

External Quality Assessment Scheme

Legionella, antigen detection in urine **Round 2, 2024**

Specimens

Please find enclosed 3 liquid, urine simulating specimens S001, S002 and S003, each 1 mL.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Examinations

Legionella pneumophila, antigen detection in urine.

Storage and use

Once samples are received, they should be stored at +2...8°C. The examinations should be performed as soon as possible. Note, that the samples should not be heated prior to the examination.

1. Allow samples to reach room temperature.
2. Dip a sample collection swab (supplied by your test kit manufacturer) into the specimen vial, completely immersing the swab head.
3. If necessary, touch the swab to the side of the vial to remove excess liquid.
4. In the sequel follow the instructions given by the test manufacturer.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you do not find your test in the registry, please contact the EQA Coordinator. All reported results will be scored.

S001



S002



S003



2024-04-30

INSTRUCTIONS

Product no. 5597
LQ760824021-023/US

Subcontracting: Sample pretesting

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

The results should be reported no later than
May 24, 2024.

The expected results of the round are published in LabScala in the View reports section by May 29, 2024.

Inquiries

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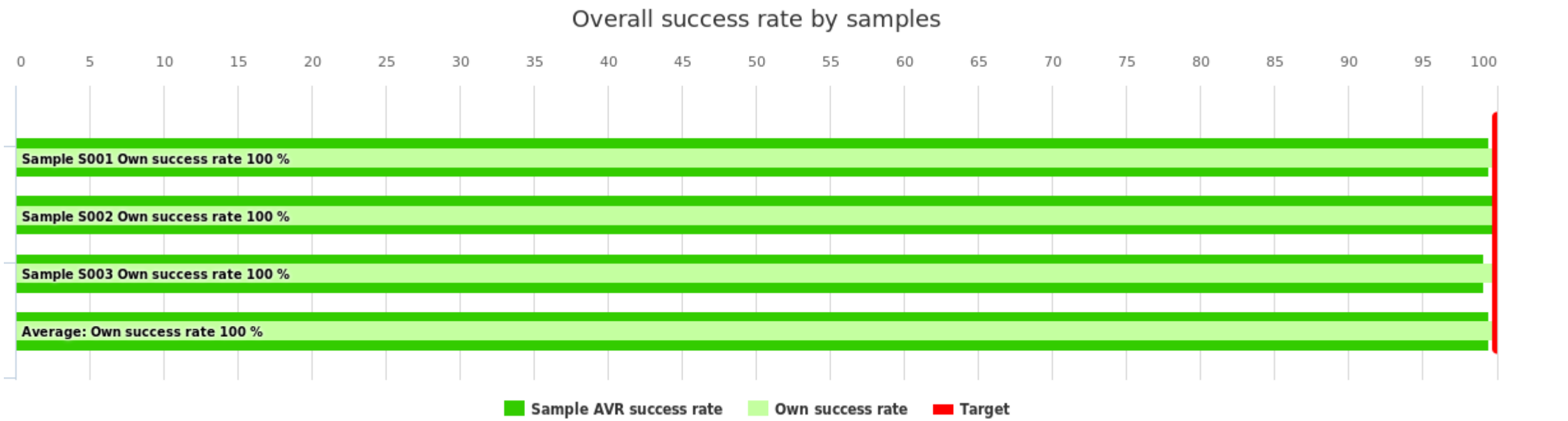
info@labquality.com
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Legionella, antigen detection in urine, May, 2-2024	212	211	99.5 %

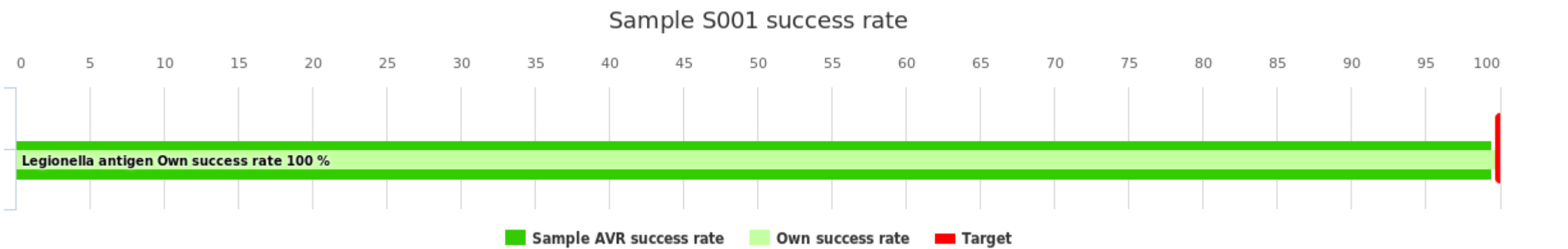
Summary



Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0.5 %	99.5 %
Sample S002	2	2	100 %	0 %	100 %
Sample S003	2	2	100 %	0.9 %	99.1 %
Average:			100 %	0.5 %	99.5 %

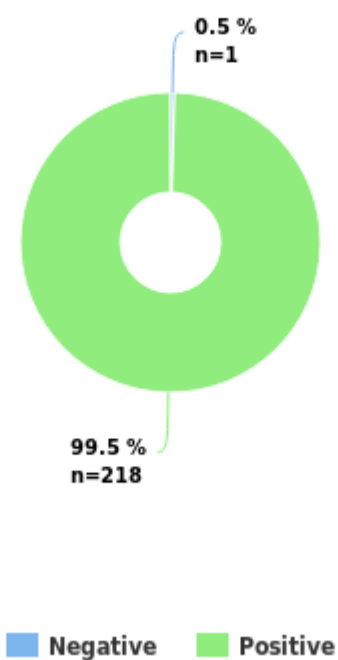
History	Test nr.	Own success rate	Difference	AVR success rate
History not found				

Sample S001



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0.5 %	99.5 %	219
Total:		2	2	100 %	0.5 %	99.5 %	219

Sample S001 Legionella antigen

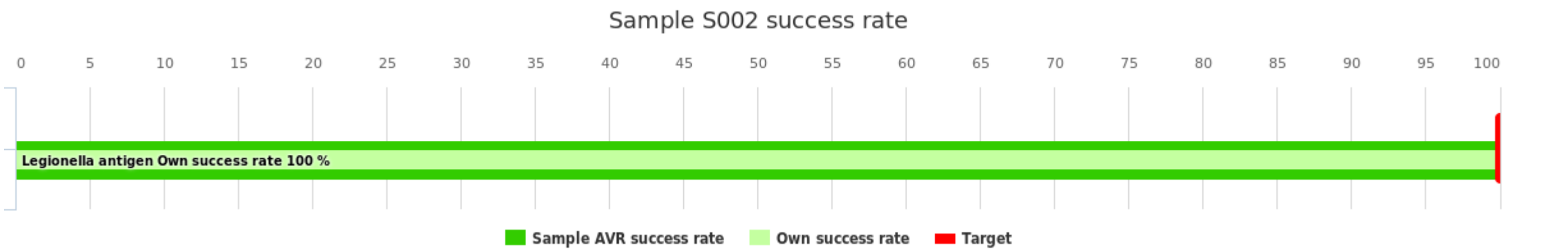


OWN DEVICE: 1

Legionella antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Quidel Sofia Legionella FIA		1					
	<input checked="" type="radio"/> Positive		218		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		104					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		37					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		2					
		Biotec CerTest Legionella		4					
		CiTEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1					
		Coris BioConcept Legionella K-SeT		4					
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1					
		LIAISON Legionella Urinary Ag		1					
		Meridian Bioscience TRU Legionella		2					
		Monlab Legionella Monlab Test		1					
		Nal von minden NADAL Legionella Test		5					
		Operon Simple Strep pneumo-Legio		2					
		Quidel Sofia Legionella FIA		21					
		<input checked="" type="radio"/> SD Biosensor Standard F Legionella Ag FIA		19					
		Servibio UriSign Legionella Color		1					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					

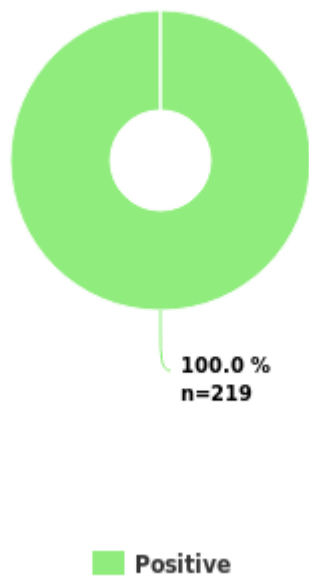
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2					
		Vidia Rapid-VIDITEST Legionella		1					
		Vitassay Legionella		1					
	Total:		219		2	2	100 %	0.5 %	99.5 %

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0 %	100 %	219
Total:		2	2	100 %	0 %	100 %	219

Sample S002 Legionella antigen

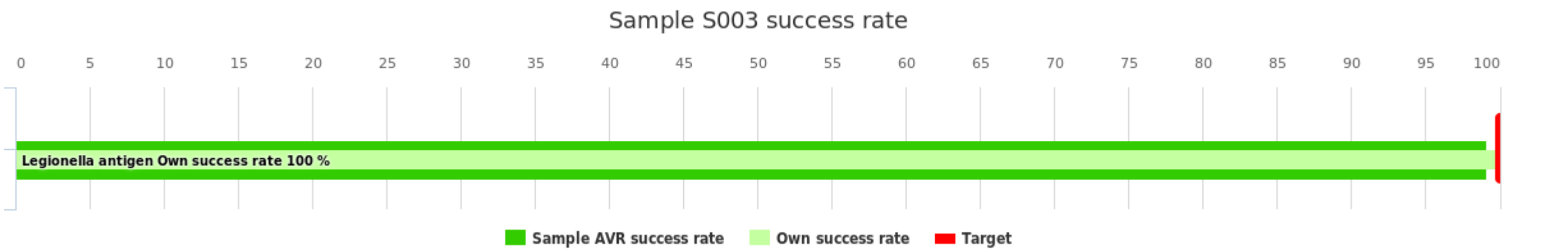


OWN DEVICE: 1

Legionella antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		219		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		105					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		36					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		2					
		Biotec CerTest Legionella		4					
		CI TEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1					
		Coris BioConcept Legionella K-SeT		4					
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1					
		LIAISON Legionella Urinary Ag		1					
		Meridian Bioscience TRU Legionella		2					
		Monlab Legionella Monlab Test		1					
		Nal von minden NADAL Legionella Test		5					
		Operon Simple Strep pneumo-Legio		2					
		Quidel Sofia Legionella FIA		22					
		<input checked="" type="radio"/> SD Biosensor Standard F Legionella Ag FIA		19					
		Servibio UriSign Legionella Color		1					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2					

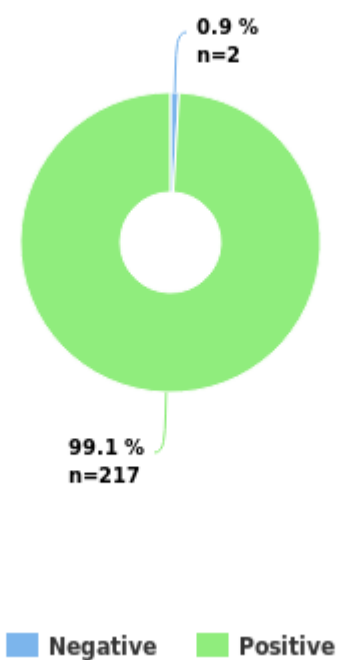
		Vidia Rapid-VIDITEST Legionella		1					
		Vitassay Legionella		1					
	Total:		219		2	2	100 %	0 %	100 %

Sample S003



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0.9 %	99.1 %	219
Total:		2	2	100 %	0.9 %	99.1 %	219

Sample S003 Legionella antigen



OWN DEVICE: 1

Legionella antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Abbott Binax NOW Legionella Urinary Antigen Card		1					
		SD Biosensor Standard F Legionella Ag FIA		1					
	Positive		217		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		104					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		36					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		2					
		Biotec CerTest Legionella		4					
		CiTEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1					
		Coris BioConcept Legionella K-SeT		4					
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1					
		LIAISON Legionella Urinary Ag		1					
		Meridian Bioscience TRU Legionella		2					
		Monlab Legionella Monlab Test		1					
		Nal von minden NADAL Legionella Test		5					
		Operon Simple Strep pneumo-Legio		2					
		Quidel Sofia Legionella FIA		22					
		SD Biosensor Standard F Legionella Ag FIA		18					
		Servibio UriSign Legionella Color		1					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5					

		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2					
		Vidia Rapid-VIDITEST Legionella		1					
		Vitassay Legionella		1					
	Total:		219		2	2	100 %	0.9 %	99.1 %

Report Info

PARTICIPANTS

Altogether 212 laboratories from 22 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:

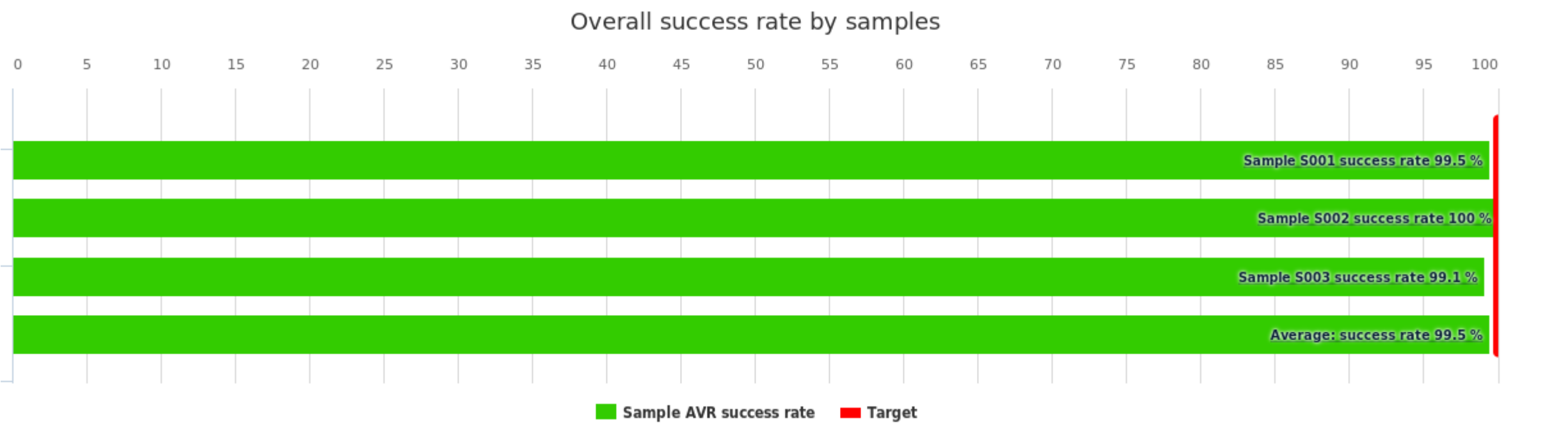
Correct/expected test result 2/2 points
False/deviating test result 0/2 points

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.

GLOBAL REPORT

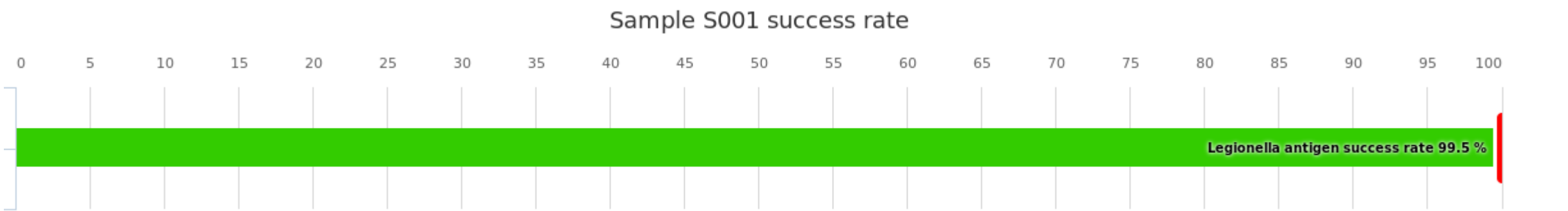
	No of participants	No of responded participants	Response percentage
Legionella, antigen detection in urine, May, 2-2024	212	211	99.5 %

Summary



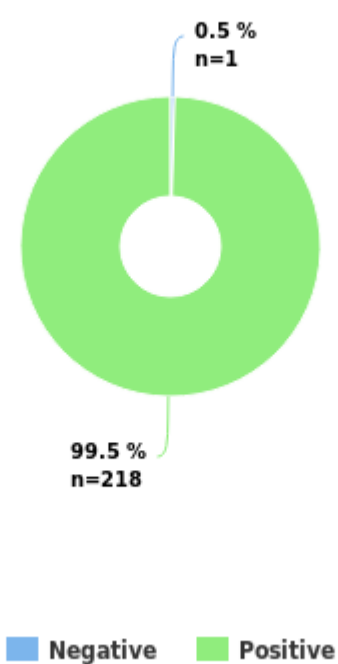
Summary	AVR success rate
Sample S001	99.5 %
Sample S002	100 %
Sample S003	99.1 %
Average:	99.5 %

Sample S001



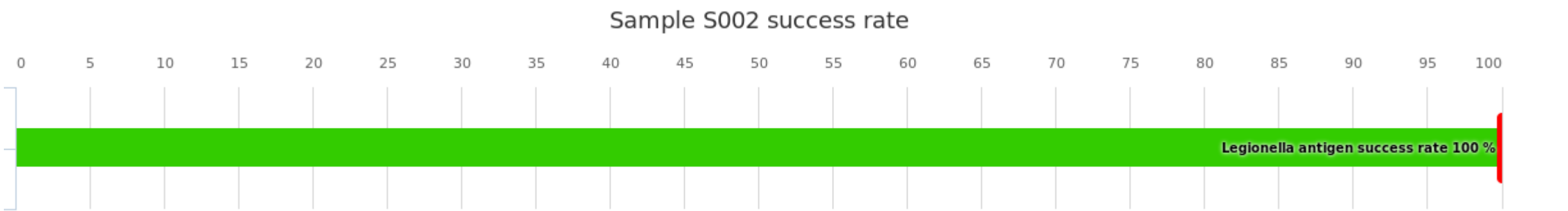
Sample S001 results	Responded	AVR success rate	Count
	Legionella antigen	99.5 %	219
Total:		99.5 %	219

Sample S001 Legionella antigen



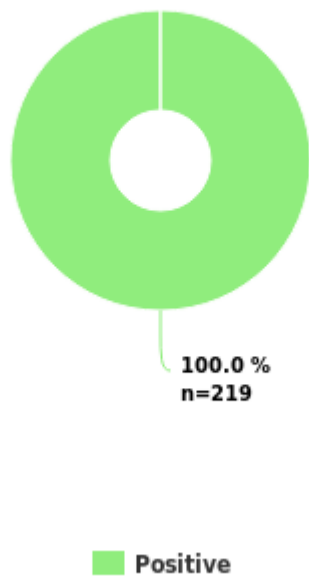
Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		1		0 %	0
		Quidel Sofia Legionella FIA		1		
	Positive		218		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		104		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		37		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		2		
		Biotec CerTest Legionella		4		
		CiTEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1		
		Coris BioConcept Legionella K-SeT		4		
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1		
		LIAISON Legionella Urinary Ag		1		
		Meridian Bioscience TRU Legionella		2		
		Monlab Legionella Monlab Test		1		
		Nal von minden NADAL Legionella Test		5		
		Operon Simple Strep pneumo-Legio		2		
		Quidel Sofia Legionella FIA		21		
		SD Biosensor Standard F Legionella Ag FIA		19		
		Servibio UriSign Legionella Color		1		
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2		
		Vidia Rapid-VIDITEST Legionella		1		
		Vitassay Legionella		1		
	Total:		219		99.5 %	

Sample S002



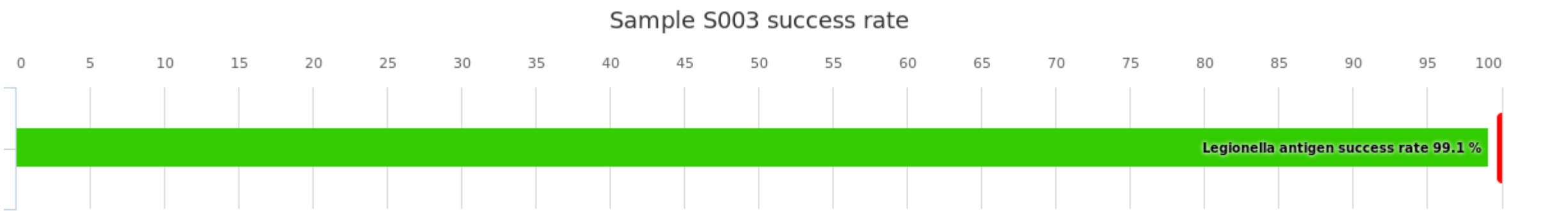
Sample S002 results	Responded	AVR success rate	Count
	Legionella antigen	100 %	219
Total:		100 %	219

Sample S002 Legionella antigen



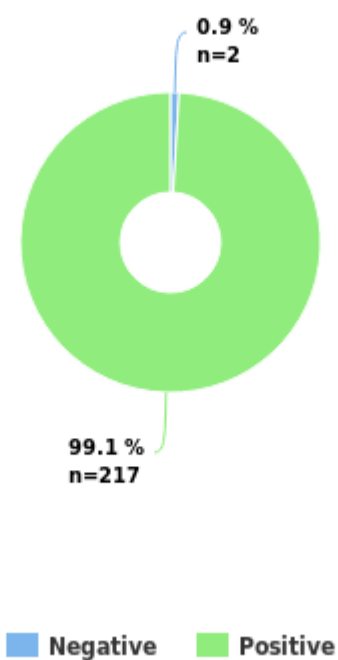
Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Positive		219		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		105		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		36		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		2		
		Biotec CerTest Legionella		4		
		CiTEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1		
		Coris BioConcept Legionella K-SeT		4		
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1		
		LIAISON Legionella Urinary Ag		1		
		Meridian Bioscience TRU Legionella		2		
		Monlab Legionella Monlab Test		1		
		Nal von minden NADAL Legionella Test		5		
		Operon Simple Strep pneumo-Legio		2		
		Quidel Sofia Legionella FIA		22		
		SD Biosensor Standard F Legionella Ag FIA		19		
		Servibio UriSign Legionella Color		1		
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2		
		Vidia Rapid-VIDITEST Legionella		1		
		Vitassay Legionella		1		
	Total:		219		100 %	

Sample S003



Sample S003 results	Responded	AVR success rate	Count
	Legionella antigen	99.1 %	219
Total:		99.1 %	219

Sample S003 Legionella antigen



Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		2		0 %	0
		Abbott Binax NOW Legionella Urinary Antigen Card		1		
		SD Biosensor Standard F Legionella Ag FIA		1		
	Positive		217		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		104		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		36		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		2		
		Biotec CerTest Legionella		4		
		CiTEST Streptococcus pneumoniae and Legionella pneumophila Combo Rapid Test		1		
		Coris BioConcept Legionella K-SeT		4		
		Hangzhou Alltest Biotech Legionella pneumophila Rapid Test Cassette		1		
		LIAISON Legionella Urinary Ag		1		
		Meridian Bioscience TRU Legionella		2		
		Monlab Legionella Monlab Test		1		
		Nal von minden NADAL Legionella Test		5		
		Operon Simple Strep pneumo-Legio		2		
		Quidel Sofia Legionella FIA		22		
		SD Biosensor Standard F Legionella Ag FIA		18		
		Servibio UriSign Legionella Color		1		
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		5		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		2		
		Vidia Rapid-VIDITEST Legionella		1		
		Vitassay Legionella		1		

	Total:		219		99.1 %	
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External Quality Assessment Scheme

Legionella, antigen detection in urine **Round 2, 2024**

Specimens

The specimens were liquid urine simulating samples. The sample lots were tested in the scheme expert's laboratory and the results were consistent with the certificates provided by the sample manufacturer. Based on the quality controls conducted by the sample material manufacturer, pre-testing 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 (LQ760824021)

Legionella antigen Positive for *L. pneumophila* serogroup 01 Ag
Negative for all other *L. pneumophila* serogroups

Sample S002 (LQ760824022)

Legionella antigen Positive for *L. pneumophila* serogroup 01 Ag
Negative for all other *L. pneumophila* serogroups

Sample S003 (LQ760824023)

Legionella antigen Positive for *L. pneumophila* serogroup 01 Ag
Negative for all other *L. pneumophila* serogroups

Pre-test method: BinaxNOW Legionella Urinary Antigen card (Abbott).

Report info

Description of the data analysis is provided on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, as it contains important information about the samples and results in each round.

Comments – Expert

All three samples in this round included antigen of *L. pneumophila* serogroup 01. Almost all reported results were correct except for just a couple of false negative results reported for sample S001 and S003. Root cause analysis is important to perform to find out the cause of these deviating results.

Exceptions in scoring

No exceptions.

End of report

2024-06-10

FINAL REPORT

Product no. 5597

Subcontracting: Sample pretesting

Samples sent	2024-04-30
Round closed	2024-05-31
Expected results	2024-06-05
Final report	2024-06-10

Request for correction

Typing errors in laboratory's result forms are the 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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