BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES

CLINICAL BIOLOGY/PATHOLOGICAL ANATOMY COMMISSION
COMMITTEE OF EXPERTS

EXTERNAL QUALITY ASSESSMENT
IN CLINICAL BIOLOGIE/PATHOLOGICAL ANATOMY

DEFINITIVE GLOBAL ANNUAL REPORT
Molecular Biology

Microbiology

2023

Sciensano/Molecular Microbiology/16-E

Biological health risks
Quality of laboratories
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1050 Brussels | Belgium

www.sciensano.be

ISSN: 2294-3471

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A preliminary version (draft) of this report was submitted to the experts on: 21/02/2024
This report was discussed at the meeting of the committee of experts on: 29/02/2024

Authorization of the report: by Bernard China, scheme coordinator

Date of publication: 15/03/2024

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I. INTRODUCTION

1.1 The surveys

In 2023, Sciensano organized directly or indirectly (subcontracted to QCMD) 14 surveys in molecular microbiology. 6 surveys were organized by Sciensano in collaboration with NRC (Table I1).

Table I1. Surveys organized by Sciensano

Survey ID	Parameters	Date of sending	Organized by
2023-S1	*Toxoplasma gondii*	21/03/2023	Sciensano
2023-S2	MPX virus	28/03/2023	Sciensano
2023-S3	*C. trachomatis*/*N. gonorrhoeae*	13/06/2023	Sciensano
2023-S4	High Risk HPV	28/03/2023	Sciensano
2023-S5	HCV+HBV	26/09/2023	Sciensano
2023-S6	*B. pertussis*	07/11/2023	Sciensano

9 surveys were outsourced to the Scottish international EQA company QCMD (Table I2).

Table I2. Surveys outsourced to QCMD

Survey ID	Parameters	Date of sending	Organized by
2023-Q1	HCV genotyping	06/03/2023	QCMD**
2023-Q2	SARS-COV-2 (1B)	Q2*	QCMD
2023-Q3	HBV-HCV	10/07/2023	QCMD**
2023-Q4	RespI	13/06/2023	QCMD**
2023-Q5	High Risk HPV	12/09/2023	QCMD**
2023-Q6	M. tuberculosis	19/09/2023	QCMD**
2023-Q7	SARS-COV-2 (1D)	Q4*	QCMD
2023-Q8	CNSI (viral meningitis)	08/11/2023	QCMD**
2023-Q9	TRANS (transplantation viruses)	08/11/2023	QCMD**

*: The samples were directly sent from QCMD to the participants therefore Sciensano doesn't know the exact date of shipment (Q2= quarter 2; Q4=quarter 4).
**: The samples were sent in batch form QCMD to Sciensano and Sciensano sent the samples to each participant.

1.2 The samples

For the surveys organized by Sciensano, we checked the homogeneity and the stability of the samples. The homogeneity control is made by sending a panel to expert laboratories to control the sample content. If the result is in agreement with the expected content (positive or negative) the samples were considered as homogeneous. If there is some divergence in the pre-survey results, the sample is sent as a didactic sample. The stability is evaluated by comparing the results of the expert laboratories before and during the survey. If the results are the same, the samples were considered as stable.

1.3 The evaluation.

Laboratories were assessed on the basis of the expected response, which was determined prior to the survey by one or more expert laboratories. The final status of a sample was determined on the basis of the consensus of the participants' results. For positive samples, a distinction was made between 'frequently detected' samples, which were detected by more than 95% of participants, 'detected' samples, which were detected by more than 65% of participants, and 'infrequently detected' samples, which were detected by less than 65% of participants. The penalty for errors depends on the status of the sample (tableau 3).

1. Table I.3. Penalty system

Status	Score for wrong answers
Negative	+3
Frequently detected	+3
Detected	+2
Infrequently detected	+1
Not determined*	+3 for a negative or a « frequently detected » sample +2 for a « detected » sample +1 for a « infrequently detected » sample

* : For surveys organised by Sciensano, it is always possible to obtain a replacement sample depending on available stock.

For quantitative results, an Z score is calculated Z= (target value of res)/SD Target value = median of participants SD = (P75-P25)/1.349 If |Z| score <1, score 0 If |Z| score between 1 and 2, score = 1 If |Z| score between 2 and 3 = score 2 Score If |Z| (3, Score = 3 (result quoted) An undetermined result is considered a wrong answer but the Z score cannot be calculated.

II. SCIENSANO SURVEYS

II.1. Toxoplasma gondii

The aim of this investigation was to evaluate the detection of *Toxoplasma gondii* in cerebrospinal fluid (CSF) samples using molecular methods. The samples were prepared by contaminating a medium mimicking the composition of CSF with *T. gondii* tachyzoites. Three samples were taken (2 positive and 1 negative).

RESULTS PER SAMPLE

Table R1. Results per sample

Sample	Expected result	Obtained results
TG2301	Positive	12 positive results
TG2302	Positive	12 positive results
TG2303	Negative	12 negative results

All the participants who submitted results obtained 100% of the expected results.

USED METHODS

Most laboratories (11/12=91.7%) used a home-made real-time PCR method.

II.2. Monkey Pox Virus

The aim of this survey was to evaluate the detection of Monkey pox virus in serum samples using molecular methods. The samples were prepared by contaminating serum with virus. The samples are then inactivated. Negative sera were supplied by Sciensano and contamination was carried out by the reference laboratory (ITM, Antwerp). Three samples were taken (2 positive and 1 negative). This investigation is not included in the classic list of EEQ parameters, but was dictated by current events.

RESULTS PER SAMPLE

Table R.2. Results per sample

SAMPLE	Expected result	Obtained results
MPX23-1	Negative	11 negative results
MPX23-2	Positive	11 positive results
MPX23-3	Positive	11 positive results

All the participants who submitted results obtained 100% of the expected results.

USED METHODS

Table R.3. Used methods

Method	N
Altona flexstar Monkey Pox Virus PCR detection Mix	3
Home made	4
Monkey pox virus real time PCR Kit bioperfectus	2
Qiagen QiaStat-Dx Viral Vesicular Panel*	1
Viasure monkeypox virus RT PCR reagents for BD-MAX	1

*This method is used to distinguish clade 1 viruses from clade 2 viruses. The positive samples were from clade 2 (West Africa).

II.3. Chlamydia trachomatis/Neisseria gonorrhoeae

Table R4. The samples

Sample	Matrix	Expected result
CTNG23-1	M4RT	CT negative, NG negative
CTNG23-2	M4RT	CT positive, NG positive
CTNG23-3	M4RT	CT positive, NG negative
CTNG23-4	M4RT	CT negative, NG positive
CTNG23-5	Urine	CT negative, NG negative
CTNG23-6	Urine	CT positive, NG Negative
CTNG23-7	Urine	CT negative, NG positive
CTNG23-8	Urine	CT positive, NG positive

A copy of each panel was sent to 3 expert laboratories prior to the survey. The results obtained were in line with the expected results except for sample CTNG2308 where positivity was not confirmed (1 positive/3 for CT and 3 negatives for NG). Samples CTG23-1 to 23-7 were considered homogeneous. Sample CTNG23-8 was sent for didactic purposes.

CHLAMYDIA TRACHOMATIS

96 participants were registered for this survey and 93 (97%) returned results. 91/93 (98%) returned one set of results and 2 returned two sets of results, giving a total of 95 sets of results.

Results per sample

Table R5. Results per sample

Sample	Expected result	Positive	Negative	ND	Status
2023-1	Negative	0	95	0	Negative
2023-2	Positive	94	1	0	Frequently detected
2023-3	Positive	95	0	0	Frequently detected
2023-4	Negative	4	91	0	Negative
2023-5	Negative	0	92	3	Negative
2023-6	Positive	93	0	2	Frequently detected
2023-7	Negative	0	93	2	Negative

7 samples and 95 participants, i.e. 665 results. 653 results were correct, i.e. 98.2%. Of the 12 incorrect results, 7 were "undetermined", 4 were false positives and 1 was a false negative.

Results per method

Table R6. Results per method

Method	N	NR	NCR	%	FP	FN	ND	ranking
seegene allplex CT/NG/MG/TV assay	21	147	147	100	0	0	0	1
ELITECH STI plus ELITE MGB Kit	9	56	56	100	0	0	0	1
Hologic Aptima combo2	7	49	49	100	0	0	0	1
Roche Cobas 4800 CT/NG	6	42	42	100	0	0	0	1
BD CTGCTV2	5	35	35	100	0	0	0	1
Roche Cobas 6800 CT/NG	5	35	35	100	0	0	0	1
Home made	3	21	21	100	0	0	0	1
Elitech Ingenius PCR cassette	2	14	14	100	0	0	0	1
viasure STD realtime PCR kit	2	14	14	100	0	0	0	1
Mikrogen Amplicube STD1	1	7	7	100	0	0	0	1
NeumoDX CT/NG	1	7	7	100	0	0	0	1
Qiagen LDT PCR	1	7	7	100	0	0	0	1
Roche Cobas 5800 CT/NG	1	7	7	100	0	0	0	1
seegene allplex STI essential assay	1	7	7	100	0	0	0	1
Abbott alinity m STI	8	56	55	98.2	0	0	1	2
Cepheid genexpert CTNG	17	119	111	93.3	2	0	6	3
Abbott real time CT/NG kit	4	28	26	92.8	1	1	0	4
Qiagen presto CTNG	1	7	6	85.7	1	0	0	5
Total	95	658	646	98,2	4	1	7	

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

Scores of the laboratories

Of the 91 laboratories that encoded a series of results, 86 received a score of 0 for 100% correct results, three laboratories obtained a score of 3, one laboratory a score of 6 and one laboratory a score of 12. As for the two laboratories that submitted two sets of results, the first obtained a cumulative score of 0 while the second obtained a cumulative score of 9 (0 for method 1 and 9 for method 2). Consequently, 87 out of 93 laboratories (93.5%) obtained the ideal score of 0.

Comment. For the detection of C. trachomatis, 98% of the results were correct. The most commonly used methods were Seegene allplex (21) and Cepheid genexpert (17).

For didactic sample 23-08, 28 results were positive (29.5%), 64 negative and 3 "not determined".

NEISSERIA GONORRHEAE

Results per sample

96 participants were registered for this survey and 93 (97%) returned results. 91/93 (98%) returned one set of results and 2 returned two sets of results, giving a total of 95 sets of results.

Table R7. Results per sample

Sample	Expected result	Positive	Negative	ND	Status
2023-1	Negative	4	90	1	Negative
2023-2	Positive	72	22	1	Detected
2023-3	Negative	5	87	3	Negative
2023-4	Positive	93	1	1	Frequently detected
2023-5	Negative	1	92	2	Negative
2023-6	Negative	3	90	2	Negative
2023-7	Positive	91	3	1	Detected

95 sets of 7 samples constituted 665 results. 615 results were correct, i.e. 92.5%. Of the 50 incorrect results, 26 were false negative, 13 false positives and 11 not determined (ND) results.

RESULTS PER METHOD.

Table R8. Results per method

Method	N	NR	NCR	%	FP	FN	ND	ranking
BD CTGCTV2	5	35	35	100,0	0	0	0	1
Elitech Ingenius PCR cassette	2	14	14	100,0	0	0	0	1
Mikrogen Amplicube STD1	1	7	7	100,0	0	0	0	1
Qiagen LDT PCR	1	7	7	100,0	0	0	0	1
seegene allplex STI essential assay	1	7	7	100,0	0	0	0	1
ELITECH STI plus ELITE MGB Kit	9	63	62	98,4	0	1	0	2
seegene allplex CT/NG/MG/TV assay	21	147	143	97,3	3	1	0	3
Home made	3	21	20	95,2	1	0	0	4
Abbott alinity m STI	8	56	53	94,6	0	0	3	5
Roche Cobas 4800 CT/NG	6	42	38	90,5	0	4	0	6
Cepheid genexpert CTNG	17	119	107	89,9	3	2	7	7
Hologic Aptima combo2	7	49	42	85,7	0	7	0	8
Roche Cobas 6800 CT/NG	5	35	30	85,7	1	4	0	8
viasure STD realtime PCR kit	2	14	12	85,7	2	0	0	8
Roche Cobas 5800 CT/NG	1	7	6	85,7	0	1	0	8
Qiagen presto CTNG	1	7	6	85,7	0	0	1	8
Abbott real time CT/NG kit	4	28	23	82,1	1	4	0	9
NeumoDX CT/NG	1	7	3	42,9	2	2	0	10
Total	95	665	615	92,5	13	26	11	

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

SCORES

Of the 91 laboratories that submitted a series of results, 60 obtained a perfect score of 0 for 100% correct answers. 17 laboratories obtained a score of 2, 9 a score of 3, 1 a score of 5, 1 a score of 7, 1 a score of 9, 1 a score of 11 and one laboratory obtained a score of 16. As for the two laboratories that encoded 2 sets of results, the first obtained a cumulative score of 2 (0+2) and the other a cumulative score of 12 (10+2).

Note. For the detection of *N. gonorrhoeae*, 92.5% of the results were correct. The most commonly used methods were Seegene allplex (21) and Cepheid genexpert (17).
For the 2023-8 didactic sample, the participants in this survey encoded the following results: 4 positive results, 90 negative results and 1 "not determined" result. Although the initial sample had to contain *N. gonorrhoeae* DNA, it seems that for the vast majority of participants, this quantity was below the limit of detection.

II.4. High risk human papillomavirus (HPV)

The samples were prepared by the NRC (AML, Sciensano-UZGent). They consist in 3 mL of Thinprep media with or without HPV (Table R9).

Table R9. the samples

Sample ID	Content
HPV23-1	HPV16, HPV18
HPV23-2	No DNA
HPV23-3	HPV18
HPV23-4	HPV6*
HPV23-5	HPV33
HPV23-6	HPV53*
HPV23-7	HPV16, HPV45
HPV23-8	HPV51, 52, 56, 58, 59
HPV23-9	HPV39
HPV23-10	Control human DNA, no HPV

*: not considered as a High risk type.

19 laboratories of pathologic anatomy and 25 laboratories of clinical biology encoded results.

RESULTS PER SAMPLE

47 datasets were encoded. 41 laboratories encoded one dataset and 3 laboratories encoded 2 datasets.

Table R10. Results per sample.

Sample ID	Content	Expected result	Positive	Negative	other
HPV23-1	HPV16, HPV18	Positive	44	3	0
HPV23-2	No DNA	ND/INH/NEG	0	15	18 INH 4 Not determined 9 Invalid 1 No DNA
HPV23-3	HPV18	Positive	47	0	0
HPV23-4	HPV6	Negative	5*	42	0
HPV23-5	HPV33	Positive	47	0	0
HPV23-6	HPV53	Negative	5**	42	0
HPV23-7	HPV16, HPV45	Positive	47	0	0
HPV23-8	HPV51, 52, 56, 58, 59	Positive	47	0	0
HPV23-9	HPV39	Positive	47	0	0
HPV23-10	No HPV	Negative	0	47	0

*: the participants used a detection kit able to detect HPV6.

**: the participants used a detection kit able to detect HPV53.

47 datasets and 10 samples= 470 results. On the 470 results, 467 results (99.4%) were correct. Only 3 false negative results were recorded for sample HPV23-1. Technically, the detection of low-risk HPV serotypes was evaluated on the basis of the method's ability to detect these serotypes. But the final report must mention that this is not a high-risk type. In sample 23-1, the levels of HPV16 and HPV 18 were low.

RESULT PER METHOD

Table R11. results per method

method	N	NR	NCR	%
Abbott Alinity m HR HPV	2	20	20	100
Abbott real time High risk HPV assay	5	50	50	100
Cepheid genexpert HPV	5	50	50	100
Roche Cobas HPV kit	13	130	130	100
Seegene allplex HPV HR	10	100	100	100
In house qPCR	1	10	10	100
Elitech High risk HPV ELITE Panel ingenius	1	10	10	100
Inno-Lipa HPV genotyping extra II	1	10	10	100
BD Onclarity HPV assay	1	10	10	100
Aptima HPV assay (Hologic panther)	7	70	67	95.7
Total	47	470	467	99.4

N: number of datasets, NR: number of results; NCR: number of correct results.

Hologic panther detected mRNA and the other methods detected DNA. The lower stability of mRNA and the low levels of contamination could explain the errors.

GENOTYPING

The genotyping was asked in a didactic way since it is not yet mandatory in the official nomenclature.
45 datasets were recorded for the genotyping.

GENOTYPE PER SAMPLE

Table R12. Genotypes recorded by sample

Sample ID	Expected result	Encoded results	
HPV 23-1	HPV16+HPV18	HPV 16, 18	**35**
		HPV 16/18, 45	**4**
		HPV16	3
		Other	2
HPV23-3	HPV18	HPV18	**37**
		HPV18/45	**8**
HPV23-4	HPV6	HPV6	**5**
HPV23-5	HPV33	HPV33	**15**
		Group A	**4**
		P3	**4**
		HR	**2**
		Other	**19**
		35, 38	1
HPV23-6	HPV53	HPV53	**5**
HPV23-7	HPV16+HPV45	HPV16+ HPV45	**22**
		HPV16+other	**14**
		16/18, 45	**6**
		16	2
		Other	1
HPV23-8	HPV51,52,56,58, 59	51,52, 56, 58, 59	**11**
		51,52, 53/56,58/59/66	**1**
		51, 52, 56	**2**
		Other	**17**
		HR	**3**
		P3, P4, P5	**3**
		Groupe A et B	**2**
		Group A	2
		16	1
		P3	1
HPV23-9	HPV39	HPV39	**15**
		Groupe B	**4**
		Other	**17**
		P5	**4**
		HR	**4**
		35/39/68	**1**

Group A: 31,33, 52, 58
Groupe B: 35,39,51,56,59,66,68
P3: 31, 33, 35, 52, 58
P4: 51,59
P5: 39,56,66,68
Other: No 16, 18 or 45
HR=31,33,35,39,45,51,52,56,58,59,66 or 68
The acceptable results were indicated in bold.
Out of the 360 encoded results, 347 (96.4%) were acceptable. 13 results were considered as incorrect.

II.5. Hepatitis (HCV-HBV)

The samples were prepared from a negative serum (HBV and HCV negative) spiked or not with HBV or HCV positive sera. These positive patient sera were provided by the NRC (UCL Saint-Luc, Brussels).

HBV

25 laboratories sent results, 24 sent quantitative results and 1 sent qualitative results only.

Results per sample

Qualitative results

Table R13. Qualitative results.

Sample ID	Expected qualitative result	Observed qualitative results
HBV23-1	Positive	25 positive results
HBV23-2	Positive	25 positive results
HBV23-3	Negative	25 negative results

All the 25 participants obtained the expected results for the qualitative detection of HBV in the serum.

Quantitative results

24 laboratories encoded quantitative results for the 2 positive samples. The median of all the results per sample was calculated and used as target value to calculate Z scores: Z=R-T/SD where R=result, T: target, SD: standard deviation. A Z score below 3 is considered as acceptable and a Z score upper or egal to 3 is unacceptable and means that the result was incorrect.

Table I. R14. Quantitative results

Sample ID	Median±SD (Log10 IU/mL)	Z<1	1≤Z<2	2≤Z<3	Z≥3	Comment
HBV23-1	6.52±0.11	16	6	0	2	2 incorrect results
HBV23-2	5.445±0.078	16	2	0	6	6 incorrect results

Out of the 48 results (24 per sample), 40 (83.3%) were acceptable (Z<3) and 8 (16.7%) were incorrect (Z≥3).

RESULTS PER METHOD

Table R15. quantitative results per method

Method	N	NR	NCR	%	Z<1	1<Z<2	2<Z<3	Z≥3	ranking
Cobas 5800 HBV test	2	4	4	100	4	0	0	0	1
Cobas 6800 HBV	2	4	4	100	4	0	0	0	1
NeuMoDx HBV quant Assay	1	2	2	100	2	0	0	0	1
Cepheid Xpert HBV viral load	9	18	17	94.4	16	1	0	1	2
Abbott ALINITY M HBV AMP KIT	7	14	10	71.4	4	6	0	4	3
Aptima HBV Quant assay	1	2	1	50	1	0	0	1	4
In house RTqPCR	2	4	2	50	1	1	0	2	4
Total	24	48	40	83.3	32	8	0	8	

HCV

The participants

32 laboratories sent results for HCV; 30 sent quantitative results and 2 sent qualitative results only.

Qualitative results

All the participants find the correct qualitative results: samples HCV23-1 and HCV23-2 were positive and the sample HCV23-3 was negative.

Quantitative results

Results per sample

Table R16. Quantitative results per sample.

Sample ID	Median±SD (Log10 IU/mL)	Z<1	1≤Z<2	2≤Z<3	Z≥3	Comment
HCV23-1	4.045±0.22	20	8	2	0	ok
HCV23-2	3.71±0.13	22	7	1	0	ok

All the results were in the acceptable range.

Results per method

Table R17. Quantitative results per method.

Method	N	NR	NCR	%	Z	<1	1<	Z	<2	2<	Z	<3	Z	>3
Cobas 4800 HBV test	1	2	2	100	1	1	0	0						
Cobas 5800 HCV test	2	4	4	100	2	2	0	0						
Cobas 6800 HCV test	4	8	8	100	5	3	0	0						
Cepheid Xpert HCV viral load	14	28	28	100	24	4	0	0						
Abbott ALINITY M HCV AMP KIT	7	14	14	100	9	4	1	0						
Aptima HCV Quant assay	2	4	4	100	1	1	2	0						
Total	30	60	60	100	42	15	3	0						

1.3.1 GENOTYPING

Only 10 laboratories sent results for the genotyping of HCV.

Table R18. Genotyping results.

Sample	Expected genotype*	Obtained results
HCV23-1	3a	7 answers 3a 3 answers 3
HCV23-2	4f	5 answers 4f 1 answer 4 *1 answer 4 and 5* 1 answer non-1 *1 answer "not determined"* *1 answer "Invalid"*

- As determined by the NRC

Out of the 20 results, 17 (85%) were considered as correct. The incorrect answers are shown in italic.

Used methods:
4 laboratories used the HCV genotype LIPA 2.0
2 laboratories used a Sanger sequencing method
2 used a real-time qPCR method
2 used a NGS method (Nanopore or Ion torrent)

II.6. Bordetella pertussis

Tableau R19. The samples

Sample	Matrix	volume	Status
BP23-1	Sputum	1 mL	Frequently detected
BP23-2	Sputum	1 mL	Frequently detected
BP23-3	Sputum	1 mL	Negative

RESULTS PER SAMPLE

Table R20. Results per sample

Sample	Expected results	Obtained results
BP23-1	Positive	23 positive results
BP23-2	Positive	23 positive results
BP23-3	Negative	23 negative results

100 % of the results received were correct.

USED DETECTION METHOD

Table R21. Used methods

DETECTION Method	Number of participants
Alethia Pertussis (LAMP)	1
Amplicube respiratory bact panel 2	1
Biofire Respiratory 2.1. plus	2
BioGX Bordetella speciation plus toxin kit	1
Bordetella Elite MGB Kit	2
Custom Taqman Array Card Respiratory Screening (LDT)	1
Qiastat-Dx-Respiratoir panel	1
Rida gene Bordetella	1
RTqPCR in house	5
Seegene Allplex pneumobacter assay	3
Seegene Allplex RP4	4
Diassorin Simplexa Bordetella direct kit	1

Summary of the Sciensano Surveys

Table R22. Summary of the sciensano surveys

Parameter	N	NR	NCR	%
T. gondii	12	36	36	100
MPXV	11	33	33	100
C. trachomatis	95	665	653	98.2
N. gonorrhoeae	95	665	615	92.5
HPV	47	470	467	99.4
HBV qualitative	25	75	75	100
HBV Quantitative	24	48	40	83.3
HCV qualitative	32	96	96	100
HCV quantitative	30	60	60	100
HCV genotyping	10	20	17	85
B. pertussis	23	69	69	100
	Total	2237	2161	96.6

N : number of datasets, NR : Number of results ; NCR : number of correct results

Overall, the rate of correct results was 96.6%, with variations from 85% to 100%.

III.ANNEX

QCMD SURVEYS

At the time of writing, Sciensano has only received the results of the HCV genotyping and SARS-COV-2 1B surveys from QCMD.

III.1.HCV genotyping

13 participants encoded results.

PANEL COMPOSITION

Table Q1. Panel composition

Sample ID	Matrix	Content
HCVGT23S-01	Plasma	No HCV
HCVGT23S-02	Plasma	Hepatitis C Virus Type 1b
HCVGT23S-03	Plasma	Hepatitis C Virus Type 4c
HCVGT23S-04	Plasma	Hepatitis C Virus Type 1b
HCVGT23S-05	Plasma	Hepatitis C Virus Type 1a
HCVGT23S-06	Plasma	Hepatitis C Virus Type 1b
HCVGT23S-07	Plasma	Hepatitis C Virus Type 4a
HCVGT23S-08	Plasma	Hepatitis C Virus Type 3a

RESULTS PER SAMPLE

Table Q2. Results per sample

Sample ID	Expected result	Encoded results	Comment
HCVGT23S-01	Negative	Negative (13)	ok
HCVGT23S-02	Type 1b	Type 1b (10) Type 1 (3)	3 wrong results
HCVGT23S-03	Type 4c	Type 4 (10) Type 4c (1) Not detected (2)	2 wrong results
HCVGT23S-04	Type 1b	Type 1b (11) Type 1 (2)	2 wrong results
HCVGT23S-05	Type 1a	Type 1a (8) Type 1 (3) Not detected (2)	5 wrong results
HCVGT23S-06	Type 1b	Type 1b (11) Type 1 (2)	2 wrong results
HCVGT23S-07	Type 4a	Type 4a (3) Type 4 (10)	ok
HCVGT23S-08	Type 3a	Type 3a (7) Type 3 (5) Not detected (1)	1 wrong result

*In interpreting the results, we have considered the type of response except for type 1, where a distinction between type 1a and type 1b is required.
13 participants and 8 samples per panel, i.e. 104 results.

89 results (85.5%) were considered correct and 15 results were not. Of the incorrect results, 10 were inaccurate genotypes and 5 were false negatives (the presence of the virus was not detected).

RESULTS PER METHOD

Table Q3. Results per method

Method	N	NR	NCR	%	FN	Wrong genotypes
Siemens Versant (kPCR)	1	8	8	100	0	0
Vela Diagnostics Sentosa NGS	1	8	8	100	0	0
Siemens Versant (LiPA)	5	40	36	90	1	3
Roche Cobas 4800	3	24	20	83,3	0	4
Conventional In-House PCR	1	8	6	75	2	0
Conventional Sequence Analysis	1	8	6	75	2	0
Abbott Genotype	1	8	5	62.5	0	3
Total	13	104	89	85.6	5	10

N: number of datasets, NR: number of results; NCR: number of correct results; FN: false negative.

Out of the 104 results, 89 (85.6%) were considered as correct.

INDIVIDUAL RESULTS AND SCORES.

Table Q4. Individual results and scores

Method	23S-01	23S-02	23S-03	23S-04	23S-05	23S-06	23S-07	23S-08	Score/8
	Negative	1b	4c	1b	1a	1b	4a	3a	
Abbott Genotype	Negative	1	4	1	1a	1	4	3	5
Conventional In-House PCR	Negative	1b	Negative	1b	Negative	1b	4a	3a	6
Conventional Sequence Analysis	Negative	1b	Negative	1b	Negative	1b	4a	3a	6
Roche Cobas 4800	Negative	1b	4	1b	1a	1b	4	3	8
Roche Cobas 4800	Negative	1b	4	1b	1a	1b	4	3	8
Roche Cobas 4800	Negative	1	4	1	1	1	4	3	4
Siemens Versant (kPCR)	Negative	1b	4	1b	1a	1b	4	3a	8
Siemens Versant (LiPA)	Negative	1	4	1b	1	1b	4	3a	6
Siemens Versant (LiPA)	Negative	1b	4	1b	1a	1b	4	3a	8
Siemens Versant (LiPA)	Negative	1b	4	1b	1	1b	4	Negative	6
Siemens Versant (LiPA)	Negative	1b	4	1b	1a	1b	4	3a	8
Siemens Versant (LiPA)	Negative	1b	4	1b	1a	1b	4	3	8
Vela Diagnostics Sentosa NGS	Negative	1b	4c	1b	1a	1b	4a	3a	8

Out of the 13 participants, 7, 4, 1 and 1 obtained 100%, 75%, 62,5% and 50% of correct results, respectively.

III.2. SARS-COV-2 (survey 1B)

THE PARTICIPATION

123 laboratories encoded results. 70 encoded one dataset, 34 encoded 2 datasets , 15 encoded 3 datasets, 2 encoded 4 datasets, and 2 encoded 5 datasets. Globally, 201 datasets were encoded.

Table Q5. Number of encoded datasets

N dataset (1)	N labs (2)	(1)*(2)
1	70	70
2	34	68
3	15	45
4	2	8
5	2	10
	123	201

THE SAMPLES

Table Q6. The samples

Sample ID	Matrix	Sample content	Status
SCV2_23C1B-01	Transport medium	SARS-CoV-2 Omicron BA.4	Frequently detected
SCV2_23C1B-02	Transport Medium	No SARS-COV-2	Negative
SCV2_23C1B-03	Transport Medium	SARS-CoV-2 Omicron BA.5	Frequently detected
SCV2_23C1B-04	Transport Medium	SARS-CoV-2 Omicron BA.4	Frequently detected
SCV2_23C1B-05	Transport Medium	SARS-CoV-2 Omicron BA.2	Frequently detected

RESULTS PER SAMPLE

Table Q7. Results pare sample

Sample ID	Status	Positive	Negative	Not determined
SCV2_23C1B-01	Frequently detected	199	0	2
SCV2_23C1B-02	Negative	0	200	1
SCV2_23C1B-03	Frequently detected	200	0	1
SCV2_23C1B-04	Frequently detected	199	0	2
SCV2_23C1B-05	Frequently detected	198	1	2

201 datasets and 5 samples per dataset gave 1005 results. 996 correct results (99.1%) and 9 uncorrect results including 8 not determined results and 1 false negative result.

RESULTS PER METHOD

Table Q8. Results per method

Method	N	NR	NCR	%	FP	FN	ND	Ranking
Abbott Alinity m Resp 4-Plex	1	5	5	100	0	0	0	1
Abbott Alinity SARS-Cov-2	9	45	45	100	0	0	0	1
Abbott ID NOW Covid-19	17	85	85	100	0	0	0	1
Abbott RealTime m2000 SARS-COV-2	2	10	10	100	0	0	0	1
Altona Diagnostics AS SCV2	1	5	5	100	0	0	0	1
Altona Diagnostics RS SCV2	1	5	5	100	0	0	0	1
BD SARS-CoV-2	1	5	5	100	0	0	0	1
BD SARS-CoV-2/Flu	4	20	20	100	0	0	0	1
BioFire FilmArray	1	5	5	100	0	0	0	1
Bio-Rad SARS-CoV-2	1	5	5	100	0	0	0	1
Certest Viasure N1 + N2	1	5	5	100	0	0	0	1
Certest Viasure ORF1 & N	2	10	10	100	0	0	0	1
Diagenode Real-Time PCR	1	5	5	100	0	0	0	1
DiaSorin Simplexa COVID-19	4	20	20	100	0	0	0	1
Elitech Elite Real Time kit	6	30	30	100	0	0	0	1
Elitech GeneFinder COVID-19	5	25	25	100	0	0	0	1
Elitech SCV2 ELITe MGB	1	5	5	100	0	0	0	1
Gerbion respiraScreen 1	1	5	5	100	0	0	0	1
Hologic Aptima SARS-CoV-2	3	15	15	100	0	0	0	1
Hologic Aptima SCV2/Flu	1	5	5	100	0	0	0	1
Hologic Panther Fusion SCV-2	1	5	5	100	0	0	0	1
Hologic Panther Fusion SCV2/Flu/RSV	1	5	5	100	0	0	0	1
Real-time In-House PCR	7	35	35	100	0	0	0	1
Kogene Powerchek	2	10	10	100	0	0	0	1
Luminex ARIES	5	25	25	100	0	0	0	1
Luminex ARIES SCV2	3	15	15	100	0	0	0	1
Menarini SCV2/Flu	1	5	5	100	0	0	0	1
PerkinElmer SARS-CoV-2 RT PCR	1	5	5	100	0	0	0	1
Qiagen NeuMoDx SARS-CoV-2	4	20	20	100	0	0	0	1
Qiagen NeuMoDx SCV2/FLU/RSV	2	10	10	100	0	0	0	1
Qiagen QIAstat-Dx SCV2	1	5	5	100	0	0	0	1
Roche Cobas Liat SARS-CoV-2	8	40	40	100	0	0	0	1
Roche Cobas Liat SCV2/INF	4	20	20	100	0	0	0	1
Roche Cobas SARS-CoV-2	14	70	70	100	0	0	0	1
Roche Cobas SCV2/Flu	1	5	5	100	0	0	0	1
Seegene Allplex SCV2 Master Assay	3	15	15	100	0	0	0	1
Seegene Allplex SCV2/FluA/FluB/RSV	2	10	10	100	0	0	0	1
Thermofisher TaqPath COVID-19	5	25	25	100	0	0	0	1
Seegene Allplex SARS-CoV-2	22	110	109	99.1	1	0	0	2
Cepheid Xpert SARS-CoV-2	35	175	170	97.1	0	0	5	3
Cepheid Xpert SCV2/FLU/RSV	15	75	72	96	0	0	3	4
Total	201	1005	996	99.1	1	0	8	

To analyse the 201 datasets, the laboratories used 41 different kits. The Cepheid Xpert SARS-CoV-2 kit is the most used (35/201=17.4%), followed by the Seegene Allplex SARS-CoV-2 (22/201=10.9%) and by the Abbott ID NOW Covid-19 (17/201=8.5%). The only clinically serious error, a false negative result, was detected with the Seegene Allplex SARS-CoV-2 kit. However, as only one out of 22 laboratories used this kit, it does not appear to be a problem with the kit.

SCORE PER LABORATORY

Out of the 123 participating laboratories, 119 laboratories (96.7%) obtained the perfect score of 0 and 4 were cited. 1 laboratory obtained the score of 3, 1 laboratory obtained a score of 6 and 2 laboratories obtained a score of 9.

Out of the 70 laboratories encoding one dataset : 69 obtained a score of 0, and 1 a score of 9.

Out of the 34 encoding 2 datasets : 31 obtained a score of 0, one a score of 3, one a score of 6 ,and one a score of 9.

COMMENT.

This provisional report will be completed as soon as QCMD has sent us the results of the remaining 2023 surveys.

END