

External Quality Assessment Scheme

## ***Streptococcus pneumoniae*, antigen detection in urine Round 1, 2023**

### **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**

*Streptococcus pneumoniae*, 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.

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](http://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



2023-02-28

### **INSTRUCTIONS**

Product no. 5598  
LQ761423011-013/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 **March 24, 2023.**

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The expected results of the round are published in LabScala in the View reports section by March 28, 2023.

### **Inquiries**

EQA Coordinator  
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### **Labquality Oy**

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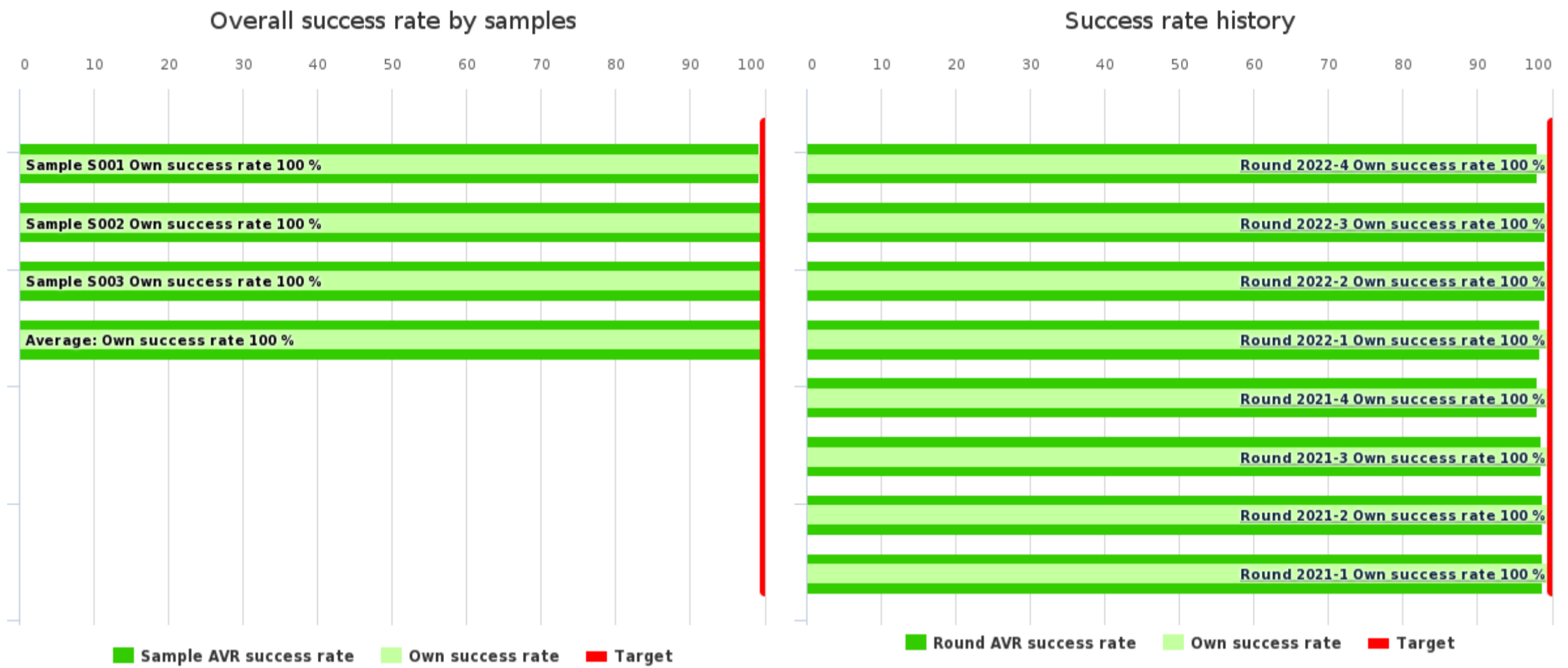
[info@labquality.fi](mailto:info@labquality.fi)  
[www.labquality.com](http://www.labquality.com)



**Client report**

	No of participants	No of responded participants	Response percentage
Streptococcus pneumoniae, antigen detection in urine, March, 1-2023	264	257	97.3 %

**Summary**

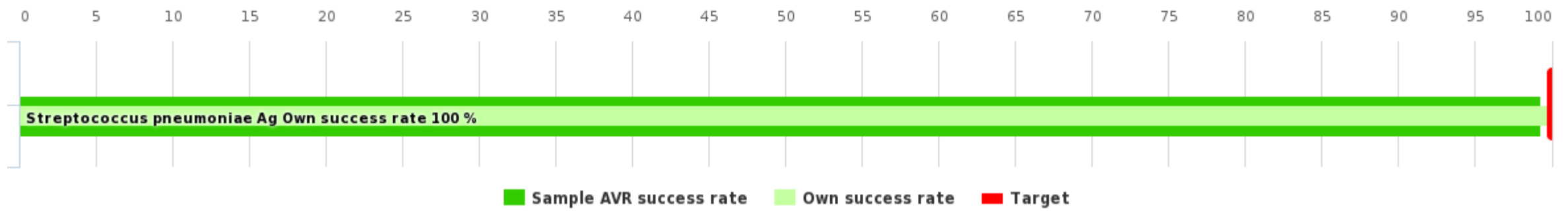


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0.7 %	99.3 %
Sample S002	2	2	100 %	0.4 %	99.6 %
Sample S003	2	2	100 %	0.4 %	99.6 %
Average:			100 %	0.5 %	99.5 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	1.9 %	98.1 %
Round 2022-3	1-1	100 %	0.9 %	99.1 %
Round 2022-2	1-1	100 %	0.8 %	99.2 %
Round 2022-1	1-1	100 %	1.5 %	98.5 %
Round 2021-4	1-1	100 %	2 %	98 %
Round 2021-3	1-1	100 %	1.4 %	98.6 %
Round 2021-2	1-1	100 %	1.2 %	98.8 %
Round 2021-1	1-1	100 %	1.3 %	98.7 %

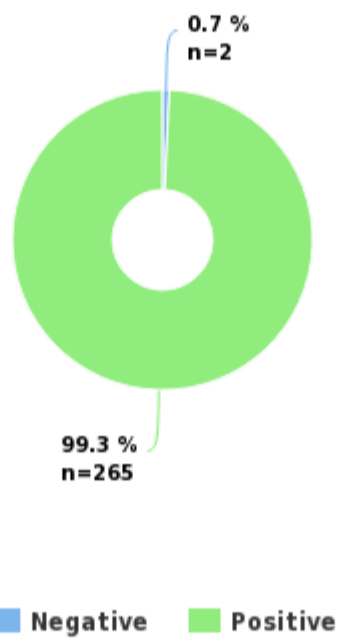
Sample S001 | Streptococcus pneumoniae, Ag: positive

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Streptococcus pneumoniae Ag	2	2	100 %	0.7 %	99.3 %	267
Total:		2	2	100 %	0.7 %	99.3 %	267

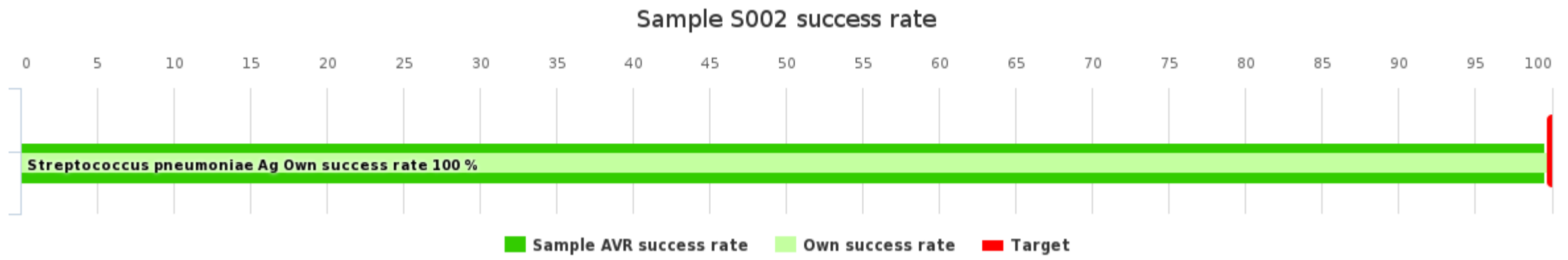
Sample S001 Streptococcus pneumoniae Ag



OWN DEVICE: 1

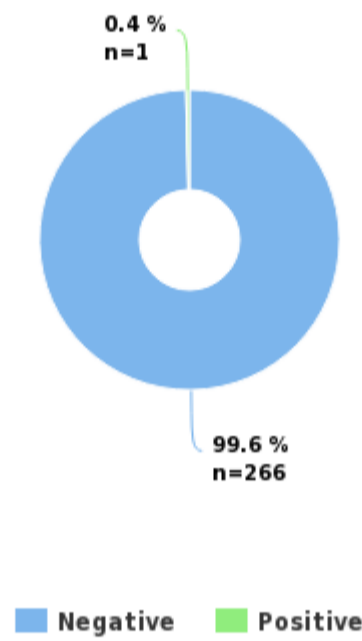
Streptococcus pneumoniae Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Abbott Binax NOW S.pneumoniae Antigen Card		2					
	<input checked="" type="radio"/> Positive		265		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Binax NOW S.pneumoniae Antigen Card		130					
		Abbott Binax NOW S.pneumoniae Antigen Card (Digival Reader)		40					
		ArcDia MariPoc RespiTest		12					
		Biosynex S. pneumoniae		5					
		Certest Biotec CerTest S. pneumoniae		6					
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1					
		Meridian Bioscience TRU Strep Pneumo		6					
		Nal von minden Dedicio Streptococcus pneumoniae Test		1					
		Nal von minden NADAL S, pneumoniae test		2					
		Operon Simple Strep pneumo-Legio		1					
		Operon Stick Strep pneumo-Legio		1					
		Quidel Sofia S. pneumoniae FIA		31					
		SD Biosensor Standard F S. pneumoniae Ag FIA		23					
		Servibio PneumoSign		3					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Vitassay Strep. pneumoniae		1					
Total:			267		2	2	100 %	0.7 %	99.3 %

Sample S002 | Streptococcus pneumoniae, Ag: negative



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Streptococcus pneumoniae Ag	2	2	100 %	0.4 %	99.6 %	267
Total:		2	2	100 %	0.4 %	99.6 %	267

Sample S002 Streptococcus pneumoniae Ag

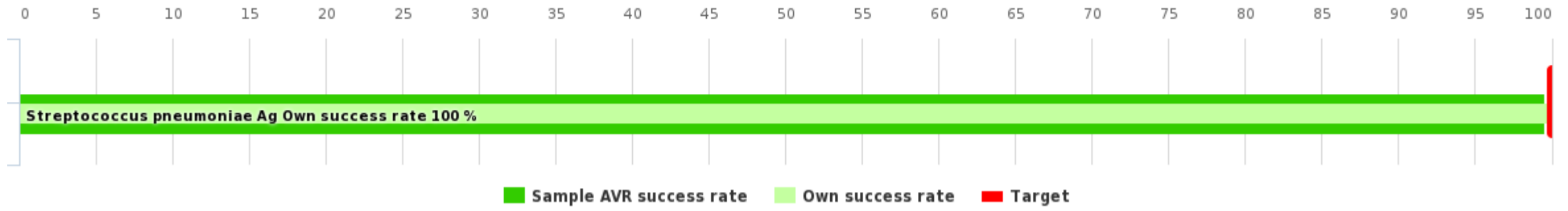


OWN DEVICE: 1

Streptococcus pneumoniae Ag	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		266		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Binax NOW S.pneumoniae Antigen Card		131					
		Abbott Binax NOW S.pneumoniae Antigen Card (Digival Reader)		40					
		ArcDia MariPoc RespiTest		12					
		Biosynex S. pneumoniae		5					
		Certest Biotec CerTest S. pneumoniae		6					
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1					
		Meridian Bioscience TRU Strep Pneumo		6					
		Nal von minden Dedicio Streptococcus pneumoniae Test		1					
		Nal von minden NADAL S, pneumoniae test		2					
		Operon Simple Strep pneumo-Legio		1					
		Operon Stick Strep pneumo-Legio		1					
		Quidel Sofia S. pneumoniae FIA		31					
		SD Biosensor Standard F S. pneumoniae Ag FIA		23					
		Servibio PneumoSign		3					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Vitassay Strep. pneumoniae		1					
	<input type="radio"/> Positive		1		-				0 %
		Abbott Binax NOW S.pneumoniae Antigen Card		1					
Total:			267		2	2	100 %	0.4 %	99.6 %

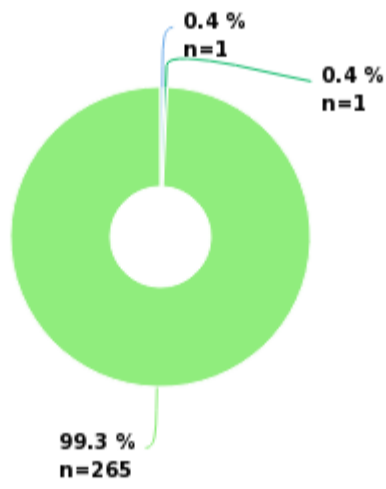
Sample S003 | Streptococcus pneumoniae, Ag: positive

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Streptococcus pneumoniae Ag	2	2	100 %	0.4 %	99.6 %	267
Total:		2	2	100 %	0.4 %	99.6 %	267

Sample S003 Streptococcus pneumoniae Ag



■ Negative ■ Weak positive ■ Positive

OWN DEVICE: 1

Streptococcus pneumoniae Ag	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 S.pneumoniae Antigen Card		1					
	Weak positive		1		-				100 %
		Abbott Binax NOW S.pneumoniae Antigen Card		1					
	<input checked="" type="radio"/> Positive		265		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Binax NOW S.pneumoniae Antigen Card		129					
		Abbott Binax NOW S.pneumoniae Antigen Card (Digival Reader)		41					
		ArcDia MariPoc RespiTest		12					
		Biosynex S. pneumoniae		5					
		Certest Biotec CerTest S. pneumoniae		6					
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1					
		Meridian Bioscience TRU Strep Pneumo		6					
		Nal von minden NADAL S, pneumoniae test		3					
		Operon Simple Strep pneumo-Legio		1					
		Operon Stick Strep pneumo-Legio		1					
		Quidel Sofia S. pneumoniae FIA		31					
		SD Biosensor Standard F S. pneumoniae Ag FIA		23					
		Servibio PneumoSign		3					
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2					
		Vitassay Strep. pneumoniae		1					

Total:		267		2	2	100 %	0.4 %	99.6 %
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## Report Info

### PARTICIPANTS

Altogether 264 laboratories from 17 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

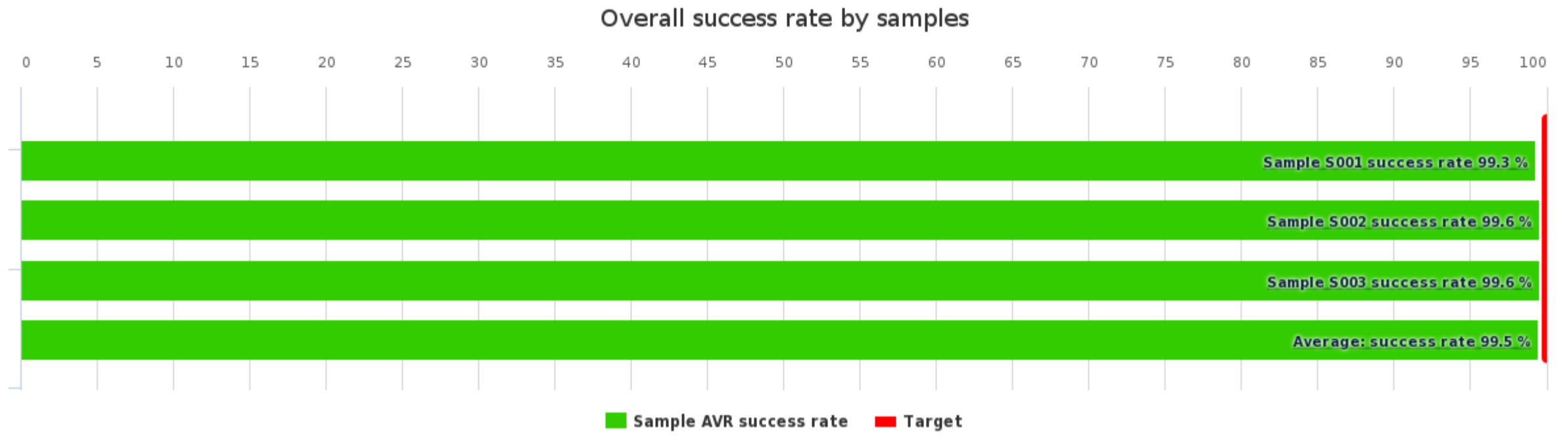
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores\*100). The Laboratory's Own success rate is the average of the sample 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
Streptococcus pneumoniae, antigen detection in urine, March, 1-2023	264	257	97.3 %

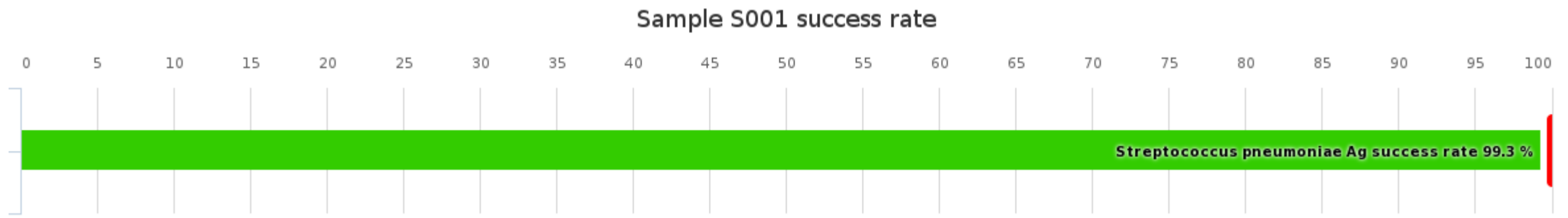
**Summary**



Summary	AVR success rate
Sample S001	99.3 %
Sample S002	99.6 %
Sample S003	99.6 %
Average:	99.5 %

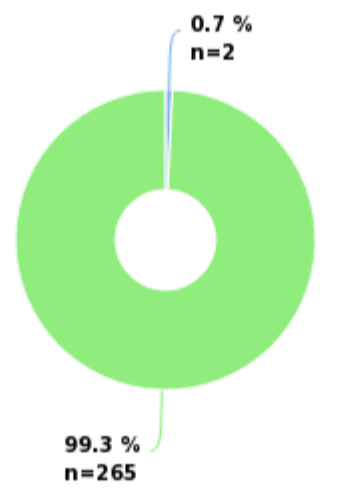


## Sample S001 | Streptococcus pneumoniae, Ag: positive



Sample S001 results	Responded	AVR success rate	Count
	Streptococcus pneumoniae Ag	99.3 %	267
Total:		99.3 %	267

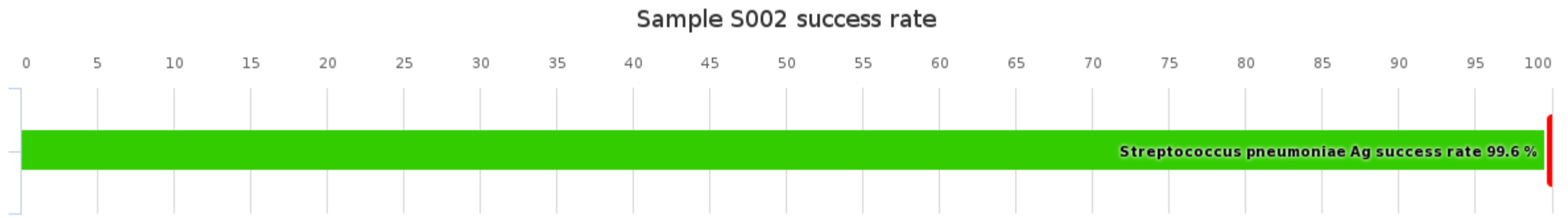
### Sample S001 Streptococcus pneumoniae Ag



■ Negative ■ Positive

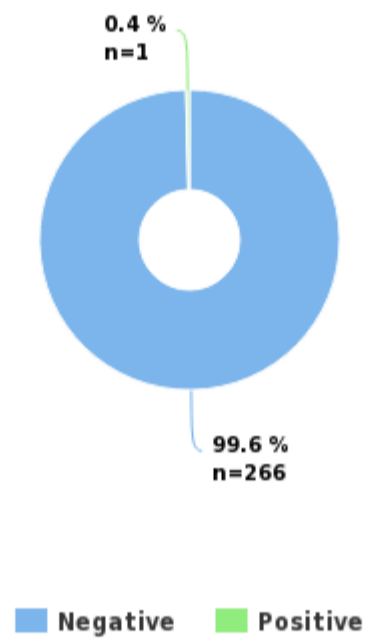
Streptococcus pneumoniae Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		2		0 %	0
		Abbott Binax NOW S.pneumoniae Antigen Card		2		
	Positive		265		100 %	2
		Abbott Binax NOW S.pneumoniae Antigen Card		130		
		Abbott Binax NOW S.pneumoniae Antigen Card (Digival Reader)		40		
		ArcDia MariPoc RespiTest		12		
		Biosynex S. pneumoniae		5		
		Certest Biotec CerTest S. pneumoniae		6		
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1		
		Meridian Bioscience TRU Strep Pneumo		6		
		Nal von minden Dedicio Streptococcus pneumoniae Test		1		
		Nal von minden NADAL S, pneumoniae test		2		
		Operon Simple Strep pneumo-Legio		1		
		Operon Stick Strep pneumo-Legio		1		
		Quidel Sofia S. pneumoniae FIA		31		
		SD Biosensor Standard F S. pneumoniae Ag FIA		23		
		Servibio PneumoSign		3		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Vitassay Strep. pneumoniae		1		
	Total:		267		99.3 %	

## Sample S002 | Streptococcus pneumoniae, Ag: negative



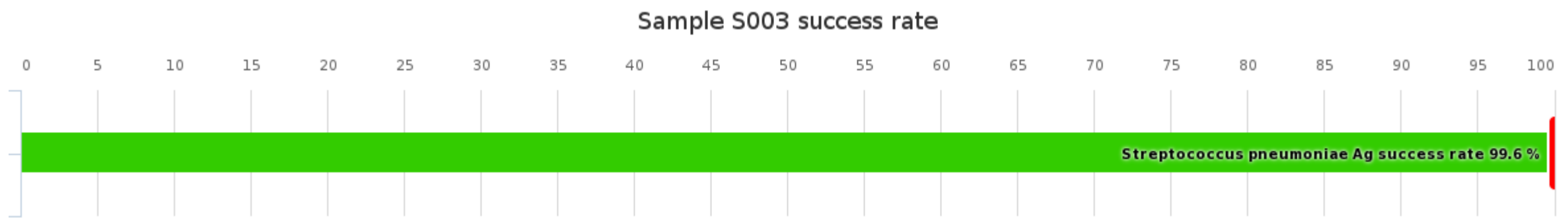
Sample S002 results	Responded	AVR success rate	Count
	Streptococcus pneumoniae Ag	99.6 %	267
Total:		99.6 %	267

### Sample S002 Streptococcus pneumoniae Ag



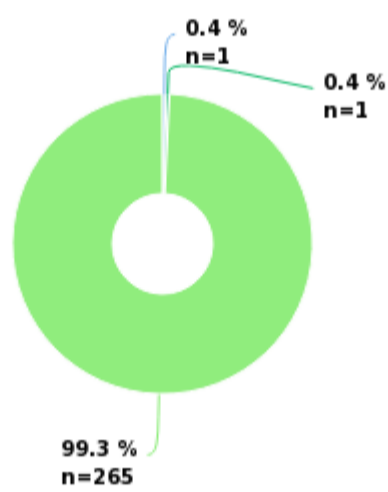
Streptococcus pneumoniae Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		266		100 %	2
		Abbott Binax NOW S.pneumoniae Antigen Card		131		
		Abbott Binax NOW S.pneumoniae Antigen Card (Digital Reader)		40		
		ArcDia MariPoc RespiTest		12		
		Biosynex S. pneumoniae		5		
		Certest Biotec CerTest S. pneumoniae		6		
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1		
		Meridian Bioscience TRU Strep Pneumo		6		
		Nal von minden Dedicio Streptococcus pneumoniae Test		1		
		Nal von minden NADAL S, pneumoniae test		2		
		Operon Simple Strep pneumo-Legio		1		
		Operon Stick Strep pneumo-Legio		1		
		Quidel Sofia S. pneumoniae FIA		31		
		SD Biosensor Standard F S. pneumoniae Ag FIA		23		
		Servibio PneumoSign		3		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Vitassay Strep. pneumoniae		1		
	Positive		1		0 %	0
		Abbott Binax NOW S.pneumoniae Antigen Card		1		
	Total:		267		99.6 %	

## Sample S003 | Streptococcus pneumoniae, Ag: positive



Sample S003 results	Responded	AVR success rate	Count
	Streptococcus pneumoniae Ag	99.6 %	267
Total:		99.6 %	267

### Sample S003 Streptococcus pneumoniae Ag



■ Negative
 ■ Weak positive
 ■ Positive

Streptococcus pneumoniae Ag	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		1		0 %	0
		Abbott Binax NOW S.pneumoniae Antigen Card		1		
	Weak positive		1		100 %	2
		Abbott Binax NOW S.pneumoniae Antigen Card		1		
	Positive		265		100 %	2
		Abbott Binax NOW S.pneumoniae Antigen Card		129		
		Abbott Binax NOW S.pneumoniae Antigen Card (Digival Reader)		41		
		ArcDia MariPoc RespiTest		12		
		Biosynex S. pneumoniae		5		
		Certest Biotec CerTest S. pneumoniae		6		
		Hangzhou Alltest Biotech S. pneumoniae Antigen Rapid Test Cassette		1		
		Meridian Bioscience TRU Strep Pneumo		6		
		Nal von minden NADAL S, pneumoniae test		3		
		Operon Simple Strep pneumo-Legio		1		
		Operon Stick Strep pneumo-Legio		1		
		Quidel Sofia S. pneumoniae FIA		31		
		SD Biosensor Standard F S. pneumoniae Ag FIA		23		
		Servibio PneumoSign		3		
		SSI Diagnostica ImmuView S. pneumoniae and L. pneumophila Urinary and CSF Antigen Test		2		
		Vitassay Strep. pneumoniae		1		
	Total:		267		99.6 %	

## Report Info

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External Quality Assessment Scheme

## ***Streptococcus pneumoniae*, antigen detection in urine Round 1, 2023**

### **Specimens**

Samples of this EQA round were 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 (LQ761423011)  
*S. pneumoniae* Ag Positive

Sample S002 (LQ761423012)  
*S. pneumoniae* Ag Negative

Sample S003 (LQ761423013)  
*S. pneumoniae* Ag Positive

Pre-test method: BinaxNOW *S. pneumoniae* 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**

Two samples in this round included *Str. pneumoniae*-antigen (samples S001 and S003). There wasn't antigen of *Str. pneumoniae* in sample S002 as it was negative. Success in this round was excellent and just a few deviant results were reported. According to the raw data, it seems that at least part of deviant results is caused by mixing of samples in analyze phase or when reporting results. It is recommended to retest samples to discover the root cause of deviation and to ensure the validity of the laboratory process.

### **Exceptions in scoring**

No exceptions.

### **End of report**

2023-04-24

### **FINAL REPORT**

Product no. 5598

Subcontracting: Sample pretesting

Samples sent	2023-02-28
Round closed	2023-03-24
Expected results	2023-03-27
Final report	2023-04-24

### **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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