

External Quality Assessment Scheme

***Mycoplasma genitalium*, drug resistance, nucleic acid detection Round 1, 2023 (pilot)**

Thank you for participating in the pilot round. There will be a feedback survey attached to the reports. Please respond to the survey and give us important information on how we can make the EQA scheme better for you.

Specimens

Please find enclosed 3 artificial swab samples S001, S002 and S003.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. According to the sample manufacturer the specimens do not contain viable microbes. However, no known test method can offer complete assurance that the specimens will not transmit any infectious diseases.

Not for patient use.

Examinations

Mycoplasma genitalium, nucleic acid detection
Macrolide (azithromycin) susceptibility

Storage and use

After arrival, the samples should be stored at +2 ... 8°C.

1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a sample collection tube / transport media (1-3 mL). Rotate the swab several times in the tube to dislodge as much material as possible. Remove the swab by pressing it towards the walls of the elution vial. You can also cut the swab into the sample collection tube.
3. Recap the collection tube and mix thoroughly.
4. Follow the test manufacturer's instructions for sample extraction and detection.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your test kit from the registry, please contact the EQA Coordinator. This round has the possibility to report three results from the same sample, if the sample volume is sufficient for several analyses. To open a new result form, press the "Add result +" button on the right side of the blue bar for each sample in LabScala. Report only the results of examinations that are in use in your laboratory. All reported examinations will be scored.

S001



S003



S002



2023-10-03

INSTRUCTIONS

Product no. 5254
LQ763423011-013/CA

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

The results should be reported no later than **October 27, 2023.**

Inquiries

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Labquality Oy

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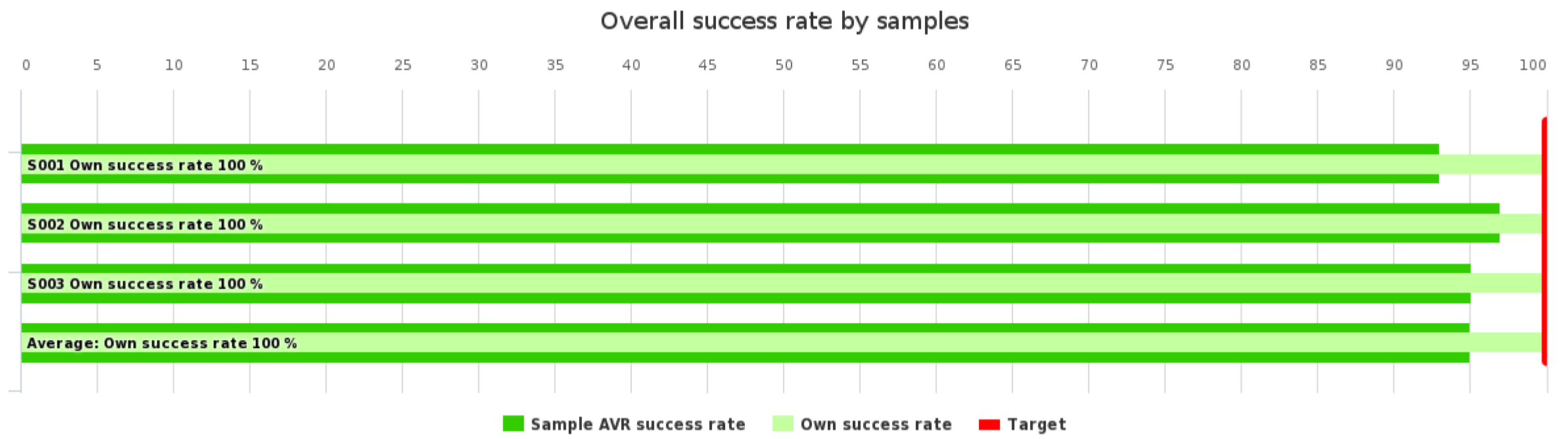
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023	44	38	86.4 %

Summary



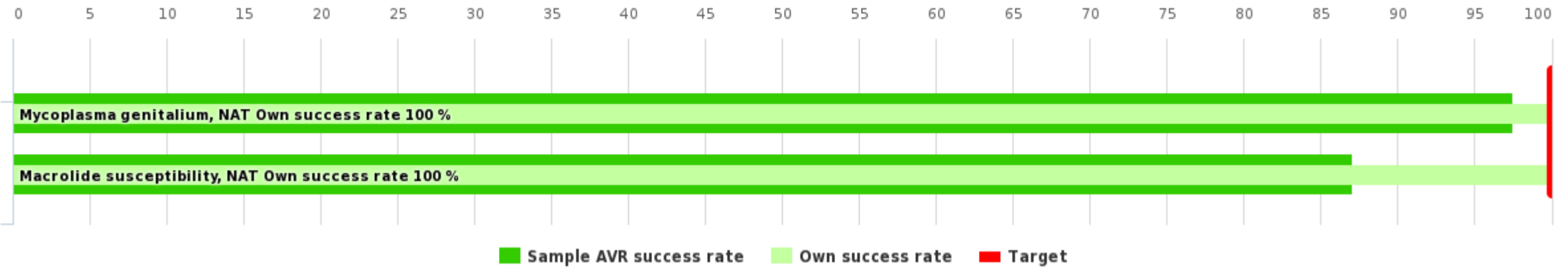
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
S001	4	4	100 %	7 %	93 %
S002	4	4	100 %	3 %	97 %
S003	4	4	100 %	4.9 %	95.1 %
Average:			100 %	5 %	95 %

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

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

S001

S001 success rate

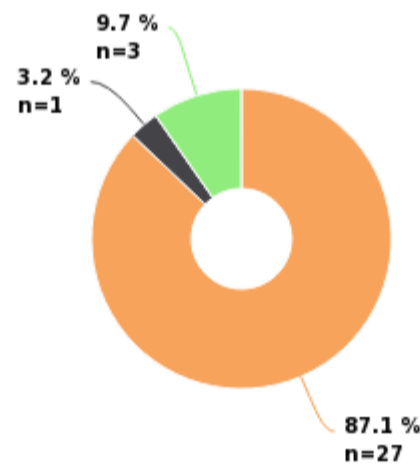


S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Mycoplasma genitalium, NAT	2	2	100 %	2.5 %	97.5 %	40
	Macrolide susceptibility, NAT	2	2	100 %	12.9 %	87.1 %	31
	Total:	4	4	100 %	7 %	93 %	106

S001 Mycoplasma genitalium, NAT



S001 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate
■ Resistance to macrolide not detected

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> M. genitalium detected		39		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		6					
		BioCorp BC-Mycoplasma		1					
		Hain Lifescience FluoroType STI		1					
		<input checked="" type="radio"/> Hologic Aptima M. genitalium assay		5					
		In house		4					
		Seegene Allplex CT/NG/MG/TV Assay		3					
		Seegene Allplex MG & AziR Assay		5					
		Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		SpeedDx ResistancePlus® MG		1					
		SpeedDx ResistancePlus® MG FlexiBle		11					
		Xema Mycoplasma genitalium		1					
	M. genitalium not detected		1		-				0 %
		In house		1					
	Total:		40		2	2	100 %	2.5 %	97.5 %

Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Resistance to macrolide detected		27		2	2	100 %	0 %	100 %
		ELITechGroup Macrolide-R/MG ELITE MGB Kit		1					
		In house		2					

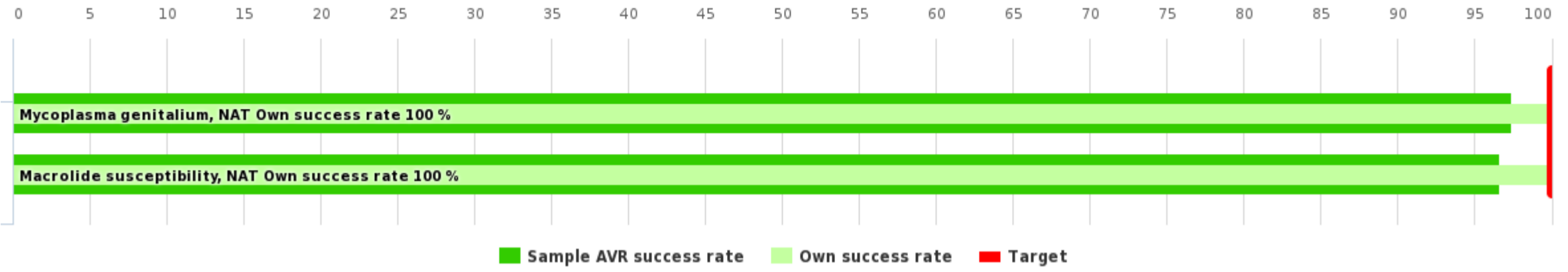
LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

		Seegene Allplex MG & AziR Assay		7					
		<input checked="" type="radio"/> SpeedDx ResistancePlus® MG		3					
		SpeedDx ResistancePlus® MG FleXible		13					
		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1					
	Resistance to macrolide indeterminate		1		-				0 %
		In house		1					
	Resistance to macrolide not detected		3		-				0 %
		ELITechGroup Macrolide-R/MG ELITe MGB Kit		1					
		In house		1					
		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1					
	Total:		31		2	2	100 %	12.9 %	87.1 %

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

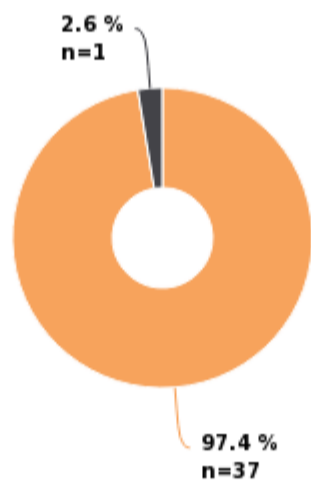
S002

S002 success rate



S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Mycoplasma genitalium, NAT	2	2	100 %	2.6 %	97.4 %	38
	Macrolide susceptibility, NAT	2	2	100 %	3.4 %	96.6 %	29
	Total:	4	4	100 %	3 %	97 %	99

S002 Mycoplasma genitalium, NAT



S002 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> M. genitalium detected		37		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		5					
		BioCorp BC-Mycoplasma		1					
		Hain Lifescience FluoroType STI		1					
		<input checked="" type="radio"/> Hologic Aptima M. genitalium assay		5					
		In house		3					
		Seegene Allplex CT/NG/MG/TV Assay		3					
		Seegene Allplex MG & AziR Assay		5					
		Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		SpeedDx ResistancePlus® MG		1					
		SpeedDx ResistancePlus® MG FlexiBle		11					
		Xema Mycoplasma genitalium		1					
	M. genitalium not detected		1		-				0 %
		In house		1					
	Total:		38		2	2	100 %	2.6 %	97.4 %

Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Resistance to macrolide detected		28		2	2	100 %	0 %	100 %
		ELITechGroup Macrolide-R/MG ELITE MGB Kit		2					
		In house		2					

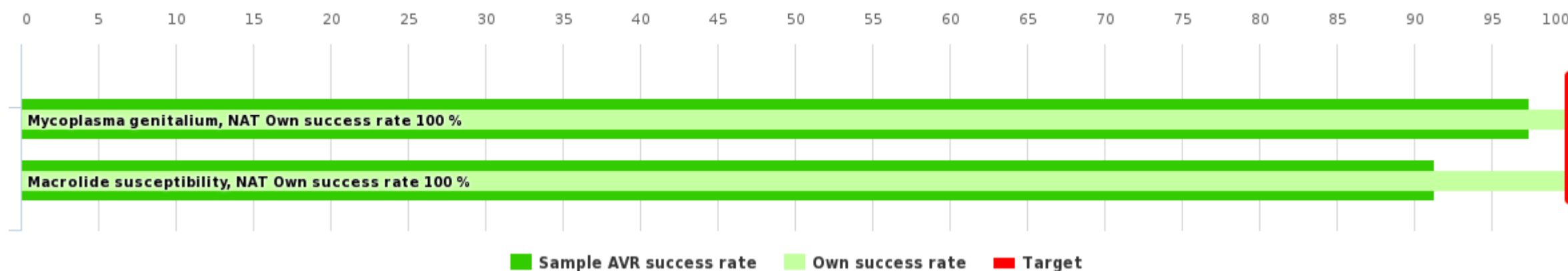
LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

		Seegene Allplex MG & AziR Assay		7					
		<input checked="" type="radio"/> SpeedDx ResistancePlus® MG		3					
		SpeedDx ResistancePlus® MG FleXible		12					
		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		2					
	Resistance to macrolide indeterminate		1		-				0 %
		In house		1					
	Total:		29		2	2	100 %	3.4 %	96.6 %

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

S003

S003 success rate

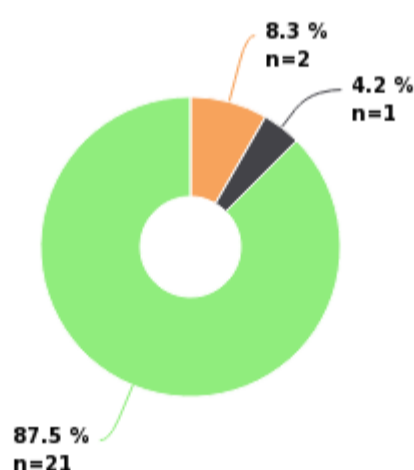


S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Mycoplasma genitalium, NAT	2	2	100 %	2.6 %	97.4 %	38
	Macrolide susceptibility, NAT	2	2	100 %	8.7 %	91.3 %	24
	Total:	4	4	100 %	4.9 %	95.1 %	92

S003 Mycoplasma genitalium, NAT



S003 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate
■ Resistance to macrolide not detected

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	M. genitalium detected		1	1	-				0 %
		SpeedDx ResistancePlus® MG Flexible		1					
	<input checked="" type="radio"/> M. genitalium not detected		37		2	2	100 %	0 %	100 %
		Abbott Alinity m STI Assay		5					
		BioCorp BC-Mycoplasma		1					
		Hain Lifescience FluoroType STI		1					
		<input checked="" type="radio"/> Hologic Aptima M. genitalium assay		5					
		In house		4					
		Seegene Allplex CT/NG/MG/TV Assay		3					
		Seegene Allplex MG & AziR Assay		5					
		Seegene Allplex STI Essential Assay Q (MH, UU)		1					
		SpeedDx ResistancePlus® MG		1					
		SpeedDx ResistancePlus® MG Flexible		10					
		Xema Mycoplasma genitalium		1					
	Total:		38		2	2	100 %	2.6 %	97.4 %

Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Resistance to macrolide detected		2	2	-				0 %
		SpeedDx ResistancePlus® MG Flexible		2					
	Resistance to macrolide indeterminate		1		-				-

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection

- Pilot, October, 1-2023

		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1					
	<input checked="" type="radio"/> Resistance to macrolide not detected		21		2	2	100 %	0 %	100 %
		In house		3					
		Seegene Allplex MG & AziR Assay		6					
		<input checked="" type="radio"/> SpeedDx ResistancePlus® MG		3					
		SpeedDx ResistancePlus® MG FleXible		9					
	Total:		24		2	2	100 %	8.7 %	91.3 %

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023	44	38	86.4 %

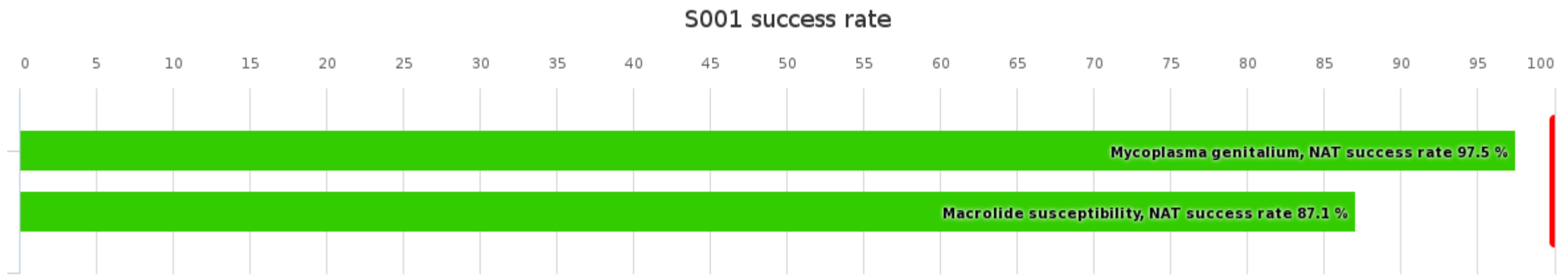
Summary



Summary	AVR success rate
S001	93 %
S002	97 %
S003	95.1 %
Average:	95 %

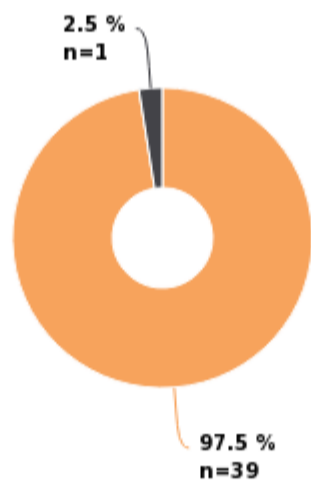
LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

S001

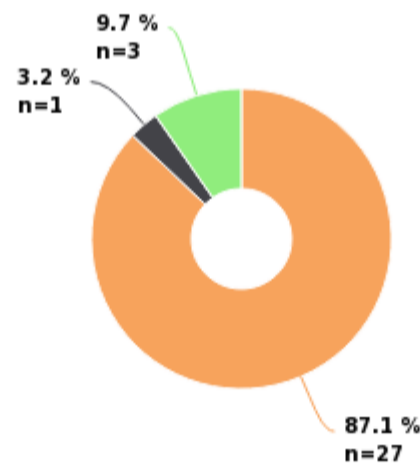


S001 results	Responded	AVR success rate	Count
	Mycoplasma genitalium, NAT	97.5 %	40
	Macrolide susceptibility, NAT	87.1 %	31
	Total:	93 %	106

S001 Mycoplasma genitalium, NAT



S001 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate
■ Resistance to macrolide not detected

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	M. genitalium detected		39		100 %	2
		Abbott Alinity m STI Assay		6		
		BioCorp BC-Mycoplasma		1		
		Hain Lifescience FluoroType STI		1		
		Hologic Aptima M. genitalium assay		5		
		In house		4		
		Seegene Allplex CT/NG/MG/TV Assay		3		
		Seegene Allplex MG & AziR Assay		5		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		SpeedDx ResistancePlus® MG		1		
		SpeedDx ResistancePlus® MG FleXible		11		
		Xema Mycoplasma genitalium		1		
	M. genitalium not detected		1		0 %	0
		In house		1		
	Total:		40		97.5 %	

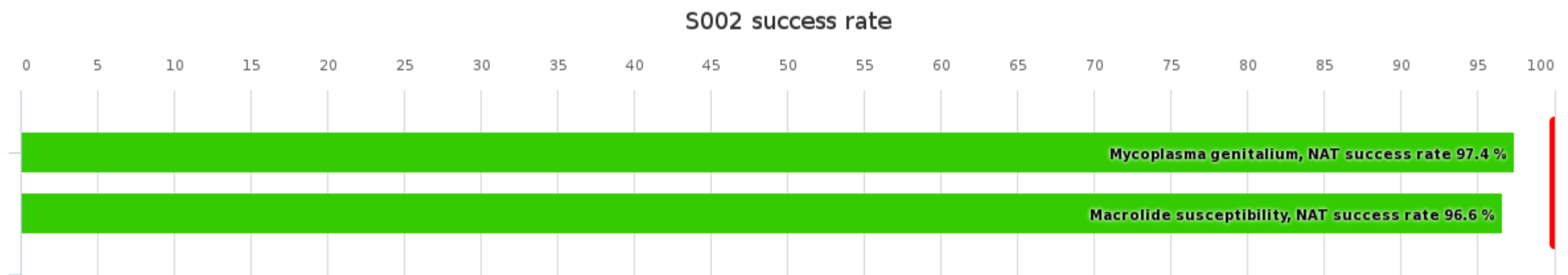
Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to macrolide detected		27		100 %	2
		ELITechGroup Macrolide-R/MG ELITe MGB Kit		1		
		In house		2		
		Seegene Allplex MG & AziR Assay		7		
		SpeedDx ResistancePlus® MG		3		
		SpeedDx ResistancePlus® MG FleXible		13		

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1		
	Resistance to macrolide indeterminate		1		0 %	0
		In house		1		
	Resistance to macrolide not detected		3		0 %	0
		ELITechGroup Macrolide-R/MG ELITe MGB Kit		1		
		In house		1		
		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1		
	Total:		31		87.1 %	

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

S002



S002 results	Responded	AVR success rate	Count
	Mycoplasma genitalium, NAT	97.4 %	38
	Macrolide susceptibility, NAT	96.6 %	29
	Total:	97 %	99

S002 Mycoplasma genitalium, NAT



S002 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	M. genitalium detected		37		100 %	2
		Abbott Alinity m STI Assay		5		
		BioCorp BC-Mycoplasma		1		
		Hain Lifescience FluoroType STI		1		
		Hologic Aptima M. genitalium assay		5		
		In house		3		
		Seegene Allplex CT/NG/MG/TV Assay		3		
		Seegene Allplex MG & AziR Assay		5		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		SpeedDx ResistancePlus® MG		1		
		SpeedDx ResistancePlus® MG FleXible		11		
		Xema Mycoplasma genitalium		1		
	M. genitalium not detected		1		0 %	0
		In house		1		
	Total:		38		97.4 %	

Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to macrolide detected		28		100 %	2
		ELITechGroup Macrolide-R/MG ELITe MGB Kit		2		
		In house		2		
		Seegene Allplex MG & AziR Assay		7		
		SpeedDx ResistancePlus® MG		3		
		SpeedDx ResistancePlus® MG FleXible		12		

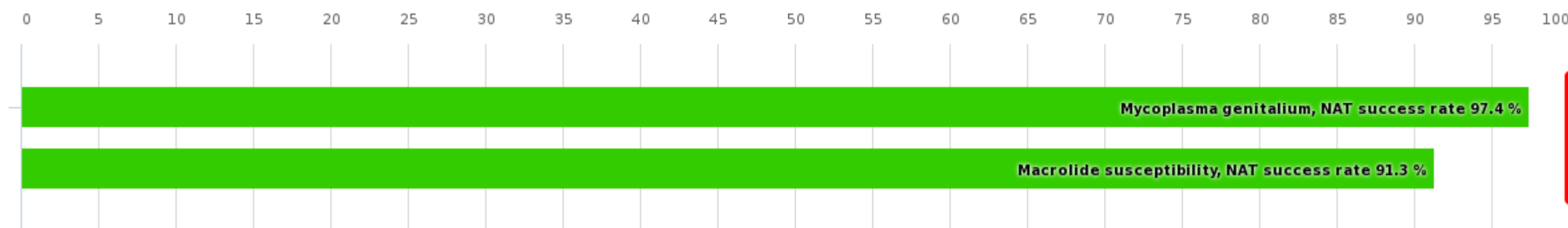
LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection
 - Pilot, October, 1-2023

		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		2		
	Resistance to macrolide indeterminate		1		0 %	0
		In house		1		
	Total:		29		96.6 %	

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

S003

S003 success rate

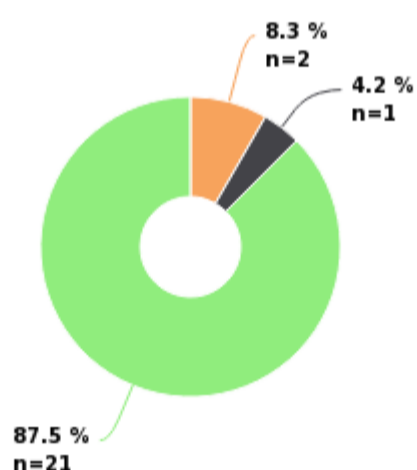


S003 results	Responded	AVR success rate	Count
	Mycoplasma genitalium, NAT	97.4 %	38
	Macrolide susceptibility, NAT	91.3 %	24
	Total:	95.1 %	92

S003 Mycoplasma genitalium, NAT



S003 Macrolide susceptibility, NAT



■ M. genitalium detected
■ M. genitalium not detected

■ Resistance to macrolide detected
■ Resistance to macrolide indeterminate
■ Resistance to macrolide not detected

Mycoplasma genitalium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	M. genitalium detected		1		0 %	0
		SpeedDx ResistancePlus® MG FleXible		1		
	M. genitalium not detected		37		100 %	2
		Abbott Alinity m STI Assay		5		
		BioCorp BC-Mycoplasma		1		
		Hain Lifescience FluoroType STI		1		
		Hologic Aptima M. genitalium assay		5		
		In house		4		
		Seegene Allplex CT/NG/MG/TV Assay		3		
		Seegene Allplex MG & AziR Assay		5		
		Seegene Allplex STI Essential Assay Q (MH, UU)		1		
		SpeedDx ResistancePlus® MG		1		
		SpeedDx ResistancePlus® MG FleXible		10		
		Xema Mycoplasma genitalium		1		
	Total:		38		97.4 %	

Macrolide susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to macrolide detected		2		0 %	0
		SpeedDx ResistancePlus® MG FleXible		2		
	Resistance to macrolide indeterminate		1		-	-
		TIB MOLBIOL/Roche LightMix Modular Mycoplasma Macrolide		1		
	Resistance to macrolide not detected		21		100 %	2
		In house		3		

LABQUALITY Mycoplasma genitalium, drug resistance, nucleic acid detection - Pilot, October, 1-2023

		Seegene Allplex MG & AziR Assay		6		
		SpeedDx ResistancePlus® MG		3		
		SpeedDx ResistancePlus® MG Flexible		9		
	Total:		24		91.3 %	

External Quality Assessment Scheme

***Mycoplasma genitalium*, drug resistance, nucleic acid detection Round 1, 2023 (pilot)**

Specimens

Samples of this EQA round were artificial swab samples. Based on the quality controls conducted by the sample material 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 (LQ763423011)

Mycoplasma genitalium, NAT *M. genitalium* detected.
Macrolide susceptibility, NAT Resistance to macrolide detected. A2058C point mutation.

Sample S002 (LQ763423012)

Mycoplasma genitalium, NAT *M. genitalium* detected.
Macrolide susceptibility, NAT Resistance to macrolide detected. A2058G point mutation.

Sample S003 (LQ763423013)

Mycoplasma genitalium, NAT *M. genitalium* not detected.
Macrolide susceptibility, NAT Resistance to macrolide not detected.

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

Mycoplasma genitalium, drug resistance, nucleic acid detection pilot round included two *M. genitalium* positive, macrolide-resistant samples (S001 and S002) and one *M. genitalium* negative sample (S003).

In the round, 14 different tests were used for *M. genitalium* detection and macrolide susceptibility was determined with eight different tests, six of the tests were suitable for both determinations.

Single point mutations in the 23sRNA gene region associated with azithromycin resistance were reported by two different tests. For sample S001, 6/8 of the results were reported as A2058C point mutation as expected, in addition, one A2058C and A2058T double result and one A2058G result were incorrectly reported. Five 23sRNA mutation results were also reported from the sample using two different tests. From sample S002, all reported mutation results were A2058G point mutations as expected, in addition, five 23sRNA mutation results were reported from the sample.

All in all, the participants performed well in this pilot round, although a few deviating results were reported for each sample, some of which were clear reporting errors. The average success rate for all samples was 95%.

2023-11-17

FINAL REPORT

Product no. 5254

Samples sent 2023-10-03
Round closed 2023-11-10
Final report 2023-11-17

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

EQA Coordinator
Kati Lairo
kati.lairo@labquality.fi

Labquality Oy

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Exceptions in scoring

The "Macrolide resistance undetermined" result reported for sample S003 was left unscored because it was a misunderstanding when responding to a *M. genitalium* negative sample.

End of report

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