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

RAPID TESTS: issues and news

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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....



SAMPLES IN DUPLICATE:

ONE BATCH, ONE PLATE, ONE CUT-OFF AND SAME TECHNICIAN

	1	2	3	4	5
Α	Ctr +	RB2303	RB2307		
В	Ctr +	RB2303	RB2307		
С	Crt -	RB2304			
D	Crt -	RB2304			
Ε	RB2301	RB2305			
F	RB2301	RB2305			
G	RB2302	RB2306			
Н	RB2302	RB2306			





TSE EURL

Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle d'Aosta – Turin

Istituto Superiore di Sanità - Rome

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



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

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 (scarsity of reference materials, biosafety issues



2

PROPOSAL FOR THE REVISION OF BATCH TESTING PROTOCOL

Three significant changes

□ 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)



3

PROPOSAL FOR THE REVISION OF BATCH TESTING PROTOCOL

Three significant changes

□ 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.



NEW BATCH TESTING PROTOCOL: NEXT STEPS

ACTIVITIES	DEC 23	JAN 24	FEB 24	MAR 24	APR 24	MAY 24	JUN 24
Pubblication 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



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:

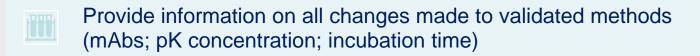
New cutoff for cervids = NCx + 0.200

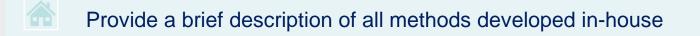
Previous cutoff for cervids = NCx + 0.150



FOR IMMUNOBLOTTING PTs

Raw data often incomplete

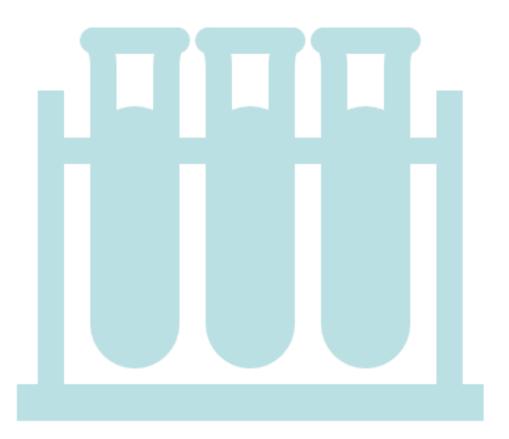




- Provide information on the chemiluminescent substrate
- Report the acquisition system to capture PrP signals (autoradiographic film or Image analysis system
- Report the exposure time for each Immunoblotting picture



ANY OTHER ISSUE?





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