

External Quality Assessment Scheme

***Mycoplasma pneumoniae* antibodies** **Round 1, 2023**

Specimens

Please find enclosed 2 human plasma samples S001 and S002, each 0.3 mL.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e., as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

MypnAb
MypnAbM qualitative
MypnAbG
MypnAbM
Clinical interpretation

Storage and use

The specimens should be stored at 2 ... 8 °C and analysed as soon as possible, preferably within a week. Analyse as adult patient samples.

Result reporting

Please enter the results and methods via LabScala. If you can't find your instrument or reagent from the registry, please contact the EQA Coordinator.

S001:



S002:



2023-02-20

INSTRUCTIONS

Product no. 5980
LQ757723011-012/FI

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

The results should be reported no later than **March 15, 2023.**

The expected results of the round are published in LabScala in the View Reports section by March 20, 2023.

Inquiries

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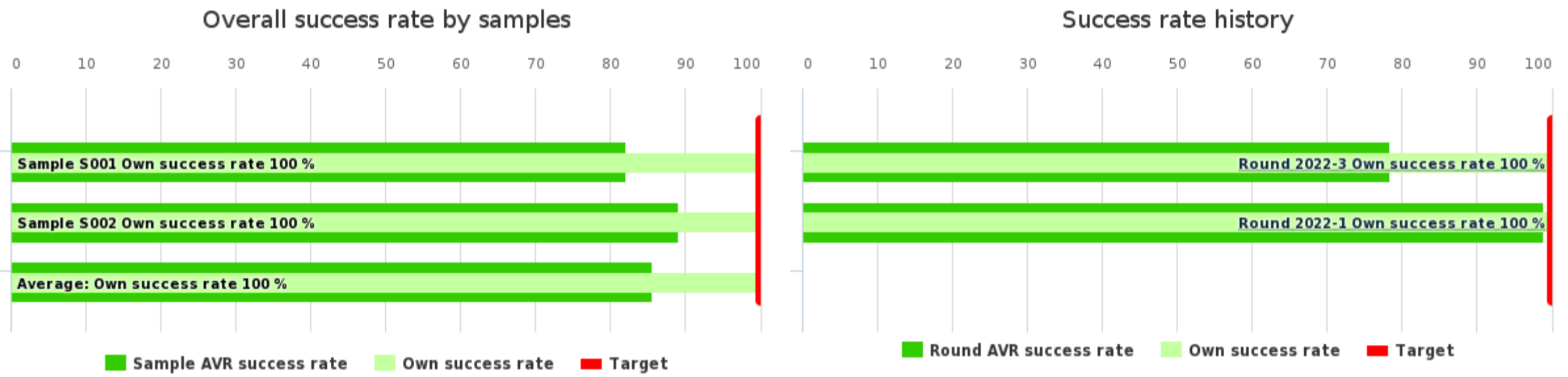
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Mycoplasma pneumoniae, antibodies, February, 1-2023	140	132	94.3 %

Summary

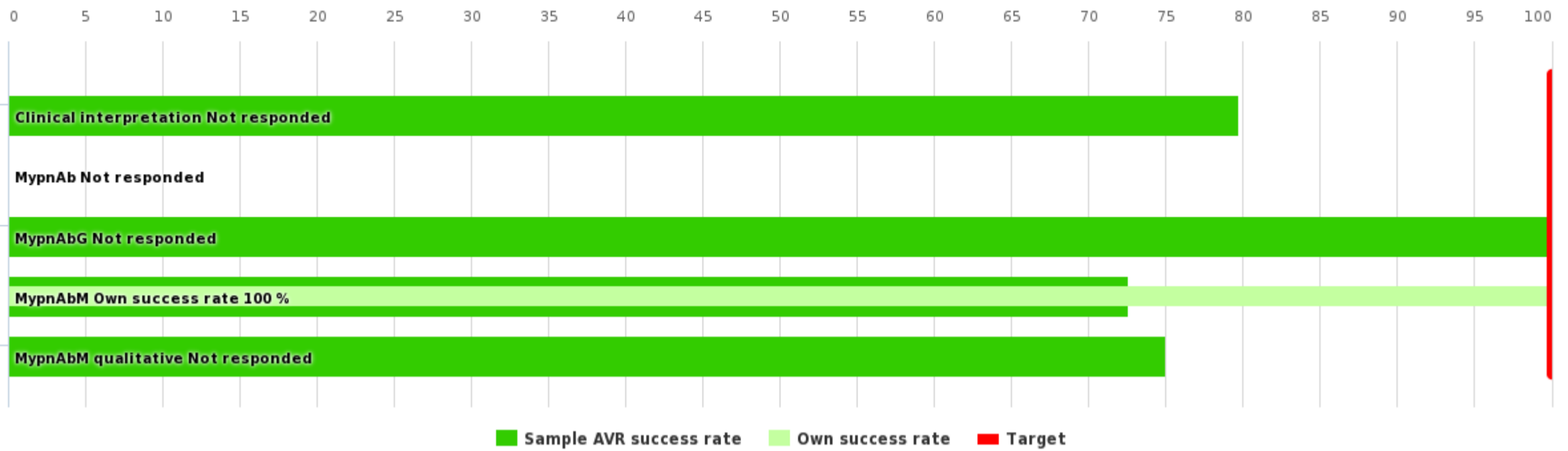


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	17.9 %	82.1 %
Sample S002	2	2	100 %	10.8 %	89.2 %
Average:			100 %	14.4 %	85.6 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-3	1-1	100 %	21.6 %	78.4 %
Round 2022-1	1-1	100 %	1 %	99 %

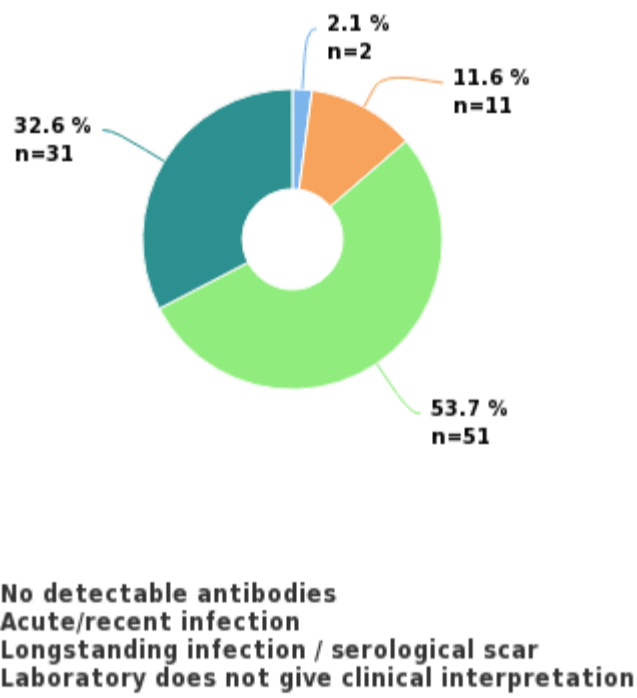
Sample S001

Sample S001 success rate



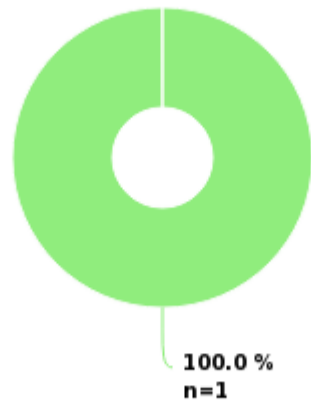
Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	79.7 %	95
	MypnAb	-	-	-	-	-	1
	MypnAbG	-	-	-	-	100 %	84
	MypnAbM	2	2	100 %	27.4 %	72.6 %	95
	MypnAbM qualitative	-	-	-	-	75 %	40
	Total:	2	2	100 %	17.9 %	82.1 %	315

Sample S001 Clinical interpretation



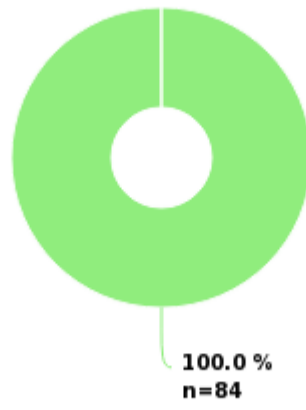
Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	No detectable antibodies		2		-				0 %
	Acute/recent infection		11		-				0 %
		New sample requested		8					
	Longstanding infection / serological scar		51		-				100 %
		New sample requested		13					
		Would be referred to another laboratory for further examination		2					
	⊙ Laboratory does not give clinical interpretation		31		-				-
		New sample requested		9					
	Total:		95		-	-	-	-	79.7 %

Sample S001 MypnAb



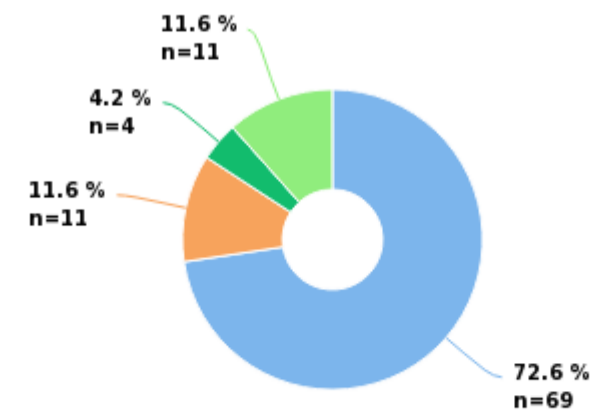
Positive

Sample S001 MypnAbG



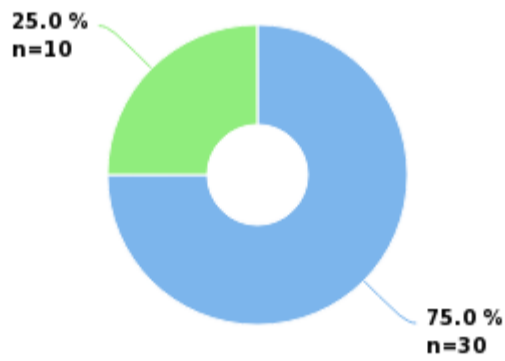
Positive

Sample S001 MypnAbM



Negative Positive Borderline Weak positive

Sample S001 MypnAbM qualitative



Negative Positive

MypnAb	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		1		-				-
		Serodia-Myco II		1					
	Total:		1		-	-	-	-	

MypnAbG	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		84		-				100 %
		Bio-Rad Platelia M. pneumoniae ELISA IgG		1					
		Diasorin Liaison Mycoplasma pn. IgG		37					
		Diesse Chorus Mycoplasma pn. IgG		3					
		Euroimmun Anti-Mycoplasma pn. ELISA IgG		8					
		Labsystem Dg Mycoplasma pn. EIA IgG		5					
		NovaTec Immunodiagnostica Novalisa mycoplasma IgG		6					
		Orgentec Alegria Anti-Mycoplasma pn. IgG		5					
		TestLine EIA Mycoplasma IgG		1					
		TestLine SmartEIA Mycoplasma IgG		2					
		Vircell Mycoplasma pn. ELISA IgG		1					
		Vircell VirClia Mykoplasma IgG monotest		14					
		Virion/Serion ELISA classic IgG		1					
	Total:		84		-	-	-	-	100 %

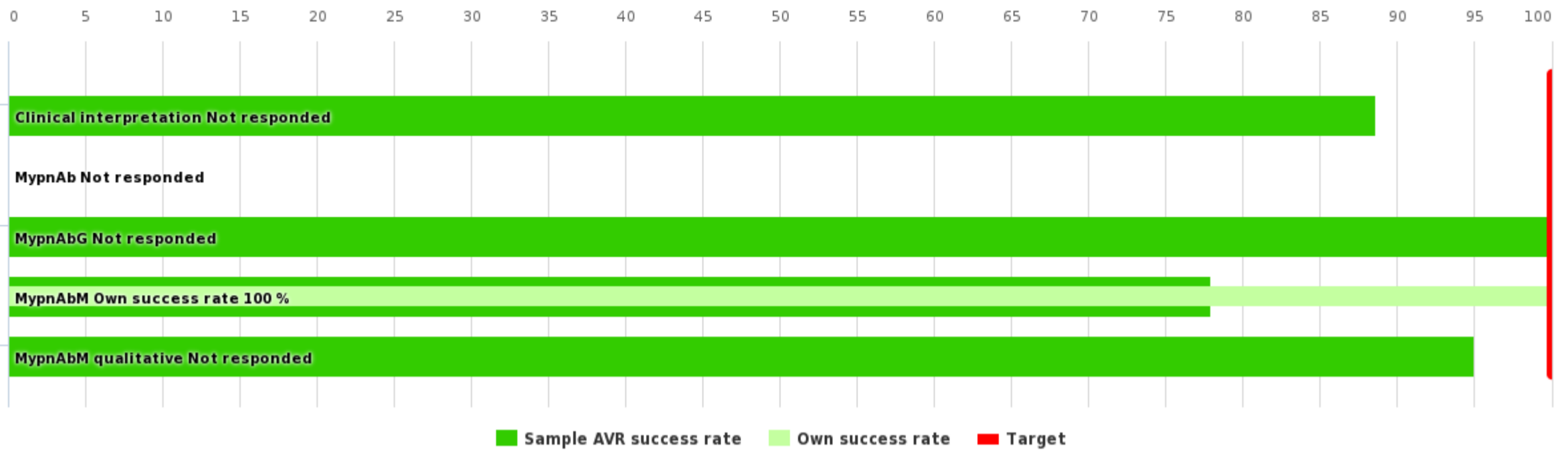
OWN DEVICE: LIA

MypnAbM	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		69		2	2	100 %	0 %	100 %
		Bio-Rad Platelia M. pneumoniae ELISA IgM		1					
		<input checked="" type="radio"/> Diasorin Liaison Mycoplasma pn. IgM		38					
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		3					
		Labsystem Dg Mycoplasma pn. EIA IgM		5					
		NovaTec Immunodiagnostica Novalisa Mycoplasma IgM		6					
		Orgentec Alegria Anti-Mycoplasma pn. IgM		6					
		Savyon Diagnostics ELISA SeroMP recombinant IgM		1					
		TestLine EIA Mycoplasma IgM		1					
		TestLine SmartEIA Mycoplasma IgM		2					
		Vircell Mycoplasma pn. ELISA IgM		1					
		Vircell VirClia Mycoplasma IgM monotest		3					
		Virion/Serion ELISA classic IgM		2					
	Borderline		11		-				0 %
		Diasorin Liaison Mycoplasma pn. IgM		3					
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		2					
		Savyon Diagnostics ELISA SeroMP recombinant IgM		1					
		Vircell VirClia Mycoplasma IgM monotest		5					
	Weak positive		4		-				0 %
		Diesse Chorus Mycoplasma pn. IgM		1					
		Vircell VirClia Mycoplasma IgM monotest		3					
	Positive		11		-				0 %
		Diasorin Liaison Mycoplasma pn. IgM		1					
		Diesse Chorus Mycoplasma pn. IgM		2					
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		3					
		Vircell VirClia Mycoplasma IgM monotest		5					
	Total:		95		2	2	100 %	27.4 %	72.6 %

MypnAbM qualitative	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		30		-				100 %
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		1					
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		29					
	Positive		10		-				0 %
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		1					
		Meridian Bioscience Immunocard Mycoplasma (IgM)		9					
	Total:		40		-	-	-	-	75 %

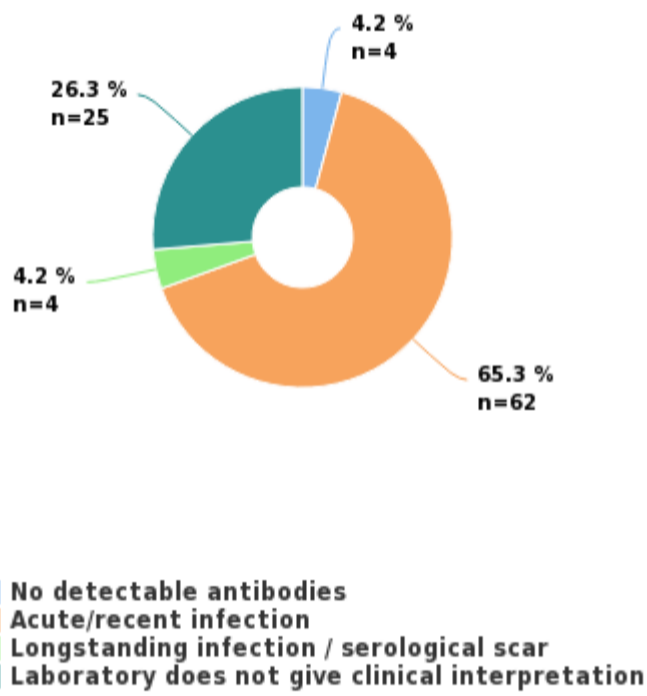
Sample S002

Sample S002 success rate



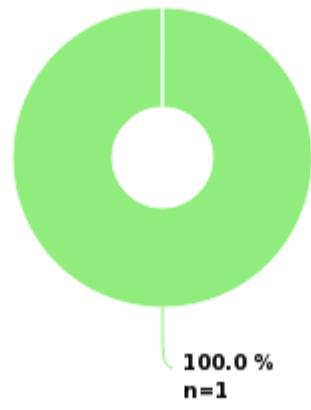
Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	88.6 %	95
	MypnAb	-	-	-	-	-	1
	MypnAbG	-	-	-	-	100 %	85
	MypnAbM	2	2	100 %	22.1 %	77.9 %	95
	MypnAbM qualitative	-	-	-	-	95 %	40
	Total:	2	2	100 %	10.8 %	89.2 %	316

Sample S002 Clinical interpretation



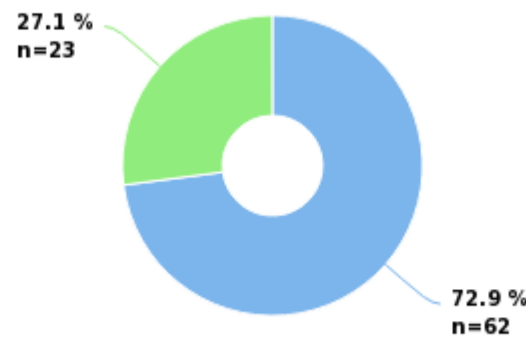
Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	No detectable antibodies		4		-				0 %
		New sample requested		1					
	Acute/recent infection		62		-				100 %
		New sample requested		35					
				2					
	Longstanding infection / serological scar		4		-				0 %
	<input checked="" type="radio"/> Laboratory does not give clinical interpretation		25		-				-
		New sample requested		4					
	Total:		95		-	-	-	-	88.6 %

Sample S002 MypnAb



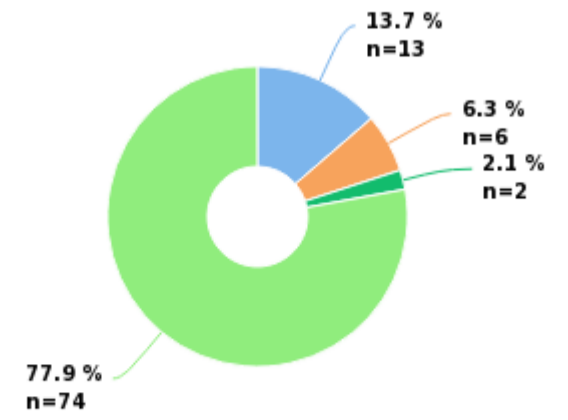
Positive

Sample S002 MypnAbG



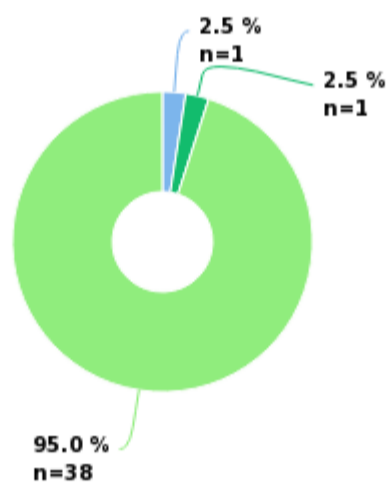
Negative Positive

Sample S002 MypnAbM



Negative Positive Borderline Weak positive

Sample S002 MypnAbM qualitative



Negative Weak positive Positive

MypnAb	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		1		-				-
		Serodia-Myco II		1					
	Total:		1		-	-	-	-	

MypnAbG	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		62		-				100 %
		Diasorin Liaison Mycoplasma pn. IgG		37					
		Labsystem Dg Mycoplasma pn. EIA IgG		1					
		NovaTec Immunodiagnostica Novalisa mycoplasma IgG		6					
		Orgentec Alegria Anti-Mycoplasma pn. IgG		4					
		Vircell Mycoplasma pn. ELISA IgG		1					
		Vircell VirClia Mykoplasma IgG monotest		13					
	Positive		23		-				100 %
		Bio-Rad Platelia M. pneumoniae ELISA IgG		1					
		Diesse Chorus Mycoplasma pn. IgG		3					
		Euroimmun Anti-Mycoplasma pn. ELISA IgG		8					
		Labsystem Dg Mycoplasma pn. EIA IgG		4					
		Orgentec Alegria Anti-Mycoplasma pn. IgG		2					
		TestLine EIA Mycoplasma IgG		1					
		TestLine SmartEIA Mycoplasma IgG		2					
		Vircell VirClia Mykoplasma IgG monotest		1					

	Virion/Serion ELISA classic IgG		1						
Total:		85		-	-	-	-	-	100 %

OWN DEVICE: LIA

MypnAbM	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		13		-				0 %
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		2					
		Labsystem Dg Mycoplasma pn. EIA IgM		2					
		NovaTec Immunodiagnostica Novalisa Mycoplasma IgM		6					
		Orgentec Alegria Anti-Mycoplasma pn. IgM		1					
		TestLine EIA Mycoplasma IgM		1					
		TestLine SmartEIA Mycoplasma IgM		1					
	Borderline		6		-				0 %
		Diesse Chorus Mycoplasma pn. IgM		1					
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		1					
		TestLine SmartEIA Mycoplasma IgM		1					
		Vircell VirClia Mycoplasma IgM monotest		2					
		Virion/Serion ELISA classic IgM		1					
	Weak positive		2		-				0 %
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		1					
		Virion/Serion ELISA classic IgM		1					
	<input checked="" type="radio"/> Positive		74		2	2	100 %	0 %	100 %
		Bio-Rad Platelia M. pneumoniae ELISA IgM		1					
		<input checked="" type="radio"/> Diasorin Liaison Mycoplasma pn. IgM		42					
		Diesse Chorus Mycoplasma pn. IgM		2					
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		4					
		Labsystem Dg Mycoplasma pn. EIA IgM		3					
		Orgentec Alegria Anti-Mycoplasma pn. IgM		5					
		Savyon Diagnostics ELISA SeroMP recombinant IgM		2					
		Vircell Mycoplasma pn. ELISA IgM		1					
		Vircell VirClia Mycoplasma IgM monotest		14					
Total:			95		2	2	100 %	22.1 %	77.9 %

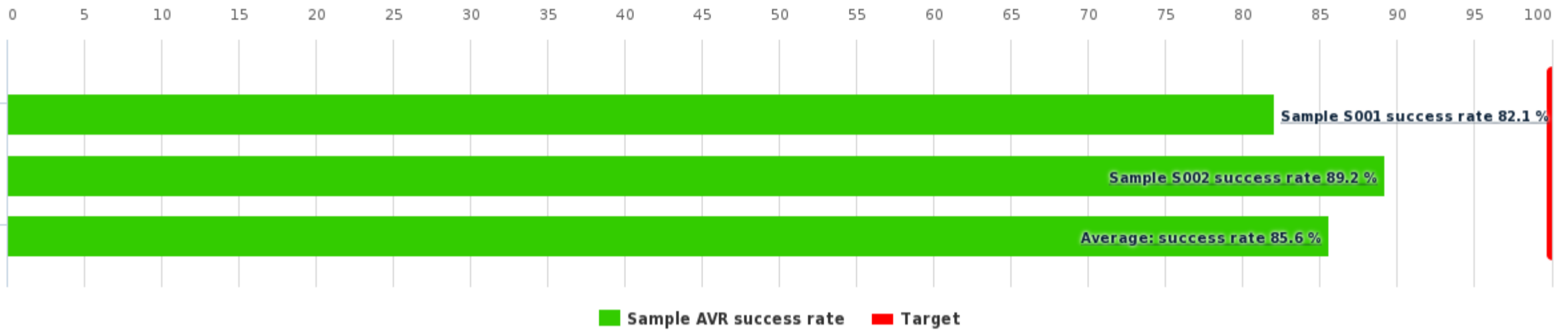
MypnAbM qualitative	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Meridian Bioscience Immunocard Mycoplasma (IgM)		1					
	Weak positive		1		-				0 %
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		1					
	<input checked="" type="radio"/> Positive		38		-				100 %
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		2					
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		28					
		Meridian Bioscience Immunocard Mycoplasma (IgM)		8					
Total:			40		-	-	-	-	95 %

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Mycoplasma pneumoniae, antibodies, February, 1-2023	140	132	94.3 %

Summary

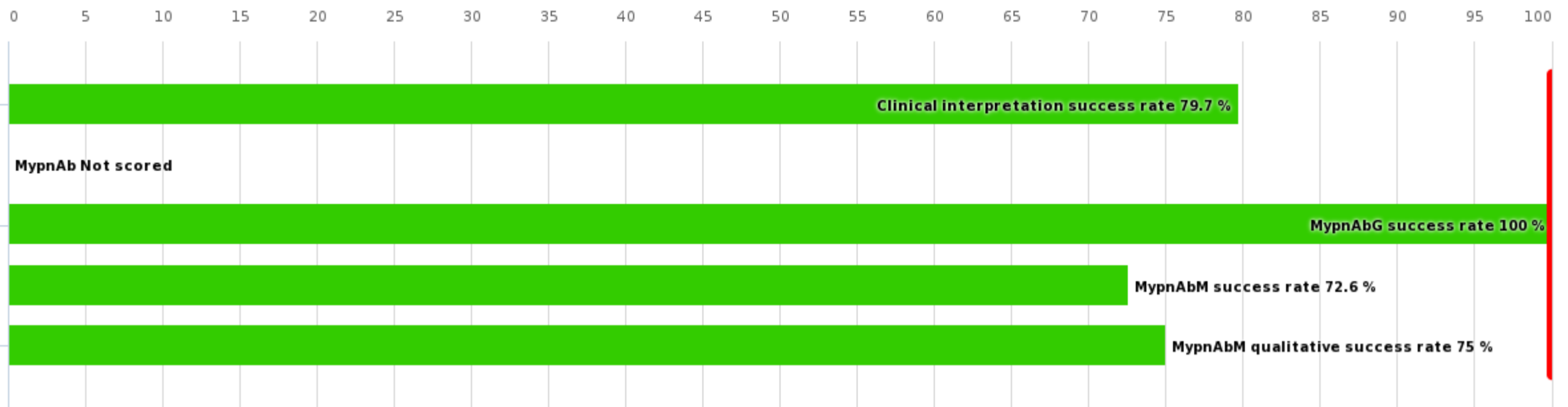
Overall success rate by samples



Summary	AVR success rate
Sample S001	82.1 %
Sample S002	89.2 %
Average:	85.6 %

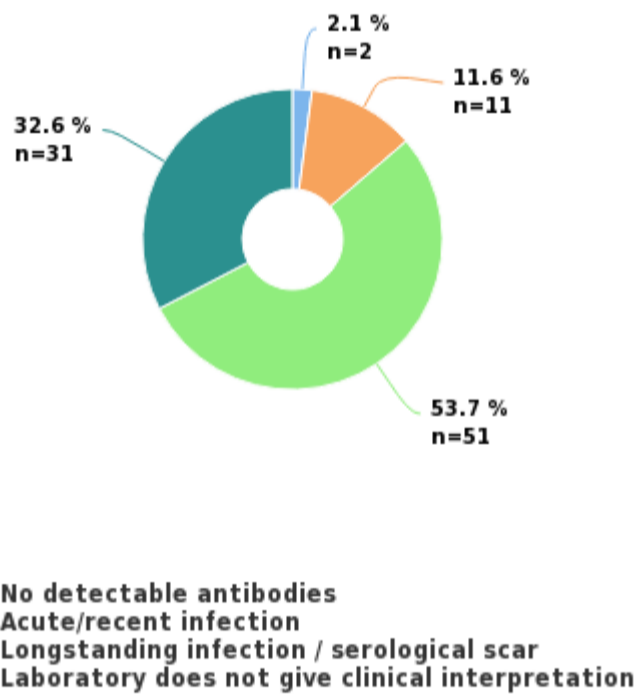
Sample S001

Sample S001 success rate



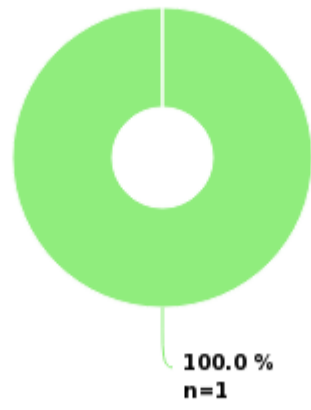
Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	79.7 %	95
	MypnAb	-	1
	MypnAbG	100 %	84
	MypnAbM	72.6 %	95
	MypnAbM qualitative	75 %	40
	Total:	82.1 %	315

Sample S001 Clinical interpretation



Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score
	No detectable antibodies		2		0 %	0
	Acute/recent infection		11		0 %	0
		New sample requested		8		
	Longstanding infection / serological scar		51		100 %	4
		New sample requested		13		
		Would be referred to another laboratory for further examination		2		
	Laboratory does not give clinical interpretation		31		-	-
		New sample requested		9		
	Total:		95		79.7 %	

Sample S001 MypnAb



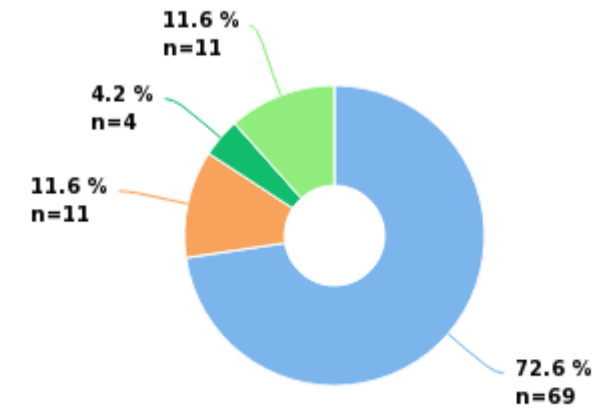
Positive

Sample S001 MypnAbG



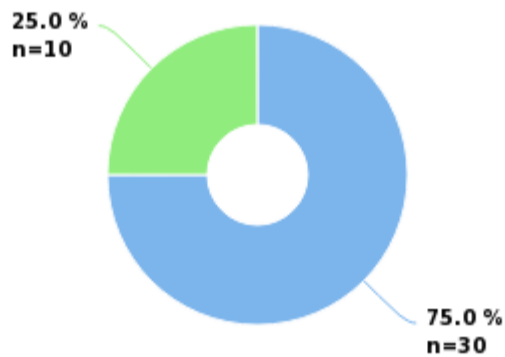
Positive

Sample S001 MypnAbM



Negative Positive Borderline Weak positive

Sample S001 MypnAbM qualitative



Negative Positive

MypnAb	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Positive		1		-	-
		Serodia-Myco II		1		
	Total:		1			

MypnAbG	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Positive		84		100 %	2
		Bio-Rad Platelia M. pneumoniae ELISA IgG		1		
		Diasorin Liaison Mycoplasma pn. IgG		37		
		Diesse Chorus Mycoplasma pn. IgG		3		
		Euroimmun Anti-Mycoplasma pn. ELISA IgG		8		
		Labsystem Dg Mycoplasma pn. EIA IgG		5		
		NovaTec Immunodiagnostica Novalisa mycoplasma IgG		6		
		Orgentec Alegria Anti-Mycoplasma pn. IgG		5		
		TestLine EIA Mycoplasma IgG		1		
		TestLine SmartEIA Mycoplasma IgG		2		
		Vircell Mycoplasma pn. ELISA IgG		1		
		Vircell VirClia Mykoplasma IgG monotest		14		
		Virion/Serion ELISA classic IgG		1		
	Total:		84		100 %	

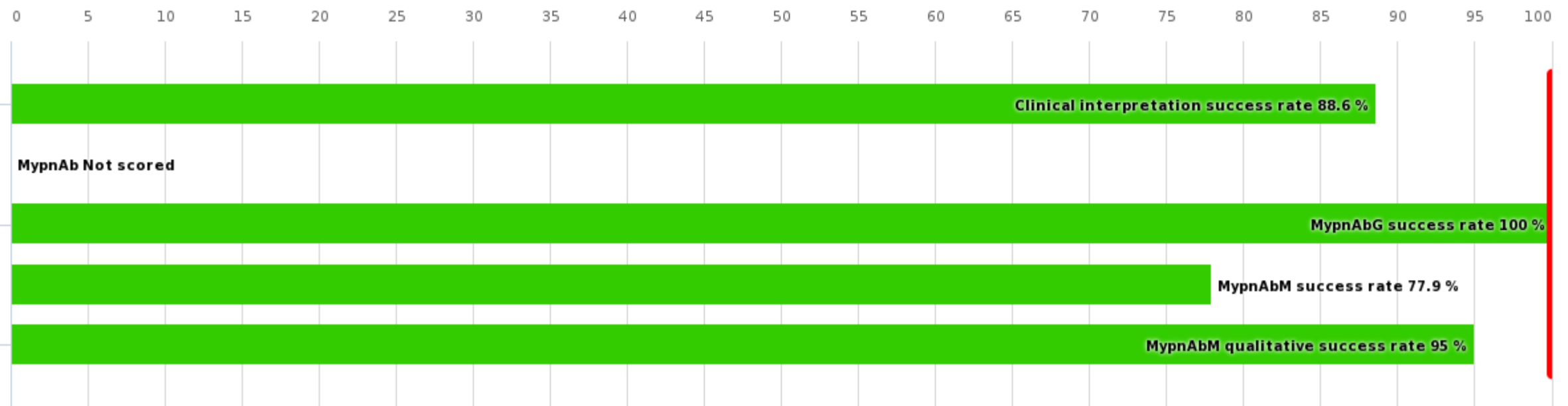
MypnAbM	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		69		100 %	2
		Bio-Rad Platelia M. pneumoniae ELISA IgM		1		
		Diasorin Liaison Mycoplasma pn. IgM		38		
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		3		
		Labsystem Dg Mycoplasma pn. EIA IgM		5		

		NovaTec Immunodiagnostica Novalisa Mycoplasma IgM		6		
		Orgentec Alegria Anti-Mycoplasma pn. IgM		6		
		Savyon Diagnostics ELISA SeroMP recombinant IgM		1		
		TestLine EIA Mycoplasma IgM		1		
		TestLine SmartEIA Mycoplasma IgM		2		
		Vircell Mycoplasma pn. ELISA IgM		1		
		Vircell VirClia Mycoplasma IgM monotest		3		
		Virion/Serion ELISA classic IgM		2		
	Borderline		11		0 %	0
		Diasorin Liaison Mycoplasma pn. IgM		3		
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		2		
		Savyon Diagnostics ELISA SeroMP recombinant IgM		1		
		Vircell VirClia Mycoplasma IgM monotest		5		
	Weak positive		4		0 %	0
		Diesse Chorus Mycoplasma pn. IgM		1		
		Vircell VirClia Mycoplasma IgM monotest		3		
	Positive		11		0 %	0
		Diasorin Liaison Mycoplasma pn. IgM		1		
		Diesse Chorus Mycoplasma pn. IgM		2		
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		3		
		Vircell VirClia Mycoplasma IgM monotest		5		
	Total:		95		72.6 %	

MypnAbM qualitative	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		30		100 %	2
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		1		
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		29		
	Positive		10		0 %	0
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		1		
		Meridian Bioscience Immunocard Mycoplasma (IgM)		9		
	Total:		40		75 %	

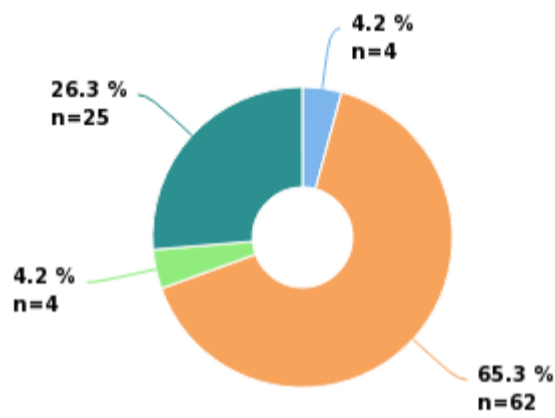
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	88.6 %	95
	MypnAb	-	1
	MypnAbG	100 %	85
	MypnAbM	77.9 %	95
	MypnAbM qualitative	95 %	40
	Total:	89.2 %	316

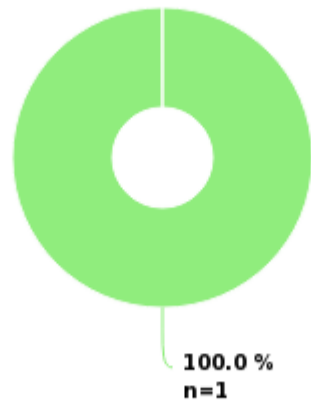
Sample S002 Clinical interpretation



- No detectable antibodies
- Acute/recent infection
- Longstanding infection / serological scar
- Laboratory does not give clinical interpretation

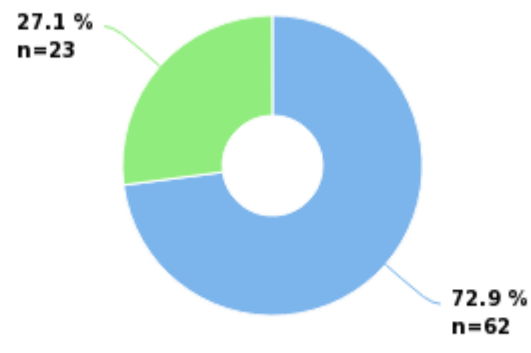
Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score
	No detectable antibodies		4		0 %	0
		New sample requested		1		
	Acute/recent infection		62		100 %	4
		New sample requested		35		
				2		
	Longstanding infection / serological scar		4		0 %	0
	Laboratory does not give clinical interpretation		25		-	-
		New sample requested		4		
	Total:		95		88.6 %	

Sample S002 MypnAb



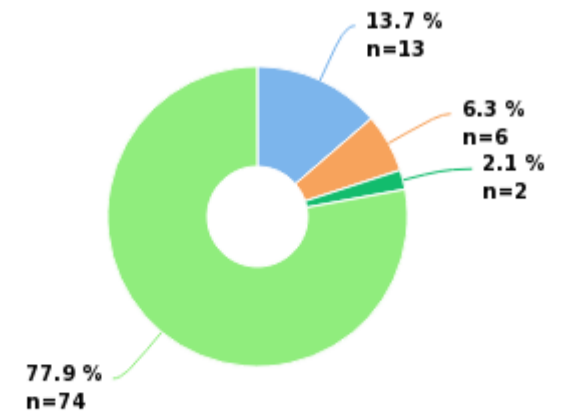
Positive

Sample S002 MypnAbG



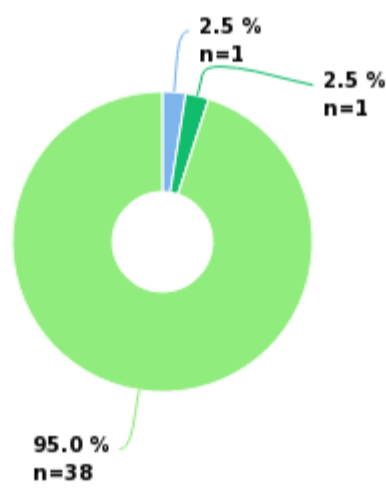
Negative Positive

Sample S002 MypnAbM



Negative Positive Borderline Weak positive

Sample S002 MypnAbM qualitative



Negative Weak positive Positive

MypnAb	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Positive		1		-	-
		Serodia-MycO II		1		
	Total:		1			

MypnAbG	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		62		100 %	2
		Diasorin Liaison Mycoplasma pn. IgG		37		
		Labsystem Dg Mycoplasma pn. EIA IgG		1		
		NovaTec Immunodiagnostica Novalisa mycoplasma IgG		6		
		Orgentec Alegria Anti-Mycoplasma pn. IgG		4		
		Vircell Mycoplasma pn. ELISA IgG		1		
		Vircell VirClia Mykoplasma IgG monotest		13		
	Positive		23		100 %	2
		Bio-Rad Platelia M. pneumoniae ELISA IgG		1		
		Diesse Chorus Mycoplasma pn. IgG		3		
		Euroimmun Anti-Mycoplasma pn. ELISA IgG		8		
		Labsystem Dg Mycoplasma pn. EIA IgG		4		
		Orgentec Alegria Anti-Mycoplasma pn. IgG		2		
		TestLine EIA Mycoplasma IgG		1		
		TestLine SmartEIA Mycoplasma IgG		2		
		Vircell VirClia Mykoplasma IgG monotest		1		
		Virion/Serion ELISA classic IgG		1		
	Total:		85		100 %	

MypnAbM	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		13		0 %	0

		Euroimmun Anti-Mycoplasma pn. ELISA IgM		2		
		Labsystem Dg Mycoplasma pn. EIA IgM		2		
		NovaTec Immunodiagnostica Novalisa Mycoplasma IgM		6		
		Orgentec Alegria Anti-Mycoplasma pn. IgM		1		
		TestLine EIA Mycoplasma IgM		1		
		TestLine SmartEIA Mycoplasma IgM		1		
	Borderline		6		0 %	0
		Diesse Chorus Mycoplasma pn. IgM		1		
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		1		
		TestLine SmartEIA Mycoplasma IgM		1		
		Viricell VirClia Mycoplasma IgM monotest		2		
		Virion/Serion ELISA classic IgM		1		
	Weak positive		2		0 %	0
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		1		
		Virion/Serion ELISA classic IgM		1		
	Positive		74		100 %	2
		Bio-Rad Platelia M. pneumoniae ELISA IgM		1		
		Diasorin Liaison Mycoplasma pn. IgM		42		
		Diesse Chorus Mycoplasma pn. IgM		2		
		Euroimmun Anti-Mycoplasma pn. ELISA IgM		4		
		Labsystem Dg Mycoplasma pn. EIA IgM		3		
		Orgentec Alegria Anti-Mycoplasma pn. IgM		5		
		Savyon Diagnostics ELISA SeroMP recombinant IgM		2		
		Viricell Mycoplasma pn. ELISA IgM		1		
		Viricell VirClia Mycoplasma IgM monotest		14		
	Total:		95		77.9 %	

MypnAbM qualitative	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		1		0 %	0
		Meridian Bioscience Immunocard Mycoplasma (IgM)		1		
	Weak positive		1		0 %	0
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		1		
	Positive		38		100 %	2
		Hangzhou AllTest Biotech Mycoplasma Pneumonia Rapid Test		2		
		ImmunoFLOW Mycoplasma pneumoniae (IgM)		28		
		Meridian Bioscience Immunocard Mycoplasma (IgM)		8		
	Total:		40		95 %	

External Quality Assessment Scheme

***Mycoplasma pneumoniae*, antibodies** **Round 1, 2023**

Specimens

Samples of this EQA round were human plasma. The homogeneity of samples was ensured during the sample preparation. The antibodies are known to be stable and there are no special requirements for their handling or storage. The samples were suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The accepted results were as follows:

Sample S001 (LQ757723011)

MypnAb	Not scored (less than three results)
MypnAbM qualitative	Negative
MypnAbG	Positive
MypnAbM	Negative
Clinical interpretation	Longstanding infection/serological scar

Sample S002 (LQ757723012)

MypnAb	Not scored (less than three results)
MypnAbM qualitative	Positive
MypnAbG	Negative/Positive
MypnAbM	Positive
Clinical interpretation	Acute/recent infection

Pre-test method: Labsystems Diagnostics *Mycoplasma pneumoniae* IgG/IgM EIA.

Report info

It is important to read the Final report first, because it contains important information of the samples and results in each round. 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 and clinical interpretations 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
- Correct/expected clinical interpretation 4/4 points
- False/deviating clinical interpretation 0/4 points

2023-03-27

FINAL REPORT

Product no. 5980

Subcontracting: Sample pretesting

Samples sent	2023-02-20
Round closed	2023-03-15
Final report	2023-03-27

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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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.

Exceptions in scoring

The analyte MypnAb was not scored because less than three results were answered.

Comments - Expert

S001: Sample was IgG positive (high level) and IgM negative in the pre-test. As expected, all laboratories participating in the round found the sample to be IgG positive. IgM class antibodies were most often interpreted as negative (73% of quantitative and 75% of qualitative test users). A positive IgM result was most often obtained with the qualitative Meridian Bioscience test (all users of that test), while the most often used qualitative test (ImmunoFLOW) gave a negative result for all users (N = 29).

S002: In pre-testing, the sample just exceeded the cut-off for IgG antibodies. As expected, some of the participating laboratories reported the sample as positive, some as negative. Here, a slight variation was noticeable from test kit to test kit. The IgM antibodies were above the cut-off value of the kit in pre-testing. Most of the laboratories answered that the sample was IgM positive. However, it is advisable to confirm the diagnostic value of a single positive IgM finding, e.g., by showing an increase in the IgG level in paired samples, as the IgM response might be an unspecific test reaction and persisting (months) after infection.

End of report

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