LABQUALITY

External Quality Assessment Scheme

Chlamydia trachomatis and *Neisseria gonorrhoeae*, nucleic acid detection Round 1, 2023

Specimens
Please find enclosed 3 simulated samples S001, S002 and S003. Shipment contains two swabs and one liquid sample (2 mL).

Caution
Each specimen simulates a clinical specimen and should therefore be handled with the same care as normal patient samples, capable of transmitting infectious disease.

Not for patient use.

Examinations
Chlamydia trachomatis and *Neisseria gonorrhoeae*, nucleic acid detection

Storage and use
After arrival, the samples should be stored at +2…8 °C. Follow the standard operating procedure of your laboratory for disposal of the samples.

Handling instructions for swabs:
1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a specimen collection tube / transport media (supplied by your kit manufacturer) and rotate to dislodge as much material as possible. Snap off or cut the shaft of the swab to fit into tube.
3. Recap the collection tube and mix thoroughly to ensure that all of the sample material is mixed with the transport media.
4. Perform the analysis according to the manufacturer's instructions.

Handling instructions for the liquid sample:
1. Let the content of the vial warm up to room temperature prior to the analysis. Mix the sample by inverting the vial a few times prior to use. The sample may appear cloudy or there may be small particles.
2. Perform the analysis according to the manufacturer's instructions for a liquid sample.

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your test from the registry, please contact the EQA Coordinator. All reported examinations will be scored, except the interpretation "Invalid/unclear test result" which is excluded from scoring.

S001

LQ778723011

S003

LQ778723013

S002

LQ778723012

2023-03-14

INSTRUCTIONS

Product no. 5612
LQ778723011-013/US
UN3373

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **April 6, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 12, 2023.

Inquiries
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FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

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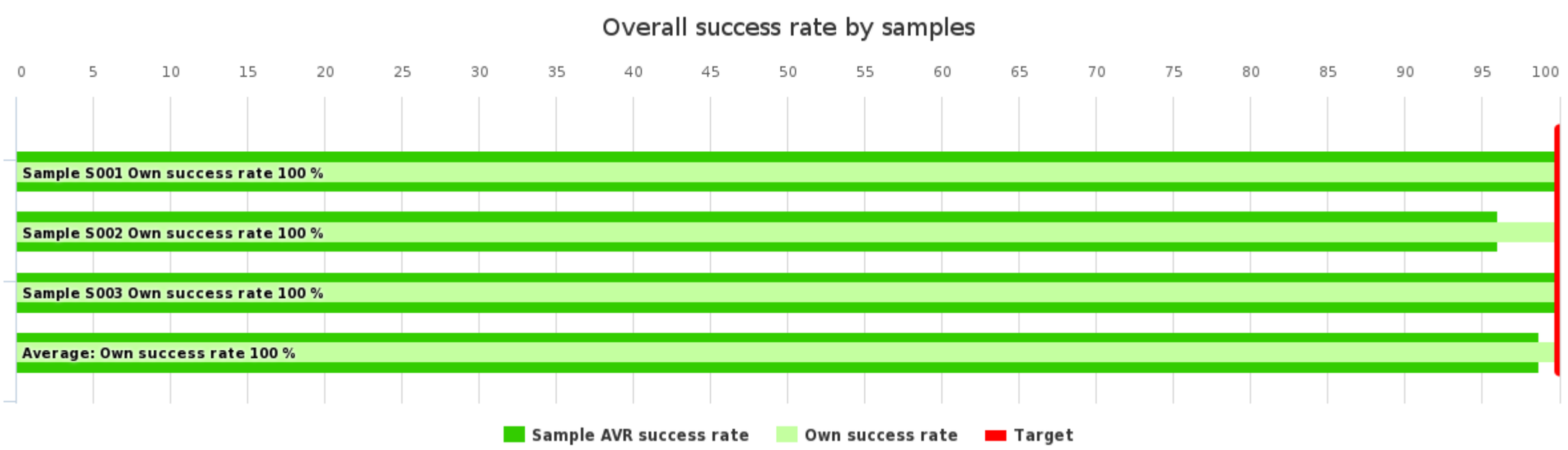
Client report

	No of participants	No of responded participants	Response percentage
Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023	52	49	94.2 %

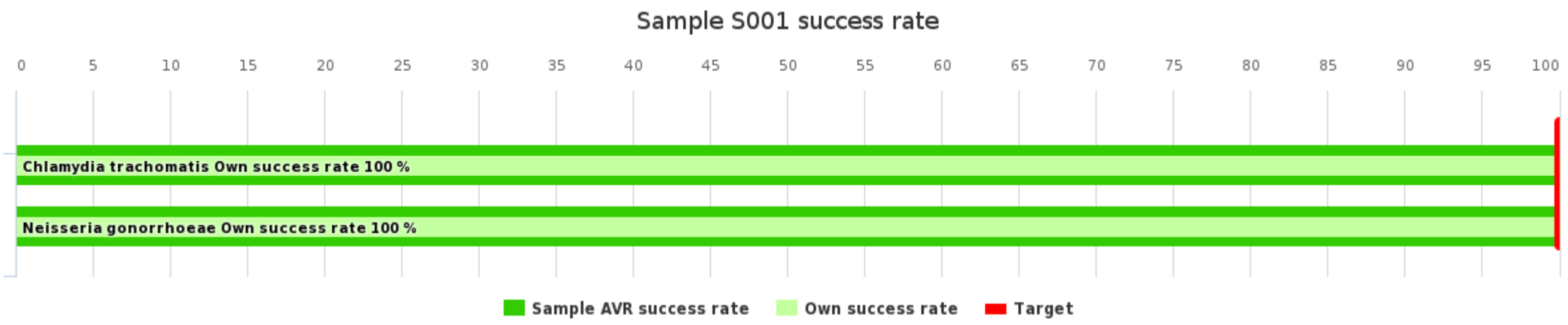
Summary



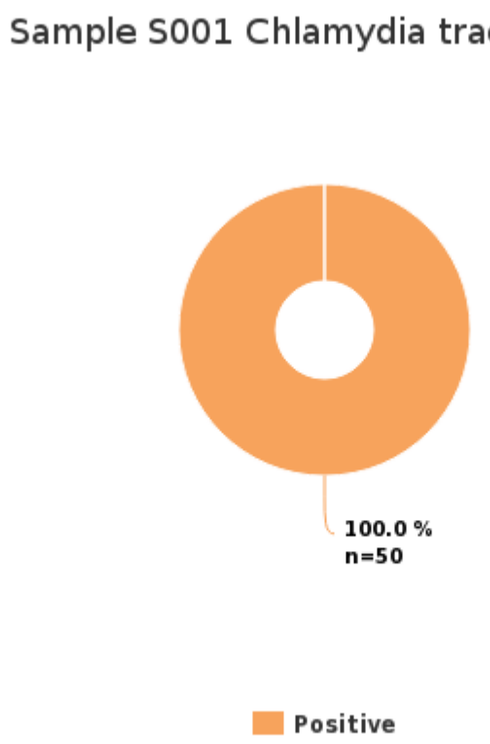
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	0 %	100 %
Sample S002	4	4	100 %	4 %	96 %
Sample S003	4	4	100 %	0 %	100 %
Average:			100 %	1.3 %	98.7 %

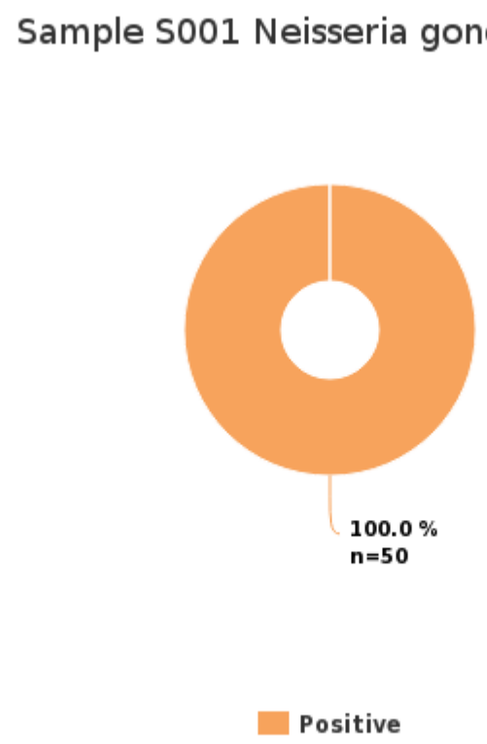
History	Test nr.	Own success rate	Difference	AVR success rate
History not found				

Sample S001



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Chlamydia trachomatis	2	2	100 %	0 %	100 %	50
	Neisseria gonorrhoeae	2	2	100 %	0 %	100 %	50
	Further action	-	-	-	-	-	7
Total:		4	4	100 %	0 %	100 %	107





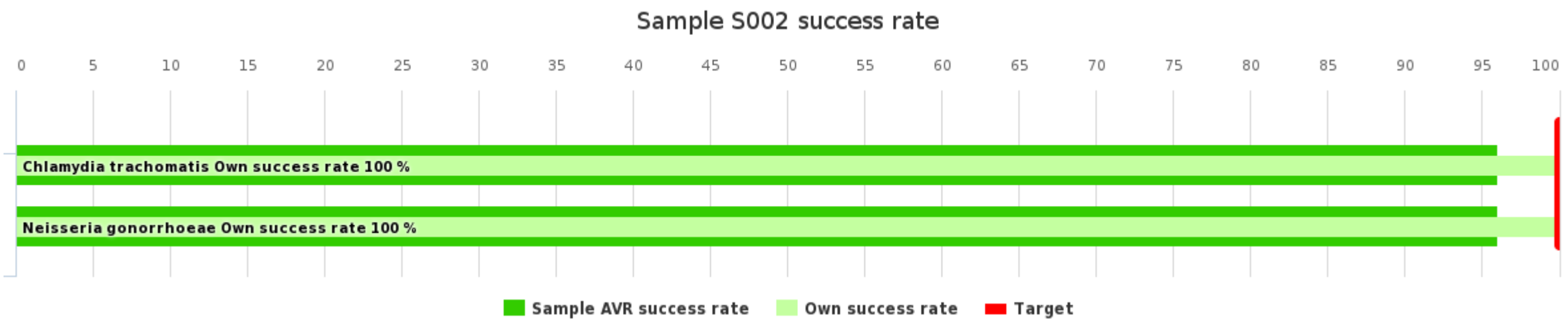
Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		50		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					
		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		2					
		Cepheid Xpert CT/NG		21					
		GeneProof Chlamydia trachomatis PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		6					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		2					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Total:		50		2	2	100 %	0 %	100 %

Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		50		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					

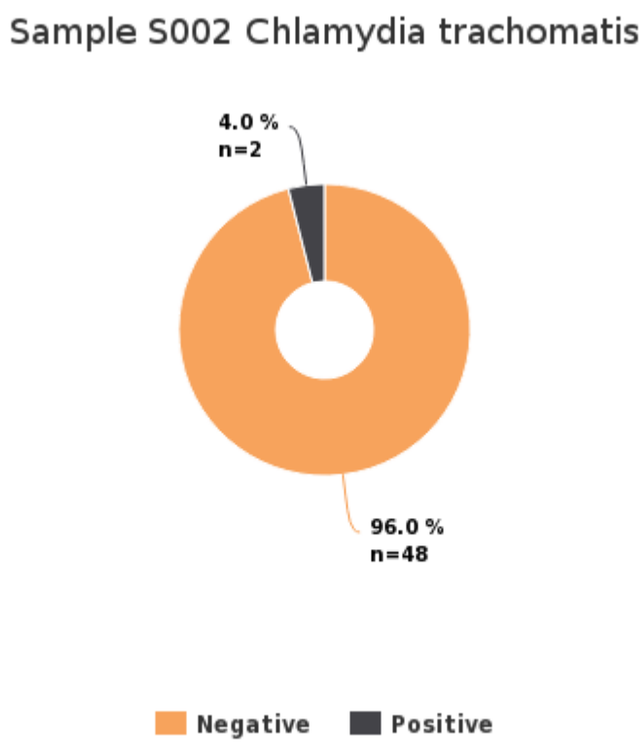
		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		2					
		Cepheid Xpert CT/NG		21					
		GeneProof Neisseria gonorrhoeae PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		6					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		2					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Total:		50		2	2	100 %	0 %	100 %

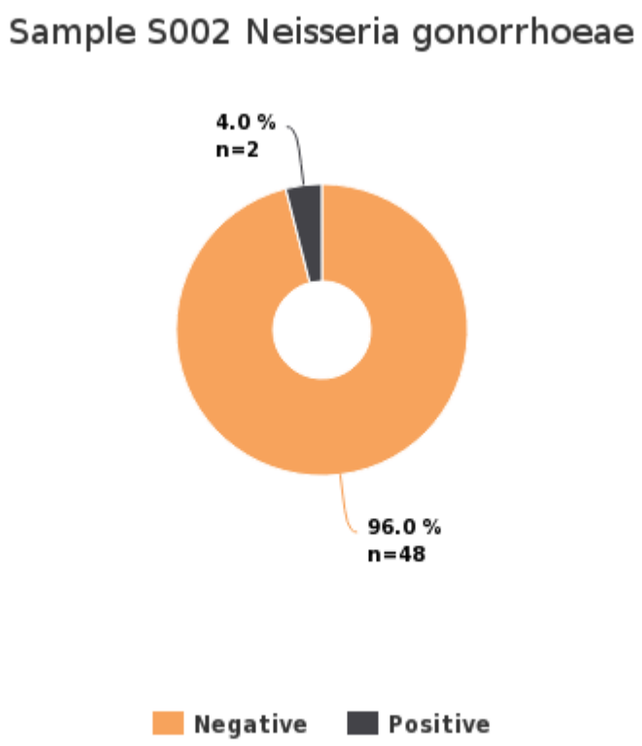
Further action	Response	Response count	Own score	Max score	Own success rate	Difference	AVR success rate
	C. trachomatis would be confirmed	2	-				-
	N. gonorrhoeae would be confirmed	5	-				-
	Total:	7	-	-	-	-	

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Chlamydia trachomatis	2	2	100 %	4 %	96 %	50
	Neisseria gonorrhoeae	2	2	100 %	4 %	96 %	50
	Further action	-	-	-	-	-	1
Total:		4	4	100 %	4 %	96 %	101



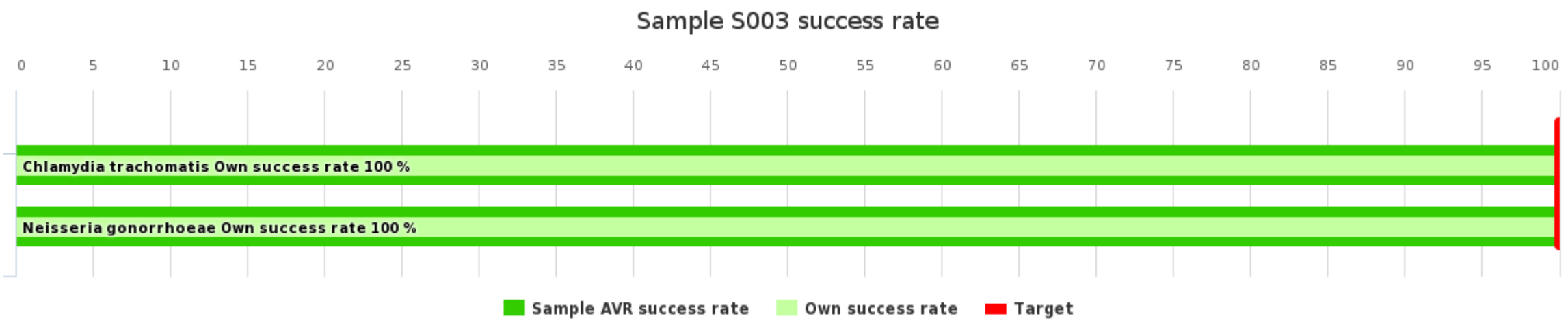


Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		48		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					
		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		1					
		Cepheid Xpert CT/NG		21					
		GeneProof Chlamydia trachomatis PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		5					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		2					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Positive		2		-				0 %
		BD Max CT/GC/TV		1					
		Hologic Aptima Combo 2 CT/NG		1					
	Total:		50		2	2	100 %	4 %	96 %

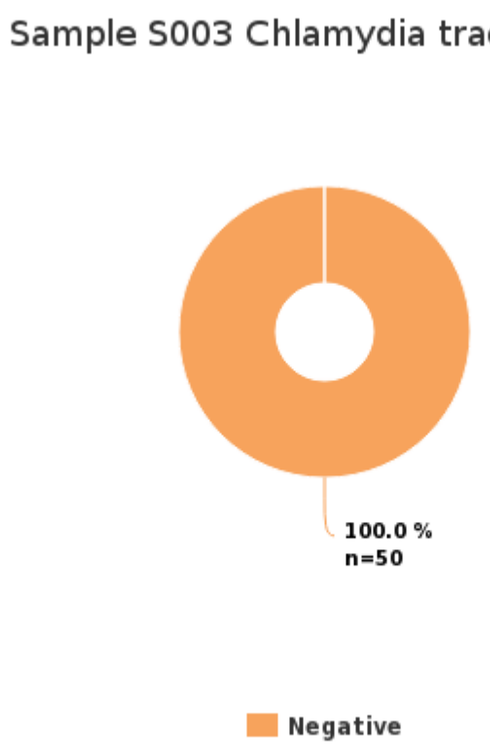
Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		48		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					
		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		2					
		Cepheid Xpert CT/NG		20					
		GeneProof Neisseria gonorrhoeae PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		6					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		1					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Positive		2		-				0 %
		Cepheid Xpert CT/NG		1					
		Roche cobas 4800 CT/NG		1					
	Total:		50		2	2	100 %	4 %	96 %

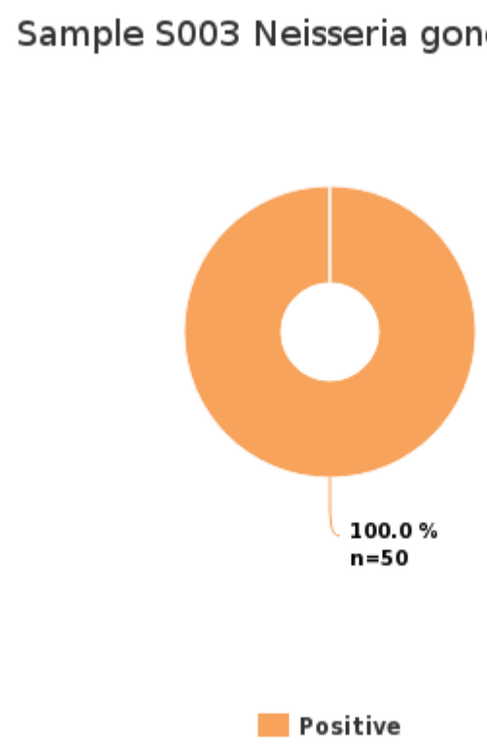
Further action	Response	Response count	Own score	Max score	Own success rate	Difference	AVR success rate
	N. gonorrhoeae would be confirmed	1	-				-
	Total:	1	-	-	-	-	

Sample S003



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Chlamydia trachomatis	2	2	100 %	0 %	100 %	50
	Neisseria gonorrhoeae	2	2	100 %	0 %	100 %	50
	Further action	-	-	-	-	-	5
Total:		4	4	100 %	0 %	100 %	105





Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		50		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					
		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		2					
		Cepheid Xpert CT/NG		21					
		GeneProof Chlamydia trachomatis PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		6					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		2					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Total:		50		2	2	100 %	0 %	100 %

Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		50		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		2					

		Abbott RealTime CT/NG		1					
		BD Max CT/GC		1					
		BD Max CT/GC/TV		2					
		Cepheid Xpert CT/NG		21					
		GeneProof Neisseria gonorrhoeae PCR Kit		1					
		Hologic Aptima Combo 2 CT/NG		6					
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2					
		NeuMoDX CT/NG Test Strip		3					
		Roche cobas 4800 CT/NG		2					
		Roche cobas 6800/8800 CT/NG		4					
		◉ Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		Seegene Anyplex CT/NG Real-time Detection		1					
		Seegene Anyplex II STI-7		3					
	Total:		50		2	2	100 %	0 %	100 %

Further action	Response	Response count	Own score	Max score	Own success rate	Difference	AVR success rate
	N. gonorrhoeae would be confirmed	5	-				-
	Total:	5	-	-	-	-	

Report Info

PARTICIPANTS

Altogether 52 laboratories from 13 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button ◉. In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported.
The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

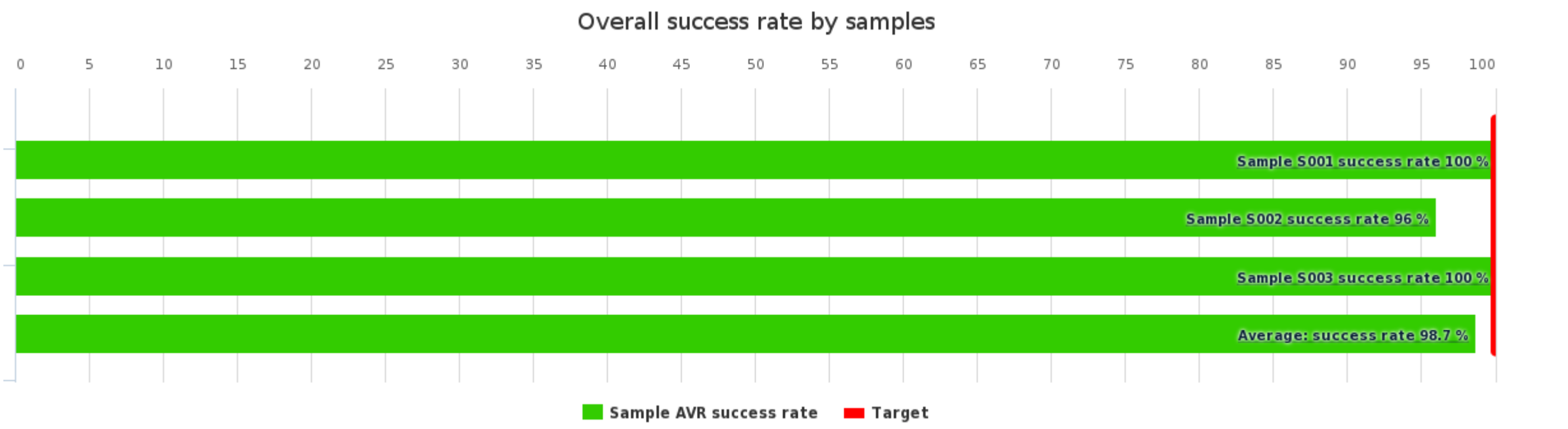
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023	52	49	94.2 %

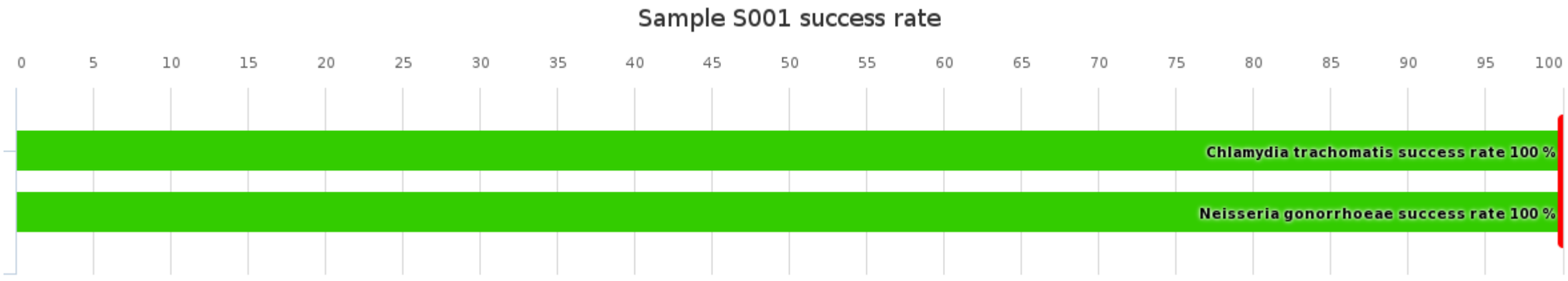
Summary



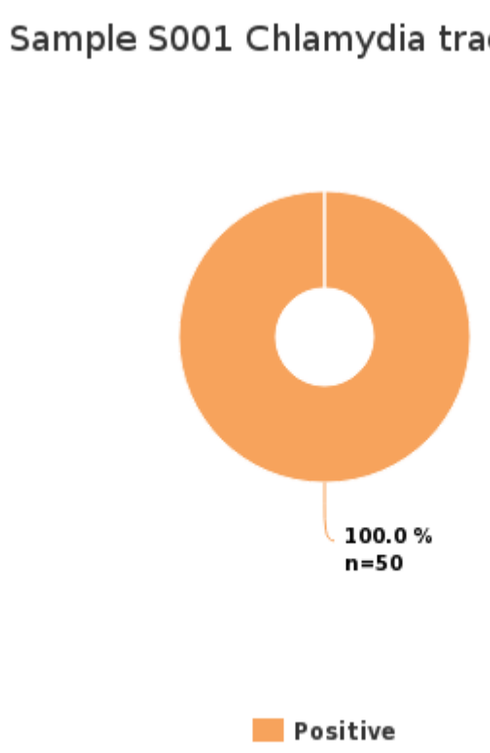
Summary	AVR success rate
Sample S001	100 %
Sample S002	96 %
Sample S003	100 %
Average:	98.7 %

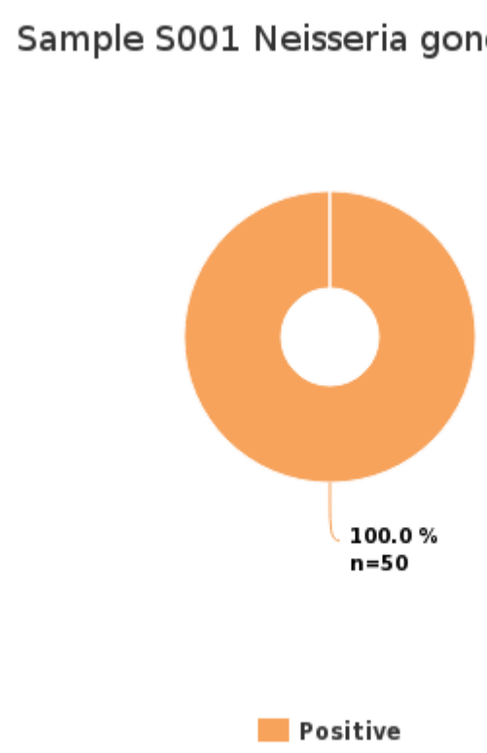
Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

Sample S001



Sample S001 results	Responded	AVR success rate	Count
	Chlamydia trachomatis	100 %	50
	Neisseria gonorrhoeae	100 %	50
	Further action	-	7
Total:		100 %	107





Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		50		100 %	2
		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		
		BD Max CT/GC/TV		2		
		Cepheid Xpert CT/NG		21		
		GeneProof Chlamydia trachomatis PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		6		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		2		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Total:		50		100 %	

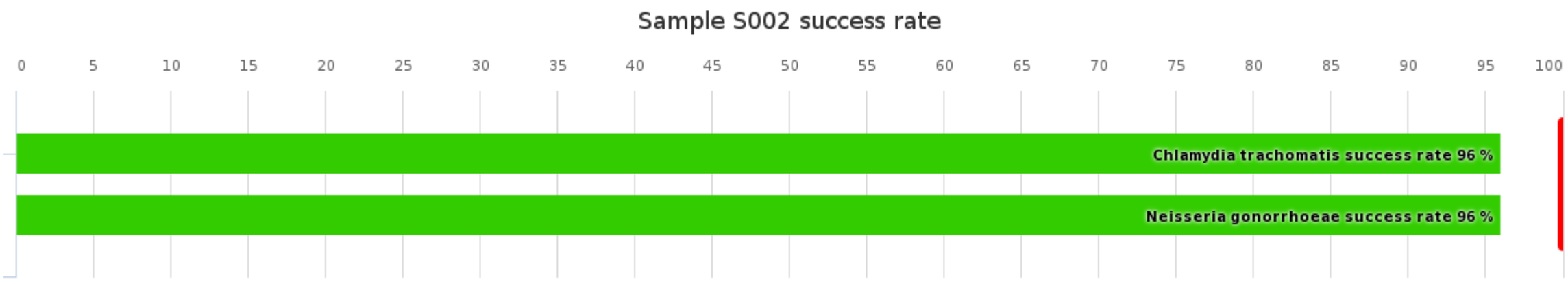
Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		50		100 %	2
		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		

		BD Max CT/GC/TV		2		
		Cepheid Xpert CT/NG		21		
		GeneProof Neisseria gonorrhoeae PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		6		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		2		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Total:		50		100 %	

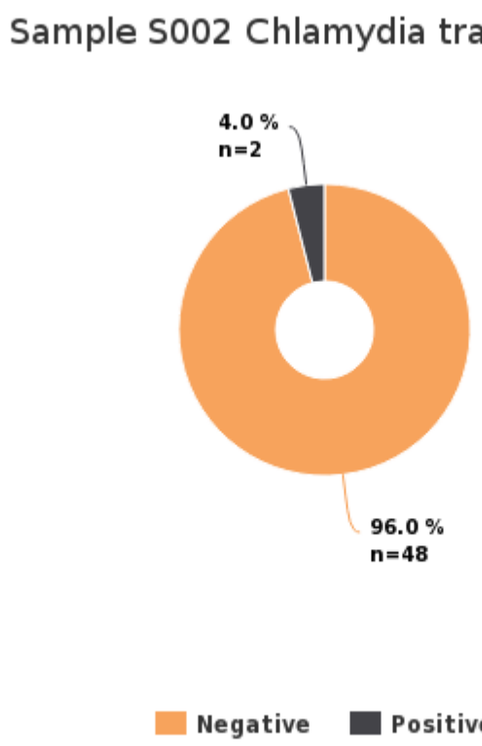
Further action	Response	Response count	AVR success rate	Response Score
	C. trachomatis would be confirmed	2	-	-
	N. gonorrhoeae would be confirmed	5	-	-
	Total:	7		

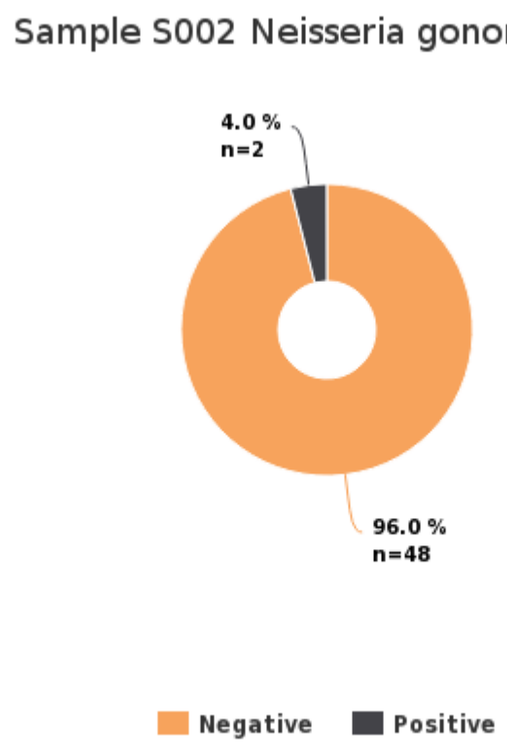
Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	Chlamydia trachomatis	96 %	50
	Neisseria gonorrhoeae	96 %	50
	Further action	-	1
Total:		96 %	101





Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		48		100 %	2
		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		
		BD Max CT/GC/TV		1		
		Cepheid Xpert CT/NG		21		
		GeneProof Chlamydia trachomatis PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		5		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		2		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Positive		2		0 %	0
		BD Max CT/GC/TV		1		
		Hologic Aptima Combo 2 CT/NG		1		
	Total:		50		96 %	

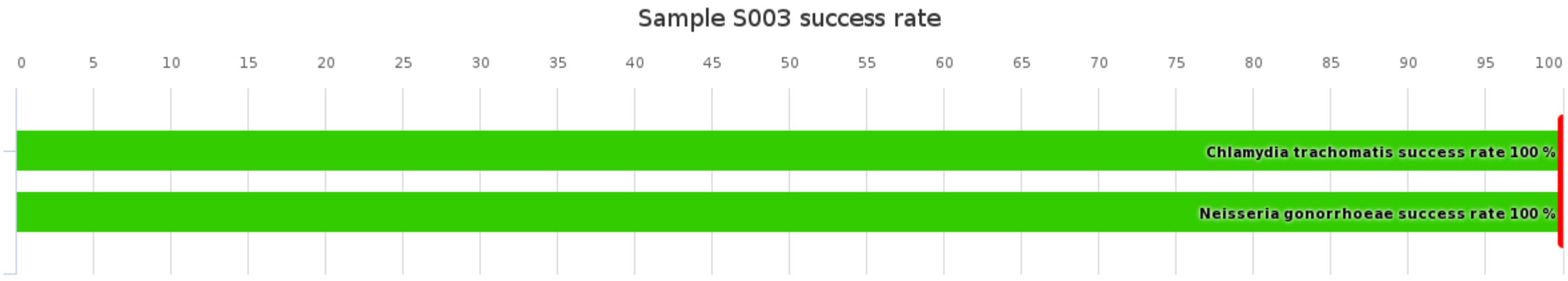
Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		48		100 %	2

		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		
		BD Max CT/GC/TV		2		
		Cepheid Xpert CT/NG		20		
		GeneProof Neisseria gonorrhoeae PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		6		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		1		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Positive		2		0 %	0
		Cepheid Xpert CT/NG		1		
		Roche cobas 4800 CT/NG		1		
	Total:		50		96 %	

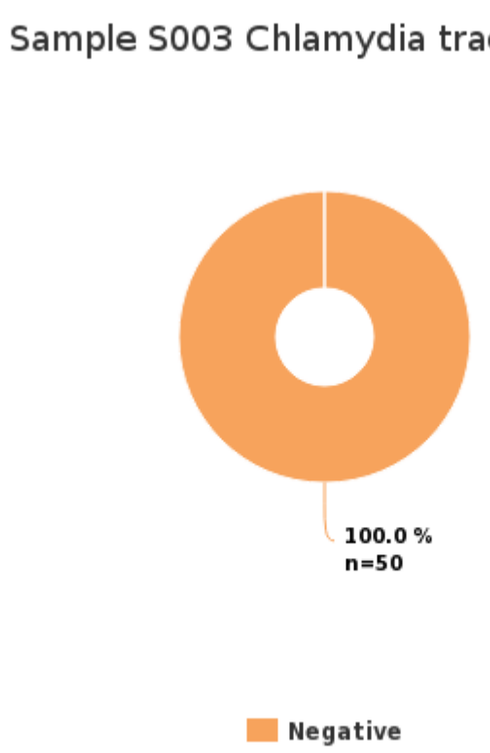
Further action	Response	Response count	AVR success rate	Response Score
	N. gonorrhoeae would be confirmed	1	-	-
	Total:	1		

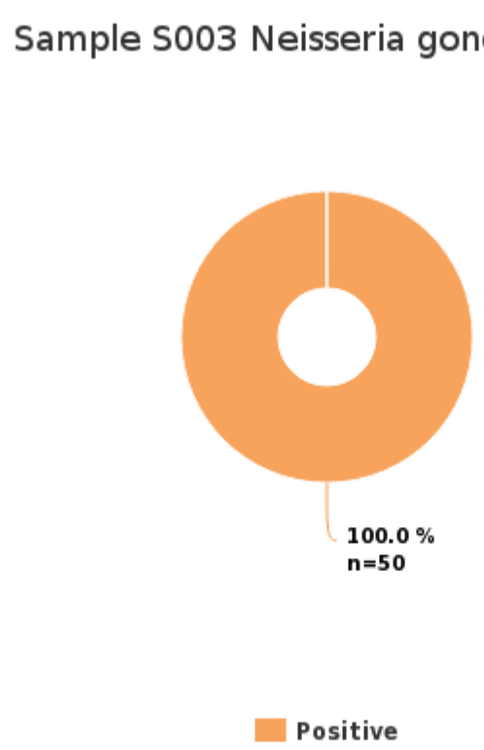
Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

Sample S003



Sample S003 results	Responded	AVR success rate	Count
	Chlamydia trachomatis	100 %	50
	Neisseria gonorrhoeae	100 %	50
	Further action	-	5
Total:		100 %	105





Chlamydia trachomatis	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		50		100 %	2
		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		
		BD Max CT/GC/TV		2		
		Cepheid Xpert CT/NG		21		
		GeneProof Chlamydia trachomatis PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		6		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		2		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Total:		50		100 %	

Neisseria gonorrhoeae	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		50		100 %	2
		Abbott Alinity m STI Assay		2		
		Abbott RealTime CT/NG		1		
		BD Max CT/GC		1		

		BD Max CT/GC/TV		2		
		Cepheid Xpert CT/NG		21		
		GeneProof Neisseria gonorrhoeae PCR Kit		1		
		Hologic Aptima Combo 2 CT/NG		6		
		Meridian Bioscience illumigene Chlamydia or Gonorrhea		2		
		NeuMoDX CT/NG Test Strip		3		
		Roche cobas 4800 CT/NG		2		
		Roche cobas 6800/8800 CT/NG		4		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		Seegene Anyplex CT/NG Real-time Detection		1		
		Seegene Anyplex II STI-7		3		
	Total:		50		100 %	

Further action	Response	Response count	AVR success rate	Response Score
	N. gonorrhoeae would be confirmed	5	-	-
	Total:	5		

Chlamydia trachomatis and Neisseria gonorrhoeae nucleic acid detection, March, 1-2023

Report Info

PARTICIPANTS

Altogether 52 laboratories from 13 countries participated in this EQA round.

REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button ◉. In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available".

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

SCORING

The round is scored based on test results when 60% or more of the participants report the expected result and when at least three results are reported.
The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample success rates.

The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

LABQUALITY

External Quality Assessment Scheme

Chlamydia trachomatis and *Neisseria gonorrhoeae*, nucleic acid detection Round 1, 2023

Specimens
Samples were artificial and contained human DNA. Based on the quality controls conducted by the sample manufacturer and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ778723011)
Chlamydia trachomatis NAT Positive
Neisseria gonorrhoeae NAT Positive

Sample S002 (LQ778723012)
Chlamydia trachomatis NAT Negative
Neisseria gonorrhoeae NAT Negative
The sample contained *Ureaplasma parvum*

Sample S003 (LQ778723013)
Chlamydia trachomatis NAT Negative
Neisseria gonorrhoeae NAT Positive

Report info
Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – EQA Coordinator
The participants performed very well in this EQA round. Only the negative sample S002 caused problems. Two false positive *Chlamydia trachomatis* and *Neisseria gonorrhoeae* results were reported from the sample.

Exceptions in scoring
No exceptions.

End of report

2023-04-13

FINAL REPORT

Product no. 5612

Samples sent	2023-03-14
Round closed	2023-04-06
Expected results	2023-04-12
Final report	2023-04-13

Request for correction
Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by
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FINAS
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PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015