

External Quality Assessment Scheme

## **Legionella, antigen detection in urine Round 4, 2022**

### **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**

After arrival, the samples 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. Let the specimens warm up to 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



2022-11-15

### **INSTRUCTIONS**

Product no. 5597  
LQ760822041-043/US

Subcontracting: Sample pretesting

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi)

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The results should be reported no later than **December 8, 2022.**

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The expected results of the round are published in LabScala in the View reports section by December 12, 2022.

### **Inquiries**

EQA Coordinator  
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### **Labquality Oy**

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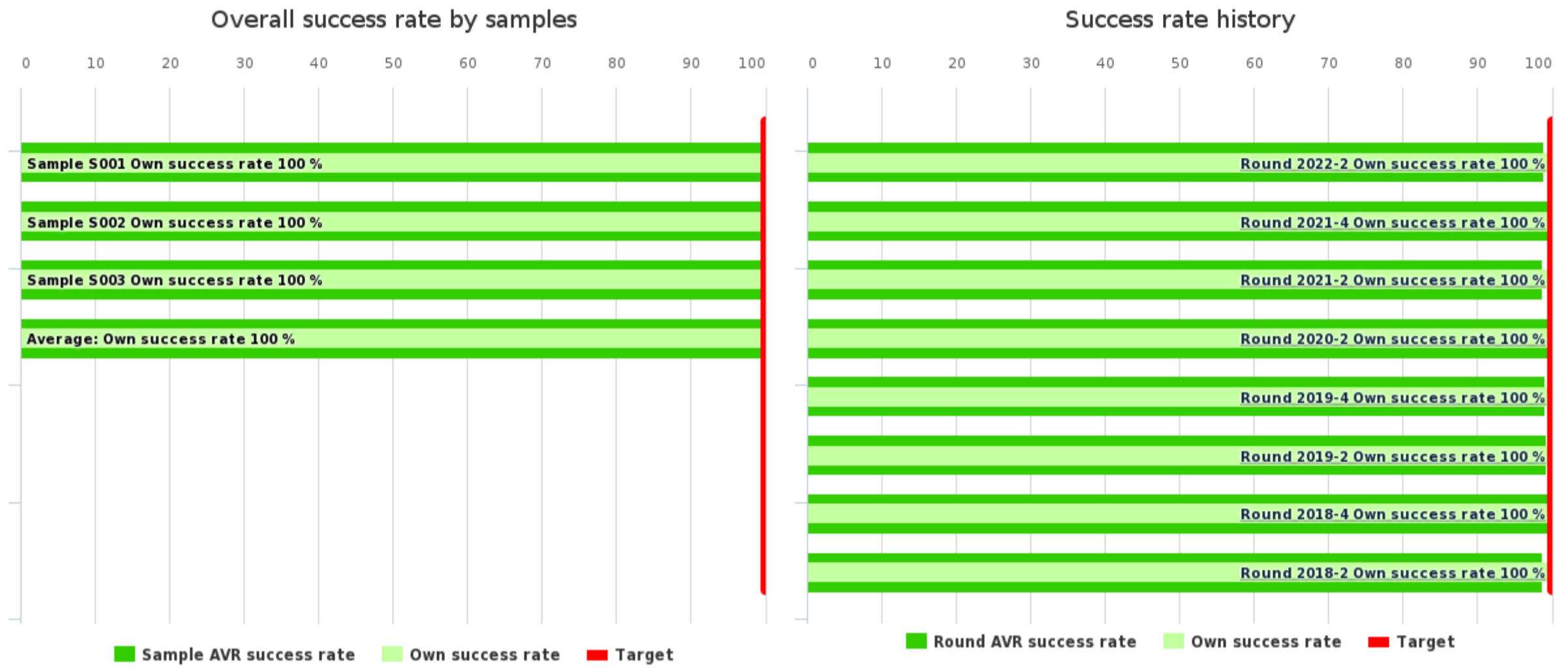
[info@labquality.fi](mailto:info@labquality.fi)  
[www.labquality.com](http://www.labquality.com)



Client report

	No of participants	No of responded participants	Response percentage
Legionella, antigen detection in urine, December, 4-2022	168	160	95.2 %

Summary

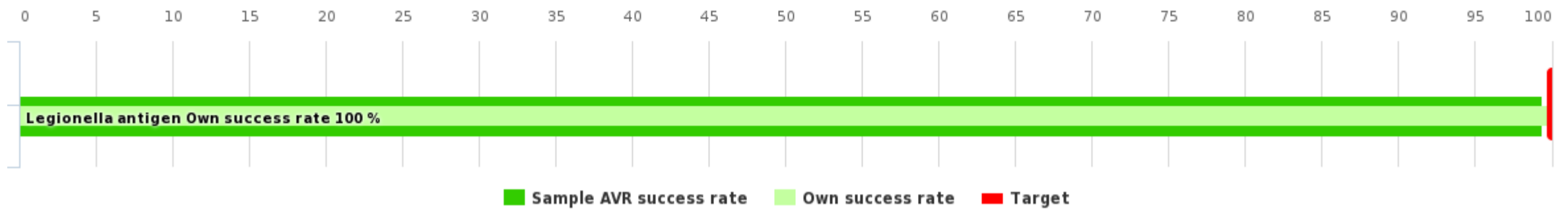


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0.6 %	99.4 %
Sample S002	2	2	100 %	0 %	100 %
Sample S003	2	2	100 %	0.6 %	99.4 %
Average:			100 %	0.4 %	99.6 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-2	1-1	100 %	1 %	99 %
Round 2021-4	1-1	100 %	0 %	100 %
Round 2021-2	1-1	100 %	1.3 %	98.7 %
Round 2020-2	1-1	100 %	0.6 %	99.4 %
Round 2019-4	1-1	100 %	0.8 %	99.2 %
Round 2019-2	1-1	100 %	0.7 %	99.3 %
Round 2018-4	1-1	100 %	0.6 %	99.4 %
Round 2018-2	1-1	100 %	1.3 %	98.7 %

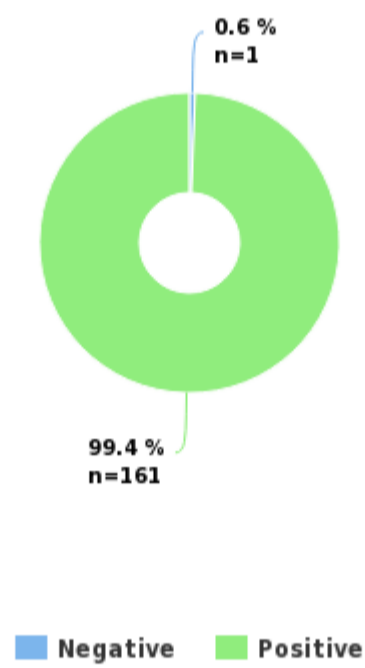
Sample S001 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0.6 %	99.4 %	162
Total:		2	2	100 %	0.6 %	99.4 %	162

Sample S001 Legionella antigen

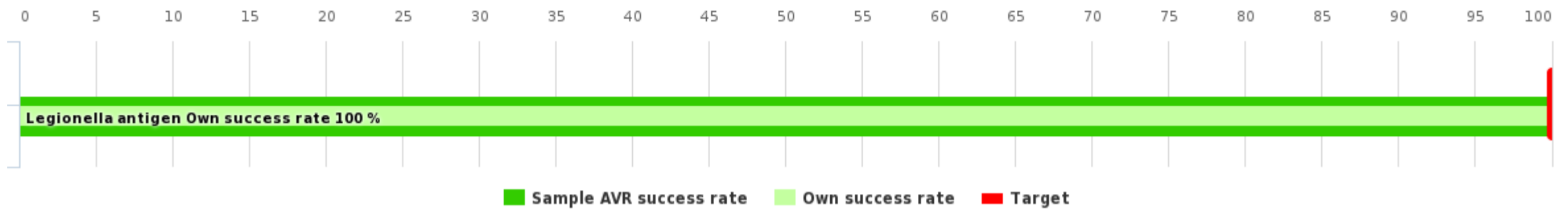


OWN DEVICE: 1

Legionella antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Abbott Binax NOW Legionella Urinary Antigen Card		1					
	<input checked="" type="radio"/> Positive		161		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		74					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		27					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		2					
		Biotec CerTest Legionella		4					
		Coris BioConcept Legionella K-SeT		3					
		Meridian Bioscience TRU Legionella		4					
		Nal von minden NADAL Legionella Test		3					
		Operon Simple Strep pneumo-Legio		1					
		<input checked="" type="radio"/> Quidel Sofia Legionella FIA		26					
		SD Biosensor Standard F Legionella Ag FIA		8					
		Servibio UriSign Legionella Color		2					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		2					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1					
	Total:		162		2	2	100 %	0.6 %	99.4 %

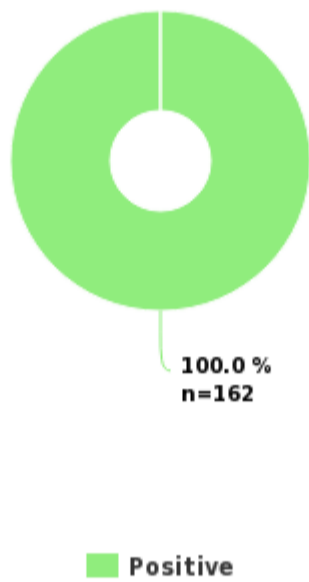
Sample S002 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0 %	100 %	162
Total:		2	2	100 %	0 %	100 %	162

Sample S002 Legionella antigen

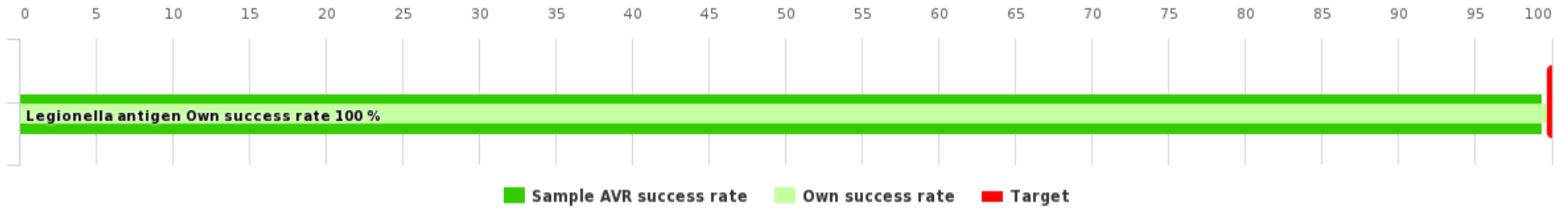


OWN DEVICE: 1

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		162		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		76					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		26					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		2					
		Biotec CerTest Legionella		4					
		Coris BioConcept Legionella K-SeT		3					
		Meridian Bioscience TRU Legionella		4					
		Nal von minden NADAL Legionella Test		3					
		Operon Simple Strep pneumo-Legio		1					
	<input checked="" type="radio"/> Quidel Sofia Legionella FIA			26					
		SD Biosensor Standard F Legionella Ag FIA		8					
		Servibio UriSign Legionella Color		2					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		2					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1					
Total:			162		2	2	100 %	0 %	100 %

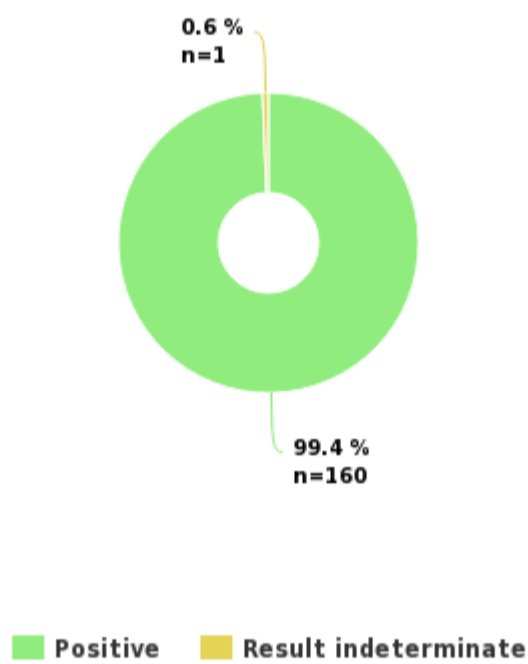
Sample S003 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Legionella antigen	2	2	100 %	0.6 %	99.4 %	161
Total:		2	2	100 %	0.6 %	99.4 %	161

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
	<input checked="" type="radio"/> Positive		160		2	2	100 %	0 %	100 %
		Abbott Binax NOW Legionella Urinary Antigen Card		76					
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		25					
		Binax Legionella Urinary Antigen EIA (Abbott)		2					
		Biosynex Legionella Test		3					
		Biotec CerTest Legionella		3					
		Coris BioConcept Legionella K-SeT		3					
		Meridian Bioscience TRU Legionella		4					
		Nal von minden NADAL Legionella Test		3					
		Operon Simple Strep pneumo-Legio		1					
	<input checked="" type="radio"/> Quidel Sofia Legionella FIA			25					
		SD Biosensor Standard F Legionella Ag FIA		8					
		Servibio UriSign Legionella Color		2					
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		2					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1					
	Result indeterminate		1		-				0 %
		Quidel Sofia Legionella FIA		1					
Total:			161		2	2	100 %	0.6 %	99.4 %

## Report Info

### PARTICIPANTS

Altogether 168 laboratories from 18 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

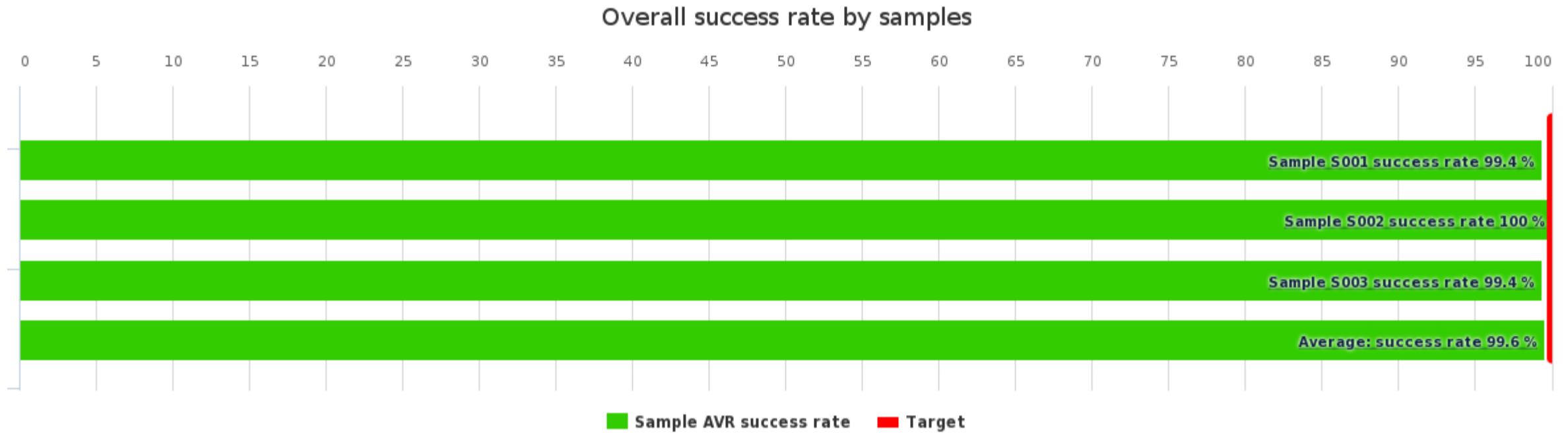
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores\*100). The Laboratory's Own success rate is the average of the sample 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, December, 4-2022	168	160	95.2 %

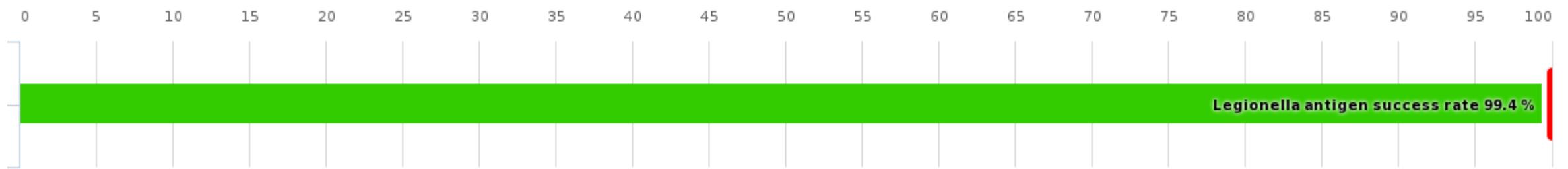
Summary



Summary	AVR success rate
Sample S001	99.4 %
Sample S002	100 %
Sample S003	99.4 %
Average:	99.6 %

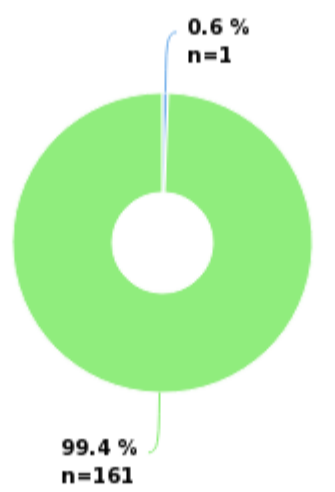
Sample S001 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Legionella antigen	99.4 %	162
Total:		99.4 %	162

Sample S001 Legionella antigen

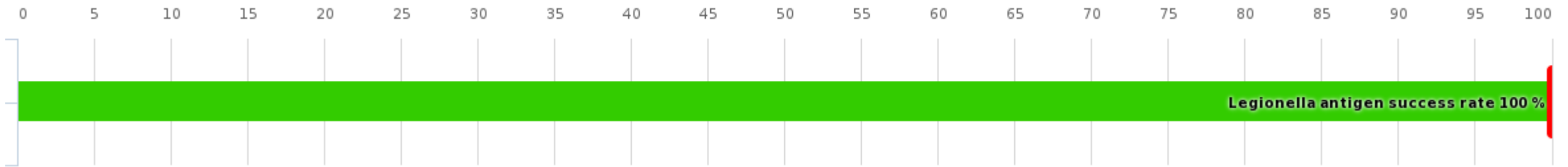


Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		1		0 %	0
		Abbott Binax NOW Legionella Urinary Antigen Card		1		
	Positive		161		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		74		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		27		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		2		
		Biotec CerTest Legionella		4		
		Coris BioConcept Legionella K-SeT		3		
		Meridian Bioscience TRU Legionella		4		
		Nal von minden NADAL Legionella Test		3		
		Operon Simple Strep pneumo-Legio		1		
		Quidel Sofia Legionella FIA		26		
		SD Biosensor Standard F Legionella Ag FIA		8		
		Servibio UriSign Legionella Color		2		
		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		2		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1		
	Total:		162		99.4 %	



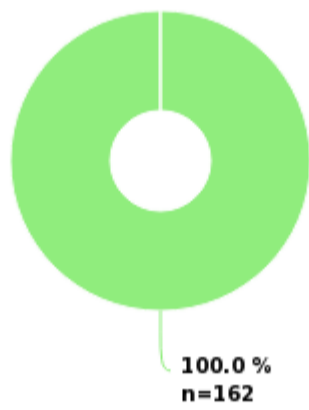
### Sample S002 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Legionella antigen	100 %	162
Total:		100 %	162

### Sample S002 Legionella antigen

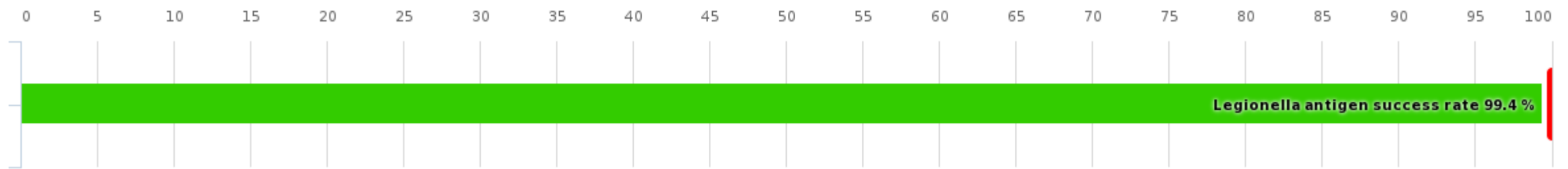


Positive

Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Positive		162		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		76		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		26		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		2		
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		Nal von minden NADAL Legionella Test		3		
		Operon Simple Strep pneumo-Legio		1		
		Quidel Sofia Legionella FIA		26		
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		SSI Diagnostica ImmuView L. pneumophila and L. longbeachae Urinary Antigen Test		2		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1		
	Total:		162		100 %	

Sample S003 | Legionella Ag: L pneumophila serogroup 01 positive

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Legionella antigen	99.4 %	161
Total:		99.4 %	161

Sample S003 Legionella antigen



Legionella antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Positive		160		100 %	2
		Abbott Binax NOW Legionella Urinary Antigen Card		76		
		Abbott Binax NOW Legionella Urinary Antigen Card (Digival Reader)		25		
		Binax Legionella Urinary Antigen EIA (Abbott)		2		
		Biosynex Legionella Test		3		
		Biotec CerTest Legionella		3		
		Coris BioConcept Legionella K-SeT		3		
		Meridian Bioscience TRU Legionella		4		
		Nal von minden NADAL Legionella Test		3		
		Operon Simple Strep pneumo-Legio		1		
		Quidel Sofia Legionella FIA		25		
		SD Biosensor Standard F Legionella Ag FIA		8		
		Servibio UriSign Legionella Color		2		
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		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Trinity Biotech Bartels ELISA Legionella Urinary Ag		1		
	Result indeterminate		1		0 %	0
		Quidel Sofia Legionella FIA		1		
	Total:		161		99.4 %	

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External Quality Assessment Scheme

## **Legionella, antigen detection in urine Round 4, 2022**

### **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 (LQ760822041)

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

Sample S002 (LQ760822042)

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

Sample S003 (LQ760822043)

*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**

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 – Expert**

This round included three *L. pneumophila* serogroup 01 antigen positive samples. The success in this round was excellent including just two divergent results reported for samples S001 and S003. It's recommended to determine the cause of deviation. Overall, well done!

### **Exceptions in scoring**

No exceptions.

### **End of report**

2022-12-22

### **FINAL REPORT**

Product no. 5597

Subcontracting: Sample pretesting

Samples sent	2022-11-15
Round closed	2022-12-08
Expected results	2022-12-12
Final report	2022-12-22

### **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  
Mira Saarinen  
mira.h.saarinen@labquality.fi

### **Expert**

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