS	POS	POS
AMM10	POS	POS	POS	POS	POS	POS	POS	NEG	POS	NEG
AMM11	POS	POS	POS	POS	POS	POS	POS	POS	POS	POS
AMM12	POS	POS	POS	POS	POS	POS	NP	POS	NEG	POS
AMM13	POS	POS	POS	POS	POS	POS	POS	POS	POS	NEG
AMM14	NP	NP	NP	NP	POS	POS	POS	POS	POS	NEG
AMM15	NP	NP	NP	NP	NP	NP	NP	NP	POS	NEG
AMM16	NP	NP	NP	NP	NP	POS	NEG	POS	POS	NEG

NP= no participation (grey). POS= positive (white). NEG= negative (black).

Comments on performance of participants: In the PT round of 2026, the PT items provided to the participants were: a fragment of *A. pegreffii* larva; a fragment of *A. simplex* ss larva; DNA from *Hysterotilacium* spp (*H. aduncum*); and DNA from *A. simplex/A. pegreffii* hybrid genotype. In particular, the latest was a hybrid genotype of *A. simplex C/A. pegreffii*, with *A. simplex C* currently known as *A. berlandi*.

Fifteen out of 16 participants received the PT items within 72 hours. The late delivery of the package for one participant was due to customs' delay.

Only five participants (31%) successfully passed the PT, whereas 11 (69%) failed. By comparison with previous years, five participants have shown a negative trend in the last five years by failing two (AMM10 and AMM16) or three times (AMM05, AMM06, AMM08). The other six participant failed the PT for the first time or after more than 5 years (AMM03). Among the participants that passed the 2026 PT round, three show a constant positive trend over the years, whereas the other two have failed one time in the last five years.

Among the failing participants, one (AMM16) was not able to amplify the DNA from *Hysterotilacium* spp. Concerning the failure in amplifying the DNA, it can be excluded any problem due to the PT item since the

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00629

same DNA stock was forwarded to all participants. None reported troubles concerning amplification of the DNAs with either EURL-P internal method MI-10 "Identification of Anisakidae Larvae at the species level by multiplex PCR", EURL-P internal method MI-04 "Identification at species level of parasites of the family Anisakidae by PCR/RFLP" or in house methods. Moreover, the PTP cannot envisage problems with PT items storage during the shipping as nothing was reported by the participant.

Ten participants did not correctly identify at least the DNA of *A. pegreffii*/*A. simplex* hybrid genotype. Among them: i) five used only the EURL-P method MI-10 (multiplex PCR) and all reported *A. pegreffii*; ii) four sequenced the PCR product resulting from EURL-P method MI-04 and reported either *A. pegreffii* (AMM05), *Anisakis* spp (AMM06), *A. simplex* C (*A. berlandi*, AMM15); iii) one used both PCR-RFLP and multiplex PCR according to in-house procedure (AMM10) reporting *A. simplex* ss. The assignment of incorrect results was based according to the methods applied.

For those participants applying the EURL-P method MI-10, a single band of 588 bp was expected for both *A. simplex* s.l. and the *A. simplex/pegreffii* hybrid genotype. Instead, a doublet of bands, 672 and 588bp, is expected for *A. pegreffii*.

For the one applying the PCR-EURLP (as according EURL-P method MI-04), the expected profile of digestion bands for the *A. simplex/pegreffii* hybrid genotype would be 34, 67, 235, 284, 331; 615 by *HinfI* digestion and 419, 532 bp by *HhaI* digestion. In the case of *A. berlandi*/*A. pegreffii* hybrid genotype, digestion by *HhaI* results in additional two bands of 142 and 279 bp, as for *A. simplex* C (*A. berlandi*). Although this hybrid is not listed in the published EURL-P methods, the presence of the extra bands would have been suggestive of hybrid genotype.

For those applying sequencing of the PCR product of the nuclear ribosomal Internal Transcribed Spacer 1 (the PCR product obtained applying EURL-P method MI-04) the electropherogram should show two mixed nucleotide positions (characterized by two overlapping peaks) one of which (T or C) correspond to the last nucleotide of a *HinfI* sequence, being responsible for missing digestion by this enzyme and being indicative of hybrid genotype.

In addition to incorrect identification of the *A. simplex/pegreffii* hybrid genotype, other incorrect results were reported. Participant AMM02 also did not amplify the DNA from *Hysterotilacium* spp. As for participant AMM16, PTP can exclude any problem due to the PT item since the same DNA stock was forwarded to all participants and PT item was shipped within 72h and as no temperature issue was reported by the participant.

Participant AMM04 also incorrectly reported *Contraecaecum osculatum* instead of *Hysterotilacium* spp by using multiplex PCR (EURL-P method MI-10). The method produces a PCR fragment of 799bp for *C. osculatum* that is well distinguishable from the 991bp fragment obtained for *Hysterotilacium* spp.

Finally, participant AMM08, despite used multiple methods (PCR_RFLP, multiplex PCR, and in house method targeting mitochondrial CO1 gene plus Sanger sequencing), mistakenly reported *A. pegreffii* instead of *Anisakis simplex* ss. With the PCR_RFLP methods, *A. pegreffii* PCR digestion with *HinfI* produces five bands (34, 67, 235, 284, 331bp) whereas *A. simplex* ss PCR digestion with *HinfI* produce four bands (34, 67, 235, 615bp) making the two restrictions profile easily distinguishable. With the multiplex PCR, *A. pegreffii* amplification produces two bands (588 and 672bp) whereas *A. simplex* s.l. (and the hybrid genotype) amplification produces only one band (588bp). Amplification and sequencing of mitochondrial cytochrome c oxidase subunit I (COI) gene can distinguish among *A. simplex* ss and *A. pegreffii*, but no publication are available concerning the resolution for hybrid genotypes. No reference to method was provided by the participant so that further comment on the method characteristics is not possible.

Performance evaluation if different methods are applied: No incorrect results were reported by any of the participant concerning the PT items corresponding to fragment of larva, suggesting that differences in DNA extraction (reported by participant four participants, AMM01, AMM02, AMM03, AMM06) do not affect the results.

Concerning the molecular methods applied (Figure 1): i) five participants (31%) applied only the EURL-P method MI-10 "Identification of Anisakidae Larvae at the species level by multiplex PCR" alone or in addition to in-house method; ii) four (26%) used the method MI-04 "Identification at species level of parasites of the family Anisakidae by PCR/RFLP" alone (2) or in combination with sequencing (2); iii) three (19%) used both MI-04 and MI-10 methods; iv) two (13%) performed the PCR amplification described by EURL-P method MI-04 directly followed by Sanger sequencing; v) one used a combination of MI-04, MI-10 and in-house PCR amplification of CO1 gene; vi) finally, one used an in-house method to amplify mitochondrial Cox2 gene followed by sanger sequencing.

As previously discussed, multiplex PCR, PCR_RFLP and sequencing of ITS1 region can all provide enough specificity to characterize at the species level the provided PT items. However, the mitochondrial Cox2 gene sequencing used by only one participant (AMM01), by targeting a mitochondrial gene inherited from the mother cannot distinguish the hybrid genotype *A. simplex* C/A. *pegreffii* from *A. simplex* C (*A. berlandi*) and for this reason the provided results were considered correct. However, the use of multiple methods or target genes or sequences can provide an higher resolution.

Overall, there was no direct correlation between PT failure and the method used for species identification.

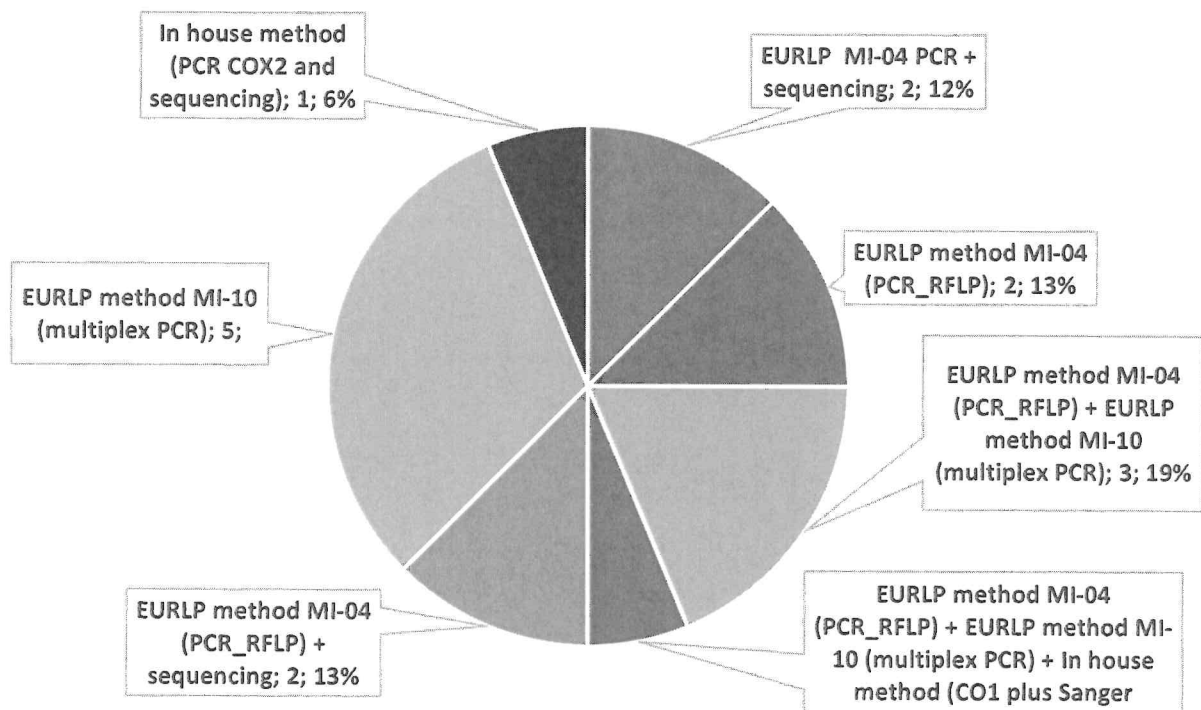


Figure 1. Number and percentage (%) of participants applying the different methods for the PT2026. *Include also one participant that used an internal procedure coinciding with EURLP method MI-04 and MI-10.

Comments and recommendations based on the outcomes of PT: At the time of the preparation of this report, specific reasons for the PT failure could not be analyzed. A request to fill in a follow-up form will be forwarded to participants that failed the PT after this Report publication and eventually discussed during the NRL Annual Workshop to be held at Istituto Superiore di Sanità in October 2026. However, the participants

that performed ITS1 sequencing provide the electropherograms. For AMM05 the obtained sequence was very short and corresponded to a region identical in *A. simplex* ss, *A. pegreffii*, *A. simplex* C (*A. berlandi*) and the *A. simplex*/*A. pegreffii* hybrid genotype. For AMM06 and AMM15, in the electropherogram was evident a mixed nucleotide position (C or T) corresponding to the last nucleotide of a *Hinf*I sequence, being responsible for missing digestion by this enzyme and being indicative of hybrid genotype. This clearly indicates an incorrect interpretation of sequencing results.

Overall, the reason for the PT failure could be due to:

- Errors or inappropriate changes made by the operator during the DNA extraction or PCR amplification steps.
- Exchange of PT objects during the analysis phase.
- DNA contamination during the analysis phase.
- Incorrect interpretation of DNA fragments observed during the electrophoresis run.
- Incomplete removal of ethanol used to preserve the larvae.
- Errors or inappropriate changes made by the operator during the DNA extraction or PCR amplification steps.
- Use of unsuitable reagents during the DNA extraction or PCR amplification steps.
- Incorrect interpretation and analysis of sequencing results is a

During a PT, the application of multiple methods or, in case of PCR and sequencing, of different target genes/sequences, might improve the overall performance of the participant. Compared to previous years the number of participants is stable, but the number of those failing has significantly increased (69%) in comparison to previous years (Figure 2). This suggests that the inclusion of more challenging PT items (e.g. the hybrid genotype) can help to highlight either weakness or strength in the competence of the participant. The overtime comparison indicates that participants that have failed in previous year have the tendency to fail again time by time. However, for some participants, efforts were made to improve the correct application of the molecular identification tests in place.

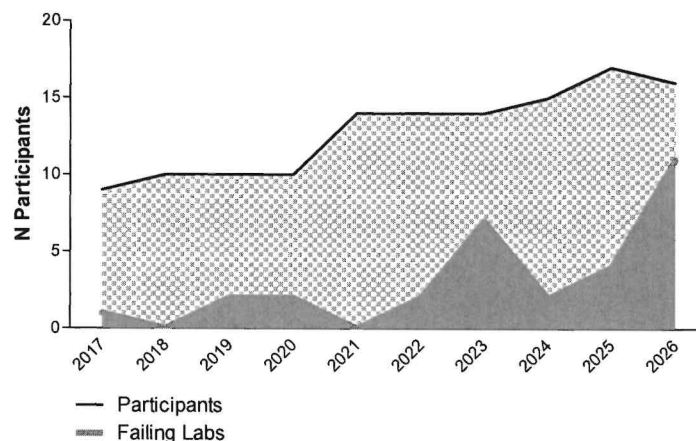


Figure 2. PT07 trend overtime



Written and elaborated by
PTP person in charge

Dr. Marco Lalle

Date 27/05/2026

Verified and issued by
The Director

Dr. A. Casulli

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.
3. Participants may use this report to support their skills to the accreditation body and other interested parties.
4. The accreditation, according to the ISO/IEC 17043 international standard, is regulated by a specific agreement and recognizes the technical competence of the PTP to organize PT schemes. The accreditation body, ACCREDIA (www.accredia.it), does not take any responsibility for the activities related to production of PT items and participants results evaluation.

End of the report

PT Provider
Unit of Foodborne and Neglected Parasitic Diseases
Istituto Superiore di Sanità

viale Regina Elena, 299 – 00161 Rome, Italy



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Person in charge of PT: Dr. Marco Lalle
e-mail: marco.lalle@iss.it;
tel: +39 0649902670