



Technische Universiteit Delft
Delft University of Technology
Faculty of Architecture, Design and the Built Environment

LEQA1

5.1.2e

kernteam | 28-01-2021





LEQA1 panel

- Composition
 - All specimens in MEM + Hanks' salts and 10,000 HEp-2 cells/ml
 - 4 specimens with 10-fold dilutions of heat-inactivated SARS-CoV-2, load around LOD many tests (n=1; educational), load 10-fold higher (n=2) and load 1000-fold higher (n=1)
 - 4 live virus specimens hCoV-OC43, hCoV-229E, hCoV-NL63, influenza virus A(H3N2)
 - 1 specimen with SARS-CoV-1 RNA (educational)
 - 1 specimen without any virus
- Testing
 - Detect SARS-CoV-2 in panel using routinely used assays
 - Provide Ct or RFU values and conclusion per target gene, and overall test conclusion
 - Provide detailed information about workflows used



Participants and scoring

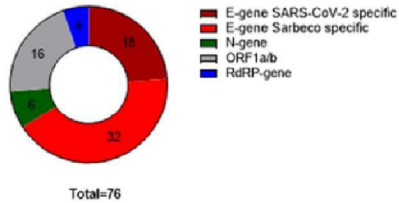
- Network of COVID-19 diagnostic labs obliged to participate
- 3 rounds of EQA, November 2020, February 2021, April/May 2021
- 70 labs received the panel in November 2020
- 65 reported results
- Results of 164 workflows were reported
- Possible conclusions: Positive, Negative, Indeterminate, Equivocal, Inconclusive or Not tested.
- Limited panel of 4 specimens allowed for mPOCT assays

- Scoring 8 core specimens
 - 1 point for full correct result each specimen
 - 1 point deducted for incorrect positive or negative
 - 0.5 point deducted for Indeterminate, Equivocal, Inconclusive

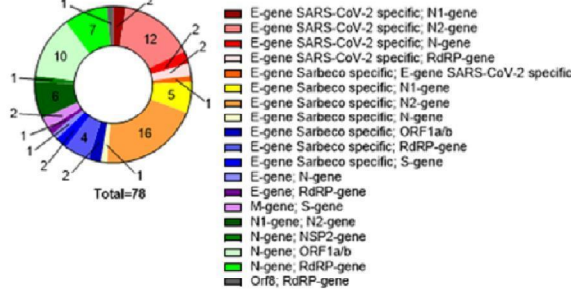


Genes used per assay

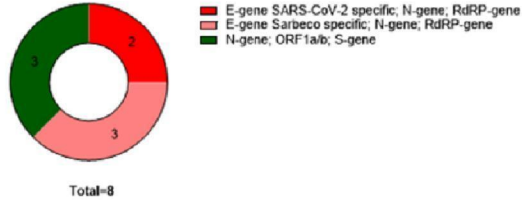
Workflows with 1 target gene



Workflows with 2 target genes



Workflows with 3 target genes



Workflows with 4 target genes



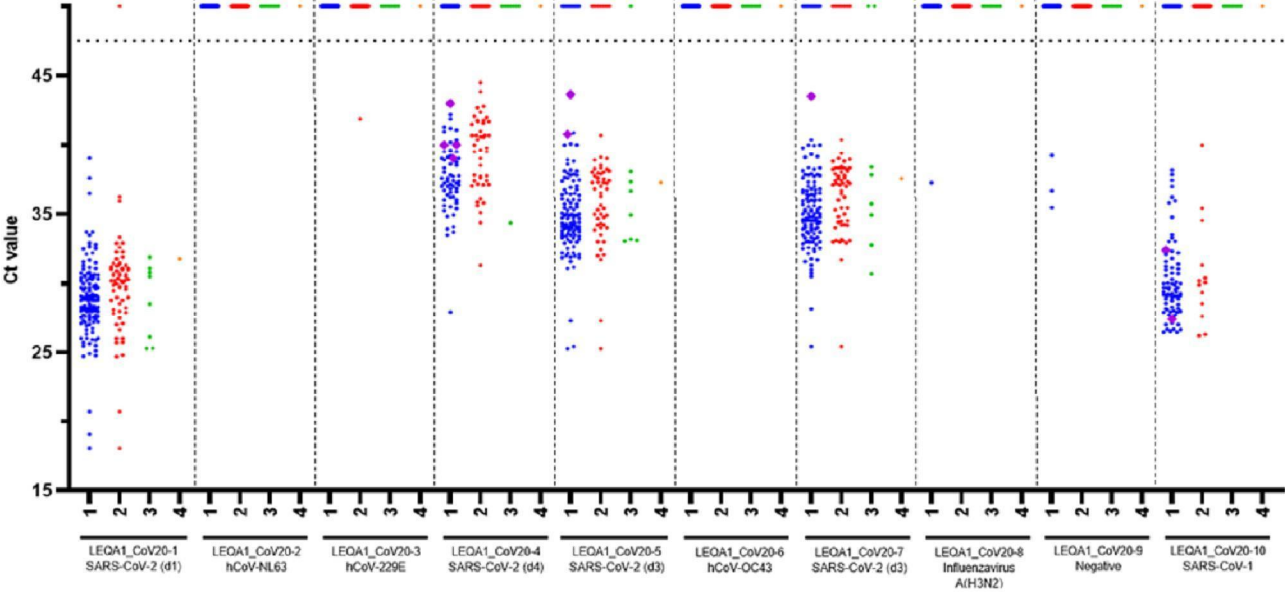


Aggregated results 164 workflows

Panel sample	Content	N° of workflows with test result reported (n=164)	SARS-CoV-2 detection workflow conclusion			
			N° Positive	N° Indeterminate, Equivocal or Inconclusive	N° Negative	Errors
LEQA1_CoV20-1	SARS-CoV-2 (d1)	162	161 (99.38%)	0	1 (0.62%)	False negative (n=1)
LEQA1_CoV20-2	hCoV-NL63	160	0	0	160 (100%)	None
ELQA1_CoV20-3	hCoV-229E	146	0	1 (0.68%)	145 (99.32%)	False indeterminate, equivocal or inconclusive (n=1)
LEQA1_CoV20-4	SARS-CoV-2 (d4)	162	78 (48.15%)	21 (12.96%)	63 (38.89%)	Not applicable, educational sample
LEQA1_CoV20-5	SARS-CoV-2 (d3)	148	131 (88.51%)	7 (4.73%)	10 (6.76%)	False negative (n=10), false indeterminate, equivocal or inconclusive (n=7)
LEQA1_CoV20-6	hCoV-OC43	145	0	0	145 (100%)	None
LEQA1_CoV20-7	SARS-CoV-2 (d3)	158	139 (87.97%)	6 (3.80%)	13 (8.23%)	False negative (n=13), false indeterminate, equivocal or inconclusive (n=6)
LEQA1_CoV20-8	Influenza virus A(H3N2)	144	0	0	144 (100%)	None
LEQA1_CoV20-9	Negative	144	0	3 (2.08%)	141 (97.92%)	False indeterminate, equivocal or inconclusive (n=3)
LEQA1_CoV20-10	SARS-CoV-1	147	63 (42.68%)	22 (14.97%)	62 (42.18%)	Not applicable, educational sample

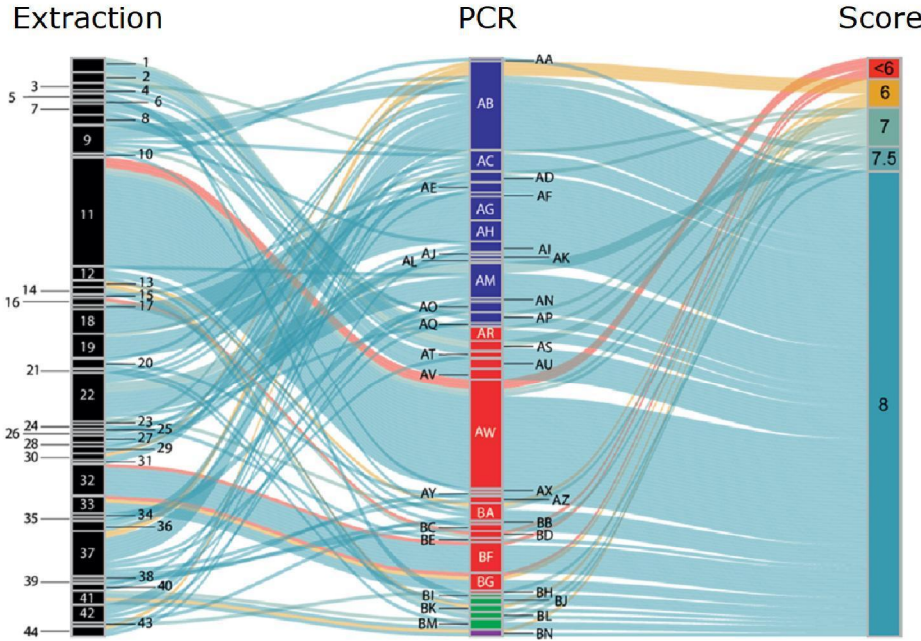
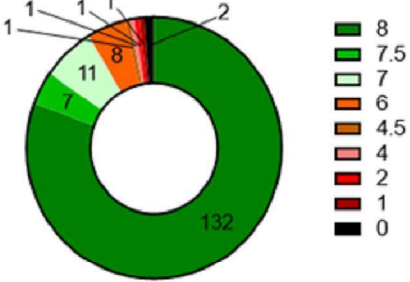


Ct distribution



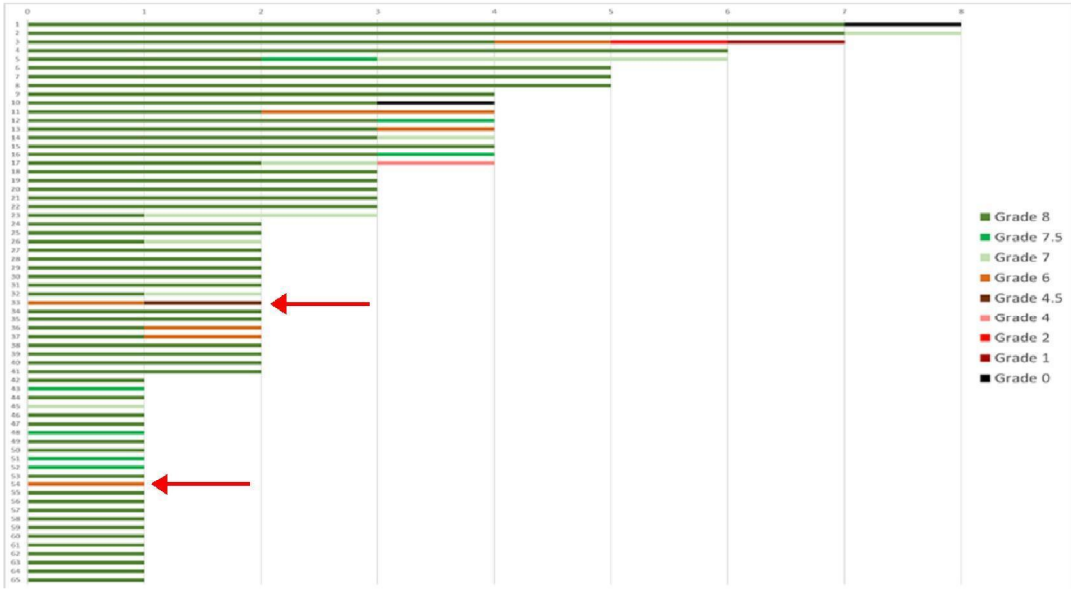


Scores by workflow





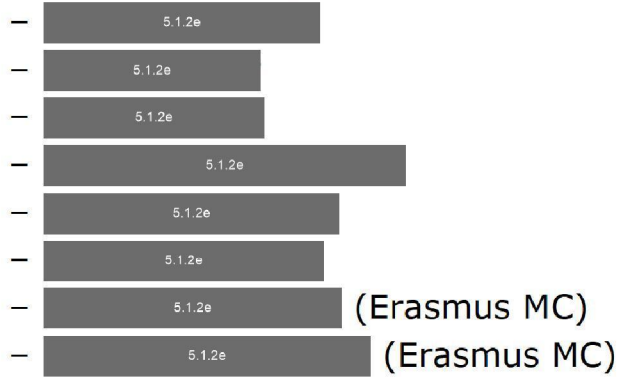
Scores by labs and workflows





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- RIVM-IDS Virology



- All participating laboratories

Laboratory	Laboratory
Admiral de Ruyter Ziekenhuis	MVC Labor Steen & Kolffem
St. Antonius Ziekenhuis Nieuwegein	Noorderst. Ziekenhuisgroep Alkmaar
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Certe	Rijstate
Deventer Ziekenhuis	ILM Dordrecht-Gorinchem
Diagnostiek voor U	Royal GD
Diagnosecentrum Utrecht	Seltra
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Eurofins NMDL-CPL	SM-rlh
Ferrelab Consortium - Maderlab	Streeklab PAMM
Ferrelab Consortium - M&F&N NutriSciences	Streeklab Naalden
Ferrelab Consortium - Nofelab BV	SYNLAB Germany Leverkusen
Ferrelab Consortium - Normac Bio-beheer	SYNLAB Hospitalis
Ferrelab Consortium - NutriControl	SYNLAB Laboratoire Collard
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