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

Instructions

PT ITEMS

Description. Each PT item consists of a vial containing swine serum positive or negative for anti-Trichinella IgG. The PT panel consists of three PT items.

Production. Matrix consists of swine serum. Analyte consists of anti-*Trichinella* IgG. Serum samples were collected from *Trichinella* spp. infected swine as well as from *Trichinella* free swine.

Distribution. Positive and negative sera were aliquoted (100µl) in vials and preserved in 1% merthiolate at a final dilution of 1:10.000. Due to the nature of the PT items, production and distribution are made some days before the shipping data and PT items are stored at temperature below +15°C.

Labeling. Each PT item is plugged and sealed with plastic film, labeled with a unique code not attributable to tube contents.

Homogeneity check. Homogeneity is ensured by providing participants with aliquots of the same serum preparations.

Packaging. Each PT panel (consisting of three PT items) is placed in a larger container (e.g. 50ml tube) to ensure that they remain grouped and protected during handling and transport. The larger container is labelled with participant code. The PT panel is placed inside a polystyrene carton, ready for shipment. Several ice packs are arranged in the package to maintain internal temperature below +15°C.

Stability and quality control. The stability of PT items in the package has been evaluated by *ad hoc* experiments made by PT provider (EURL-P) on vacuum sealed samples stored below +15°C. Quality control requires that PT provider's staff analyse sera to produce PT items. Sera are tested by EURL-P internal methods, accredited according to ISO 17025, "Detection of anti-*Trichinella* antibodies in swine serum by indirect ELISA" and confirmed by EURL-P internal methods, accredited according to ISO 17025, "Identification of *Trichinell*a spp. proteins recognized by specific IgG in serum of infected pigs by western blotting"

SUBMIT A PARTICIPATION REQUEST

The PT provider (EURL-P) announces the PT via e-mail addressed to potential participant. The email provides information on: PT items shipping date, PT scheme scheduled, the link to the participation form and the deadline, a summary of all deadline dates for the different phases of the PT scheme and the link to the PT provider's website for further information on PT scheme.

Participation request has to be submitted by completing the participation form (PT request form) within the due date indicated in the form and in the email.

At the time of PT items shipment, the PT provider sends participants a link to the on-line form where participant is requested to provide the following information:

- Package content and its condition of preservation
- Timing of analysis
- Materials and Methods used to analyze PT items
- Results

PT ITEMS STORAGE

- Store PT items refrigerated at a temperature below +15°C until the analysis is performed
- Check the packaging and its contents for correctness and completeness: three PT items properly labeled, vacuum sealed, internal temperature of the package below +15°C
- Record the verification of the packaging upon arrival in the on-line form (see point 3)
- In case of discrepancy, fill in the claim form available at EURL-P website: https://www.iss.it/documents/20126/6678302/Claim-Appeal-rev-1.pdf/f9bba72e-3032-88fd-9d05-2b04ad45d1f1?t=1716802008339 or contact via e-mail the person in charge of the PT

PT ITEMS ANALYSIS

1. The code assigned to participant is reported both on a paper sheet contained in the package and on the secondary envelope containing the PT panel.
2. PT items treatment:

- Treat PT items as routine samples
- record the code reported on the larger container (participant code) and the code written on each PT item (PT item identification code).
- handle PT items according to safety procedures required for infectious biological material, i.e. wearing personal protective equipment (coat, mask and gloves)

3. Analysis: each participant is requested to apply any method suitable for the purpose of the scheme, preferably the one used routinely
4. Results: each participant is requested to indicate the assigned code, the PT item codes and positivity or negativity of each tested PT item, together with the IgG titer found in each positive PT item. Each PT item has to be tested in duplicated, and result of each duplicate has to be reported in the on-line form. It is not allowed to submit results after the due date.

   Results have to be reported on the on-line form addressed to participants by PT provider on the same day the PT items are shipped.

   In the on-line form, participant has to specify if a validated in-house method is used or indicate the commercial kit used or full reference if a published method is applied and report any relevant deviation from the chosen.
5. Deadlines:
   - Shipping is usually performed on Monday
   - PT items should be delivered within 48-72 hours
   - The deadline for results submission is indicated in the annual timetable available on the EURL-P website (https://www.iss.it/en/eurlp-prove-valutative-interlaboratorio), in the PT request form and in results form.
   - The final PT report is published on the EURL-P website according to the annual timetable available online (https://www.iss.it/en/eurlp-prove-valutative-interlaboratorio)
6. Perform evaluation: Result evaluation in qualitative. Result is considered “correct” if the participant properly identifies positive and negative PT items and “incorrect” in case of false positive or false negative identification. Results have to be expressed indicating the IgG titers considered as additional information to compare the performance of tests used and allowing the PT provider a more accurate evaluation of participant performance. Due to the nature of PT items, no statistical parameters are applied for result evaluation. Each result is evaluated against the value assigned by the PT provider. The final evaluation is “positive” if all PT items are correctly identified, otherwise it is “negative”.
7. Report: PT provider drafts the Final PT Report, including, for each participant, information on: i) expected vs observed test classification of each Pt item; ii) the final evaluation and iii) comments and/or recommendations based on participants performance and an updated summary of participant performance over successive PT rounds. To ensure confidentiality each participant is identified by an alphanumeric code changed annually. The final PT report is published on the EURL-P website (https://www.iss.it/en/rapporti-finali-prove-valutative-interlaboratorio) and presented to the National Reference Laboratories during the annual workshop.
8. Follow up: in case of negative result, the PT provider contacts the participant who fails the PT and sends a link to a form where the participant is asked to analyze the causes of failure and indicate the corrective actions planned or implemented.
9. Confidentiality: EURL-P retains the PT Reports for 10 years. PT provider staff signs a confidential agreement regarding acquired data. In the final PT report, each participant is identified by alpha code. The PT provider reserves the right to provide participant PT results to competent authority and accreditation body, upon request. In such cases, the PT provider informs the participant in writing.

For any information or problem related to the web site access, please address:

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