



Report SARS-CoV-2 EQA molecular detection

Progress report of the services and deliverables as requested in ECDC specific contract No 3 ECD.10833 implementing Framework contract No ECDC/2017/002. This report gives an overview on the services and deliverables since May 19th 2020. The previous services and deliverables were described in the interim report that was sent to ECDC on May 19th 2020.

DL2

Service 2.3 Package insert (safety and testing instructions)

The technical information sheet and the safety and testing instructions (**appendix 1**) were shared with ECDC on May 27th 2020, before the EQA panels were sent out to the laboratories.

Service 2.4 Pretesting of whole inactivated panel

Pre-testing of the panels and the online form for result submission was finalized on June 4th 2020.

Service 2.5 Prepare panels for shipment and distribution of panels

The EQA panels were shipped on June 10th and June 11th by Charité University Berlin. Laboratories had until July 6th 2020 to submit their results. This date was extended once to July 13th 2020. In total 80 panels were sent out to the participants.

Service 2.7 Prepare Expected results sheet / Service 2.8 Data collection

Data were collected via an online submission form. In total 68 laboratories submitted 70 test results via the submission form.

DL3

Service 3.1 Expected results sheet to individual labs as soon as they finish reporting

On July 24th 2020 all participants and ECDC were individually sent the preliminary analysis of the results of the EQA. On September 16th 2020 ECDC was sent the raw data at institute level of the laboratories that gave consent to sharing their results with ECDC during the EQA registration and of all laboratories that are part of ERLI-Net.

Service 3.2 Data analysis

Please see Service 4.1.

Service 3.3 Certificates

All laboratories were sent their individual participation certificates on September 11th 2020.

Service 3.4 Providing trouble shooting services and advice to laboratories and ECDC in relation to EQA (ad hoc)

In the email from July 24th 2020 that included the preliminary analysis of the EQA results, all laboratories were offered coordinated support, if needed urgently. None of the laboratories used this offer. Three laboratories asked whether it was possible to receive another panel, so they could do further testing, based on their results. However, these could not be provided, because all 80 panels were shipped within the EQA.



Quality of laboratory infrastructure

Beyond technical details the EQA manuscript also includes an analysis whether the EQA performance was correlated with socio-economic factors represented by the human development index (HDI). No correlation between HDI and EQA performance was found. It was further assessed whether the EQA performance was correlated to the composite index of national public health laboratory capacity (EULabCap index) (1). Also for the EULabCap index no correlation was found with EQA performance (Figure 3, Spearman's rank correlation test p-value = 0.8521).

The score is only available for the EU/EEA countries and not the pre-accession countries.

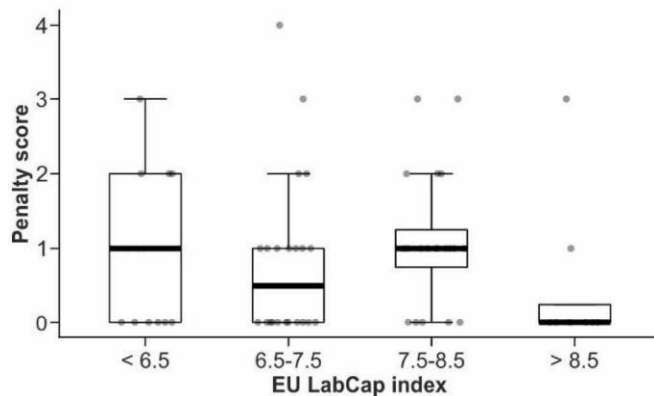


Figure 3. EQA performance depending on EU/EEA countries EULabCap index.

EU status

Both the HDI and the EULabCap index analysis did not reveal any statistical differences in the EQA performance of laboratories due to socio-economic factors or national public health laboratory capacity.

However to show the performances based on EU status of the laboratories the relevant results of the manuscript were re-analyzed by EU status: EU/EEA, pre-accession countries and non-EU/EEA countries (Figure 4, Figure 5 and Table 1).

It is not possible to conclude on differences in the performances based on EU status, because of the very limited number of participants from the pre-accession and non-EU/EEA countries.

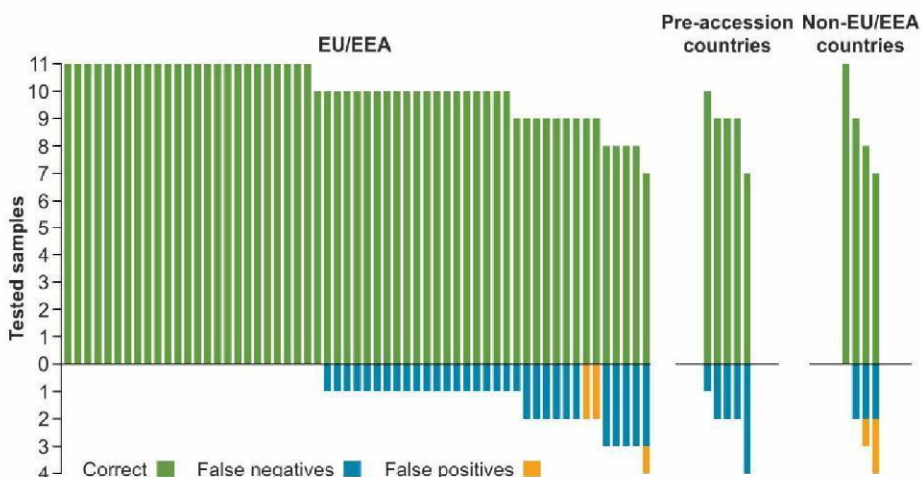


Figure 4. The number of correct, false negative and false positive samples per laboratory.

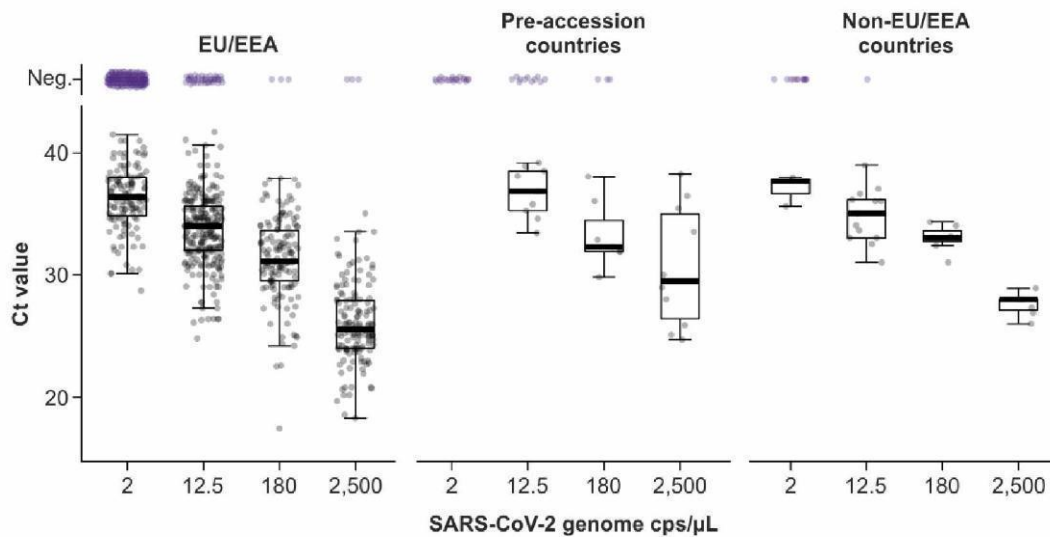


Figure 5. Reported Ct values per SARS-CoV-2 positive samples considering all results reported including multiple tests conducted by one participant. Median Ct values are indicated by bars, quartiles by boxes, and interquartile range by whiskers. Single events are indicated by grey (positive) and purple (negative) dots.



Table 3. Performance among different real-time RT-PCR assays. None of the assays performed significantly better than “Others” considering two-sided Yates corrected chi square. Sample 9 was excluded for calculation of the EQA performances.

RT-PCR assay		Genome target		EU/EEA				pre-accession countries			other				
				No. of submitted EQA results	Performance (core samples)			No. of submitted EQA results	Performance (core samples)			No. of submitted EQA results	Performance (core samples)		
Name	Method type	Gene	Specificity		Total correct	False pos.	False neg.		Total correct	False pos.	False neg.		Total correct	False pos.	False neg.
Corman <i>et al.</i> (6)	in house	E	Sarbeco	28	89%	1%	22%	1	73%	0%	50%	2	73%	20%	33%
Corman <i>et al.</i> (6)	in house	RdRp	SARS-CoV-2	10	83%	2%	28%	1	82%	0%	18%	0			
US CDC, USA (xxx)	in house	N	SARS-CoV-2	10	90%	0%	18%	0				0			
Institute Pasteur, Paris, France (xxx)	in house	RdRp	SARS-CoV-2	10	92%	0%	15%	0				0			
Allplex 2019-nCoV Assay	commercial	E	Sarbeco	7	90%	0%	19%	1	64%	0%	67%	1	73%	0%	50%
Allplex 2019-nCoV Assay	commercial	N	SARS-CoV-2	7	92%	0%	14%	1	73%	0%	50%	1	73%	20%	33%
Allplex 2019-nCoV Assay	commercial	RdRp	SARS-CoV-2	7	87%	0%	24%	1	56%	0%	83%	1	82%	0%	33%
RealStar SARS-CoV-2 RT-PCR Kit 1.0	commercial	E	Sarbeco	5	89%	0%	20%	0				0			
RealStar SARS-CoV-2 RT-PCR Kit 1.0	commercial	S	SARS-CoV-2	5	87%	0%	23%	0				0			
Cobas SARS-CoV-2 Test	commercial	E	Sarbeco	4	80%	0%	38%	0				1	100%	0%	0%
Cobas SARS-CoV-2 Test	commercial	ORF1ab	SARS-CoV-2	4	86%	0%	25%	0				1	91%	0%	83%
Corman <i>et al.</i> (6)	in house	N	Sarbeco	5	78%	0%	40%	0				0			
Viasure SARS-CoV-2 Real Time PCR Detection Kit	commercial	N	SARS-CoV-2	5	84%	4%	27%	0				0			
Viasure SARS-CoV-2 Real Time PCR Detection Kit	commercial	ORF1ab	SARS-CoV-2	5	80%	0%	37%	0				0			
Others	both	various	n.a.	33	84%	2%	27%	5	69%	0%	57%	0			



References

1. ECDC. EULabCap composite index 2018 [Available from:
<http://dx.doi.org/10.1787/888933836808>

Appendixes

1. technical information sheet and the safety and testing instructions
2. EQA manuscript