

# 21<sup>st</sup> Annual Meeting of the TSE EURL



Rome 13<sup>rd</sup> -15<sup>th</sup> May 2024

Rapid Tests EQA (RB & RS): results of the 2023 round and forthcoming 2024 round

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# Results of the 2023 EQA round

## BSE



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# Results of the 2023 EQA round - BSE

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## 25 Participating MS:

Austria	Germany	Portugal
Belgium	Greece	Romania
Bulgaria	Hungary	Slovakia
Croatia	Italy	Slovenia
Cyprus	Latvia	Spain
Czech Republic	Lithuania	Sweden
Estonia	Netherlands	Switzerland
Finland	Norway	
France	Poland	

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1 participating extra UE: North Macedonia



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# Methods of the 2023 EQA round - BSE

## Samples included in the PT

Sample ID	Gold Standard	Dilution	Bovine Tissue Homogenate
RB2301	NEGATIVE	////	NEGATIVE
RB2302	POSITIVE	1:2	POSITIVE
RB2303	NEGATIVE	////	NEGATIVE
RB2304	POSITIVE	1:4	POSITIVE
RB2305	POSITIVE	1:4	POSITIVE
RB2306	NEGATIVE	////	NEGATIVE
RB2307	NEGATIVE	////	NEGATIVE

RB2301 = RB2303 = RB2306 = RB2307  
RB2304 = RB2305



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# Methods of the 2023 EQA round - BSE

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**Homogeneity**  
**Stability**



**Distribution date 17<sup>th</sup> – 18<sup>th</sup> July 2023**

**Deadline 31<sup>st</sup> August 2023 (extended to 18<sup>th</sup> September 2023)**



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# 2023 EQA round - BSE



All labs have passed  
this PT round



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# Results of the 2023 round of EQA - BSE

## TeSeE SAP Combi Kit - BioRad

Batch #	# of NRL per batch routine	# of NRL per batch alternative
3C0089	3	2
2K0088	7	1

10 labs use this test as routine and 3 labs as alternative



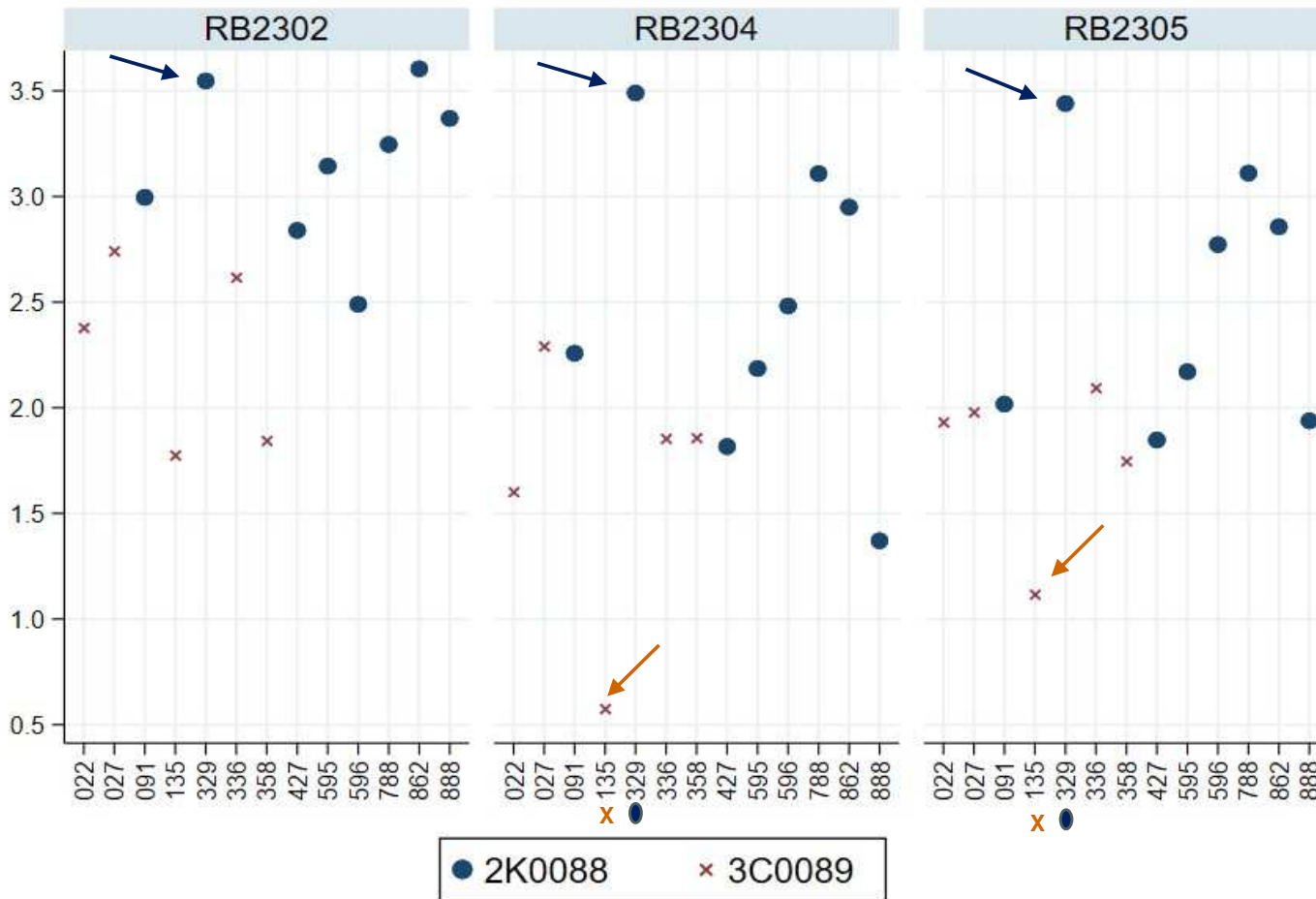
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# Results of the 2023 round of EQA - BSE

## TeSeE SAP Combi Kit - BioRad

OD reported from the labs for each batch and positive samples



Lab 135 (3C0089) reported OD lower than other labs

Lab 329 (2K0088) reported OD higher than other labs



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# Results of the 2023 round of EQA - BSE

## IDEXX Herd-Chek BSE-Scrapie Ag (Short protocol)

Batch #	# of NRL per batch routine	# of NRL per batch alternative
MU803	4	1
BW844	2	////
EW332	1	////
EU608	2	////

9 labs use this test as routine and 1 lab as alternative



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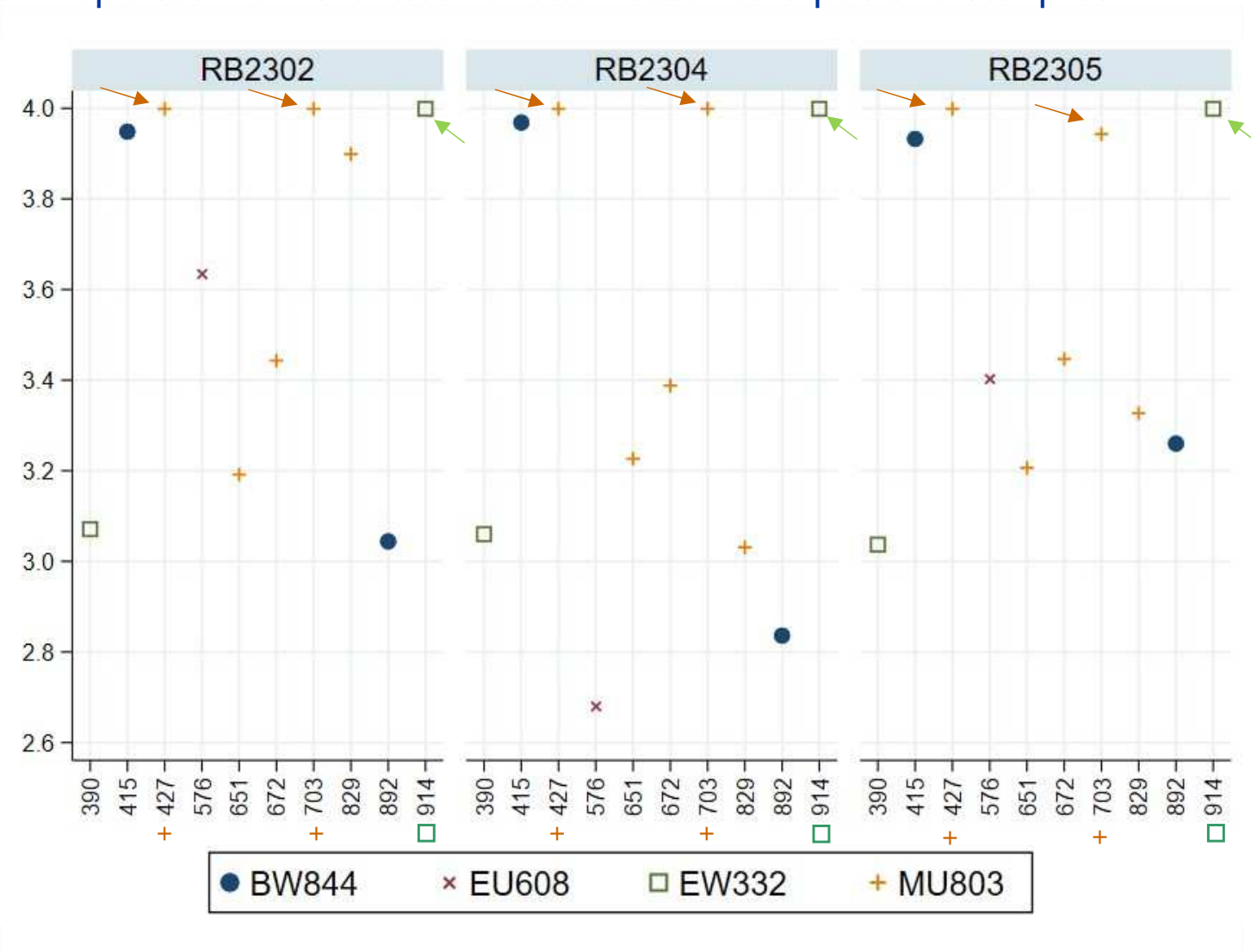
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# Results of the 2023 round of EQA - BSE

## IDEXX Herd-Chek BSE-Scrapie Ag (Short protocol)

OD reported from the labs for each batch and positive samples

Labs 427, 703 and 914 reported overflow values (like: >3.999, or like: >3.5)



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# Results of the 2023 round of EQA - BSE

## Idexx Herd-Chek BSE-Scrapie Ag (Ultra-Short protocol)

Batch #	# of NRL per batch routine	# of NRL per batch alternative
MU803	4	////
BW844	2	////
JU609	1	////

7 labs use this test as routine



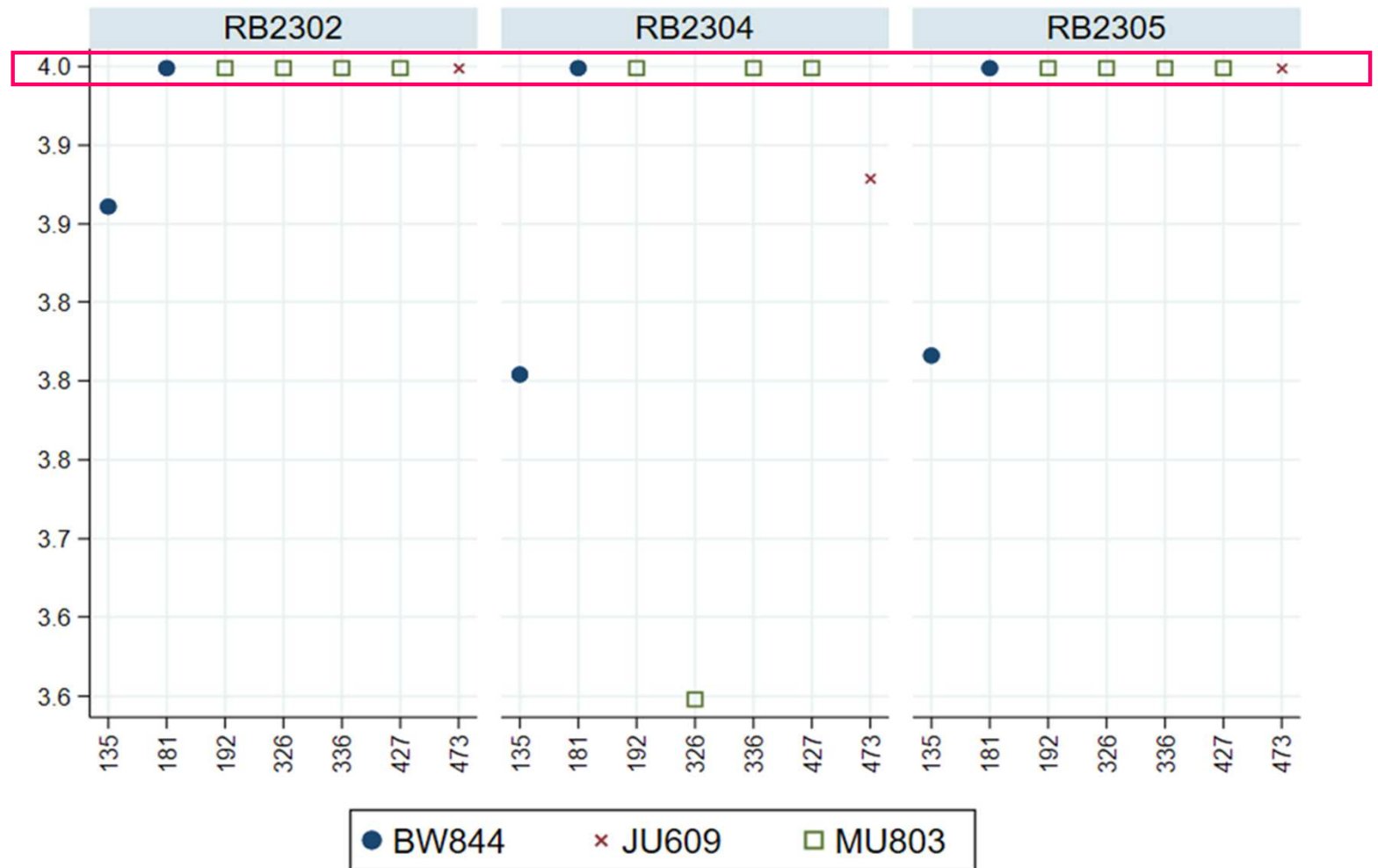
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# Results of the 2023 round of EQA - BSE

## Idexx Herd-Chek BSE-Scrapie Ag (Ultra-Short protocol)

OD reported from the labs for each batch and positive sample



All the labs, excepted 135, reported overflow values



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# Results of the 2023 round of EQA - BSE

## BETAPRION BSE - Roboscreen

Batch #	# of NRL per batch alternative
0323-01	1

**Only one lab used this test as alternative**



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# SHORT CONCLUSIONS: PT BSE

## TeSeE SAP Combi Kit - BioRad

- It was the first most used test in routine: 38% (10/26) of the laboratories. Three labs applied this test as alternative test
- Two batches were applied: 2K0088 (8 labs), 3C0089 (5 labs)
- Lab 135 (batch 3C0089) reported OD lower than other labs; lab 329 (batch 2K0088) reported OD higher than other labs
- No statistical significant differences among participants (Kruskal-Wallis test for sample RB2302, RB2304 and RB2305:  $p = 0.4457$ )
- Statistical significant differences among batches for the sample RB2305 (Kruskal-Wallis test):  $p = 0.0404$ : the large part of participants applied the batch 3C0089 and obtained ODs lower than participants applying the other batch



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# SHORT CONCLUSIONS: PT BSE

## IDEXX Herd-Chek BSE-Scrapie Ag (Short protocol)

- It was the second most used test in routine: 35% (9/26) of the laboratories. One lab applied this test as alternative test
- Four batches were applied: MU803 (5 labs), BW844 (2 labs), EW332 (2 labs) and EU608 (1 lab)
- Three labs (ID: 427, 703, 914) reported overflow values (>3.999', or>3.5')
- No statistical significant differences among participants for the positive samples and cut-off
- No statistical significant differences among batches for the positive samples and cut-off



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# SHORT CONCLUSIONS: PT BSE

## IDEXX Herd-Chek BSE-Scrapie Ag (ULTRA-SHORT PROTOCOL)

- It was the last test used in routine: 27% (7/26) of the laboratories. None applied this test as alternative test
- Three batches were applied: MU803 (4 labs), BW844 (2 labs) and JU609 (1 lab);
- All the labs, except for participant 135, reported overflow values (like: '>3.999', or like: '>3.5')
- No statistical significant differences among participants for the positive samples and cut-off
- No statistical significant differences among batches for the positive samples and cut-off

## BETAPRION BSE - ROBOSCREEN

- Only one participant used this kit as alternative test.
- No statistical evaluation can be performed.



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# SHORT CONCLUSIONS: PT BSE

## QUALITATIVE RESULTS

- General reproducibility among labs about tests used in routine: Cohen's kappa is 1.
- The reproducibility for categorical results (-, +, ++, +++) is very good, excellent: Cohen's kappa is 0.9256 (95%CI: 0.8396 - 1). A slightly increase of the level of the reproducibility from the PT in 2022 was highlighted: Cohen's kappa was 0.8707 (95%CI: 0.7946 - 0.9467)
- Some participants reported different qualitative results in the 2 runs for the same sample
- Good agreement between each lab and the result reported from most part of the labs for each sample: Cohen's kappa is  $> 0.6$  for all participants.



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# Results of the 2023 EQA round

## Scrapie



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# Results of the 2023 EQA round - SCRAPIE

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## 26 Participating MS:

Austria	Germany	Poland
Belgium	Greece	Portugal
Bulgaria	Hungary	Romania
Croatia	Iceland	Slovakia
Cyprus	Italy	Slovenia
Czech Republic	Latvia	Spain
Estonia	Lithuania	Sweden
Finland	Netherlands	Switzerland
France	Norway	

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1 participating extra UE: North Macedonia



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# Methods of the 2023 round of EQA - Scrapie

## Samples included in the PT

Sample ID	Gold Standard	Dilution	Ovine Tissue Homogenate
RS2301	NEGATIVE	////	NEGATIVE
RS2302	POSITIVE	1:4	CLASSICAL SCRAPIE POSITIVE
RS2303	POSITIVE	1:2	CLASSICAL SCRAPIE POSITIVE
RS2304	POSITIVE	1:4	CLASSICAL SCRAPIE POSITIVE
RS2305	POSITIVE	////	ATYPICAL SCRAPIE POSITIVE
RS2306	NEGATIVE	////	NEGATIVE
RS2307	NEGATIVE	////	NEGATIVE

RS2301 = RS2306 = RS2307

RS2302 = RS2304



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# Methods of the 2023 EQA round - BSE

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**Homogeneity**  
**Stability**



**Distribution date 17<sup>th</sup> – 18<sup>th</sup> July 2023**

**Deadline 31<sup>st</sup> August 2023 (extended to 18<sup>th</sup> September)**



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# 2023 EQA round - SCRAPIE

All labs have  
passed the  
PT round

Congratulations!!



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# Results of the 2023 round of EQA - Scrapie

## TeSeE SAP Combi Kit - BioRad

Batch #	# of NRL per batch routine	# of NRL per batch alternative
2K0088	8	1
3C0089	3	2

11 labs use this test as routine and 3 labs as alternative



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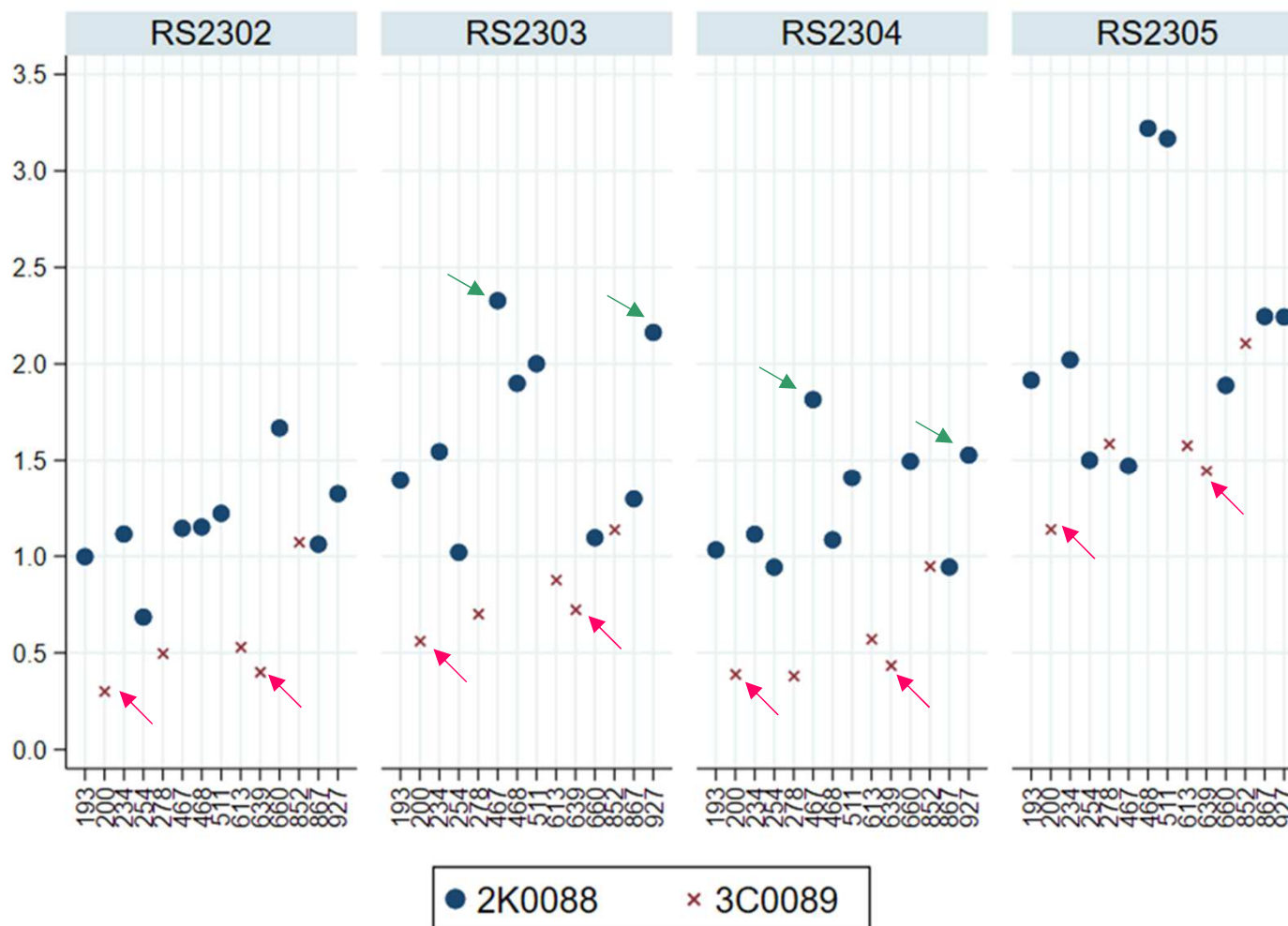
# Results of the 2023 round of EQA - Scrapie

## TeSeE SAP Combi Kit - BioRad

OD reported from the labs for each batch and positive samples

✓ Labs 467 and 927 (batch: 2K0088) often reported ODs higher than others for the positive samples

✓ Labs 200 and 639 (batch: 3C0089) often reported ODs lower than others



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# Results of the 2023 round of EQA - Scrapie

## IDEXX Herd-Chek BSE-Scrapie Ag (Short protocol)

Batch #	# of NRL per batch routine	# of NRL per batch alternative
MU803	7	////
BW844	3	////
EW332	2	////
EU608	1	////

13 labs use this test as routine and 1 lab as alternative



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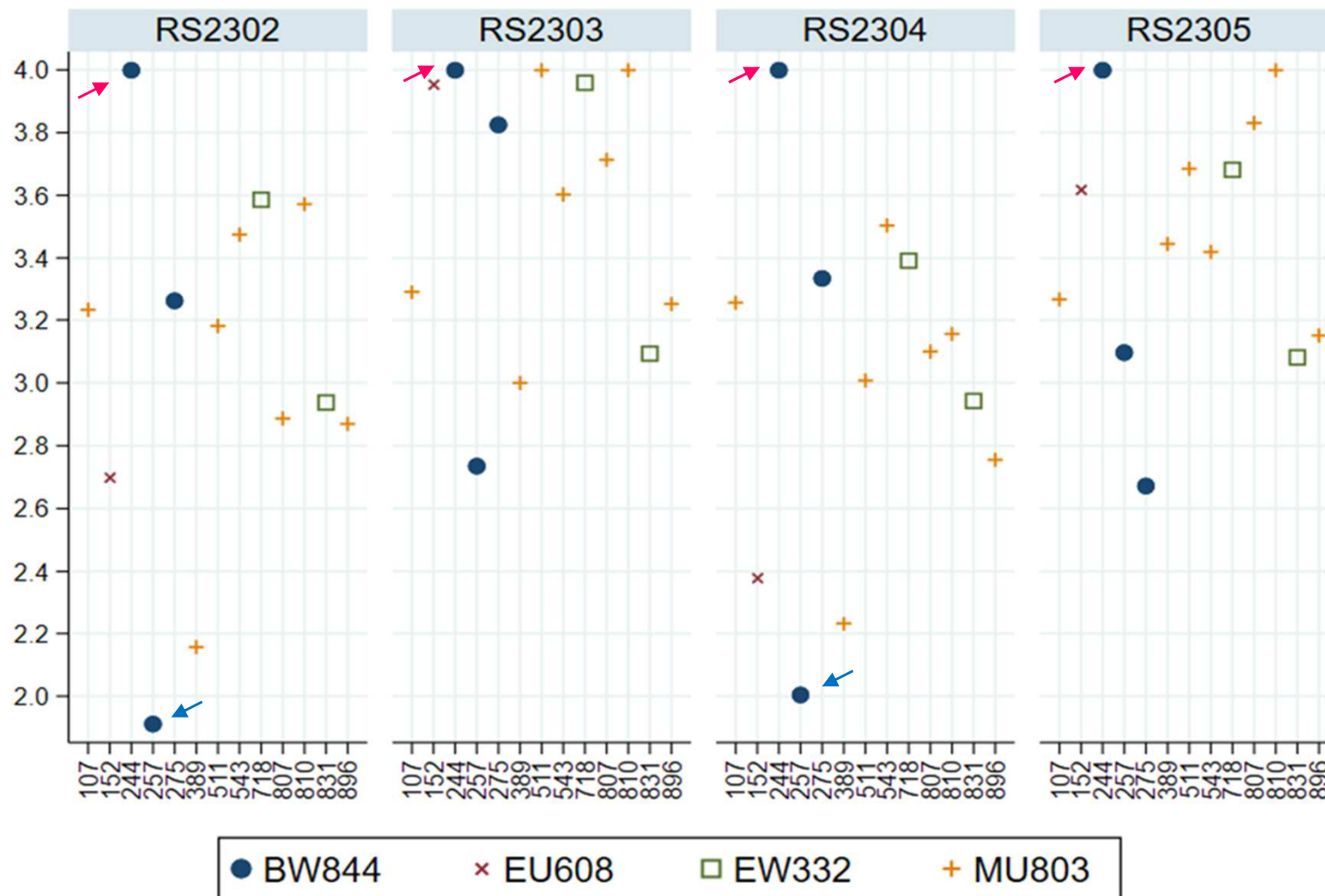
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# Results of the 2023 round of EQA - Scrapie

## IDEXX Herd-Chek BSE-Scrapie Ag (Short protocol)

OD reported from the labs for each batch and positive samples

- ✓ Many labs reported overflow values (>3.999)
- ✓ Lab 244 (batch BW844) reported ODs higher than other labs
- ✓ Participant 257 using batch BW844 usually reported lowest ODs



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# Results of the 2023 round of EQA - Scrapie

## Idexx Herd-Chek BSE-Scrapie Ag (Ultra-Short protocol)

Batch #	# of NRL per batch routine	# of NRL per batch alternative
MU803	1	1
JU609	1	////
BW844	1	////

3 labs use this test as routine and 1 lab as alternative



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# Results of the 2023 round of EQA - Scrapie

## **Idexx Herd-Chek BSE-Scrapie Ag (Ultra-Short protocol)**

OD reported from the labs for each batch and positive sample



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# SHORT CONCLUSIONS: PT SCRAPIE

## TeSeE SAP Combi Kit - BioRad

- It was the second most used test in routine: 41% (11/27) of the laboratories. Three labs applied this test as alternative test
- Two batches were applied: 2K0088 (9 labs), 3C0089 (5 labs)
- Lab 467 (batch: 2K0088) and Lab 927 (batch: 2K0088) often reported ODs higher than others for the positive samples; labs 200 (batch: 3C0089) and 639 (batch: 3C0089) often reported ODs lower than others
- No statistical significant differences among participants
- Statistical significant differences among batches (p-value for Kruskal-Wallis test):  $p = 0.0093$  for RS2302;  $p = 0.0063$  for RS2303;  $p = 0.0063$  for RS2304



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# SHORT CONCLUSIONS: PT SCRAPIE

## IDEXX Herd-Chek BSE-Scrapie Ag (SHORT PROTOCOL)

- It was the first most used test in routine: 48% (13/27) of the laboratories.
- Four batches were applied: MU803 (7 labs), BW844 (3 labs), EW332 (2 labs) and EU608 (1 lab)
- Lab 244 (batch BW844) usually reported ODs higher than other labs. Many labs reported overflow values ( $>3.999$ ). Participant 257 using batch BW844 usually reported lowest ODs
- No statistical significant differences among participants (p-value for Kruskal-Wallis test):  $p = 0.4483$  for the cut-off;  $p = 0.4457$  for RS2302;  $p = 0.4563$  for RS2303;  $p = 0.4457$  for RS2304;  $p = 0.4483$  for RS2305
- **Statistical significant differences among batches only for the cut-off** (p-value for Kruskal-Wallis test):  $p = 0.0187$



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# SHORT CONCLUSIONS: PT SCRAPIE

## IDEXX Herd-Chek BSE-Scrapie Ag (ULTRA-SHORT PROTOCOL)

- Three laboratories, 11% (3/27) of participants. One lab applied this test as alternative test
- Three batches were applied: MU803 (2 labs), BW844 (1 lab), JU609 (1 lab)
- No statistical significant differences among participants (p-value for Kruskal-Wallis test):  $p = 0.3916$  for the cut-off and all positive samples
- No statistical significant differences among batches



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# SHORT CONCLUSIONS: PT SCRAPIE

## QUALITATIVE RESULT

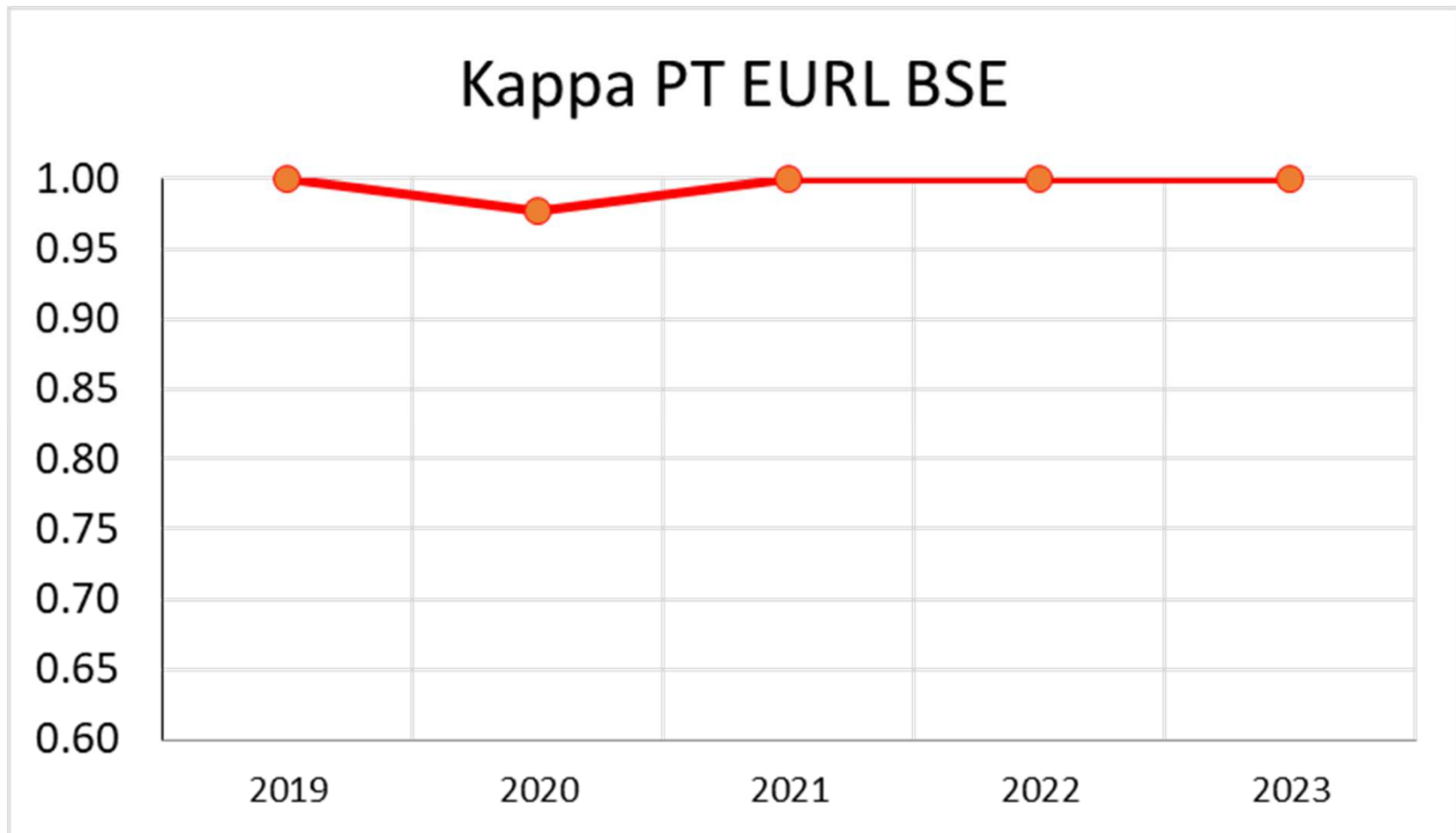
- General reproducibility among labs about tests used in routine: Cohen's kappa is 1
- The reproducibility for categorical results (-, +, ++, +++): is very good, Cohen's kappa is 0.8088 (95%CI: 0.6115 - 1)
- A slight increase of the level of the reproducibility from the previous PT: in 2022 it was substantial, fair to good (Cohen's kappa was 0.6856 (95%CI: 0.4347 - 0.9364)
- Some participant reported different qualitative results in the 2 runs for the same sample
- Agreement between each lab and the Majority Judgment (i.e. the result reported from the most part of the labs for each sample): the lower limit of the 95%CI for Cohen's kappa is higher than 0.6 for 8 participants out of 27. Three participants (193, 278, 639) obtained  $k < 0.6$  (Cohen's kappa = 0.5714, 95%CI: 0.1954 - 0.9475). A decrease in the level of agreement between each laboratory and the majority judgment can be assumed: last year the lower limit of the 95%CI for Cohen's kappa was higher than 0.6 for 13 participants and 2 obtained  $k < 0.6$ .



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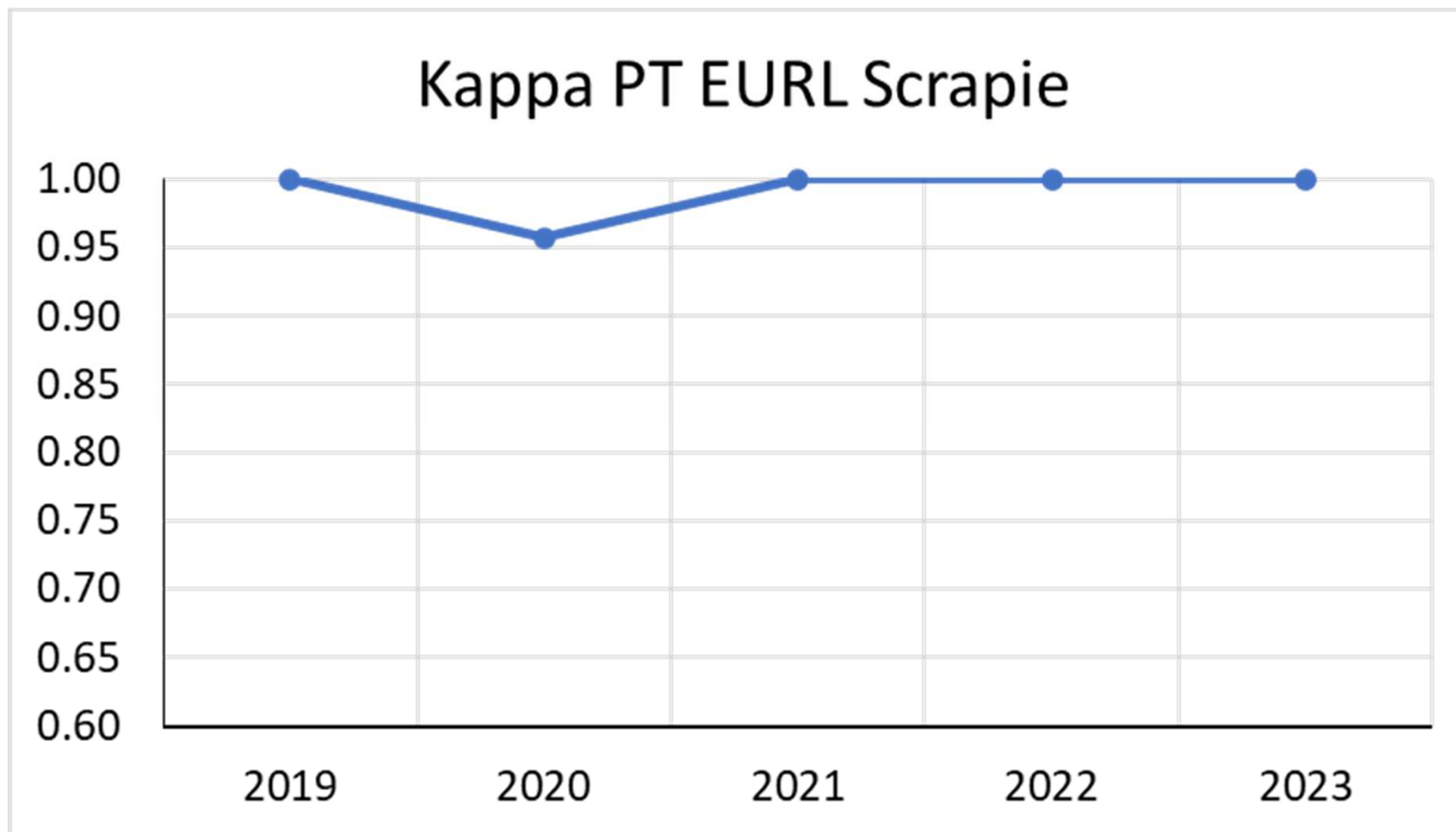




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# The forthcoming 2024 round of EQA Rapid Tests



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# Proficiency Testing -1

- Homogenisation, dilution and creation of aliquots of brain tissue for preparation of Proficiency Samples.
- Analysis by Rapid Tests (IDEXX HerdChek BSE– Scrapie Ag Test Kit and Bio-Rad TeSeE SAP Combi Kit) and Western Blot.
- Interpretation of the results.
- Homogeneity and Stability assessment.



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# Proficiency Testing - 2

- Packaging and dispatch (dry ice - UN3373 – Import permit).
- Scrapie and BSE Rapid Test and Confirmatory Western Blot schemes: same package (delivery).
- Documenting of results: submission by EURL web site.



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# Proficiency Testing - 3

## Timescale

- Dispatch of PTs samples: mid November 2024.
- Deadline to perform the PTs and send back the results to EURL: 3 weeks after the shipment
- Results obtained twice by **the same operator and in the same analysis session** will be required.



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# PTs results



**The results of the PTs round 2024 will be reported at the next TSE EURL Meeting**



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## EURL Contact Rapid Test



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**Thanks for your attention!!!**



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