

22nd Annual Meeting of the TSE EURL

Turin 12th-13th May 2025

RAPID AND CONFIRMATORY TESTS PTs: issues and news

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SOME ISSUES ON PTs

- In 2025 we will schedule the PTs in different periods
- Every participant has a ID CODE that is a PERSONAL identification code



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SOME ISSUES ON PTs



One laboratory did not reported the results for a long period after the deadline



Sometime results are reported after the deadline



Data reported are often incomplete



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SOME ISSUES ON PTs



Rapid test results can be reported as “routine test,” 1st or 2nd «alternative test»



there is still some confusion on what «alternative test» means



some NRLs are still not interpreting in the right way what “IN DUPLICATE” means....



some NRLs report more than one cut off



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**SAMPLES
IN
DUPLICATE:**

**ONE BATCH,
ONE PLATE,
ONE CUT-OFF
THE SAME
TECHNICIAN**

	1	2	3	4	5
A	Ctr +	RB2303	RB2307		
B	Ctr +	RB2303	RB2307		
C	Crt -	RB2304			
D	Crt -	RB2304			
E	RB2301	RB2305			
F	RB2301	RB2305			
G	RB2302	RB2306			
H	RB2302	RB2306			



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Guidelines for the participation, execution, and results submission of Proficiency Tests (PTs) organized by EURL TSE



General remarks

Acceptance of participation in the proficiency test(s), confirmed through the form “Call of interest” sent annually by the NRL to the EURL TSE, requires that the following conditions are respected:

**EACH PT
SET
€ 1.000**

**WASTE OF
REFERENCE
MATERIAL!!**



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Biosafety

Bovine material: for “*in vitro*” use only. Considered as hazard group 3 and handled accordingly in a derogated containment level 3 laboratory.

Ovine and caprine material: for “*in vitro*” use only. Considered as a hazard group 3** and handled accordingly in a derogated containment level 3 laboratory.



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Test execution



The laboratory must ensure that the proficiencies test will be carried out within the deadline **by operators trained** to perform the procedure, using calibrated instruments and **appropriate (non-expired) reagents**.

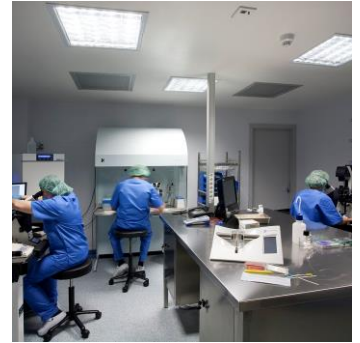
Standard Operating Procedures (SOPs) in use regarding each proficiency test must be submitted with the test results.



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Test execution



All samples of the screening rounds with the rapid test (RB, RS), confirmatory and discriminatory western blot (WB, WS, DB, DS) and *PRNP* sheep and goats genotyping are supplied **as frozen materials and must be stored as such until analysis**, as follows:

- ✚ RB, RS, WB, WS, DB, DS – the samples are homogenates of nervous tissue prepared in an equal volume of distilled water (50/50) and must be stored between -70 °C or -80 °C until analysis.
- ✚ GS, GG – the blood samples in EDTA must be kept at -20 °C until testing.
- ✚ If samples are received thawed, please contact EURL TSE immediately.
- ✚ **Homogenate samples have to be treated as fresh tissue!!**
- ✚ Shake vigorously or vortex each sample after complete thawing and before the analysis.



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Submission of results



- SUBMIT YOUR PT RESULTS WITH ALL THE REQUIRED DOCUMENTATION BY THE DEADLINE!!
- RESULTS SUBMITTED AFTER DEADLINE OR INCOMPLETE SUBMISSIONS WILL NOT BE CONSIDERED
- IF SUBMISSION IS NOT POSSIBLE DUE TO MAJOR ISSUES, PLEASE CONTACT THE EURL BEFORE THE DEADLINE.



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Submission of results



The presentation of results must be performed exclusively on the EURL TSE website at the address: <https://www.eurl-tse.eu> – in the section “*Personal Area*”.

Steps for the submission:

- ✚ Follow the instructions in the “*How to proceed*” section of each PT round.
- ✚ Fill in all fields on the template for each PT round on the EURL TSE website.
- ✚ Enter using the **personal identification code (ID code) notified by e-mail and associated with the reference person** for the PT.
 - ✓ Important: before entering the results of a round, ensure you have the ID code. **Do not use an ID code associated with another colleague, even if they belong to the same Laboratory/NRL.**
 - ✓ For assistance, contact Francesco Ingravalle at the following e-mail addresses:
francesco.ingravalle@izsplv.it; eurl.tse@izsplv.it



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RB, RS, WB, WS



After selecting the test, indicate whether it is used as routine diagnostic activity or an alternative test. If the laboratory uses two or three different methods, the results of all the tests must be submitted separately.

Do not enter the results of the samples by an alternative method (e.g. rapid test O.D.) simultaneously with results obtained by the immunoblot method. A new submission must be done for each method.



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- ✚ Upload the raw data (rapid test O.D.; picture of western blot analysis for each antibody used, indicating the exposure time). Please note a single pdf file with the raw data (blot images) must also be uploaded for any repeated test of the same method.
- ✚ Report information concerning the batch number and expiry of kits or other reagents used in the tests.
- ✚ **GS, GG** - in the “Test Method Used” field, title and details about the method and the approach used (e.g. sequencing analysis, real time PCR with MGB probes, etc.) must be reported to obtain the genotype of the samples.
- ✚ Report any additional information associated with the tests in the “Note” field.

Please note that the instructions for each PT, available on the EURL TSE website, specifically state the procedures to be followed in carrying out the analyses.



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Actions foreseen for non-compliant PTs results

- In the case of non-compliant PT results from an NRL, **a detailed analysis of the causes should be sent** promptly (no later than 5 days) to the EURL TSE who, in collaboration with the laboratory staff, will attempt to resolve the issue.
- Subsequently, **EURL TSE will send a second set of samples** to be analyzed by the laboratory in a timely manner and the results submitted on time.



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Actions foreseen for non-compliant PTs results

- A failure also of the second round will result in an action by EURL TSE staff to assess the state of the laboratory, also by means of **audits and possible new training of technical staff** on the method applied.
- **The persistence of the problems and the lack of cooperation from the NRL following the actions taken by EURL TSE will result in the involvement of the European Commission**, which in agreement with the staff of EURL TSE will assess the appropriate measures to be applied to the laboratory.

Please note that following the failure of a PT circuit the NRL will have to stop its activity and transfer it to another NRL or to the EURL TSE laboratories

until the issue is addressed



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BATCH TESTING PROTOCOL FOR BATCH RELEASE OF TSE RAPID TEST KITS

**To be used by all participating EU TSE National Reference
Laboratories and TSE rapid test kit manufacturers**

REVISION PROPOSAL



Version 02



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ANY OTHER ISSUE?



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