Animal & Plant Health Agency

TSE EURL
EQA Activities
2018

Carmen Garcia-Pelayo & Daniele Khor

Pathology Department

APHA Weybridge

OVERVIEW

- Rapid Testing PT Exercises
- Western Blotting PT Exercises
- EU-Approved Rapid-Test Batch Approval
- Manufacturer Test Kit Changes
- Genotyping PT Exercise

Rapid Testing: BSE Rapid Test
PT0029
Distribution 13430/SE - 24.07.2018

- 26 laboratories participated in the PT scheme.
- The panel included 2 negative, 1 weak positive, 2 medium positive and 2 strong positive samples.
- Participants passed the PT round using:
  - Bio-Rad TeSeE SAP
  - IDEXX Herdchek
  - Prionics Check PrioSTRIP
  - Roboscreen BetaPrion
- **The BSE Rapid Test PT round was completed successfully by all participants.**
- **There was one transcription error resolved at the time of data review.**

BSE Rapid Testing PT Trends 2009-2018

Lab Code	BSE Rapid Test PT0029									
	6290/SE 28/07/09	6815/SE 27/07/10	8363/SE 26/07/11	10687/SE 24/07/12	11161/SE 23/07/13	11619/SE 19/08/14	12045/SE 28/07/15	12456/SE 26/07/16	12961/SE 25/07/17	13430/SE 24/07/18
1016/2227										
1034/2152	●1034									
1054/1705										
1078/1774										
1094/1237										
1110/1243										
1232										
1247/2306										
1301/1314										
1349										n.d.
1374/2042/1113	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
1392/1406/1281										
1429/2261										
1489/1803										
1492										
1510/2233										
1539/ 1672/ 2069/ 2504					n.d.	n.d.				
1589							n.d.	n.d.	n.d.	n.d.
1643										
1656/1763										n.d.
1680/1772										
1859/2188										
1870										
1898/2198										
2012/2081										
2035										●

Passed

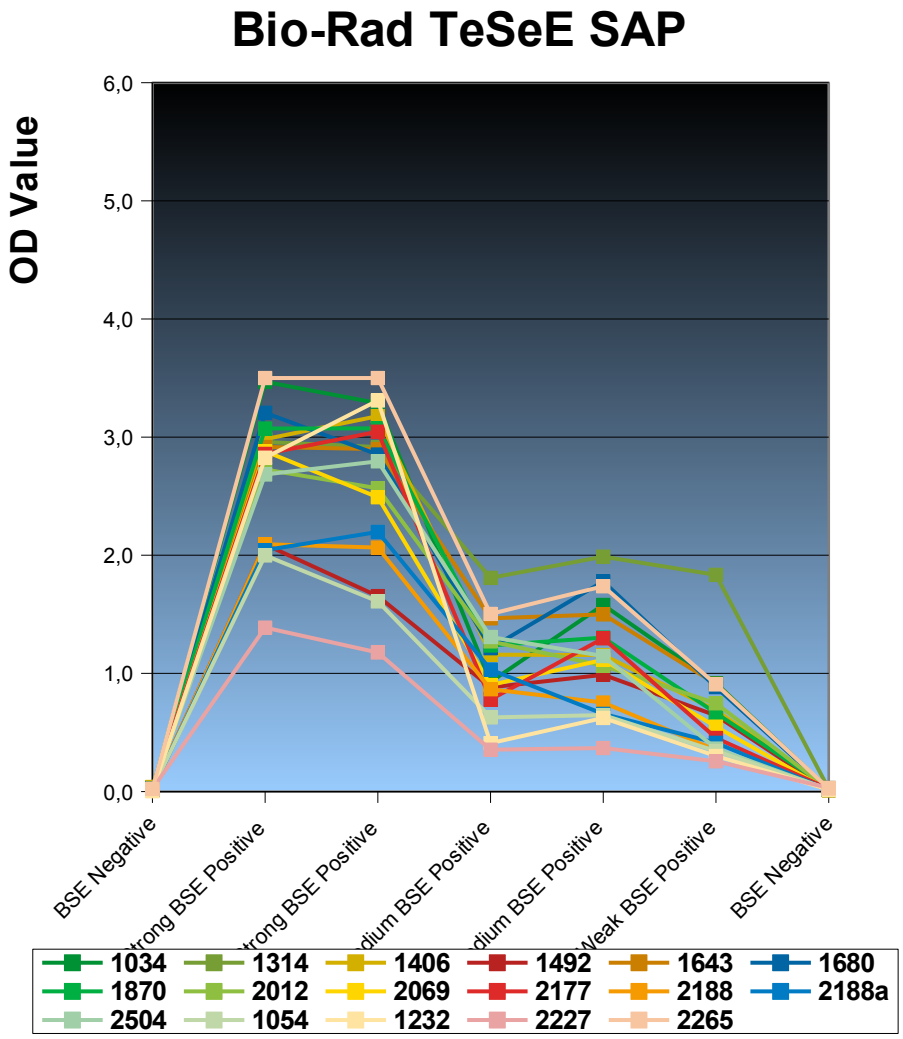
Passed on 1st repeat EQA

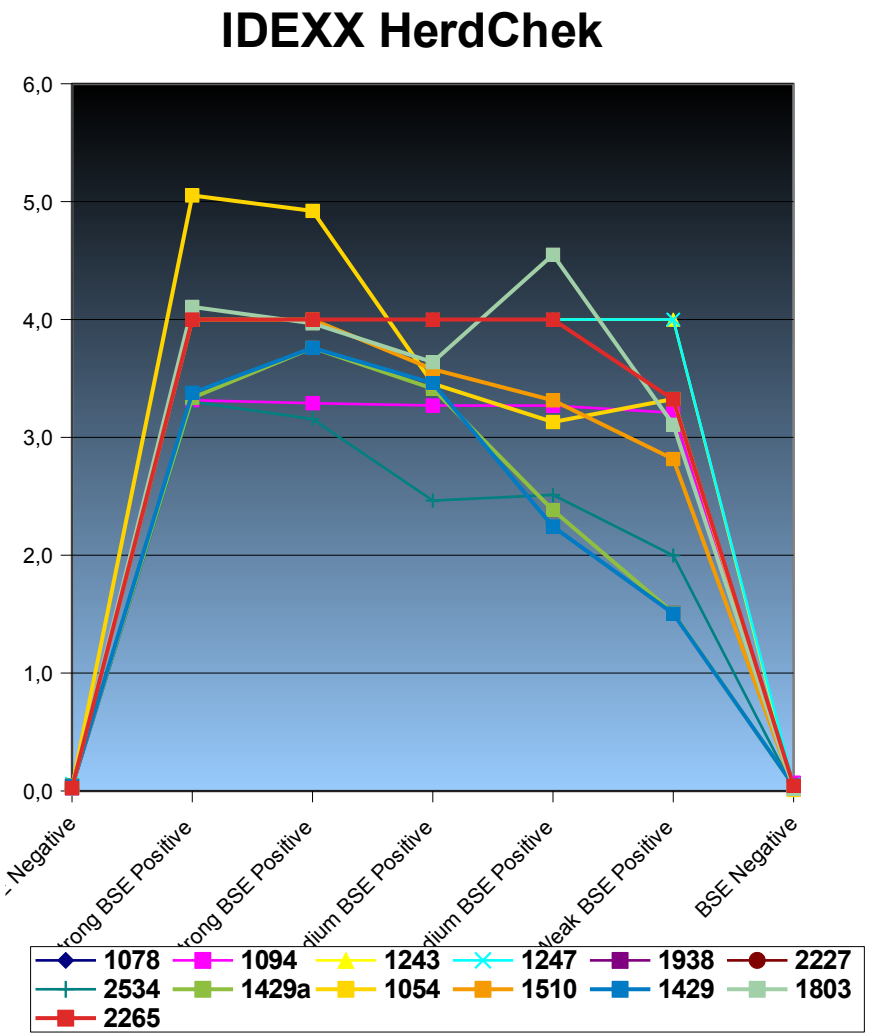
Passed on 2nd repeat EQA

Failed

● This was dealt with by investigation no repeat round sent.

BSE Rapid Testing PT Results 2018





Rapid Testing: Scrapie Rapid Test
PT0095
Distribution 13547/SE - 23.10.2018

- 28 laboratories participated in the PT scheme.
- The PT sample panel included 3 negatives, 2 weak classical scrapie, 1 medium classical scrapie and 1 strong classical scrapie sample.
- Participants passed the PT round using:
  - Bio-Rad TeSeE SAP
  - IDEXX Herdchek
- **The Scrapie Rapid Test PT round was completed successfully by all participants.**
- **There was one transcription error resolved at the time of data review.**

Scrapie Rapid Testing PT Trends 2009-2018

Lab Code	Ovine TSE Rapid Test PT0095									
	6475/SE 24/11/09	6944/SE 23/11/10	8532/SE 22/11/11	10851/SE 27/11/12	11281/SE 29/10/13	11735/SE 28/10/14	12156/SE 27/10/15	12571/SE 25/10/16	13088/SE 24/10/17	13547/SE 23/10/18
1016/2227								2227		
1034/2152			1034							
1054/1705									1054	
1078/1774										
1094/1237								1094	1094	
1110/1243										
1232										
1247/2306									1247	
1301/1314										
1349		n.d.							n.d	n.d
1374/2042/1113	n.d.	n.d.	n.d.	n.d.	n.d.	n.d	n.d	n.d	n.d	n.d
1392/1406/1281										
1429/2261								1429	1429	
1489/1803									1803	
1492										
1510/2233										
1539/ 1672/ 2069/ 2504										
1589						n.d	n.d	n.d	n.d	n.d.
1643										
1656/1763								1656		
1680/1772										
1859/2188										
1870										
1928/2198										
2012/2081										
2025					••					

Passed

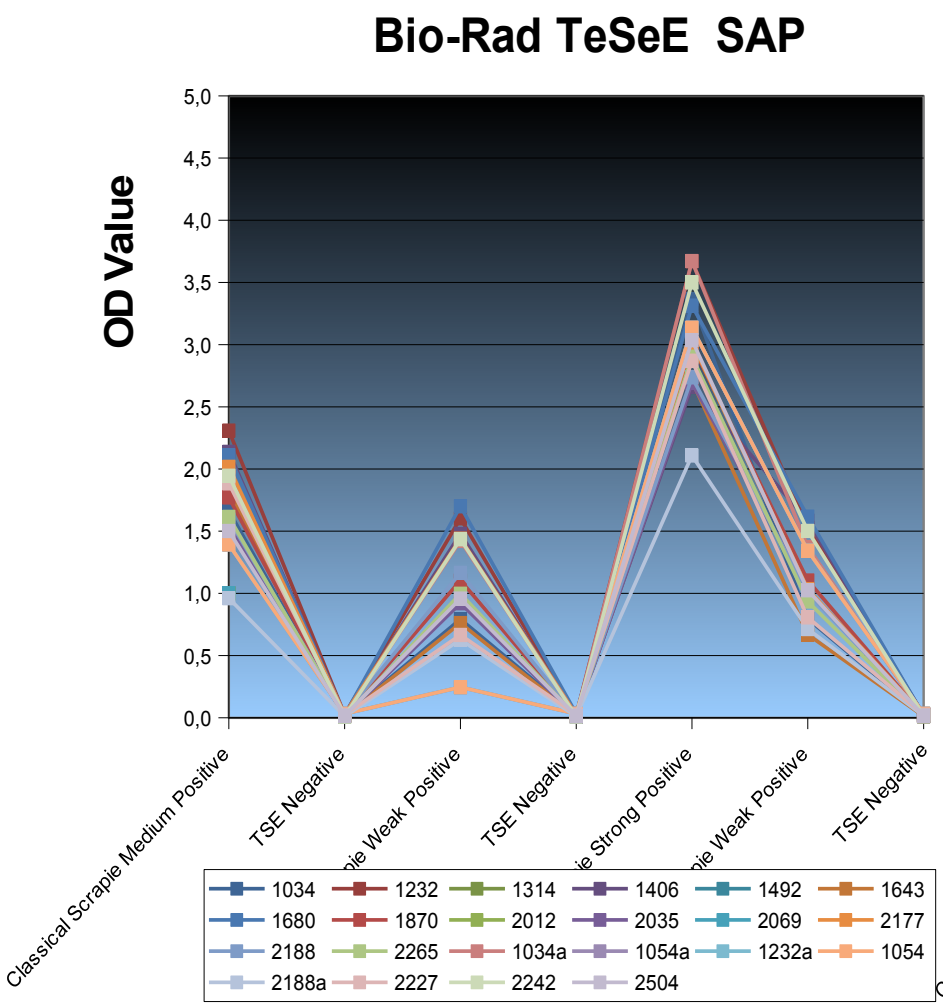
Passed on 1st repeat EQA

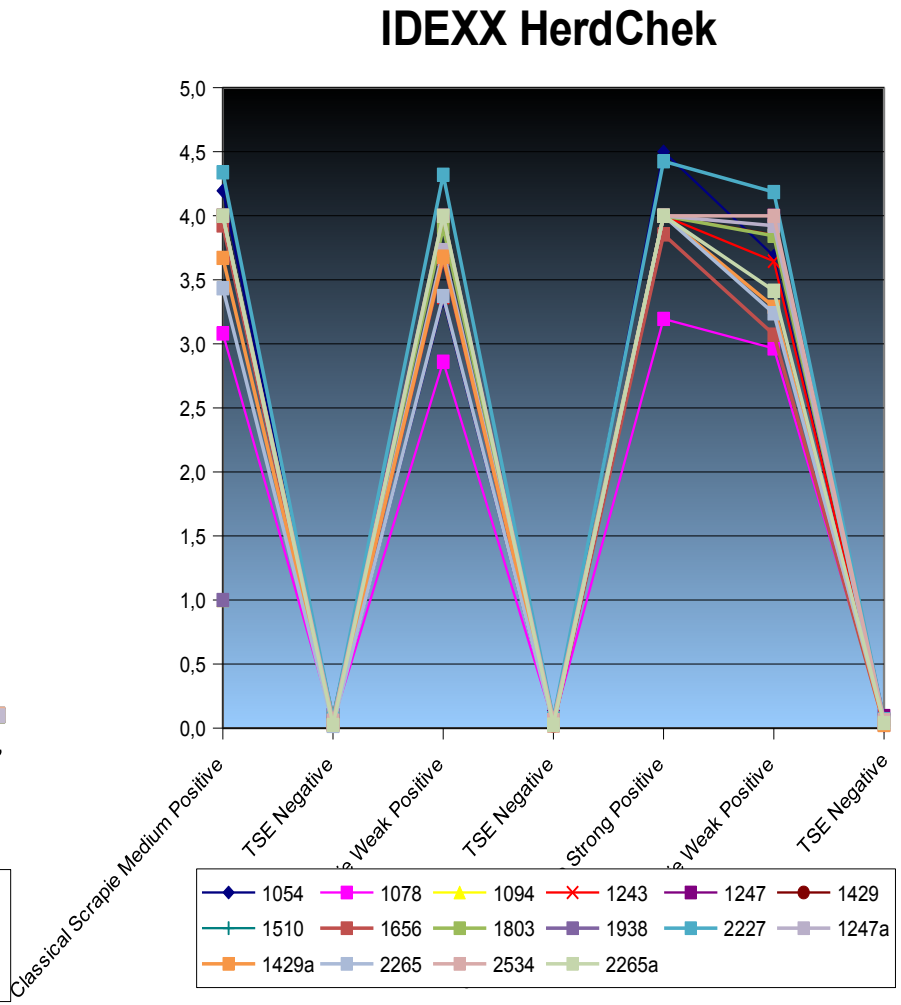
Passed on 2nd repeat EQA

Failed

- This was dealt with by investigation no repeat round sent.

Scrapie Rapid Testing PT Graphs 2018





BSE Confirmatory Western Blot
PT0028
Distribution 13429/SE - 24.07.2018

- 24 laboratories participated in the PT scheme.
- The PT sample panel included 1 weak BSE, 1 medium BSE and 3 strong BSE samples.
- Participants passed the PT round using:
  - Bio-Rad WB (13)
  - APHA-Bio-Rad Hybrid WB (2)
  - Prionics Check WB (3)
  - APHA-Prionics Hybrid WB (2)
  - In-house/unnamed WB (2)
  - SAF WB (2)
- **All Laboratories passed the PT round.**

Scrapie Confirmatory Western Blot

PT0097

Distribution 13549/SE – 23.10.2018

- 24 laboratories participated in the PT scheme.
- The PT sample panel included: 2 weak positive classical scrapie, 2 medium positive classical scrapie and 1 strong positive classical scrapie sample.
- Participants passed the PT round using :
  - Bio-Rad WB (14)
  - Bio-Rad Hybrid WB (2)
  - In-house/unnamed WB (2)
  - Prionics Check WB (1)
  - Prionics Hybrid WB (1)
  - CEA Western blot (1)
  - SAF WB (1)
  - Prionics SLO modified (1)
  - Ridascreen with P4 Mab (1)
- **All laboratories passed the PT round.**
- **One laboratory was initially unable to carry out testing and was issued with a further PT round which was successfully tested & interpreted.**

Atypical BSE Western Blot

PT0174

Distribution 13438/SE – 24.7.2018

- 11 laboratories participated in the PT scheme.
- The PT sample panel included: 2 BSE weak positives, 1 strong L-type BSE positive and 1 medium H-type BSE positive sample.
- Participants passed the PT round using :
  - APHA Bio-Rad Hybrid WB (4)
  - In-house/unnamed WB (3)
  - APHA- Prionics Hybrid WB (1)
  - FLI Discriminatory Immunoblot (1)
  - ISS BSE Discriminatory WB (1)
  - ANSES Discriminatory WB (1)
- **10 laboratories passed the PT round; 1 laboratory following investigation, resulting in identification of a typographical error.**
- **One laboratory failed the PT round as they diagnosed the Medium H-type BSE as BSE negative. The follow-up round was distributed by APHA and reported by the new EURL.**

June 2018 Ovine TSE strain characterisation from Western Blot Images (Visual Interpretation)

- This was a voluntary PT round.
- Results were received from 34 individual participants from 18 labs.
- All participants correctly interpreted two ovine classical scrapie and two atypical scrapie profiles.
- 14/34 participants interpreted all 14 lanes as EURL.
- 16/34 participants interpreted between 1-3 results differently to EURL.
- 4/34 participants interpreted the negative samples in lanes 1 and 2 as atypical scrapie.
- 1/34 identified classical scrapie in lane 5 as atypical scrapie.
- 1/34 identified the classical scrapie in lanes 3, 4 and 5 as ovine BSE.
- 3/34 identified the classical BSE in lane 9 as possible BSE in sheep.
- 9/34 reported at least one inconclusive result

EU-Approved BSE Rapid-Test Batch Approval 2018

- **IDEXX HerdChek x 6 *(previous year x 10)***
- **Bio-Rad TeSeE x 3 *(previous year x 3)***
- **Roboscreen BetaPrion x 3 *(previous year x 2)***
- **Prionics Check Western x 3 *(previous year x 4)***
- **Prionics Check PrioSTRIP x 2 *(previous year x 1)***

EURL Approval of minor testing kit changes 2018

Manufacturer	Test Kit	Details of Change	Reason for Change	EURL conclusion	Date of EURL conclusion
Thermo Fisher Scientific	Prionics® Check Western and Prionics® Check PrioSTRIP	Change to the machine used for measurement of Protein Kinase (PK) activity during the production process	Old machinery is not supported anymore, spare parts are no longer available	Approved	12/01/2018
Bio-Rad	Bio-Rad TeSeE test kit	Update to CD to include CWD Addendum as well as IFU Doc	New instructions included within kit to cover CWD testing	Approved	26/01/2018
Thermo Fisher Scientific	Prionics® Check Western	Transfer of 6H4 supernatant production from Thermo Fisher Schlieren, Switzerland (Prionics AG) to Thermo Fisher Lelystad, The Netherlands (Prionics Lelystad B.V.)	Transfer of production processes to new location	Approved	01/02/2018
Thermo Fisher Scientific	Prionics® Check PrioSTRIP	The updated labels and IFU provide new safety specific information and rebranding.Additionally, the German language version of information has been added version number and typographical error corrections.	Change to safety regulations and product rebranding Thermo Fisher Scientific. The German language added in order to be compliant with German regulations.	Approved	12/02/2018
IDEXX	IDEXX Herdchek BSE-Scrapie Antigen Test Kit	The updated IFU now provides specific information about changes to the test protocol and includes information for IDEXX customers in Germany wishing to use the HerdChek Bovine Spongiform Encephalopathy-Scrapie Antigen Test Kit, EIA to test cervid samples for detection of CWD.	The requirement of the TSE NRL for laboratories in Germany to test both obex and retropharyngeal lymph nodes, as part of the EU- cervid survey.	Approved	06/04/2018
Thermo Fisher Scientific	Prionics® Check PrioSTRIP	The updated IFU provides new safety specific information, version number and typographical error corrections.	Change to safety regulations and IFU periodic review by Thermo Fisher Scientific	Approved	08/06/2018
Bio-Rad	Bio-Rad TeSeE & Bio-Rad Sheep and Goat test kit	Product substitution of approved calibration syringe	The change proposed by Bio-Rad is as a consequence of ongoing supply issues with the current approved calibration syringe manufacturer.	Approved	18/09/2018
Thermo Fisher Scientific	Prionics® Check PrioSTRIP	Change to the production location for lyophilisation of kit controls and conjugate componets of the Prionics® Check PrioSTRIP	Transfer of production processes to new location	Approved	23/11/2018

Outstanding minor testing kit changes at end of 2018

Manufacturer	Test Kit	Details of Change	Reason for Change	Outcome at end of 2018
AJ-Roboscreen	BetaPrion	Question from Ingolf Lachmann - 'I have question regarding our IFU 3.3 and equipment named on page 4. We have described there Microplate reader, Anthos Reader 2001 (Anthos Labtec Instruments GmbH Austria) or CM Sunrise reader (Tecan Deutschland GmbH Germany) Meanwhile the company Anthos has updates of Reader 2001 named now e.g. Anthos2010 or PHOMO – Anthos Reader 2001 is no more available. Could we integrate the reader also inside our IFU?'	Response from CC on 15.11.2018 - 'Could you tell me the difference between the reader named in your current IFU and the new one please? If there is no difference then I would be grateful if you send me the proposed draft changes you would like to make to IFU 3.4.' We can then easily approve this modification to the IFU.	No further communications from AJ-Roboscreen regarding this issue - Current EURL to follow up
Bio-Rad	Bio-Rad TeSeE test kit	Validation of a proposed replacement grinding system	VALIDATION OF A NEW GRINDING SYSTEM (PRECELLYS® EVOLUTION) BEFORE PROCESSING SAMPLES WITH THE Bio-Rad's TeSeE kits	APHA approved protocol (V3). Trial undertaken in Norway and Canada - Current EURL to follow up
Bio-Rad	Bio-Rad TeSeE test kit	The updated IFU now provides specific information about changes to the test protocol and includes information for Bio-Rad customers wishing to use Bio-Rad TeSeE SAP to test cervid samples for detection of CWD. The IFU also confirms that this test has undergone validation and is USDA & CFIA - approved for use with cervis tissue	The recommendation by EFSA for the use of rapid TSE tests approved by USDA and CFIA and for testing of both obex and retropharyngeal lymph nodes, as part of the EU- cervid survey.	Awaiting IFU draft changes in order to make approval – Current EURL to follow up
IDEXX	IDEXX Herdchek BSE-Scrapie Antigen Test Kit	Validation of replacement ribolysers	The change proposed by IDEXX results from the discontinuation of certain ribolyser manufacture	Awaiting IFU draft changes in order to make approval – Current EURL to follow up
Bio-Rad	Bio-Rad TeSeE test kit	One component (triton) of the buffer A (involved in the pK treatment) is part of the list of the restricted substances covered under the REACH regulation (REACH stand for registration, evaluation, authorisation and restriction of chemicals). The consequence is that Bio-Rad France can not store this substance in a high quantity. We are dealing with a	Response from CC on 15.11.2018 - 'I looked at the guidelines and my interpretation is that you would need to provide a comparative study to show the new reagent was equivalent or better in performance to the existing reagent – see Section 3.5. This proposed change would need to be planned into a protocol which I can then review and sign-off.	Current EURL to follow up

Scrapie blood genotyping
PT0093
Distribution 13247/SE - 27.02.2018

- 25 laboratories received the PT panel, 24 laboratories returned results.
- 3 laboratories failed to identify the panel correctly:
  - 1 laboratory reported genotype ALRQ/ALRQ instead of the intended ALRR/ALRR (sample 18/7119)
  - 1 laboratory reported genotype ALRQ/VFRQ instead of the intended AFRQ/VLRQ (sample 18/7117).
  - 1 laboratory reported genotype VFRQ/VLRQ instead of the intended AFRQ/VLRQ (sample 18/7117).
- **Therefore 21 Laboratories passed the PT round.**
- **A follow-up round was distributed on 19/06/2018, all 3 laboratories passed this round.**