

20th Annual Meeting of the TSE EURL Rome 2nd-3rd October 2023

RAPID TESTS: issues and news

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Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta – Turin
Istituto Superiore di Sanità - Rome

SOME ISSUES ON PTs



...first of all...SORRY
FOR THE PROBLEMS
OF OUR WEBSITE!!



for 2023 we will schedule
again PTs in different
periods (the program will
be available for the
beginning of the year) in
order to facilitate your
activities



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



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**SAMPLES IN
DUPLICATE:**

**ONE BATCH, ONE
PLATE, ONE CUT-
OFF AND 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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**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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PROPOSAL FOR THE REVISION OF BATCH TESTING PROTOCOL

Three significant changes

1

- Reduction of number of positive samples**
in the sample set from 3 to 2 (withdrawing the strong positive)

This to meet the need of reducing the use of TSE positive reference material (scarcity of reference materials, biosafety issues)



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Three significant changes

2

Removal of the manufactures samples set

originally included in order to verify possible issues deriving from the use of water as diluent instead of the specific manufacturer buffer (problems were related to Prionics tests, those showed lower sensitivity with nervous tissue prepared in water; after the withdrawal of Prionics tests from the market this doesn't represent a problem anymore)



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PROPOSAL FOR THE REVISION OF BATCH TESTING PROTOCOL

Three significant changes

3

- ❑ **Addition of a set of small ruminats TSE positive and negative samples** in order to evaluate the reliability of batches released also for TSE monitoring in sheep and goats.



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NEW BATCH TESTING PROTOCOL: NEXT STEPS

ACTIVITIES	DEC 23	JAN 24	FEB 24	MAR 24	APR 24	MAY 24	JUN 24
Publication of the new batch testing release protocol on the TSE EURL website	X						
Supply of BSE samples by the manufacturers to TSE EURL	X						
Supply of Scrapie samples by TSE EURL	X						
BSE homogenates preparation for each test and diagnostic analysis on this reference material		X	X	X			
Scrapie homogenates preparation for each test and diagnostic analysis on this reference material		X	X	X			
Shipment reference material to the manufacturers					X		
Shipment reference material to NRLs and establish ILA						X	
Application of new batch testing release protocol by the NRLs in charge							X



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NEWS IDEXX TEST FOR CERVIDS

HerdChek BSE-SCRAPIE ANTIGEN KIT

Starting with the **EW332** batch, a new cutoff was introduced for cervid samples, approved by the TSE EURL. The new cutoff, reported in insert **06-08519-13**, is shown below:

New cutoff for cervids = $NCx + 0.200$

Previous cutoff for cervids = $NCx + 0.150$



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FOR IMMUNOBLOTTING PTs

Raw data often incomplete



Provide information on all changes made to validated methods (mAbs; pK concentration; incubation time)



Provide a brief description of all methods developed in-house



Provide information on the chemiluminescent substrate



Report the acquisition system to capture PrP signals (autoradiographic film or Image analysis system)



Report the exposure time for each Immunoblotting picture



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ANY OTHER ISSUE?



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