

**BIOLOGICAL HEALTH RISKS
QUALITY OF LABORATORIES**

**CLINICAL BIOLOGY
COMMITTEE OF EXPERTS**

**EXTERNAL QUALITY ASSESSMENT
IN CLINICAL BIOLOGY**

DEFINITIVE GLOBAL REPORT

Molecular Microbiology

Chlamydia trachomatis/ Neisseria gonorrhoeae

SURVEY 2022/3

Sciensano/Clinical Biology/Molecular Microbiology/4-E

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1 INTRODUCTION

1.1.1 THE SAMPLES

The panel consisted of 5 samples of urines and 4 samples of transport medium (M4RT).

Table I1. The samples

Sample ID	matrix	Prepared from	Expected status
CTNG2201	Urine	Sample CTNG2017-3 diluted 1/10	CT + NG +
CTNG2202	Urine	Sample CTNG2017-4 diluted 1/10	CT + NG +
CTNG2203	Urine	Single donor urine	Negative
CTNG2204	Urine	Sample CTNG2017-3 diluted 1/7	CT + NG -
CTNG2205	Urine	Single donor urine	Negative
CTNG2206	M4RT	Commercial swab (Microbiologics)	CT + NG +
CTNG2207	M4RT	Commercial Swab(Microbiologics)	Negative
CTNG2208	M4RT	M4RT plus human DNA	Negative
CTNG2209	M4RT	Culture of <i>N. gonorrhoeae</i>	CT – NG +

CT: *Chlamydia trachomatis*; NG: *Neisseria gonorrhoeae*

1.1.2 HOMOGENEITY

The samples were tested before the survey by expert's laboratories. The status of the samples was confirmed. The samples were considered as homogeneous.

1.1.3 STABILITY

The results of the expert's laboratories before and during the survey were compared. The status of the samples were the same, so the samples were considered as stabile.

1.1.4 TARGET VALUE

The target values are based on the expected values (meaning what is normally present in the sample or not) and on a consensus between the results of expert's laboratories.

Table I2. Target values

Sample ID	matrix	<i>C. trachomatis</i>	<i>N. gonorrhoeae</i>
CTNG2201	Urine	Positive	Positive
CTNG2202	Urine	Positive	Positive
CTNG2203	Urine	Negative	Negative
CTNG2204	Urine	Positive	Negative
CTNG2205	Urine	Negative	Negative
CTNG2206	M4RT	Positive	Positive
CTNG2207	M4RT	Negative	Negative
CTNG2208	M4RT	Negative	Negative
CTNG2209	M4RT	Negative	Positive

1.1.5 THE PARTICIPANTS

94 Belgian laboratories were registered. 90 (95.7%) laboratories returned results.

1.1.6 SCORING SYSTEM

The scoring system of QCMD was applied

Table I3. The scoring system

Status	Score in case of correct answer	Score in case of incorrect result
Negative	0	+3
Frequently detected	0	+3
Detected	0	+2
Infrequently detected	0	+1

Frequently detected: detected by more than 95% of the participants

Detected: detected by more than 65% of the participants (between 65 and 95%).

Infrequently detected; detected by less than 65% of the participants

1.1.7. THE SURVEY

The samples were sent on: 14/06/2022

The survey was closed on: 30/06/2022

A preliminary report was produced on: 05/07/2022

2 RESULTS

2.1 C. trachomatis

2.1.1 RESULTS PER SAMPLE

89 laboratories encoded results. 83 encoded one dataset, five encoded 2 datasets and 1 encoded 3 datasets. In total 96 datasets were encoded.

Table R1. Results per sample for the detection of *C. trachomatis* using molecular methods

Sample ID	Expected result	Positive	Negative	ND	Status
CTNG2201	Positive	95	0	1	Frequently detected
CTNG2202	Positive	94	2	0	Frequently detected
CTNG2203	Negative	0	95	1	Negative
CTNG2204	Positive	96	0	0	Frequently detected
CTNG2205	Negative	1	94	1	Negative
CTNG2206	Positive	91	4	1	Detected
CTNG2207	Negative	3	92	1	Negative
CTNG2208	Negative	0	95	1	Negative
CTNG2209	Negative	1	93	2	Negative

96 datasets and 9 results per dataset meaning 864 results. Out of 864 results, 845 (97.8%) were correct and 19 (2.1%) were incorrect. Among them, 8 were not determined results, 6 were false negative results and 5 were false positive results.

2.1.2 RESULTS PER METHOD

Table R2. Results per method for the detection of *C. trachomatis* using molecular methods

Method	N	NR	NCR	%	FP	FN	ND	#
BDCTGLTV2 Triplex BDMAX	5	45	45	100,0	0	0	0	1
Roche Cobas 4800 CT/NG	11	99	99	100,0	0	0	0	1
Roche Cobas 6800 Roche CT/NG test	2	18	18	100,0	0	0	0	1
Viasure CT NG	2	18	18	100,0	0	0	0	1
Elitech ELITE Ingenius STI plus	11	99	99	100,0	0	0	0	1
Home RTqPCR	3	27	27	100,0	0	0	0	1
LDT PCR	1	9	9	100,0	0	0	0	1
Meridian	1	9	9	100,0	0	0	0	1
Microgen Amplcube STD Panel 1	1	9	9	100,0	0	0	0	1
NeuMo DCX CT/NG	2	18	18	100,0	0	0	0	1
Presto CT NG	2	18	18	100,0	0	0	0	1
Abbott Alinity m STI	9	81	80	98,8	0	1	0	2
Abbott CT NG	6	54	53	98,1	1	0	0	3
Seegene Allplex STI Essential Assay	5	45	44	97,8	1	0	0	4
Gene Xpert CT NG	18	162	158	97,5	2	0	2	5
Aptima Combo 2	6	54	50	92,6	0	3	1	6
Seegene Allplex CT/ NG/ MG/TV	11	99	91	91,9	1	2	5	7
Total	96	864	845	97,8	5	6	8	p

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

FP: false positive; FN: false negative; ND: not determined

Detailed results per dataset can be found in annex 1.

2.1.3 SCORES PER LABORATORY

75 (84.3%) out of 89 laboratories obtained the ideal score of 0.

Among the 14 others laboratories: 3 laboratories obtained the score of 2, 9 obtained the score of 3, one obtained the score of 5, one obtained the score of 15.

All the laboratories encoding more than one dataset obtained the ideal score of 0.

2.1.4 CONCLUSIONS

The percentage of correct results was high (97.8%). All the methods gave a percentage of correct answer higher than 90%. Only one laboratory seems to encounter problems with a score of 15 due to five not determined results.

2.2 *Neisseria gonorrhoeae*

2.2.1 RESULTS PER SAMPLE

90 laboratories encoded results. 84 encoded one dataset, 5 encoded 2 datasets and 1 encoded 3 datasets. Therefore, 97 datasets were encoded.

Table R3. Results per sample for the detection of *N. gonorrhoeae* using molecular methods

Sample ID	Expected result	Positive	Negative	ND	Status
CTNG2201	Positive	89	6	2	Detected
CTNG2202	Positive	55	42	0	Infrequently detected
CTNG2203	Negative	0	96	1	Negative
CTNG2204	Negative	0	96	1	Negative
CTNG2205	Negative	1	95	1	Negative
CTNG2206	Positive	89	7	1	Detected
CTNG2207	Negative	0	95	2	Negative
CTNG2208	Negative	0	95	2	Negative
CTNG2209	Positive	96	1	0	Frequently detected

Total answers: 873

Total correct answers: 806 (92.3%)

False positive results: 1

False negative results: 56

Not determined results: 10

2.2.2 RESULTS PER METHOD

Table R4. Results per method for the detection of *N. gonorrhoeae* using molecular methods

Method	N	NR	NCR	%	FP	FN	ND	#
BDCTGLTV2 Triplex BDMAX	5	45	45	100,0	0	0	0	1
Viasure CT NG	2	18	18	100,0	0	0	0	1
Elitech ELITE <i>Ingenius STI plus</i>	10	90	90	100,0	0	0	0	1
LDT PCR	1	9	9	100,0	0	0	0	1
NeuMo DCX CT/NG	2	18	18	100,0	0	0	0	1
Presto CT NG	2	18	18	100,0	0	0	0	1
Gene Xpert CT NG	18	162	154	95,1	0	7	1	2
Home rtqPCR	4	36	34	94,4	0	2	0	3
Abbott Alinity m STI	9	81	76	93,8	0	4	1	4
Abbott CT NG	6	54	50	92,6	0	4	0	5
Roche Cobas 4800 CT/NG	11	99	89	89,9	0	10	0	6
Seegene Allplex CT/ NG/ MG/TV	11	99	88	88,9	1	5	5	7
Meridian	1	9	8	88,9	0	1	0	7
Seegene Allplex STI Essential Assay	6	54	46	85,2	0	6	2	8
Aptima Combo 2 CT/NG	6	54	42	77,8	0	11	1	9
Roche Cobas 6800 Roche CT/NG	2	18	14	77,8	0	4	0	9
Microgen Amplcube STD Panel 1	1	9	7	77,8	0	2	0	9
Total	97	873	806	92,3	1	56	10	

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

FP: false positive; FN: false negative; ND: not determined

Detailed results per dataset can be found in annex 1.

2.2.3 SCORES PER LABORATORY

Among the 84 laboratories encoding one dataset, 44 (52.4%) obtained the ideal score of 0, 24 (28.6%) obtained the score of 1, one obtained the score of 2, 12 (14.3%) obtained the score of 3, one obtained the score of 4, one the score of 5 and one the score of 15.

Among the 5 laboratories encoding 2 datasets, 3 obtained the ideal score of 0. One obtained the score of 1 (0+1), one obtained the score of 8 (1+7).

Finally, the laboratory encoding 3 datasets obtained the score of 2 (0+1+1).

2.2.4 CONCLUSION

Concerning the detection of *N. gonorrhoeae*, the percentage of correct results (92.3%) is lower than for *C. trachomatis* (97.8%). It is mainly due to the presence of an infrequently detected sample (2022-02?). This sample had a Ct/Cq value of 36 in the expert laboratory, which is an indication of a weak positive result probably close to the limit of detection of most methods. It is interesting to observe that with some methods *N. gonorrhoeae* was always detected in sample 2022-02, as with other methods variable results were observed. The proficiency of the methods ranged from 77.8% to 100%. One laboratory obtained a score of 15 for 5 not determined results. After examination, it is the same lab as the lab that for *C. trachomatis*. The inspector has been notified.

Annex 1: Results par dataset and per method

1. *C. trachomatis*

Method	CTNG2201 Frequently detected	CTNG2202 Frequently detected	CTNG2203 Negative	CTNG2204 Frequently detected	CTNG2205 Negative	CTNG2206 Detected	CTNG2207 Negative	CTNG2208 Negative	CTNG2209 Negative	Score
Abbott CT/NG RT	1	1	0	1	0	1	0	0	0	0
Abbott CT/NG RT	1	1	0	1	0	1	0	0	0	0
Abbott CT/NG RT	1	1	0	1	0	1	1	0	0	3
Abbott CT/NG RT	1	1	0	1	0	1	0	0	0	0
Abbott CT/NG RT	1	1	0	1	0	1	0	0	0	0
Abbott CT/NG RT	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	0	0	1	0	1	0	0	0	3
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Alinity m STI	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	1	0	0	0	0	5
Allplex CT/NG/MG/TV Assay	1	1	ND	1	ND	1	ND	ND	ND	15
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV Assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV assay	1	1	0	1	0	1	0	0	0	0
Allplex CT/NG/MG/TV assay	1	1	0	1	0	1	1	0	0	3

Method	CTNG2201	CTNG2202	CTNG2203	CTNG2204	CTNG2205	CTNG2206	CTNG2207	CTNG2208	CTNG2209	Score
Allplex STI Essential Assay	1	0	0	1	0	1	0	0	0	3
Allplex STI Essential Assay	1	1	0	1	0	1	0	0	0	0
Allplex STI Essential Assay	1	1	0	1	0	1	0	0	0	0
Allplex STI Essential Assay	1	1	0	1	0	1	0	0	0	0
Allplex STI Essential Assay	1	1	0	1	0	1	0	0	0	0
Aptima Combo 2	ND	1	0	1	0	1	0	0	0	3
Aptima Combo 2	1	1	0	1	0	0	0	0	0	2
Aptima Combo 2	1	1	0	1	0	0	0	0	0	2
Aptima Combo 2 for CT/NG	1	1	0	1	0	0	0	0	0	2
Aptima Combo 2 for CT/NG	1	1	0	1	0	1	0	0	0	0
Aptima Combo 2 for CT/NG	1	1	0	1	0	1	0	0	0	0
BD CTGLTV2 Triplex BDMAX	1	1	0	1	0	1	0	0	0	0
BD CTGLTV2 Triplex BDMAX	1	1	0	1	0	1	0	0	0	0
BD CTGLTV2 Triplex BDMAX	1	1	0	1	0	1	0	0	0	0
BD CTGLTV2 Triplex BDMAX	1	1	0	1	0	1	0	0	0	0
BD CTGLTV2 Triplex BDMAX	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 4800 CT/NG	1	1	0	1	0	1	0	0	0	0
Cobas 6800 CT-NG	1	1	0	1	0	1	0	0	0	0
Cobas 6800 CT-NG	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0
ELITE Ingenius STI plus	1	1	0	1	0	1	0	0	0	0

2. *N. gonorrhoeae*

Detection Method	CTNG2201	CTNG2202	CTNG2203	CTNG2204	CTNG2205	CTNG2206	CTNG2207	CTNG2208	CTNG2209	score
	Detected	Infrequently detected	Negative	Negative	Negative	Detected	Negative	Negative	Frequently detected	
Abbott CT/NG	1	0	0	0	0	1	0	0	1	1
Abbott CT/NG	1	0	0	0	0	1	0	0	1	1
Abbott CT/NG	1	0	0	0	0	1	0	0	1	1
Abbott CT/NG	1	1	0	0	0	1	0	0	1	0
Abbott CT/NG	1	1	0	0	0	1	0	0	1	0
Abbott CT/NG	1	0	0	0	0	1	0	0	1	1
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	1	0	0	0	1	0	0	1	0
Alinity m STI	1	0	0	0	0	1	0	0	1	1
Alinity m STI	1	0	0	0	0	1	0	0	1	1
Alinity m STI	ND	0	0	0	0	1	0	0	1	3
Allplex CT/NG/MG/TV	1	1	0	0	1	0	0	0	1	5
Allplex CT/NG/MG/TV	1	1	0	0	0	1	0	0	1	0
Allplex CT/NG/MG/TV	1	1	0	0	0	1	0	0	1	0
Allplex CT/NG/MG/TV	1	0	0	0	0	1	0	0	1	1
Allplex CT/NG/MG/TV	1	0	0	0	0	1	0	0	1	1
Allplex CT/NG/MG/TV	1	1	0	0	0	1	0	0	1	0
Allplex CT/NG/MG/TV	1	0	0	0	0	1	0	0	1	1
Allplex CT/NG/MG/TV	1	1	0	0	0	1	0	0	1	0
Allplex CT/NG/MG/TV	1	1	ND	ND	ND	1	ND	INH	1	15
Allplex CT/NG/MG/TV	1	0	0	0	0	1	0	0	1	1
Allplex CT/NG/MG/TV	1	1	0	0	0	1	0	0	1	0
Allplex STI Essential Assay	1	0	0	0	0	1	ND	ND	1	7
Allplex STI Essential Assay	1	0	0	0	0	1	0	0	1	1
Allplex STI Essential Assay	0	0	0	0	0	1	0	0	1	3
Allplex STI Essential Assay	1	1	0	0	0	1	0	0	1	0
Allplex STI Essential Assay	1	0	0	0	0	1	0	0	1	1
Allplex STI Essential Assay	1	0	0	0	0	1	0	0	1	1

Method	CTNG2201	CTNG2202	CTNG2203	CTNG2204	CTNG2205	CTNG2206	CTNG2207	CTNG2208	CTNG2209	score
Aptima Combo 2 for CT/NG	1	0	0	0	0	0	0	0	1	3
3Aptima Combo 2 for CT/NG	ND	0	0	0	0	0	0	0	1	5
Aptima Combo 2 for CT/NG	1	0	0	0	0	0	0	0	1	3
Aptima Combo 2 for CT/NG	1	0	0	0	0	0	0	0	1	3
Aptima Combo 2 for CT/NG	1	0	0	0	0	0	0	0	1	3
Aptima Combo 2 for CT/NG	1	0	0	0	0	0	0	0	1	3
BD CTGCTV2	1	1	0	0	0	1	0	0	1	0
BD CTGCTV2	1	1	0	0	0	1	0	0	1	0
BD CTGCTV2	1	1	0	0	0	1	0	0	1	0
BD CTGCTV2	1	1	0	0	0	1	0	0	1	0
BD CTGLTV2	1	1	0	0	0	1	0	0	1	0
Cobas 4800 CT/NG	1	0	0	0	0	1	0	0	1	1
Cobas 4800 CT/NG	1	1	0	0	0	1	0	0	1	0
Cobas 4800 CT/NG	1	0	0	0	0	1	0	0	0	4
Cobas 4800 CT/NG	1	1	0	0	0	1	0	0	1	0
Cobas 4800 CT/NG	1	0	0	0	0	1	0	0	1	1
Cobas 4800 CT/NG	1	0	0	0	0	1	0	0	1	1
Cobas 4800 CT/NG	0	0	0	0	0	1	0	0	1	3
Cobas 4800 CT/NG	1	1	0	0	0	1	0	0	1	0
Cobas 4800 CT/NG	1	0	0	0	0	1	0	0	1	1
Cobas 4800 CT/NG	0	0	0	0	0	1	0	0	1	3
Cobas 4800 CT/NG	1	1	0	0	0	1	0	0	1	0
Cobas 6800 CT-NG	0	0	0	0	0	1	0	0	1	3
Cobas 6800 CT-NG	0	0	0	0	0	1	0	0	1	3
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
ELITE IngeniusS TI plus	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0

GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
Method	CTNG2201	CTNG2202	CTNG2203	CTNG2204	CTNG2205	CTNG2206	CTNG2207	CTNG2208	CTNG2209	score
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	0	0	0	0	ND	0	0	1	3
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	0	0	0	0	1	0	0	1	1
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
GeneXpert CT/NG	1	1	0	0	0	1	0	0	1	0
Home rtqPCR	1	0	0	0	0	1	0	0	1	1
Home rtqPCR	1	0	0	0	0	1	0	0	1	1
Home rtqPCR	1	1	0	0	0	1	0	0	1	0
Home rtqPCR	1	1	0	0	0	1	0	0	1	0
LDT PCR	1	1	0	0	0	1	0	0	1	0
Meridian Alethia	1	0	0	0	0	1	0	0	1	1
Microgen Amplcube STD	0	0	0	0	0	1	0	0	1	3
Neu MoDx CT-NG test strip	1	1	0	0	0	1	0	0	1	0
Neu MoDx CT-NG test strip	1	1	0	0	0	1	0	0	1	0
Presto CT NG	1	1	0	0	0	1	0	0	1	0
Presto CT NG	1	1	0	0	0	1	0	0	1	0
Viasure CT NG	1	1	0	0	0	1	0	0	1	0
Viasure CT NG	1	1	0	0	0	1	0	0	1	0

Color code: green: good answer, yellow: incorrect result for a infrequently detected sample, orange: incorrect result for a detected sample, red: incorrect result for a frequently detected or a negative sample
0= negative result, 1= positive result, ND: not determined result

END

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