BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

CLINICAL BIOLOGY
COMMITTEE OF EXPERTS

EXTERNAL QUALITY ASSESSMENT
IN CLINICAL BIOLOGIE

DEFINITIVE GLOBAL ANNUAL REPORT

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J. Wytsmanstreet, 14
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COMMITTEE OF EXPERTS

Sciensano					
Secretariat		PHONE:	02/642.55.22	FAX:	02/642.56.45
Bernard China	Scheme coordinator	PHONE:	026425385		
		e-mail:	Bernard.china@sciensano.be		
Kris Vernelen	Alternate coordinator	PHONE:			
		e-mail:	Kris.Vernelen@sciensano.be		
Experts	**Institute**				
M-P Hayette	**CHU Liège**				
T. Crucitti	**IMT Anvers**				
S. Desmet	**UZ Leuven**				
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Ina Benoy	**AML**				
V. Matheeussen	**UZ Antwerpen**				
Walter Verstrepen	**ZNA**				
H. De Beenhouwer	**OLV Ziekenhuis**				

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Authorization of the report: by Bernard China, scheme coordinator

Bernard China

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Abbreviations

N: number of datasets NR: number of results NCR: number of correct results FP: false positive result FN: false negative result ND: not determined result NRC: National reference centrum Cp: crossing point	HSV: Herpes Simplex Virus EV: Enterovirus PEV: Parechovirus VZV: Varicella-Zoster Virus CMV: Cytomegalovirus EBV: Epstein-Barr Virus HPV: Human papilloma Virus HCV: Hepatitis C virus HBV: Heptitis B virus SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

1 INTRODUCTION

THE SURVEYS

In 2021, 12 surveys were organized. The samples for *Chlamydia trachomatis*, *Neisseiria gonorrhoeae*,*Toxoplasma gondii et Bordetella pertussis* were produced by sciensano. The other samples were provided by QCMD (www.qcmd.org). A panel of samples were sent for each parameter. The panels included samples of different status (negative, infrequently detected, detected or frequently detected).
In 2021 as in 2020, multi-parameter panels were sent for the respiratory pathogens (Influenza and RSV),for the viruses responsible of meningitis (HSV, EV, PEV, VZV) or for the viruses involved in infections in transplat patients (CMV, EBV , BK virus, B19 virus, Adenovirus). In addition, two surveys for the detection of SARS-CoV-2 by PCR were organized in collaboration with QCMD. For these SARS-CoV-2 surveys, the samples were directly sent from QCMD to the participants (table 1).

Table 1. The surveys organized in 2021

Survey	Parameter
2021.1	Toxoplasma gondii (Sciensano)
2021.2	HCV genotyping (QCMD)
2021.3	Chlamydia trachomatis/Neisseria gonorrhoeae (Sciensano)
2021.4	HCV/HBV (QCMD)
2021.5	Respiratory Viruses (influenza, RSV) (QCMD)
2021.6	M. tuberculosis complex (QCMD)
2020.7	High Risk HPV (QCMD)
2020.8	B. pertussis (Sciensano)
2020.9	Meningites viral meningitis (EV,PEV, VZV, HSV) (QCMD)
2020.10	Viruses in transplatation (Adenovirus, BK19, CMV, EBV) (QCMD)
2020.11	Sars-Cov-2 survey 1 (SCV2_21C1B) (QCMD)
2020.12	Sars-Cov-2 survey 2 (SCV2-21C1C) (QCMD)

QCMD garanted the homogeneity and the stability of their samples. For the samples produced by sciensano the homogeneity and the stability were based on the expert's laboratories results.

EVALUATION

QCMD established a scoring system depending of the status of the sample. A sample can be negative (absence of the researched pathogen), frequently detected (detected by more than 95% of the participants), detected (detected by more than 65% of the participants) or infrequently detected (detected by less than 65% of the participants).
Qualitative results
Table 2. Score in function of the sample status

Status	Correct answer	Incorrect answer
Frequently detected	0	3
Negative	0	3
Detected	0	2
Infrequently detected	0	1

The infrequently detected samples were not included in the "core" of the panel and must be considerate as educational sample.

Quantitative results

Z score= (Result-Target value)/SD
Target value= mean of the method
SD= standard deviation of the method

Z-score	Score
Z <1	0
1≤Z<2	1
2≤Z<3	2
Z≥3	3
ND for an infrequently detected sample	1
ND for a detected sample	2
ND for a frequently detected sample	3

2. RESULTS
I. BACTERIA

A. CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

The samples

In 2021, the panel consisted of 4 samples of transport medium (M4RT containing 10 ng/µl human DNA) and 4 urine samples.

Table B1. The samples

Sample	Matrix	Content
CTNG2101	M4RT	*C. trachomatis*
CTNG2102	M4RT	*N. gonorrhoeae*
CTNG2103	M4RT	*C.trachomatis* *N. gonorrhoeae*
CTNG2104	M4RT	Negative
CTNG2105	Urine	Negative
CTNG2106	Urine	*N. gonorrhoeae*
CTNG2107	Urine	*C. trachomatis*
CTNG2108	Urine	*C. trachomatis*

Chlamydia trachomatis

88 laboratories encoded one dataset.

Results per sample

Table B2. Results for the detection of C. *trachomatis*

Sample	Expected results	Positive	Negative	ND	Status
CTNG2101	Positive	88	0	0	Frequently detected
CTNG2102	Negative	0	88	0	Negative
CTNG2103	Positive	68	19	1 inhibition	Detected
CTNG2104	negative	0	88	0	Negative
CTNG2105	negative	0	78	10	Negative
CTNG2106	negative	0	87	1 Inhibition	Negative
CTNG2107	Positive	88	0	0	Frequently detected
CTNG2108	Positive	88	0	0	Frequently detected

ND : not determined

Out of 704 results, 673 (95,6%) were correct. Only the sample CTNG2103 seemed to be more difficult to detect with 20 (22.7%) non correct answers.

Results per method

Table B3. Results per method

Method	N	NR	NCR	%	FP	FN	ND
102. Abbott real time CT/NG	12	96	93	96.9	0	2	1
109. Abbott alinity STI	1	8	8	100	0	0	0
111.Artuc C.trachomatis plus kit	1	8	8	100	0	0	0
122. BD MAX CT/NG//TV	3	24	24	100	0	0	0
141. Genexpert CT/NG	21	168	152	90.5	0	7	9
152 Diagenode CT/NG	2	16	16	100	0	0	0
171. Presto CT-NG PCR test	2	16	15	93.75	0	1	0
182. Illumigene Chlamydia trachomatis	1	8	7	87.5	0	1	0
189. Meridian other	1	8	7	87.5	0	1	0
201. Roche Cobas 4800 CT/NG test	17	136	130	95.6	0	6	0
203. Roche Amplicor CT/NG	1	8	6	75	0	0	2
204. Roche Cobase 6800 CT/NG	1	8	8	100	0	0	0
221. Seegene STI-EA Assay	3	24	24	100	0	0	0
229. Seegene (other)	4	32	32	100	0	0	0
241. ELITECH Ingenius STI plus	8	64	64	100	0	0	0
249. ELITECH other	1	8	8	100	0	0	0
251. Hologic Aptima Combo2 test CT/NG	4	32	32	100	0	0	0
998. RT-qPCR home made	4	32	31	96.9	0	1	0
999.Qiagen NeuMoDx CT/NG Test strip	1	8	8	100	0	0	0
Total	88	704	673	95.6	0	19	12

NR : number of results ; NCR : number of correct results, FP : false positive ; FN : false negative ; ND : not determined.

Score per laboratory

For *C.trachomatis*, the score ranged from 0 (100% of correct results) to 23 (100% of incorrect results). 60 laboratories (68.2%) obtained a perfect score of 0, 18 (20.4%) obtained a score of 2, 6 (6.8%)a score of 3, 3 (3.4%) a score of 5 and one participant a score of 6.

Discussion of the results for *C. trachomatis*

95.6% of the results were correct. Only sample CTNG2103 seemed more difficult to detect with 20 (22.7%) non-compliant responses. Probably due to a low concentration of target DNA both for C. trachomatis and N. gonorrhoeae. Sample CTNG2105 seemed to pose a problem for users of the Genexpert method with 9 indeterminate results out of 21 participants (42.9%) possibly due to the inability to detect human DNA which serves as internal control.

Neisseria gonorrhoeae

87 laboratories encoded results.

Results per sample

Table B4. Results per sample for the detection of *N. gonorrhoeae*

Sample	Expected result	Positive	Negative	ND	Status
CTNG2101	Negative	0	87	0	Negative
CTNG2102	Positive	87	0	0	Frequently detected
CTNG2103	Positive	23	64	0	Infrequently detected
CTNG2104	Negative	0	87	0	Negative
CTNG2105	Negative	0	78	9	Negative
CTNG2106	Positive	72	15	0	Detected
CTNG2107	Negative	0	86	1	Negative
CTNG2108	Negative	0	86	1	Negative

Out of 696 encoded results, 606 (87.1%) were correct.

Results per method

Table B5. Results per method

Method	N	NR	NCR	%	FP	FN	ND
102. Abbott real time CT/NG	12	96	82	85.4	0	14	0
109. Abbott (Other)	1	8	7	87.5	0	1	0
122. BD MAX CT/NG//TV	3	24	22	91.7	0	2	0
141. Genexpert CT/NG	21	168	145	86.3	0	15	8
152. Diagenode CT/NG real time PCR	2	16	14	87.5	0	2	0
171. Presto CT-NG PCR test	2	16	16	100	0	0	0
181. Illumigene Neisseria gonorrhoeae	1	8	7	87.5	0	1	0
189. Meridian other	1	8	6	75	0	2	0
201. Roche Cobas 4800 CT/NG	17	136	119	87.5	0	17	0
203. Roche Amplicor CT/NG	1	8	4	50	0	1	3
204. Roche Cobas 6800 CT/NG	1	8	8	100	0	0	0
221. Seegene STI-EA Assay	3	24	19	79.2	0	5	0
229. Seegene (other)	4	32	27	84.4	0	5	0
241. ELITECH INGENIUS STI plus	8	64	57	89.1	0	7	0
249. ELITECH other	1	8	8	100	0	0	0
251. Hologic Aptima Combo2 test CT/NG	4	32	28	87.5	0	4	0
998. RT-qPCR home made	3	24	22	91.7	0	2	0
999.Qiagen NeuMoDx CT/NG Test strip	1	8	8	100	0	0	0
119. Artus NG	1	8	7	87.5	0	1	0
Total	87	696	606	87.1	0	79	11

NR : number of results ; NCR : number of correct results, FP : false positive ; FN : false negative ; ND : not determined.

Score per laboratory

The score ranged from 0 (100% of correct results) to 21 (100% of incorrect results).
19 laboratories obtained the ideal score of 0, 44 laboratories obtained the score of 1, 4 laboratories the score of 2, 12 laboratories the score of 3, 7 laboratories the score of 4en one laboratory the score of 10.

Discussion of the results for N. gonorrhoeae

The CTNG2103 sample was very weakly positive and most (64/87 or 73.6%) could not detect it. On the other hand, the other samples did not really pose any problems with 95.7% of correct answers (583/609).

Conclusion.

Since sample CTNG2103 caused problems for both the detection of C. trachomatis and the detection of *N. gonorrhoeae*, it should not be part of the laboratory evaluation. If sample CTNG2103 is removed from the evaluation, the percentage of correct results reaches 98.2% for C. trachomatis and 95.7% for *N. gonorrhoeae*. On the other hand, for the analysis of sample CTNG2105, by the Genxpert method, 9 laboratories out of 21 for *C. trachomatis* (i.e. 43%) and 8 laboratories out of 21 for *N. gonorrhoeae* (i.e. 38%) did not get results.

B. MYCOBACTERIUM TUBERCULOSIS

35 participants encoded one dataset.

THE SAMPLES

Table B6. The samples for the M. tuberculosis complex panel

Sample ID	Sample content	Matrix	Status
MTBDNA21S-01	M. tuberculosis	Synthetic CSF	Frequently Detected
MTBDNA21S-02	Mycobacterium Negative	Synthetic CSF	Negative
MTBDNA20S-03	M. bovis (BCG)	Synthetic CSF	Detected
MTBDNA20S-04	M. bovis (BCG)	Synthetic CSF	Frequently Detected
MTBDNA20S-05	M. bovis (BCG)	Synthetic CSF	Frequently Detected
MTBDNA20S-06	M. xenopi	Synthetic Sputum	Negative
MTBDNA20S-07	M. tuberculosis	Synthetic Sputum	Frequently Detected
MTBDNA20S-08	M. bovis (BCG)	Synthetic Sputum	Frequently Detected
MTBDNA20S-09	Mycobacterium Negative	Synthetic Sputum	Negative
MTBDNA20S-10	M. bovis (BCG)	Synthetic Sputum	Detected

RESULTS PER SAMPLE

Table B7. Results per sample

Sample ID	Expected result	Positive	negative	ND
MTBDNA21S-01	Frequently Detected	33	1	1
MTBDNA21S-02	Negative	1	33	1
MTBDNA20S-03	Detected	33	1	1
MTBDNA20S-04	Frequently Detected	32	1	2
MTBDNA20S-05	Frequently Detected	32	1	2
MTBDNA20S-06	Negative	0	33	2
MTBDNA20S-07	Frequently Detected	35	0	0
MTBDNA20S-08	Frequently Detected	32	2	1
MTBDNA20S-09	Negative	0	32	3
MTBDNA20S-10	Detected	32	1	2

35 participants and 10 samples means 350 results. Out of 350 results, 327(93.4%) were correct. Out of the 23 incorrect results, 15 were not determined results, 7 were false negative and 1 was a false positive result.

RESULTS PER METHOD

Table B8. Results per method

Method	N	NR	NCR	%	FP	FN	ND
Cepheid Xpert kit	26	260	244	93.8	0	1	15
Conventional In-House PCR	2	20	13	65	1	6	0
Diagenode Real Time kit	1	10	10	100	0	0	0
Elitech Elite Real Time kit	1	10	10	100	0	0	0
PathoFinder Real Time PCR	1	10	10	100	0	0	0
Real time PCR in house	4	40	40	100	0	0	0
Total	35	350	327	93.4	1	7	15

N: number of datasets; NR: number of results; NCR; number of correct results; FP: false positive; FN: false negative result; ND: not determined result

Table B9. Score per laboratory and per sample

	21S-01	21S-02	21S-03	21S-04	21S-05	21S-06	21S-07	21S-08	21S-09	21S-10
Method	**FD**	**N**	**D**	**FD**	**FD**	**N**	**FD**	**FD**	**N**	**D**
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	3	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	3	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	3	0	3	0	3	0	3	0	2
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	2	3	3	0	0	0	3	2
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	3	3	0
Cepheid Xpert kit	0	0	0	0	3	0	0	0	0	0
Cepheid Xpert kit	3	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0	0	0
Conventional In-House PCR	0	0	0	0	0	0	0	0	0	0
Conventional In-House PCR	3	3	2	3	3	0	0	3	0	2
Diagenode Real Time kit	0	0	0	0	0	0	0	0	0	0
Elitech Elite Real Time kit	0	0	0	0	0	0	0	0	0	0
PathoFinder Real Time PCR	0	0	0	0	0	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0	0	0	0	0	0

Color code. Blue=Not determined; green= correct answer; orange; false negative for a detected sample; red= false negative for a frequently detected sample or false positive result.

SCORE PER LABORATORY

The score can range from 0 (100% correct results) to 28 (100% false answers)
27 laboratories (77.1%) obtained the ideal score of 0, 4 (11.4%) obtained the score of 3, one laboratory obtained the score of 6, one laboratory obtained the score of 13, one laboratory the score of 14 and one laboratory the score of 19.

CONCLUSION

3 laboratories performed badly with a score of 13, 14 and 19, respectively.
Two used the Cepheid method and obtained 50% of “not determined” results and one used a conventional PCR method (7 wrong results).

C. BORDETELLA PERTUSSIS

THE SAMPLES

Table B10. Panel Composition

Sample ID	Matrix	Sample content	Status
BP2101	Sputum	*No Bordetella*	Negative
BP2102	Sputum	*Bordetella pertussis*	Frequently detected
BP2103	Sputum	*Bordetella pertussis*	Frequently detected
BP2104	Sputum	*Bordetella pertussis*	Frequently detected
BP2105	Sputum	*No Bordetella*	Negative

BP2101=BP2105

PARTICIPANTS

23 participants were registered and 17 (74%) encoded results. 14 laboratories introduced one dataset and 3 laboratories encoded 2 datasets resulting in 20 datasets in total.

RESULTS

Results per sample

Table B11. Results per sample

Sample ID	Expected result	Positive	Negative	Status
BP2101	Negative	0	20	Negative
BP2102	Positive	20	0	Frequently detected
BP2103	Positive	20	0	Frequently detected
BP2104	Positive	20	0	Frequently detected
BP2105	Negative	0	20	Negative

All the encoded results were correct

Used methods

Table B10. Used methods

Method	Target DNA	N
ALETHIA Pertussis Meridian	IS481	1
Aries Bordetella	ptxA promotor	1
Biofire Respiratory 2.1. plus panel (Biomérieux)	ptxP	2
BioGX Bordetella speciation plus toxin	ptxS1, pIS1001, IS481,hIS1001	1
Bordetella ELITE MGB Kit	IS481, ptxA, recA, IS1001	1
Bordetella R-gene (Biomérieux)	IS481	1
In house RT-qPCR	IS1002	1
In house RT-qPCR	IS481 + ptS1	1
In house RT-qPCR	IS481 + 16S	1
In house RT-qPCR	IS481	5
Pathofinder realaccurate Quadruplex Bordetella	IS481	1
Qiastat DX respiratory SARS-COV-2 panel	IS481	1
Seegene (Allplex RP4-kit)	BP485	2
Simplexa Bordetella direct	IS481, IS1001	1
	Total	20

Conclusion

All encoded results were correct regardless of the method used. We can only regret the low participation (74%).

II. VIRUSES

A. HEPATITIS B VIRUS (HBV)

The samples

Table V1. Panel composition

Sample ID	Content	Matrix	Qualitative	Quantitative mean±SD(Log IU/ml)
HBVDNA21S-01	HBV Type A	Plasma	Frequently detected	1,898±0.193
HBVDNA21S-02	HBV Type A	Plasma	Frequently detected	2.879±0.159
HBVDNA21S-03	HBV Type D	Plasma	Frequently detected	2.687±0.161
HBVDNA21S-04	HBV Type A	Plasma	Frequently Detected	2.851±0.153
HBVDNA21S-05	HBV Type D	Plasma	Frequently Detected	3.657±0.196
HBVDNA21S-06	HBV Type A	Plasma	Frequently Detected	3.84±0.168
HBVDNA21S-07	HBV Type D	Plasma	Detected	1.741±0.226
HBVDNA21S-08	HBV Negative	Plasma	Negative	NA

The participants

26 laboratories encoded results, 25 encoded one dataset and 1 laboratory encoded 2 datasets. Therefore, 27 datasets were encoded.

Qualitative results per sample

Table V2. Qualitative results per sample

Sample ID	Expected results	Positive	Negative	ND
HBVDNA21S-01	Frequently detected	27	0	0
HBVDNA21S-02	Frequently detected	26	0	1
HBVDNA21S-03	Frequently detected	27	0	0
HBVDNA21S-04	Frequently Detected	25	0	2
HBVDNA21S-05	Frequently Detected	27	0	0
HBVDNA21S-06	Frequently Detected	26	0	1
HBVDNA21S-07	Detected	25	0	2
HBVDNA21S-08	Negative	0	26	1

27 datasets and 8 samples per dataset giving 216 results. Out of the 216 encoded results, 209 (96.8%) were correct. Seven “not determined” results were encoded.

Results per method

Table V3. Qualitative results per method

Method	N	NR	NCR	%	ND
Abbott Alinity m	3	24	24	100	0
Abbott RealTime m2000	4	32	32	100	0
Cepheid Xpert kit	9	72	66	91.7	6
Hologic Aptima	2	16	16	100	0
Qiagen NeuMoDx	1	8	8	100	0
Real-time In-House PCR	2	16	16	100	0
Roche Cobas 4800	4	32	32	100	0
Roche Cobas 6800/8800	1	8	7	87.5	1
Roche Cobas Amplicor	1	8	8	100	0
Total	27	216	209	96.8	7

Score per laboratory

Out of the 25 laboratories encoded one dataset, 22 (88%) obtained the ideal score of 0, one laboratory obtained the score of 2, one laboratory obtained the score of 3 and one laboratory obtained the score of 12. The laboratory encoding two datasets obtained the score of 0.

Quantitative results per sample

24 laboratories encoded quantitative results, 23 encoded one dataset and one laboratory encoded 2 datasets.
The Z score was calculated= (encoded value-target value)/SD
The target value is the consensus mean per method.
Table V4. Quantitative results per sample

Sample ID	IZ scorel <1	1≤IZscorel<2	2≤IZ scorel<3	IZ scorel ≥3	ND
HBVDNA21S-01	13	10	0	1	1
HBVDNA21S-02	17	4	2	1	1
HBVDNA21S-03	15	8	2	0	0
HBVDNA21S-04	12	11	1	0	1
HBVDNA21S-05	15	6	3	1	0
HBVDNA21S-06	16	6	2	0	1
HBVDNA21S-07	13	8	0	1	3

25 datasets and 7 results giving 175 results. Out the 175 results, 164 (93.7%) were acceptable (Z score <3).
4 results gave a Z score ≥3 and 7 results were “not detected” results.

Distribution of the results

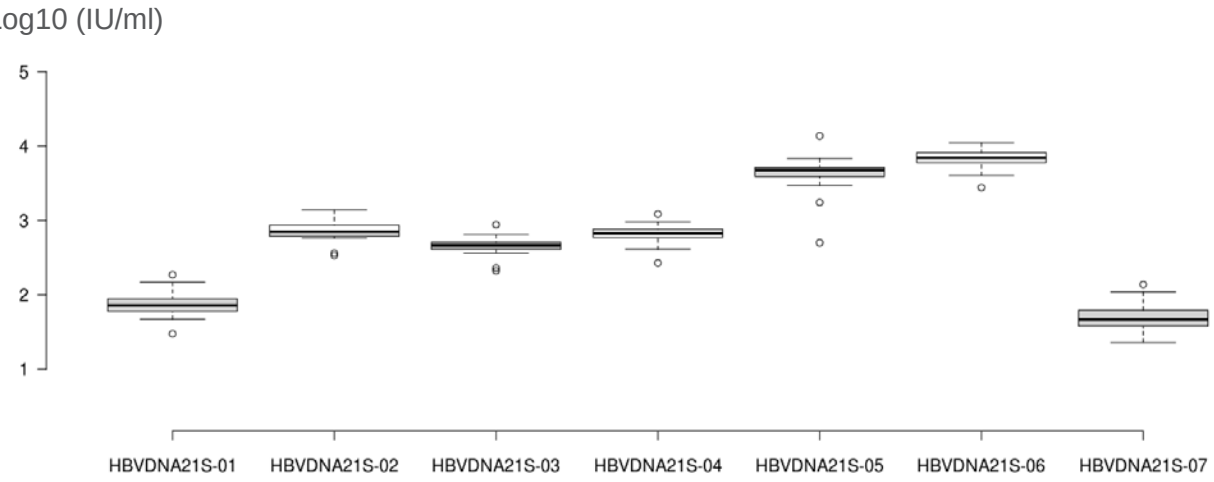

Figure V1. Distribution of the results (boxplots) per sample.

Evaluation per method

Table V5. Quantitative results per method

Method	N	NR	Z<1	1<Z<2	2<Z<3	Z>3	ND
Abbott Alinity m	3	21	13	7	1	0	0
Abbott RealTime m2000	4	28	17	9	0	2	0
Cepheid Xpert kit	9	63	42	14	2	1	4
Hologic Aptima	2	14	12	2	0	0	0
Qiagen NeuMoDx	1	7	1	4	0	2	0
Real-time In-House PCR	2	14	6	1	5	0	2
Roche Cobas 4800	4	28	15	12	1	0	0
Total	25	175	106	49	9	5	6

Table V6. Score per sample, per method and per laboratory

Method	Sample ID 21S-01 Quant Score	21S-02 Quant Score	21S-03 Quant Score	21S-04 Quant Score	21S-05 Quant Score	21S-06 Quant Score	21S-07 Quant Score
Abbott Alinity m	0	0	0	0	0	0	0
Abbott Alinity m	0	0	0	1	0	0	1
Abbott Alinity m	1	1	1	1	2	1	0
Abbott RealTime m2000	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	1	1	0	1
Abbott RealTime m2000	0	0	0	0	3	0	3
Abbott RealTime m2000	1	1	1	1	1	0	1
Cepheid Xpert kit	0	0	0	0	0	0	0
Cepheid Xpert kit	1	ND	1	ND	0	3	0
Cepheid Xpert kit	0	0	1	0	0	0	1
Cepheid Xpert kit	0	0	0	1	0	0	ND
Cepheid Xpert kit	0	0	1	0	2	0	0
Cepheid Xpert kit	1	0	1	0	0	0	ND
Cepheid Xpert kit	1	0	0	1	0	0	0
Cepheid Xpert kit	0	2	0	1	1	1	0
Cepheid Xpert kit	1	0	0	1	0	0	0
Hologic Aptima	0	0	0	0	0	0	0
Hologic Aptima	0	1	0	0	0	0	1
Qiagen NeuMoDx	3	3	1	1	1	0	1
Real-time In-House PCR	1	2	2	2	2	2	0
Real-time In-House PCR	ND	0	0	0	0	0	ND
Roche Cobas 4800	1	0	2	1	1	0	0
Roche Cobas 4800	1	0	0	0	0	0	0
Roche Cobas 4800	0	1	1	0	0	0	1
Roche Cobas 4800	1	0	0	1	1	1	1

Colour code. Blue: not determined result; green: Z score <1; yellow: Z score between 1 and 2, orange: Z score between 2 and 3, red: Z score upper or equal to 3.

Score per laboratory

For the quantitative results, the scoring system was based on the cumulative Z score.
The score was 0 for a Z score <1; the score was 1 for a Z score between 1 and 2, the score was 2 for a Z score between 2 and 3, the score was 3 for a Z score upper than 3 and for a ND result.
Therefore, out of the 23 laboratories encoding one dataset, 2 obtained the score of 0, 1 obtained the score of 1, 6 obtained the score of 2; two obtained the score of 3, one the score of 4, four the score of 5, two the score of 6, two the score of 7, one the score of 8 and 2 the score of 11.
The laboratory encoding 2 datasets obtained the score of 4 (0+4).

B. HEPATITIS C VIRUS (HCV

The samples

Table V7. Panel composition

Sample ID	Content	Matrix	status	Quantitative values (mean±SD)
HCVRNA101S-01	HCV Type 3a	Plasma	Frequently Detected	3.109±0.277
HCVRNA101S-02	HCV Type 3a	Plasma	detected	2.109±0.286
HCVRNA101S-03	HCV Type 1b	Plasma	Frequently Detected	2.848±0.181
HCVRNA101S-04	HCV Type 1b	Plasma	Frequently Detected	2.846±0.201
HCVRNA101S-05	HCV Type 1b	Plasma	Frequently Detected	3.092±0.204
HCVRNA101S-06	HCV Type 1b	Plasma	Detected	1.793±0.228
HCVRNA101S-07	HCV Type 3a	Plasma	Frequently Detected	2.343±0.281
HCVRNA101S-08	HCV Negative	Plasma	Negative	Not applicable

Qualitative results
The participants

30 laboratories encoded results. 29 laboratories encoded one dataset and one laboratory encoded two datasets. Therefore, 31 datasets were encoded

Qualitative results per sample

Table V8. Qualitative results per sample

Sample ID	Status	Positive	Negative	ND
HCVRNA101S-01	Frequently Detected	31	0	0
HCVRNA101S-02	detected	29	0	2
HCVRNA101S-03	Frequently Detected	31	0	0
HCVRNA101S-04	Frequently Detected	30	0	1
HCVRNA101S-05	Frequently Detected	30	0	1
HCVRNA101S-06	Detected	30	0	1
HCVRNA101S-07	Frequently Detected	31	0	0
HCVRNA101S-08	Negative	0	30	1

31 datasets and 8 results per dataset giving 248 results. Out of the 248 qualitative results, 242 (97.6%) were correct. Only 6 results were encoded as “not determined”.

Results per method

Table V9. Qualitative results per method

Method	N	NR	NCR	%	ND
Alinity m	3	24	24	100	0
Abbott RealTime m2000	5	40	40	100	0
Cepheid Xpert kit	14	112	106	94.6	6
Hologic Aptima	2	16	16	100	0
Roche Cobas 4800	5	40	40	100	0
Roche Cobas 6800/8800	2	16	16	100	0
TOTAL	31	248	242	97.6	0

Table V10. Score per sample, per method and per laboratory

Method	21S-01 Qual Score	21S-02 Qual Score	21S-03 Qual Score	21S-04 Qual Score	21S-05 Qual Score	21S-06 Qual Score	21S-07 Qual Score	21S-08 Qual Score
Abbott Alinity m	0	0	0	0	0	0	0	0
Abbott Alinity m	0	0	0	0	0	0	0	0
Abbott Alinity m	0	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	0	0	0	0	0
Abbott RealTime m2000	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	2	0	3	0	2	0	3
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	2	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	3	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	0	0	0
Hologic Aptima	0	0	0	0	0	0	0	0
Hologic Aptima	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 6800/8800	0	0	0	0	0	0	0	0
Roche Cobas 6800/8800	0	0	0	0	0	0	0	0

Score per laboratory

Out of the 29 laboratories encoded one dataset, 26 obtained the score of 0, 1 the score 2, 1 the score of 3 and 1 the score of 10. The laboratory encoding 2 datasets obtained the score of 0.

Quantitative results
The participants.

28 laboratories encoded quantitative results, 27 encoded one dataset and one laboratory encoded two datasets meaning 29 datasets in total.

Results per sample

Table V11. Quantitative results per sample

Sample ID	Z<1	1≤Z<2	2<≤Z<3	Z>≥3	ND	Total
HCVRNA101S-01	17	10	1	1	0	29
HCVRNA101S-02	19	7	1	0	2	29
HCVRNA101S-03	19	8	2	0	0	29
HCVRNA101S-04	21	4	3	0	1	29
HCVRNA101S-05	22	4	1	1	1	29
HCVRNA101S-06	19	7	0	1	2	29
HCVRNA101S-07	16	12	1	0	0	29
Total	133	52	9	3	6	203

Out of 203 results, 133 (65.5%) corresponded to a Z score <1, 52 to a Z score between 1 and 2, 9 to a Z score between 2 and 3, 6 to a Z score >3 and 6 were “not determined” results. Globally, out of 203 results, 194 (95.6%) were correct.

Distribution of the results

Log 10 (IU/ml)

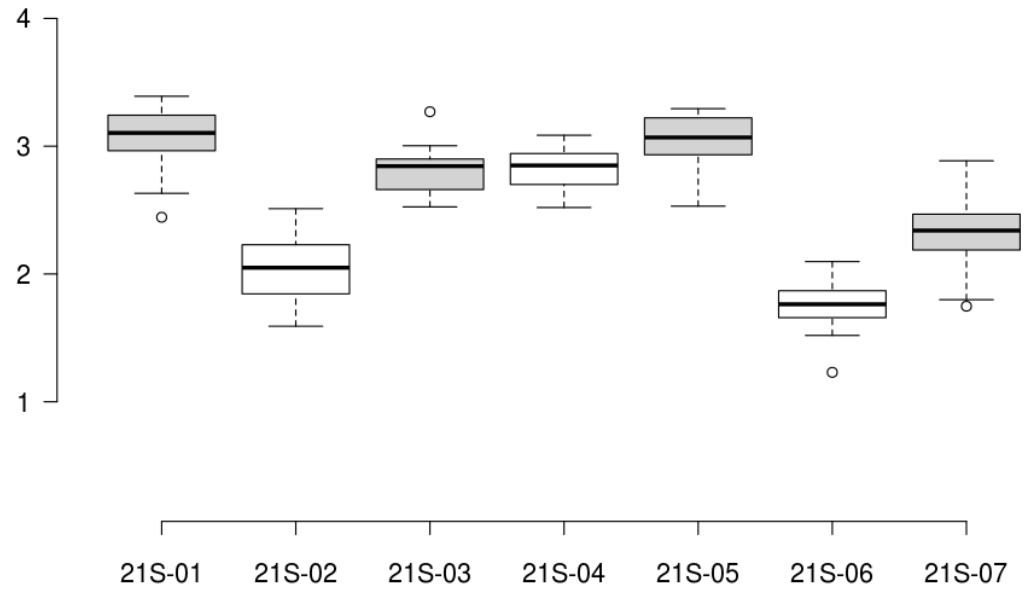

Figure V2. Distribution of the results (boxplots) per sample.

Quantitative results per method

Table V12. Quantitative results per method

Method	N	NR	Z<1	1<Z<2	2<Z<3	Z>3	ND
Alinity m	3	21	12	7	2	0	0
Abbott RealTime m2000	5	35	21	9	3	1	1
Cepheid Xpert kit	14	70	36	23	4	2	5
Hologic Aptima	2	14	8	6	0	0	0
Roche Cobas 4800	4	28	21	7	0	0	0
Roche Cobas 6800/8800	1	7	7	0	0	0	0
TOTAL	29	203	133	52	9	3	6

Table V13. Score per sample, per method and per laboratory

Method	21S-01 Quant Score	21S-02 Quant Score	21S-03 Quant Score	21S-04 Quant Score	21S-05 Quant Score	21S-06 Quant Score	21S-07 Quant Score
Abbott Alinity m	0	0	0	0	0	0	1
Abbott Alinity m	0	1	1	0	2	0	1
Abbott Alinity m	2	0	1	0	0	1	1
Abbott RealTime m2000	3	2	1	0	1	3	1
Abbott RealTime m2000	1	0	0	0	0	0	0
Abbott RealTime m2000	1	0	1	2	0	0	2
Abbott RealTime m2000	0	0	0	0	0	1	0
Abbott RealTime m2000	1	1	0	0	0	0	0
Cepheid Xpert kit	1	0	2	2	0	0	0
Cepheid Xpert kit	0	0	0	0	3	1	0
Cepheid Xpert kit	1	1	1	0	0	0	1
Cepheid Xpert kit	1	3	0	3	0	3	0
Cepheid Xpert kit	0	0	0	0	0	0	1
Cepheid Xpert kit	0	0	0	0	0	0	1
Cepheid Xpert kit	0	3	0	1	0	0	0
Cepheid Xpert kit	0	0	2	0	0	0	0
Cepheid Xpert kit	0	0	0	0	0	1	1
Cepheid Xpert kit	0	1	0	0	1	0	0
Cepheid Xpert kit	0	1	1	2	3	0	0
Cepheid Xpert kit	0	1	0	1	0	0	0
Cepheid Xpert kit	0	0	0	0	1	1	1
Cepheid Xpert kit	1	0	1	0	0	3	0
Hologic Aptima	0	0	0	0	0	0	1
Hologic Aptima	1	0	1	1	1	0	1
Roche Cobas 4800	0	0	0	0	0	0	0
Roche Cobas 4800	1	1	0	1	0	0	0
Roche Cobas 4800	1	0	0	0	0	1	0
Roche Cobas 4800	0	0	0	0	0	1	1
Roche Cobas 6800/8800	0	0	0	0	0	0	0

Blue: not determined result; green: Z socre<1; yellow: Z score between 1 and 2; orange: z score between 2 and 3; red: z score upper or equal to 3.

Quantitative Score per laboratory

For the quantitative results, the scoring system was based on the cumulative Z score.
The score was 0 for a Z score <1; the score was 1 for a Z score between 1 and 2, the score was 2 for a Z score between 2 and 3 and for a ND result for a detected sample, the score was 3 for a Z score upper than 3 and for a ND result for a frequently detected sample.
Out of the 27 laboratories encoding one dataset, 2 obtained the perfect score of 0, 5 obtained the score of 1, 7 obtained the score of 2, 2 obtained the score of 3, 3 obtained the score of 4, 5 obtained the score of 5, 1 obtained the score of 7, 1 obtained the core of 10 and 1 obtained the score of 11. The laboratory encoding two datasets obtained the score of 7 (6+1).

C. HCV GENOTYPING

The samples

Table V14. Panel composition

Sample ID	Matrix	content
HCVGT21S-01	Plasma	HCV Type 3a
HCVGT21S-02	Plasma	HCV Type 2b
HCVGT21S-03	Plasma	HCV Type 5a
HCVGT21S-04	Plasma	HCV Type 4c
HCVGT20S-05	Plasma	HCV Type 1b
HCVGT21S-06	Plasma	HCV Type 1b
HCVGT21S-07	Plasma	HCV Negative
HCVGT20S-08	Plasma	HCV Type 1a

The participants

17 laboratories encoded one dataset.

Results per sample

Table V14. Results per sample

Sample ID	content	Encoded results	Comment
HCVGT21S-01	HCV Type 3a	10 HCV Type 3a 7 HCV Type 3	OK
HCVGT21S-02	HCV Type 2b	8 HCV type 2b 7 HCV 2 2 not detected	2 wrong results
HCVGT21S-03	HCV Type 5a	8 HCV type 5a 7 HCV 5 2 not detected	2 wrong results
HCVGT21S-04	HCV Type 4c	3 HCV type 4c 13 HCV type 4 1 not detected	1 wrong result
HCVGT20S-05	HCV Type 1b	12 HCV type 1b 5 HCV type 1	5 wrong results
HCVGT21S-06	HCV Type 1b	14 HCV type 1b 3 HCV type 1	3 wrong results
HCVGT21S-07	HCV Negative	17 negative result	Ok
HCVGT20S-08	HCV Type 1a	16 HCV type 1a 1 HCV type b	1 wrong result

17 laboratories and 8 samples giving 136 results. Out of the 136 results, 122 (93.4%) were correct.

Results par method

Table V15. Results per method

Method	N	NR	NCR	%	NWR	ND
Abbott Real Time PCR	5	40	32	80	8	0
Conventional In-House PCR	1	8	7	87.5	0	1
Roche Cobas 4800	2	16	16	100	0	0
Siemens Versant (kPCR)	2	16	16	100	0	0
Siemens Versant (LiPA)	5	40	37	92.5	1	2
Vela Dx Sentosa	2	16	14	87.5	0	2
Total	17	136	122	89.7	9	5

NR: number of results; NCR: number of correct results; NWR: number of wrong results; ND: not determined

Table V15. Scores per sample per method and per laboratory

METHOD	Samples (ID+ genotype)							
	S1 3a	S2 2b	S3 5a	S4 4c	S5 1b	S6 1b	S7 NEG	S8 1a
Abbott Real Time PCR	0	0	0	0	1	0	0	0
Abbott Real Time PCR	0	0	0	0	1	1	0	0
Abbott Real Time PCR	0	0	0	0	1	0	0	0
Abbott Real Time PCR	0	0	0	0	1	1	0	0
Abbott Real Time PCR	0	0	0	0	1	1	0	0
Conventional In-House PCR	0	0	3	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Roche Cobas 4800	0	0	0	0	0	0	0	0
Siemens Versant (kPCR)	0	0	0	0	0	0	0	0
Siemens Versant (kPCR)	0	0	0	0	0	0	0	0
Siemens Versant (LiPA)	0	0	0	0	0	0	0	1
Siemens Versant (LiPA)	0	0	0	0	0	0	0	0
Siemens Versant (LiPA)	0	0	0	3	0	0	0	0
Siemens Versant (LiPA)	0	0	0	0	0	0	0	0
Siemens Versant (LiPA)	0	0	3	0	0	0	0	0
Vela Dx Sentosa	0	3	0	0	0	0	0	0
Vela Dx Sentosa	0	3	0	0	0	0	0	0

Blue: not determined result, red: uncorrected typing

Score per laboratory

6 laboratories obtained the ideal score of 0. Three laboratories obtained the score of 1. Three laboratories obtained the score of 2. Five laboratories obtained the score of 3 (absence of results).

Conclusion.

For the genotyping, the subtyping is especially important for 1a and 1b subtypes because it is linked to a potential treatment. It is less critical for the others types. The evaluation took this point into account.

D. SARS-COV-2

In 2021, two surveys were organized in collaboration with QCMD for the dectection of SARS-CoV-2 virus using molecular methods. .

Survey 1.

1. THE SAMPLES

The samples were produced and shipped by QCMD (Scotland). The homogeneity and the stability of the samples were guaranteed by QCMD.

Table V16. Panel composition

Sample ID	Sample content	Sample status*
SCV2_21C1B-01	SARS-CoV-2 Lineage B.1	Frequently detected
SCV2_21C1B-02	SARS-CoV-2 Lineage B.1.1.298	Frequently detected
SCV2_21C1B-03	SARS-CoV-2 Lineage B.1	detected
SCV2_21C1B-04	SARS-CoV-2 Lineage B.1.1.2	Frequently detected
SCV2_21C1B-05	SARS-CoV-2 Lineage B.1	Frequently detected

2. THE PARTICIPANTS

106 Belgian laboratories participated to this survey.
55 laboratories encoded 1 dataset, 28 laboratories encoded 2 datasets, 18 laboratories encoded 3 datasets, 3 laboratories encoded 4 datasets, 1 laboratory encoded 5 datasets and 1 laboratory encoded 6 datasets. In total, 188 datasets were encoded

3. RESULTS PER SAMPLE

Table V17. Results per sample

Sample ID	expected result	positive	Negative	ND
SCV2_21C1B-01	Positive	188	0	0
SCV2_21C1B-02	Positive	180	8	0
SCV2_21C1B-03	Positive	166	22	0
SCV2_21C1B-04	Positive	183	4	1
SCV2_21C1B-05	Positive	183	4	1

188 datasets and 5 samples for 940 results. 900 results (95.7%) were correct. 38 results were false negative results and 2 results were not determined.

4. SCORE PER LABORATORY

The score ranged from 0 to 16 per dataset.
Out of the 55 laboratories encoding one dataset, 46 (83.6%) obtained a perfect score of 0. Five (9%) obtained the score of 2, 2 obtained the score of 5, one the score of 8 and one the score of 11.
Out of the 28 laboratories encoding two datasets, 25 (89,3%) obtained the ideal score of 0, 2 laboratories obtained a score of 2 and 1 laboratory obtained the score of 3.
Out of the 18 laboratories encoding 3 datasets, 11 (61.1%) obtained the score of 0, 2 obtained a score of 2, 1 obtained a score of 4 (2+2+0), one obtained a score of 5 (5+0+0), one obtained a score of 8 (8+0+0), one a score of 11 and one a score of 13 (8+5+0).

For the 3 laboratories encoding 4 datasets, 2 obtained the score of 0 and 1 the score of 2.
The laboratory encoding 5 datasets obtained the score of 0 and the laboratory encoding 6 datasets obtained the score of 2.
In summary, out of the 106 laboratories, 85 (80.2%) obtained the ideal score of 0. 11 obtained the score of 2, 1 obtained the score of 3, 1 the score of 4, 3 obtained the score of 5, 2 the score of 8, 2 the score of 11 and 1 the score of 13.

5. RESULTS PER METHOD

Table V18. results per method

Method	N	NR	NCR	%	FN	ND	#
Abbott Alinity SARS-CoV-2	7	35	35	100,0	0	0	1
Altona Diagnostics AS SCV2	4	20	20	100,0	0	0	1
Cepheid Xpert SCV2/Flu/RSV	1	5	5	100,0	0	0	1
Certest Viasure N1 + N2	2	10	10	100,0	0	0	1
Diagenode Real-Time PCR	2	10	10	100,0	0	0	1
Elitech Elite SCV-2	2	10	10	100,0	0	0	1
Hologic Aptima SARS-CoV-2	9	45	45	100,0	0	0	1
Kogene Powerchek	4	20	20	100,0	0	0	1
Luminex ARIES SCV2	9	45	45	100,0	0	0	1
PerkinElmer SARS-CoV-2 Real Time PCR	2	10	10	100,0	0	0	1
Qiagen NeuMoDx SARS-CoV-2	3	15	15	100,0	0	0	1
Roche Cobas Liat SCV2/INF	6	30	30	100,0	0	0	1
Roche Cobas SARS-CoV 2	4	20	20	100,0	0	0	1
Seegene Allplex 2019 – nCoV	1	5	5	100,0	0	0	1
TIB MolBiol LightMix E-gene	5	25	25	100,0	0	0	1
Cepheid Xpert SARS-CoV-2	30	150	149	99,3	1	0	2
Elitech GeneFinder COVID-19	18	90	89	98,9	1	0	3
Real-time In-House PCR	13	65	62	95,4	3	0	4
DiaSorin Simplexa COVID-19	3	15	14	93,3	1	0	5
Seegene Allplex SCV2/Flu/RSV	3	15	14	93,3	1	0	5
Seegene Allplex SARS-CoV-2	23	115	106	92,2	9	0	6
Thermofisher TaqPath COVID-19	23	115	105	91,3	8	2	7
Abbott SARS-CoV-2	3	15	13	86,7	2	0	8
Abbott ID NOW Covid-19	5	25	20	80,0	5	0	9
BD SARS-CoV-2	3	15	12	80,0	3	0	9
Certest Viasure ORF1 & N	1	5	4	80,0	1	0	9
FTD SARS-CoV-2	1	5	4	80,0	1	0	9
Credo Diagnostics SARS-CoV-2	1	5	3	60,0	2	0	10
Total	188	940	900	95,7	38	2	

N=number of datasets, NR= number of results, NCR=number of correct results, FN: false negative, ND: not determined, #: ranking

6. RESULT PER METHOD AND PER SAMPLE

Table V19. Score per dataset, per method and per sample

Method	B-01	B-02	B-03	B-04	B-05
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott ID NOW Covid-19	0	0	0	0	0
Abbott ID NOW Covid-19	0	0	2	0	3
Abbott ID NOW Covid-19	0	0	0	0	0
Abbott ID NOW Covid-19	0	0	2	0	3
Abbott ID NOW Covid-19	0	0	2	0	0
Abbott SARS-CoV-2	0	0	0	0	0
Abbott SARS-CoV-2	0	0	0	0	0
Abbott SARS-CoV-2	0	0	2	0	3
Altona Diagnostics AS SCV2	0	0	0	0	0
Altona Diagnostics RS SCV2	0	0	0	0	0
Altona Diagnostics RS SCV2	0	0	0	0	0
Altona Diagnostics RS SCV2	0	0	0	0	0
BD SARS-CoV-2	0	0	0	0	0
BD SARS-CoV-2	0	0	0	0	0
BD SARS-CoV-2	0	3	2	3	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	2	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SCV2/Flu/RSV	0	0	0	0	0

Table V19. following

Method	B-01	B-02	B-03	B-04	B-05
Certest Viasure N1 + N2	0	0	0	0	0
Certest Viasure N1 + N2	0	0	0	0	0
Certest Viasure ORF1 & N	0	0	2	0	0
Credo Diagnostics SARS-CoV-2	0	3	2	0	0
Diagenode Real-Time PCR	0	0	0	0	0
Diagenode Real-Time PCR	0	0	0	0	0
DiaSorin Simplexa COVID-19	0	0	0	0	0
DiaSorin Simplexa COVID-19	0	0	2	0	0
DiaSorin Simplexa COVID-19	0	0	0	0	0
Elitech Elite SCV-2	0	0	0	0	0
Elitech Elite SCV-2	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	2	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
FTD SARS-CoV-2	0	0	2	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Kogene Powerchek	0	0	0	0	0
Kogene Powerchek	0	0	0	0	0
Kogene Powerchek	0	0	0	0	0
Kogene Powerchek	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
PerkinElmer SARS-CoV-2 Real Time PCR	0	0	0	0	0
PerkinElmer SARS-CoV-2 Real Time PCR	0	0	0	0	0
Qiagen NeuMoDx SARS-CoV-2	0	0	0	0	0
Qiagen NeuMoDx SARS-CoV-2	0	0	0	0	0
Qiagen NeuMoDx SARS-CoV-2	0	0	0	0	0
Qiagen QIAprep & amp	0	0	0	0	0

Table V19. following

Method	B-01	B-02	B-03	B-04	B-05
Real-time In-House PCR	0	0	2	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	2	0	0
Real-time In-House PCR	0	0	2	0	0
Real-time In-House PCR	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Seegene Allplex 2019 - nCoV	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	2	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	3	2	3	3
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	2	0	0
Seegene Allplex SARS-CoV-2	0	3	2	3	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SCV2/Flu/RSV	0	0	2	0	0
Seegene Allplex SCV2/Flu/RSV	0	0	0	0	0
Seegene Allplex SCV2/Flu/RSV	0	0	0	0	0

Table V19. end

Method	B-01	B-02	B-03	B-04	B-05
Thermofisher TaqPath COVID-19	0	3	2	3	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	3	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	2	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	3	2	3	3
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	3	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0

SURVEY 2

The samples

Table V20: the samples

Sample ID	Matrix	Content	Status
SCV2_21C1C-01	Transport medium	SARS-CoV-2 Variant B.1	detected
SCV2_21C1C-02	Transport medium	SARS-CoV-2 Variant B.1	Frequently detected
SCV2_21C1C-03	Transport medium	SARS-CoV-2 UK (Alpha) Variant B1.1.7	Frequently detected
SCV2_21C1C-04	Transport medium	SARS-CoV-2 SA (Beta) Variant B1.351	Frequently detected
SCV2_21C1C-05	Transport medium	SARS-CoV-2 Variant B.1	Frequently detected

The participants

114 laboratories encoded results. 57 laboratories encoded one dataset, 37 laboratories encoded two datasets, 17 laboratories encoded 3 datasets, 1 laboratory encoded 4 datasets, 2 laboratories encoded 5 datasets. In total; 196 datasets were encoded.

RESULTS PER SAMPLE

Table V21. Results per sample

Sample ID	Expected result	Positive	Negative	ND
SCV2_21C1C-01	Positive	184	14	0
SCV2_21C1C-02	Positive	193	2	1
SCV2_21C1C-03	FPositive	193	3	0
SCV2_21C1C-04	Positive	193	3	0
SCV2_21C1C-05	Positive	195	1	0

196 datasets and 5 samples per dataset giving 980 results. 956 correct results (97.6%) and 24 (3.4%) were encoded. Out of the 24 wrong results,23 were false negative results and one was a “not determined” result.

Results per method

Table v22 : results per method

Method	N	NR	NCR	%	FN	ND	#
BD SARS-CoV-2	3	15	15	100	0	0	1
Certest Viasure N1 + N2	3	15	15	100	0	0	1
Certest Viasure ORF1 & N	1	5	5	100	0	0	1
Diagenode Real-Time PCR	2	10	10	100	0	0	1
DiaSorin Simplexa COVID-19	3	15	15	100	0	0	1
Elitech Elite Real Time kit	5	25	25	100	0	0	1
Hologic Aptima SARS-CoV-2	9	45	45	100	0	0	1
Kogene Powerchek	5	25	25	100	0	0	1
Luminex ARIES SCV2	9	45	45	100	0	0	1
Luminex NxTAG RPP + SCV2	1	5	5	100	0	0	1
NZYTech SARS-CoV-2	1	5	5	100	0	0	1
Qiagen NeuMoDx SARS-CoV-2	1	5	5	100	0	0	1
Real-time In-House PCR	9	45	45	100	0	0	1
Roche Cobas Liat SARS-CoV 2	1	5	5	100	0	0	1
Roche Cobas Liat SCV2/INF	4	20	20	100	0	0	1
Seegene Allplex SCV2/Flu/RSV	1	5	5	100	0	0	1
Cepheid Xpert SARS-CoV-2	40	200	199	99.5	0	1	2
Elitech GeneFinder COVID-19	16	90	89	98.9	1	0	3
Thermofisher TaqPath COVID-19	22	110	108	98.2	2	0	4
Abbott Alinity SARS-CoV-2	7	35	34	97.1	1	0	5
TIB MolBiol LightMix E-gene	5	25	24	96	1	0	6
Seegene Allplex SARS-CoV-2	29	145	139	95.9	6	0	7
PerkinElmer SARS-CoV-2 Real Time PCR	2	10	9	90	1	0	8
Abbott ID NOW Covid-19	7	35	28	80.0	7		9
FTD SARS-CoV-2	1	5	4	80	1	0	9
Credo Diagnostics SARS-CoV-2	1	5	2	40	3	0	10
Total	196	980	956	97.6	23	1	

Results per laboratory, per sample and per method

Table V23 : score per laboratory, per method and per sample

Kit	21C1C-01	21C1C-02	21C1C-03	21C1C-04	21C1C-05
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	2	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott Alinity SARS-CoV-2	0	0	0	0	0
Abbott ID NOW Covid-19	2	0	0	0	0
Altona Diagnostics RS SCV2	0	0	0	0	0
Altona Diagnostics RS SCV2	0	0	0	0	0
BD SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	3	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Cepheid Xpert SARS-CoV-2	0	0	0	0	0
Certest Viasure N1 + N2	0	0	0	0	0
Certest Viasure N1 + N2	0	0	0	0	0
Certest Viasure ORF1 & N	0	0	0	0	0
Credo Diagnostics SARS-CoV-2	2	3	0	0	3
DiaSorin Simplexa COVID-19	0	0	0	0	0
Elitech Elite Real Time kit	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Elitech GeneFinder COVID-19	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0
Hologic Aptima SARS-CoV-2	0	0	0	0	0

Table V22: following

Kogene Powerchek	0	0	0	0	0
Kogene Powerchek	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex ARIES SCV2	0	0	0	0	0
Luminex NxTAG RPP + SCV2	0	0	0	0	0
PerkinElmer SARS-CoV-2 Real Time PCR	2	0	0	0	0
PerkinElmer SARS-CoV-2 Real Time PCR	0	0	0	0	0
Qiagen NeuMoDx SARS-CoV-2	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Real-time In-House PCR	0	0	0	0	0
Roche Cobas Liat SARS-CoV 2	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas Liat SCV2/INF	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Roche Cobas SARS-CoV 2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	2	3	3	3	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	2	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SARS-CoV-2	0	0	0	0	0
Seegene Allplex SCV2/Flu/RSV	0	0	0	0	0

Table V22. end

Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	2	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	3	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
Thermofisher TaqPath COVID-19	0	0	0	0	0
TIB MolBiol LightMix E-gene	2	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0
TIB MolBiol LightMix E-gene	0	0	0	0	0

Score per laboratory

The score per dataset can range from 0 (100% good results) to 14 (100% of wrong results). For the participants encoded more than one dataset, the scores of the datasets were added.

Out of the 57 laboratories encoded one dataset, 53 obtained the ideal score of 0 and 4 obtained the score of 2.

Out of 37 laboratories encoded 2 datasets, 31 obtained the score of 0, 3 obtained the score of 2, 2 obtained the score of 3 and one obtained the core of 4.

Out of the 17 laboratories encoding 3 datasets, 14 obtained the ideal score of 0, One obtained the score of 5 (0+0+5), one obtained the score of 8 (0+0+8) and one obtained the score of 11 (0+0+11).

The laboratory encoding 4 datasets obtained the score of 0.

Out of the 2 laboratories encoding 5 datasets; one obtained the score of 0 and one obtained the score of 3 (0+0+0+0+3).

Out of the 114 laboratories, 100 (87.7%) obtained the ideal score of 0.

E. RESPIRATORY VIRUSES

1.1.1.1.1 The samples

The multi-parameters panels allow to detect different pathogens in a same sample. In the RESPI21S panel (catalogue number QAV164188_1) the pathogens are: Influenza virus and Respiratory Syncytial virus.

Table V23. The samples

Sample ID	Matrix	Sample content	Status
RESPI101S-01	Transport Medium	Influenza Virus A (H3N2)	Frequently detected
RESPI101S-02	Transport Medium	Influenza Virus B (Victoria)	Frequently detected
RESPI101S-03	Transport Medium	Influenza Virus A H1N1 (pdm09)	Frequently detected
RESPI101S-04	Transport Medium	No viruses	Negative
RESPI101S-05	Transport Medium	Influenza virus A (H3N2)	Detected
RESPI101S-06	Transport Medium	Influenza (Type A) and Respiratory Syncytial Virus (type A)	Detected
RESPI101S-07	Transport Medium	Influenza type A (H1N1) pdm09	Frequently detected
RESPI101S-08	Transport Medium	Respiratory Syncytial Virus (type A)	Frequently detected
RESPI101S-09	Transport Medium	Influenza virus B (Yamagata)	Frequently detected
RESPI101S-10	Transport Medium	Respiratory Syncytial Virus (type B)	Frequently detected

Participants

24 laboratories encoded results.

Results per sample

Table V24. Results per sample

Sample ID	Sample content	Encoded results
RESPI101S-01	Influenza Virus A (H3N2)	24 influenza virus
RESPI101S-02	Influenza Virus B (Victoria)	24 influenza virus
RESPI101S-03	Influenza Virus A H1N1 (pdm09)	23 influenza virus 1 false negative result
RESPI101S-04	Negative	24 negative results
RESPI101S-05	Influenza virus A (H3N2)	23 influenza Virus 1 false negative result
RESPI101S-06	Influenza (Type A) and Respiratory Syncytial Virus (type A)	20 influenza virus and RSV 3 influenza virus 1 false negative result
RESPI101S-07	Influenza type A (H1N1)	23 influenza virus 1 false negative result
RESPI101S-08	Respiratory Syncytial Virus (type A)	24 RSV
RESPI101S-09	Influenza virus B (Yamagata)	23 influenza virus 1 false negative results
RESPI101S-10	Respiratory Syncytial Virus (type B)	24 RSV

For all the participants, their workflow included the detection of both influenza and respiratory syncytial viruses.
Therefore, out of the 240 encoded results, 232 (96.7%) were correct. 5 false negative results and 3 incomplete results were encoded.

Score per laboratory

The score can range from 0 (100% correct results) to 28 (100% of false results). 18 (75%) laboratories obtained the ideal score of 0, four laboratories obtained the score of 2, 1 laboratory the score of 3 and one laboratory the score of 14.

F. VIRUSES IN THE CONTEXT OF TRANSPLANTATION

The panel TRANS21S (catalogue number QAM174198_1) from QCMD was used in this survey. This multi-parameters panel allows the detection of several viruses involved in transplantation problems such as: adenovirus, Epstein Barr Virus (EBV), Cytomegalovirus (CMV), B19 virus, human Herpes virus 6 or BK virus.

The samples

Table V25. Panel composition

Sample ID	Matrix	content	Status
TRANS101S-01	Plasma	Adenovirus	Frequently detected
TRANS101S-02	Plasma	Adenovirus	Detected
TRANS101S-03	Plasma	Epstein-Barr virus	Detected
TRANS101S-04	Plasma	B19 virus	Detected
TRANS101S-05	Plasma	No virus	Negative
TRANS101S-06	Plasma	CMV	Frequently detected
TRANS101S-07	Plasma	CMV	Detected
TRANS101S-08	Plasma	Epstein-Barr virus	Frequently detected
TRANS101S-09	Transport Medium	human herpes virus 6	Frequently detected
TRANS101S-10	Transport Medium	BK virus	Frequently detected

The Participants

17 laboratories encoded results, 16 encoded one dataset and one encoded two datasets giving 18 datasets. Not all the participants analysed all the parameters. If the used method is unable to detect the pathogens present, the result was considered as “not tested”.

Results per sample

Table V26. Results per sample

Sample ID	content	Encoded results
TRANS101S-01	Adenovirus	8 denovirus 10 “not tested”
TRANS101S-02	Adenovirus	7 Adenovirus 10 “not tested” 1 false negative r
TRANS101S-03	Epstein-Barr virus	14 EBV 3 not tested 1 EBV+Adenovirus
TRANS101S-04	B19 virus	12 not tested 5 B19 1 B19+ HHV6
TRANS101S-05	Negative	18 negative s
TRANS101S-06	CMV	18 CMV
TRANS101S-07	CMV	17 CMV 1cytomegalovirus|human herpes virus 6
TRANS101S-08	Epstein-Barr virus	15 EBV 3 not tested
TRANS101S-09	human herpes virus 6	7 HHV 6 11 not tested results
TRANS101S-10	BK virus	9 BK virus 9 not tested

Finally, 104 results were evaluable. Out of the 104 results, 100 (96.2%) were correct.

Results per pathogen

Table V27. Results per pathogen

Pathogen	N	NR	NCR	%
Adenovirus	8	16	15	93.75
EBV	15	30	29	96.7
B19 virus	6	6	5	83.3
CMV	18	36	35	97.2
Human Herpes virus 6	7	7	7	100
BK virus	9	9	9	100

N: number of participants; NR: number of results; NCR: number of correct results

Score per laboratory

Out of the 16 laboratories encoding one dataset, 12 (75%) obtained the ideal score of 0, two the score of 2, one the score of 6 and one the score of 9. The laboratory encoding two datasets obtained the score of 0.

G. VIRAL MENINGITIS

The samples

The CNSI21S panel (Catalogue code QAV174195_1) of QCMD was used.

Table V28. Panel composition

Sample ID	Matrix	content	Status
CNSI21S-01	Transport medium	Echovirus 30	Detected
CNSI21S-02	Transport medium	Herpes Simplex Virus Type 2	Frequently detected
CNSI21S-03	Transport medium	Parechovirus Type 1	Detected
CNSI21S-04	Transport medium	Varicella-Zoster Virus (9/84)	Frequently detected
CNSI21S-05	Transport medium	No virus	negative
CNSI21S-06	Transport medium	Herpes Simplex Virus Type 1	Frequently detected
CNSI21S-07	Transport medium	Enterovirus A71	Detected
CNSI21S-08	Transport medium	Parechovirus Type 3	Frequently detected
CNSI21S-09	Transport medium	Herpes Simplex Virus Type 1	Detected
CNSI21S-10	Transport medium	Varicella-Zoster Virus (Ellen)	Frequently detected

The participants

31 laboratories encoded one dataset. Two laboratories encoded 2 datasets, one laboratory encoded 3 datasets. In total, 38 datasets were encoded. Not all the participants detected all the parameters. If the method did not allow to detect the pathogen, the result was indicated as “not tested”.

Results per sample

Table V29. Results per sample

Sample ID	content	Encoded results
CNSI21S-01	Echovirus 30	33 enterovirus 4 not tested r 1 wrong enterovirus+ HSV
CNSI21S-02	Herpes Simplex Virus Type 2	32 HSV 5 Not tested 1 false negative
CNSI21S-03	Parechovirus Type 1	18 parechovirus 16 Not tested r 1 false negative r 3 wrong results:“Haemophilus influenza+parechovirus”, “Herpes simplex virus”, “Enterovirus”
CNSI21S-04	Varicella-Zoster Virus (9/84)	31 VZV 7 Not tested r
CNSI21S-05	Negative	37 negative 1 HSV
CNSI21S-06	Herpes Simplex Virus Type 1	34 HSV 2 not tested 2 false negative
CNSI21S-07	Enterovirus A71	34 enterovirus 2 not tested 2 false negative
CNSI21S-08	Parechovirus Type 3	19 Parechovirus r 16 not tested

		2 false negative 1enterovirus
CNSI21S-09	Herpes Simplex Virus Type 1	26 HSV 5 not tested 6 false negative 1 HSV-enterovirus
CNSI21S-10	Varicella-Zoster Virus (Ellen)	29 VZV 7 not tested 2 false negative

Out of the 380 possible result, 65 were not tested results.
Out of 315 evaluable results, 292 (92.7%) were correct. Among the 23 wrong results, 16 were false negative results, 1 was a false positive result and 6 were wrong result (wrong identification).

Results per pathogen

Table V30. Results per pathogen

Pathogen	NR	NCR	%	FN	Wrong identification
Enterovirus	70	67	98.7	2	1
HSV	102	92	90.2	9	1
Parechovirus	44	37	84.1	3	4
VZV	62	60	96.8	2	0

NR: number of results; NCR: number of correct results.

Score per participant

Out of the 31 laboratories encoding one dataset, 20 (64.5%) obtained the ideal score of 0, 3 obtained the score of 2, 5 obtained the score of 3, one obtained the score of 6, one the score of 8 and 1 the score of 13.
The two laboratories encoding 2 datasets obtained the score of 0 and 2 (0+2), respectively.
The laboratory encoding 3 datasets obtained the score of 7 (0+0+7).

Comment.

For the syndromic panels, QCMD don't give us the used method or kit. Therefore, we can't evaluate the method.

H. HIGH RISK HPV

The samples

Table V31. The samples

Sample ID	Matrix	Sample content	Status
HPVPRES21S-01	PreservCyt+BSM	HPV45 (CC10b)	Detected
HPVPRES21S-02	PreservCyt+BSM	No HPV	Negative
HPVPRES21S-03	PreservCyt+BSM	HPV18 (Hela)	Frequently detected
HPVPRES21S-04	PreservCyt+BSM	HPV16 (Caski)	Detected
HPVPRES21S-05	PreservCyt+BSM	HPV16 (Caski)	Frequently detected
HPVPRES21S-06	PreservCyt+BSM	HPV45(CC10b)	Frequently detected
HPVPRES21S-07	PreservCyt+BSM	HPV18 (Hela)	Frequently detected
HPVPRES21S-08	PreservCyt+BSM	HPV16 (Caski)	Frequently detected
HPVPRES21S-09	PreservCyt+BSM	No HPV	Negative
HPVPRES21S-10	PreservCyt+BSM	HPV16 (Caski)	Frequently detected
HPVPRES21S-11	PreservCyt+BSM	HPV18 (Hela)	Frequently detected
HPVPRES21S-12	PreservCyt+BSM	HPV18 (Hela)	Frequently detected

The participants

40 laboratories encoded results. 36 encoded one dataset, 3 laboratories encoded two datasets, one laboratory encoded 3 datasets. In total, 45 datasets were encoded.

Results per sample

Table V32. Results per sample

Sample ID	Status	Positive	Negative	ND
HPVPRES21S-01	Detected	43	2	0
HPVPRES21S-02	Negative	1	42	2
HPVPRES21S-03	Frequently detected	45	0	0
HPVPRES21S-04	Detected	44	1	0
HPVPRES21S-05	Frequently detected	45	0	0
HPVPRES21S-06	Frequently detected	44	1	0
HPVPRES21S-07	Frequently detected	45	0	0
HPVPRES21S-08	Frequently detected	45	0	0
HPVPRES21S-09	Negative	0	42	2
HPVPRES21S-10	Frequently detected	45	0	0
HPVPRES21S-11	Frequently detected	45	0	0
HPVPRES21S-12	Frequently detected	45	0	0

45 datasets and 12 samples per datasets meaning 540 results, 531(98.3%) were correct.

Results per method

Table V33. Results per method

Method	N	NR	NCR	%	FP	FN	ND
Abbott Alinity m	1	12	12	100	0	0	0
Abbott RealTime m2000	10	120	118	98.3	0	2	0
BD Onclarity	1	12	12	100	0	0	0
Cepheid Xpert kit	3	36	36	100	0	0	0
Elitech Elite Real time kit	2	24	24	100	0	0	0
Fujirebio INNO-LIPA	1	12	12	100	0	0	0
Hologic Aptima	6	72	67	93.1	0	1	4
Real-time In-House PCR	1	12	12	100	0	0	0
Roche Cobas 4800	12	144	142	98.6	1	1	0
Sacace Real TM	1	12	12	100	0	0	0
Seegene Anyplex II	7	84	84	100	0	0	0
Total	45	540	531	98.3	1	4	4

Score per laboratory

Out of the 36 laboratories encoding one dataset, 33 (91.7%) obtained the ideal score of 0. One laboratory obtained the score of 2 and 2 laboratories obtained the score of 5.
Out of the 3 laboratories encoding two datasets, one obtained the score of 0 and two the score of 6 (0+6).
The laboratory encoding 3 datasets obtained the score of 0.

III. PARASITES

TOXOPLASMA GONDII

THE SAMPLES

In 2021, the samples were produced by Sciensano. A panel consisted of 5 samples, 4 positive and 1 negative.

Table P1. The samples

Sample ID	Matrix	Content	Status	NRCCp values
TG2021-1	CSF	T. gondii	Positive	24.88
TG2021-2	CSF	T. gondii[1]	Positive	27.70
TG2021-3	CSF	T. gondii[2]	Positive	30.12
TG2021-4	CSF	T. gondii[3]	Positive	27.04
TG2021-5	CSF	No T. gondii	negative	No Cp

CSF: cerebrospinal fluid.

1= dilution 1/8 of TG2021-1; 2= dilution 1/8 of TG2021-2; 3= dilution 1/5 of TG2021-1

RESULTS

13 laboratories were registered but only 11 (84.6%) encoded results.

Results per sample

Table P2. Results per method.

Sample ID	Expected results	Encoded results
TG2021-1	Positive	11 positive results
TG2021-2	Positive	11 Positive results
TG2021-2	Positive	11 Positive results
TG2021-3	Positive	11 Positive results
TG2021-4	Positive	11 Positive results
TG2021-5	Negative	11 negative results

100% of the encoded results were correct.

Used method

100% of the participants used homemade RT-qPCR validated methods.

Table P3. Used methods.

Method	Reference	N
Home made	Delhommeau F., Forestier F. (2002) Quantification of *Toxoplasma gondii* in Amniotic Fluid by Rapid Cycle Real-Time PCR. In: Reischl U., Wittwer C., Cockerill F. (eds) Rapid Cycle Real-Time PCR — Methods and Applications. Springer, Berlin, Heidelberg. Pp133-138.	1
Home made	Reischl U, Bretagne S, Krüger D, Ernault P, Costa JM. Comparison of two DNA targets for the diagnosis of Toxoplasmosis by real-time PCR using fluorescence resonance energy transfer hybridization probes. BMC Infect Dis. 2003 May 2;3:7.	3
Home made	Kupferschmidt O, Krüger D, Held TK, Ellerbrok H, Siegert W, Janitschke K. Quantitative detection of Toxoplasma gondii DNA in human body fluids by TaqMan polymerase chain reaction. Clin Microbiol Infect. 2001 Mar;7(3):120-4.	1
Home made	Not specified	2

Home made	Kasper DC, Sadeghi K, Prusa AR, Reischer GH, Kratochwill K, Förster-Waldl E, Gerstl N, Hayde M, Pollak A, Herkner KR. Quantitative real-time polymerase chain reaction for the accurate detection of Toxoplasma gondii in amniotic fluid. Diagn Microbiol Infect Dis. 2009 Jan;63(1):10-5. Lin MH, Chen TC, Kuo TT, et al. Real-time PCR for quantitative detection of Toxoplasma gondii. J Clin Microbiol. 2000;38(11):4121–5	1
Home made	Menotti J, Garin YJ, Thulliez P, Sérugue MC, Stanislawiak J, Ribaud P, de Castro N, Houzé S, Derouin F. Evaluation of a new 5'-nuclease real-time PCR assay targeting the Toxoplasma gondii AF146527 genomic repeat. Clin Microbiol Infect. 2010 Apr;16(4):363-8. Wahab T, Edvinsson B, Palm D, Lindh J. Comparison of the AF146527 and B1 repeated elements, two real-time PCR targets used for detection of Toxoplasma gondii. J Clin Microbiol. 2010 Feb;48(2):591-2.	1
Home made	Target gene: AF146527	1
Home made	Lin MH, Chen TC, Kuo TT, et al. Real-time PCR for quantitative detection of Toxoplasma gondii. J Clin Microbiol. 2000;38(11):4121–5	1

Conclusion.

All the participants encoded 100% of correct results independently of the used method.

GENERAL CONCLUSION

Tableau GC1. Summary og the proficiency for the different parameters

Paramètres	participants	datasets	NR	NCR	%
T.gondii	11	11	88	88	100
Bordetella pertussis	16	17	85	85	100,00
HPV	39	45	540	531	98,33
HCV qualitatif	30	31	248	242	97,58
SARS-COV-2 Eq 2	114	196	980	956	97,55
HBV qual	26	27	216	209	96,76
Virus transplantation (CMV, EBV, B19, BK)	17	18	180	173	96,11
HCV quant	28	29	203	195	96,06
SARS-COV-2 Eq 1	106	188	940	900	95,74
CT	88	88	704	673	95,60
pathogènes respiratoires (influenza, RSV)	24	24	240	229	95,42
M. tuberculosis	35	35	350	330	94,29
Meningites virales (HSV, VZV, EV, PEV)	34	38	380	358	94,21
HBV quantitatif	24	25	175	164	93,71
HCVGT	17	17	136	122	89,71
NG	87	87	696	606	87,07
Total			4424	4281	96,77

The results indicated that the percentage of correct results ranged from 87.1% (N. gonorrhoeae) to 100% (T. gondii and B. pertussis). The overall percentage of correct answers was 96.8% (97.1% in 2020). The comparison of the surveys is presented for information only. Indeed, the composition of the various panels may differ from one survey to another.

Tableau GC2. Comparison with the previous surveys (% of correct results).

Survey	2016	2017	2018	2019	2020	2021	trend
HCV qualitative	99.2	100	98.5	99.5	99,2	97.58	↓
N.gonorrhoeae	97.0	97.5	98.3	99.1	98,7	87,07	↓
HBV qualitative	99.4	100	100	99.0	99	93.71	↓
T. gondii	88.4	92.7	100	98.9	100	100	↔
C.trachomatis	97.2	97.0	98.8	97.6	99,3	95.6	↓
HPV	93.2	96.7	98.5	95.9	97,4	98.33	↑
EV	87.7	93.4	88.3	92.1	88,06	94.21	↑
VZV	92.9	93.3	83.2	90.7	88,06	94.21	↑
HCV genotyping	96.1	95.4	86.8	89.5	92,6	89.71	↓
HSV	97.7	92.6	82.2	88.9	88,06	94.21	↑
M.tuberculosis	94.9	86.9	92.5	96.2	96,6	94.29	↔

END