

20th Annual Meeting of the TSE EURL

Rome 2nd-3rd October 2023

Rapid Tests EQA (RB & RS): results of the 2022 round and forthcoming 2024 round

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Results of the 2022 EQA round

BSE



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Results of the 2022 EQA round - BSE

26 Participating MS:

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

1 participating extra UE: North Macedonia



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Methods of the 2022 EQA round - BSE

Samples included in the PT

Sample ID	Gold Standard	Dilution	Bovine Tissue Homogenate
RB2201	POSITIVE	1:2	POSITIVE
RB2202	NEGATIVE	////	NEGATIVE
RB2203	NEGATIVE	////	NEGATIVE
RB2204	NEGATIVE	////	NEGATIVE
RB2205	NEGATIVE	////	NEGATIVE
RB2206	POSITIVE	1:4	POSITIVE
RB2207	NEGATIVE	////	NEGATIVE

RB2202 = RB2203 = RB2204 = RB2205 = RB2207



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Methods of the 2022 EQA round - BSE



ISO/IEC 17043:2023

Conformity assessment — General requirements for the competence of proficiency testing providers

Homogeneity

Stability

INTERNATIONAL
STANDARD

ISO
17034

General requirements for the
competence of reference material
producers



Distribution date 21 - 22 November 2022

Deadline 16 December 2022



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2022 EQA round - BSE

All labs have passed this PT round



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Results of the 2022 round of EQA - BSE

TeSeE SAP Combi Kit - BioRad

Batch #	# of NRL per batch routine	# of NRL per batch alternative
2F0086	5	2
2C0085	3	1
2H0087	3	////

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



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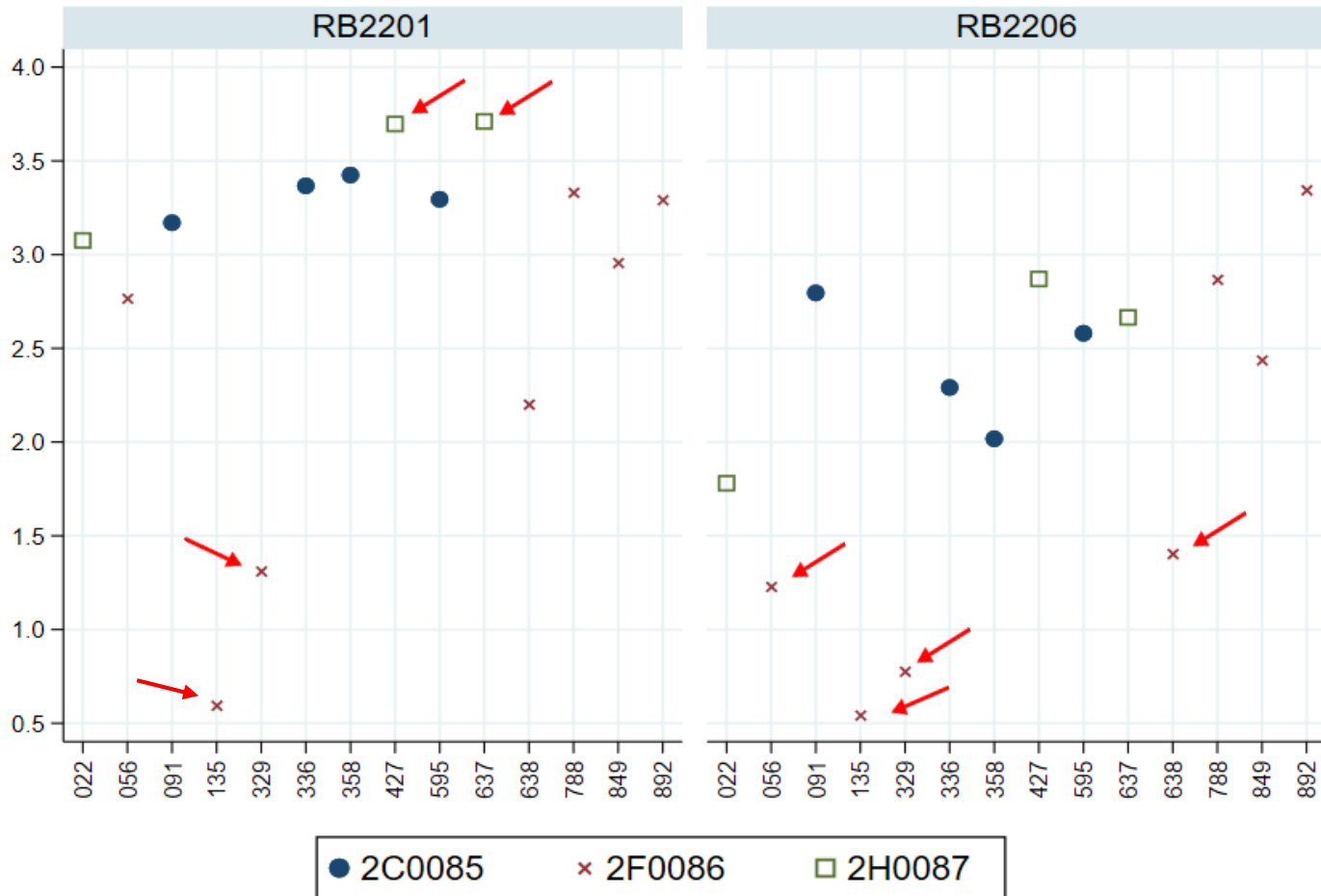
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Results of the 2022 round of EQA - BSE

TeSeE SAP Combi Kit - BioRad

Labs 427 and 637 reported ODs ↑

Labs 135 and 329 reported ODs ↓



OD reported from the labs for each batch and positive samples



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Results of the 2022 round of EQA - BSE

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

Batch #	# of NRL per batch routine	# of NRL per batch alternative
EU608	4	1
AU487	3	////
CU304	2	////

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

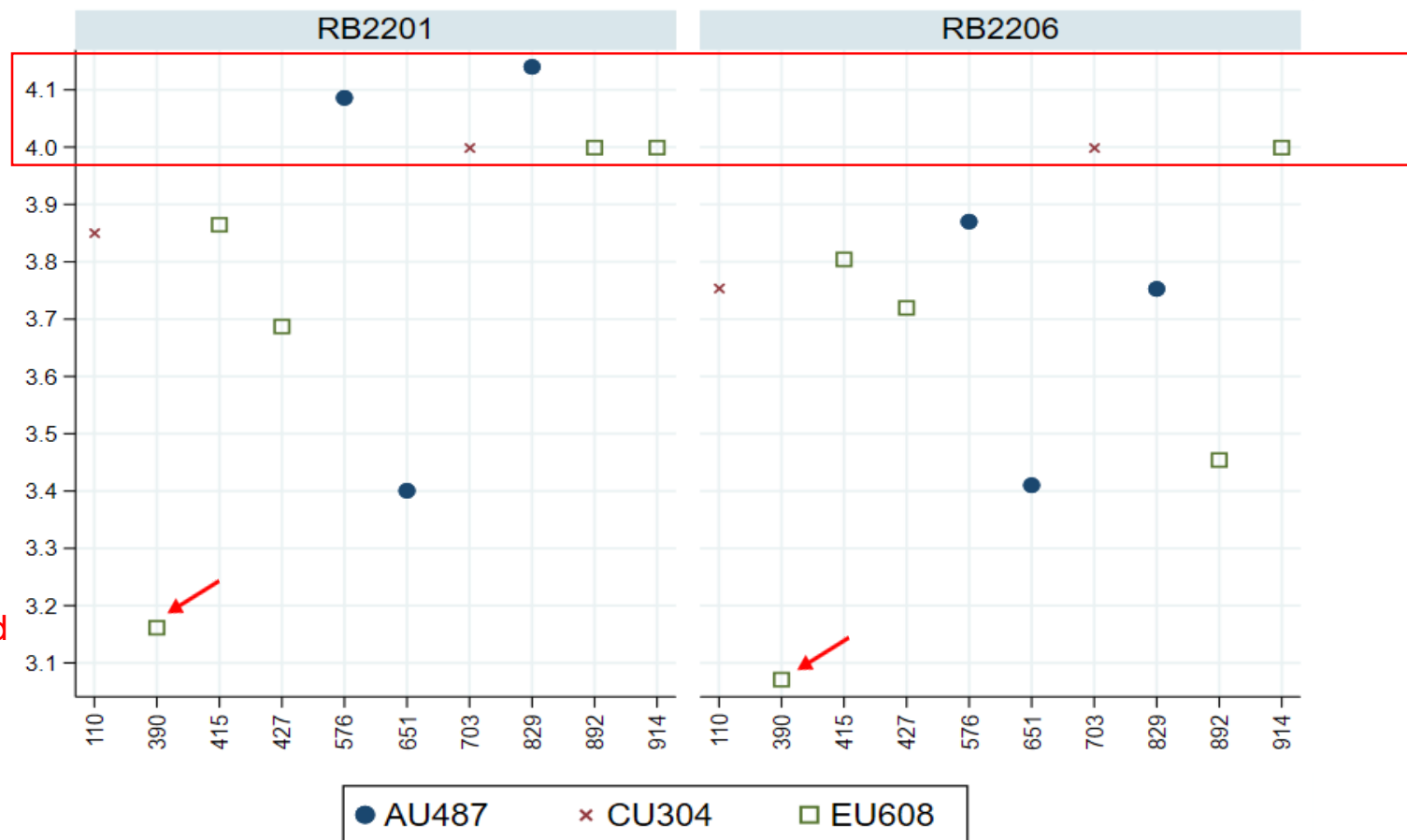


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Results of the 2022 round of EQA - BSE

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



Labs 576, 703, 829, 892 and 914 reported overflow values (>3.999 or >3.5)

Lab 390 reported ODs values ↓

OD reported from the labs for each batch and positive samples



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Results of the 2022 round of EQA - BSE

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

Batch #	# of NRL per batch routine	# of NRL per batch alternative
EU608	5	2
AU487	1	///
JU609	1	///

5 labs use this test as routine and 2 labs as alternative

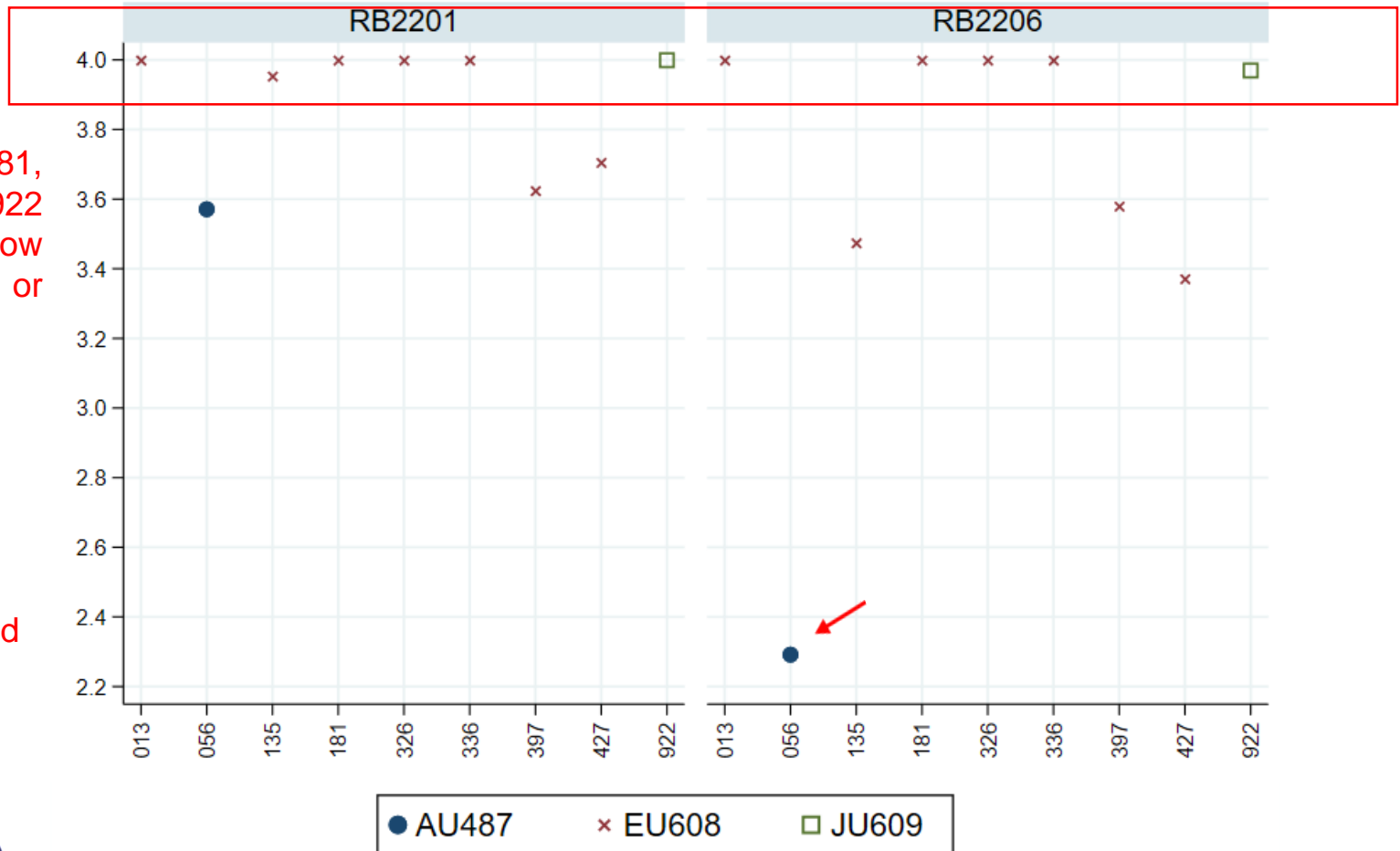


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Results of the 2022 round of EQA - BSE

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



Labs 013, 181, 326, 336 and 922 reported overflow values (>3.999 or >3.5)

Lab 056 reported OD value ↓ for RB2206

OD reported from the labs for each batch and positive sample

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Results of the 2022 round of EQA - BSE

BETAPRION BSE - Roboscreen

Batch #	# of NRL per batch alternative
0422-01	1

Only one lab used this test as alternative



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SHORT CONCLUSIONS: PT BSE

TeSeE SAP COMBI – BioRad

- It is the most used test in routine: 41% (11/27) of the laboratories. Three labs applied this test as alternative.
- Lab 135 (batch 2F0086) and 329 (batch 2F0086) reported ODs lower than other labs; lab 427 (batch 2H0087) and 637 (batch 2H0087) reported ODs higher than other labs.
- No statistical significant differences among participants for two positive samples RB2201 and RB2206.
- Statistical significant differences among batches for the sample RB2201; the large part of participants applied the batch 2F0086, obtained ODs lower than participants applied other batches.



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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: 33% (9/27) of the labs. One lab applied this test as alternative.
- Many labs (ID: 576, 703, 829, 892, 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: 26% (7/27) of the labs. Two labs applied this test as alternative.
- Many labs (ID: 013, 181, 326, 336, 922) reported overflow values (>3.999 or >3.5);
- No statistical significant differences among participants for the only positive sample RB2203.
- No statistical significant differences among batches for the only positive sample RB2203.

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 0.8707 (95%CI: 0.7946 - 0.9467).
- Good agreement between each lab and the result reported from the most part of the labs for each sample: Cohen's kappa is higher than 0.6 for all participants.



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Results of the 2022 EQA round

Scrapie



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Results of the 2022 EQA round - SCRAPIE

27 Participating MS:

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

1 participating extra UE: North Macedonia



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Methods of the 2022 round of EQA - Scrapie

Samples included in the PT

Sample ID	Gold Standard	Dilution	Ovine Tissue Homogenate
RS2201	POSITIVE	1:6	Positive Classical Scrapie
RS2202	NEGATIVE	////	TSE Negative
RS2203	NEGATIVE	////	TSE Negative
RS2204	POSITIVE	1:3	Positive Classical Scrapie
RS2205	POSITIVE	1:3	Positive Classical Scrapie
RS2206	POSITIVE	1:6	Positive Classical Scrapie
RS2207	NEGATIVE	////	TSE Negative

RS2202 = RS2203 = RS2207; RS2201 = RS2206; RS2204= RS2205



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Methods of the 2022 EQA round - SCRAPIE



ISO/IEC 17043:2023

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Stability

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2022 EQA round - SCRAPIE

All labs have passed the PT round



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Results of the 2022 round of EQA - Scrapie

TeSeE SAP Combi Kit - BioRad

Batch #	# of NRL per batch routine	# of NRL per batch alternative
2F0086	6	1
2C0085	4	1
2H0087	3	////

13 labs use this test as routine and 2 lab as alternative

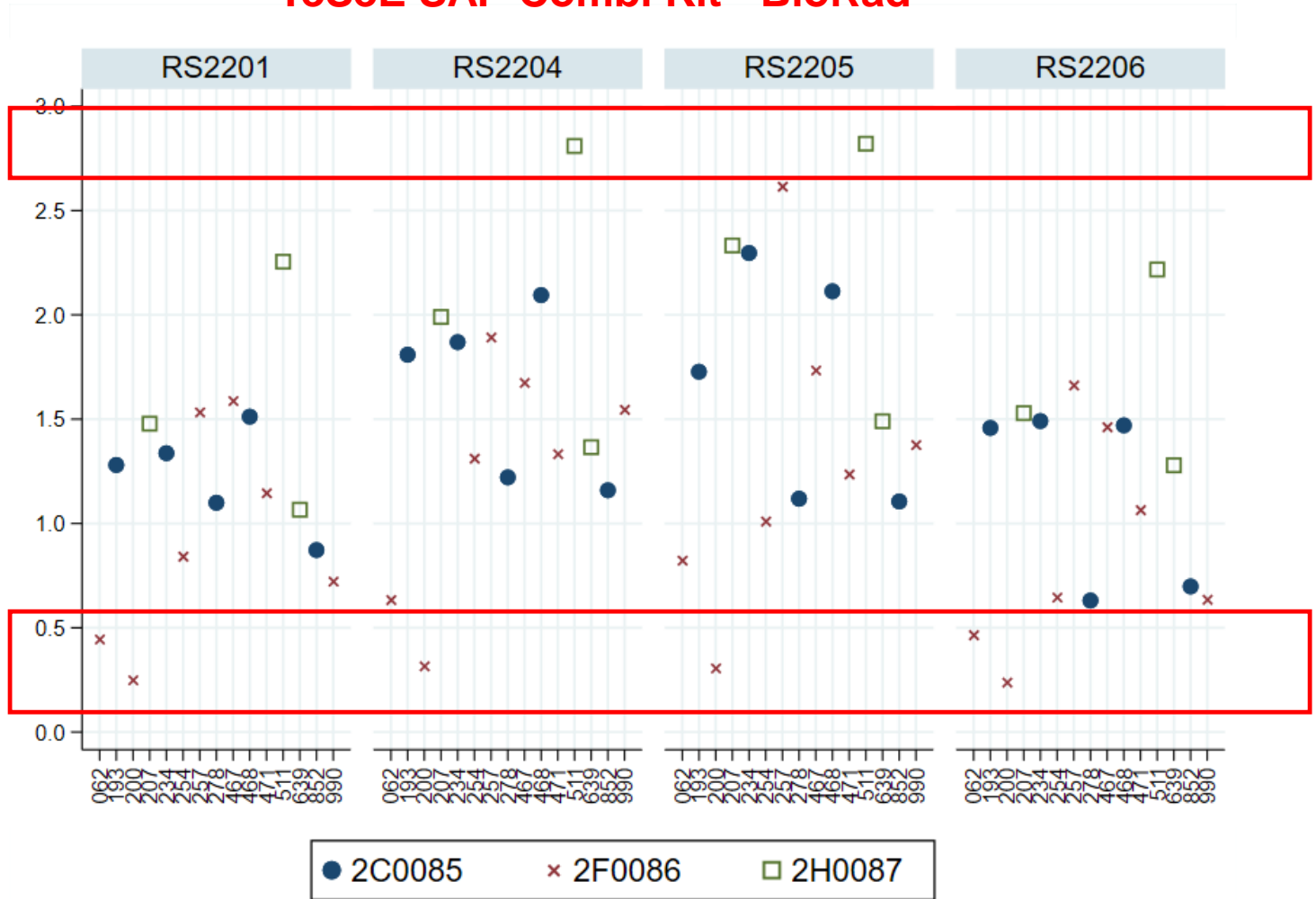


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Results of the 2020 round of EQA - Scrapie

TeSeE SAP Combi Kit - BioRad



OD reported from the labs for each batch and positive samples

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Results of the 2022 round of EQA - Scrapie

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

Batch #	# of NRL per batch routine	# of NRL per batch alternative
AU487	4	///
EU608	4	2
CU304	1	///

9 labs use this test as routine and 2 lab as alternative

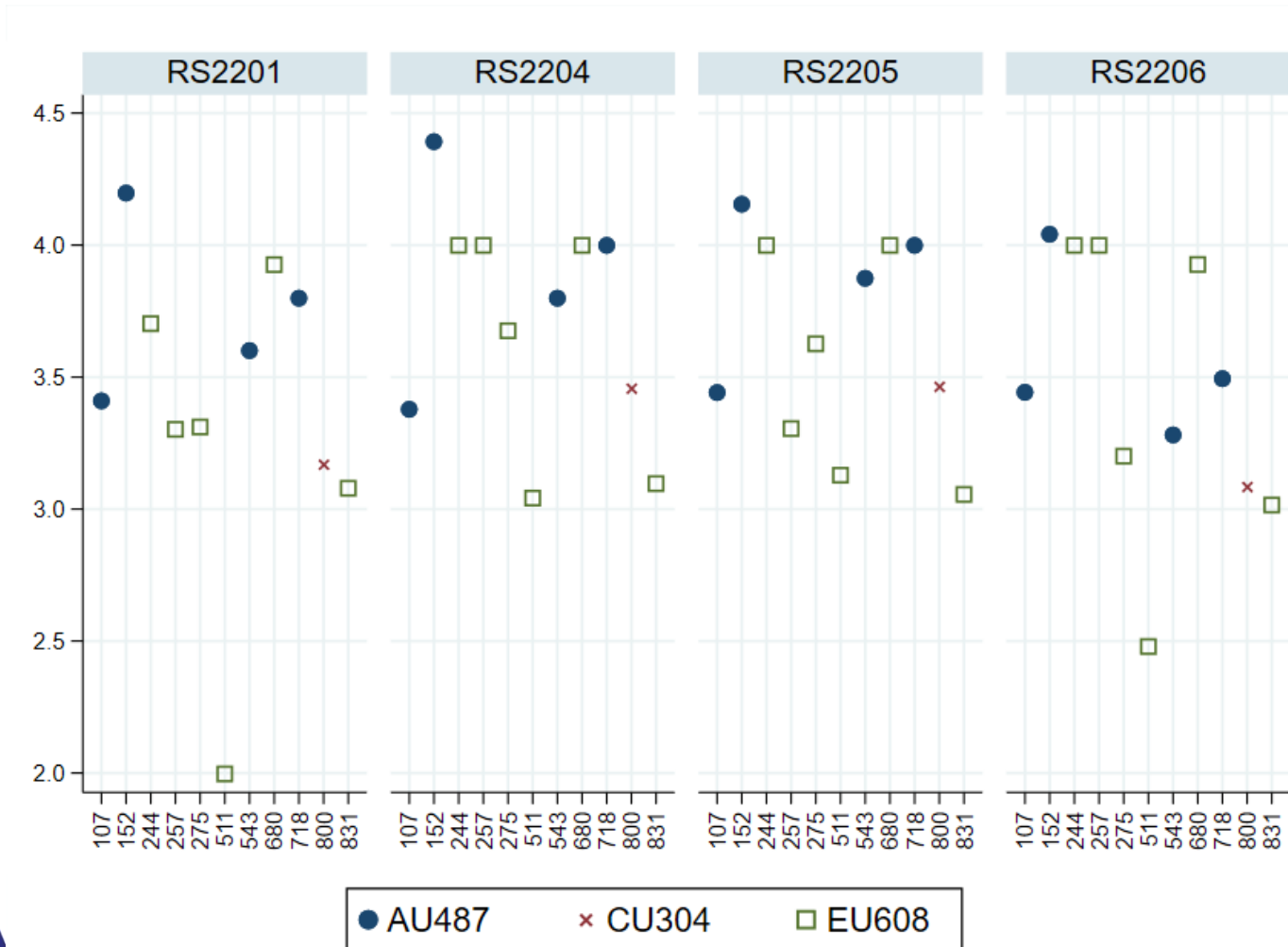


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Results of the 2020 round of EQA - Scrapie

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



Labs 152, 244, 680 reported ODs ↑

Labs 511 and 831 reported ODs ↓



OD reported from the labs for each batch and positive samples

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Results of the 2022 round of EQA - Scrapie

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

Batch #	# of NRL per batch routine	# of NRL per batch alternative
EU608	3	2
JU609	1	////
CU304	1	////
AU487	1	////

6 labs use this test as routine and 2 lab as alternative



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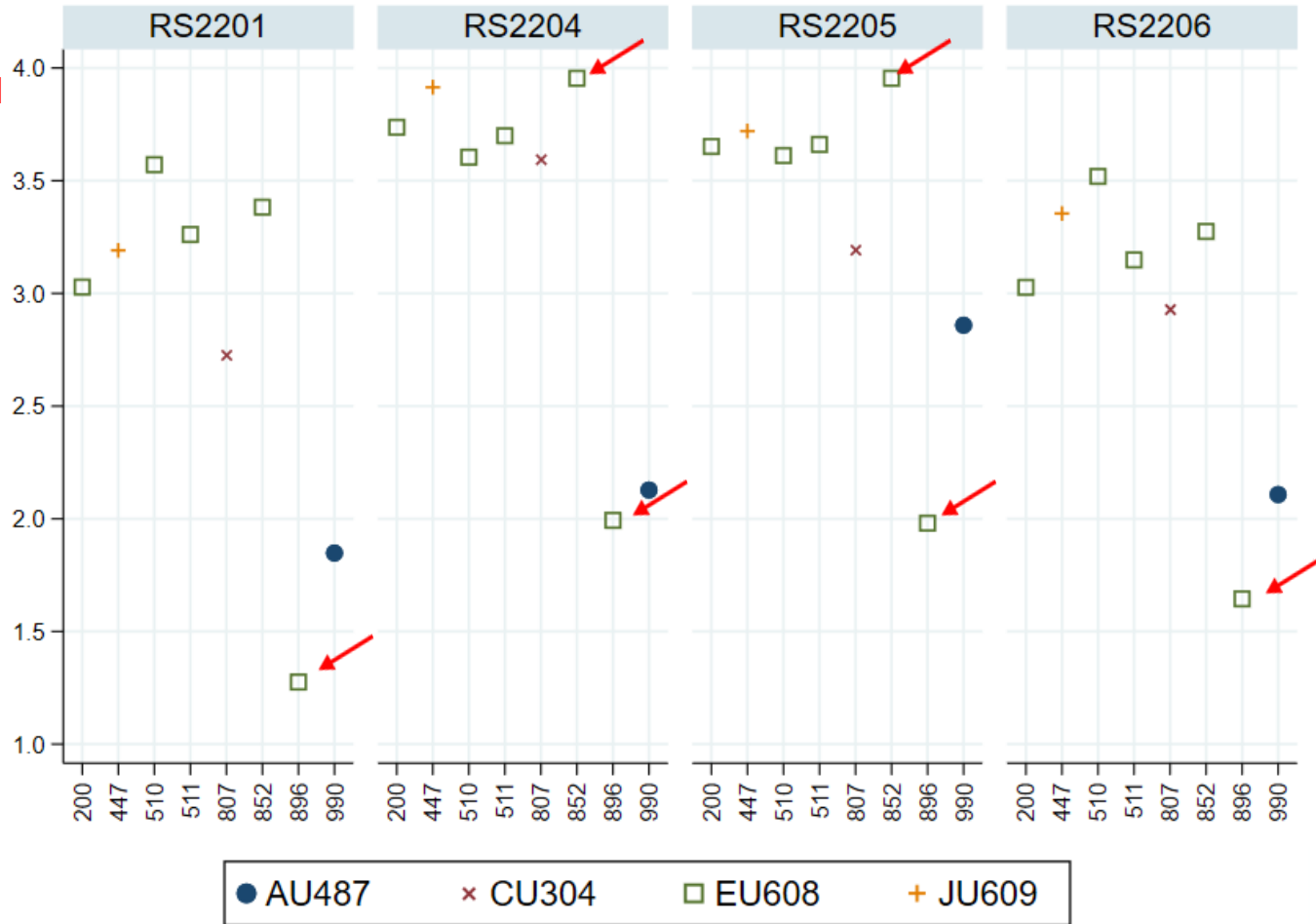
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Results of the 2020 round of EQA - Scrapie

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

Lab 852 reported
ODs ↑

Lab 896 reported
ODs ↓



OD reported from the labs for each batch and positive sample

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SHORT CONCLUSIONS: PT SCRAPIE

TeSeE SAP COMBI – BioRad

- It was the first most used test in routine: 46% (13/28) of the laboratories. Two labs applied this test as alternative.
- Lab 511 (batch: 2H0087) reported ODs higher than others for the positive samples; labs 200 (batch: 2F0086) and 062 (batch: 2F0086) reported ODs lower than others.
- No statistical significant differences among participants.
- Statistical significant differences among batches only for the cut-off.



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SHORT CONCLUSIONS: PT SCRAPIE

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

- It was the second most used test in routine: 32% (9/28) of the laboratories. Two labs applied this test as alternative.
- Lab 152 (batch AU487), 244 (batch EU608) and 680 (batch: EU608) usually reported ODs higher than other labs. Many labs reported overflow values (>3.999). Participant 831 using batch EU608 usually reported lowest ODs.
- No statistical significant differences among participants for the cut-off and for all positive samples.
- Statistical significant differences among batches only for the cut-off.



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SHORT CONCLUSIONS: PT SCRAPIE

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

- Six laboratories, 21% (6/28) of participants applied this test in routine. Two labs applied this test as alternative test.
- Lab 852 (batch: EU608) usually reported ODs higher than other labs. None reported overflow values (>3.999); Lab 896 (batch EU608) usually reported lowest Ods.
- No statistical significant differences among participants for the cut-off and 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 fair to good, Cohen's kappa is 0.6856 (95%CI: 0.4347 - 0.9364).
- Good agreement between each lab and the result reported from the most part of the labs for each sample: Cohen's kappa is higher than 0.6 for 13 participants out of 28. Two participants (257, 990) obtained $k < 0.6$ (Cohen's kappa = 0.5377; 95%CI: 0.1297 - 0.9458).



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The ongoing 2023 round of EQA Rapid Tests



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..some data are still missing

...but as an overall also for 2023 PTs results are compliant!



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PTs results

**The results of the PTs round 2023 and
2024 will be reported at the next TSE
EURL Meeting**



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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 June 2024.
- Deadline to perform the PTs and send back the results to EURL: 3 weeks after the shipment (*there will be no more extensions to the deadline*).
- Results obtained twice by the same operator and in the same analysis session will be required.



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**THANK YOU
FOR YOUR
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