

External Quality Assessment Scheme

RS virus, antigen detection Round 1, 2023

Specimens

Please find enclosed 3 simulated 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.

Examinations

RS virus, antigen detection

Not for patient use.

Storage and use

After arrival, the samples should be stored at +2...30 °C, and used as soon as possible, preferably within a week. Analyse as patient samples and follow the instructions given by the test manufacturer.

Handling instructions for the swab samples:

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. If the method you are using does not specify the sample volume, dip the swab in ≤0.5 mL of transport medium. Incubate the sample for 1-2 minutes at room temperature. Rotate the swab 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. Proceed with detection step by using the test volume specified in the assay instruction for use.

Result reporting

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

S001



S002



S003



2023-01-31

INSTRUCTIONS

Product no. 5672
LQ773823011-013/CA
UN3373

Subcontracting: Sample pretesting

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

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

The expected results of the round are published in LabScala in the View Reports section by March 2, 2023.

Inquiries

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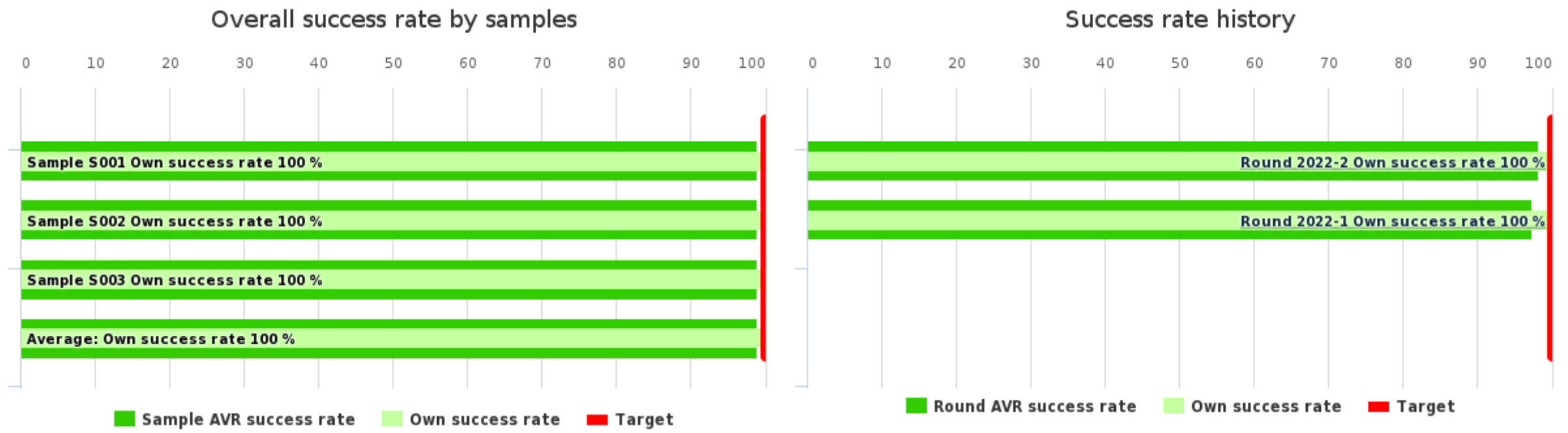
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
RS virus, antigen detection, February, 1-2023	187	181	96.8 %

Summary

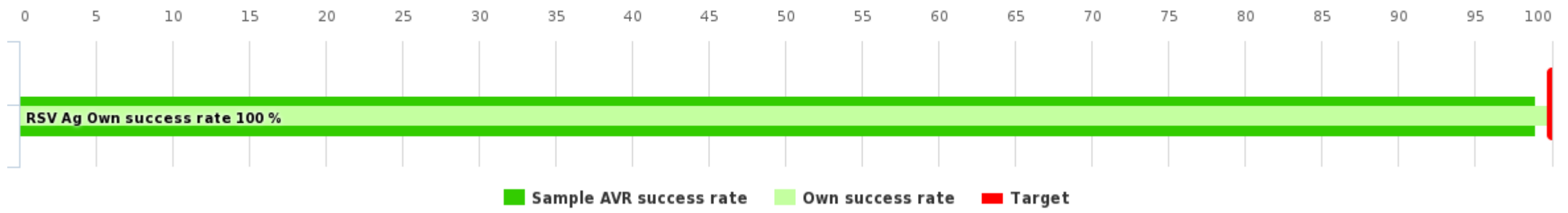


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	1 %	99 %
Sample S002	2	2	100 %	1 %	99 %
Sample S003	2	2	100 %	1 %	99 %
Average:			100 %	1 %	99 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-2	1-1	100 %	1.8 %	98.2 %
Round 2022-1	1-1	100 %	2.7 %	97.3 %

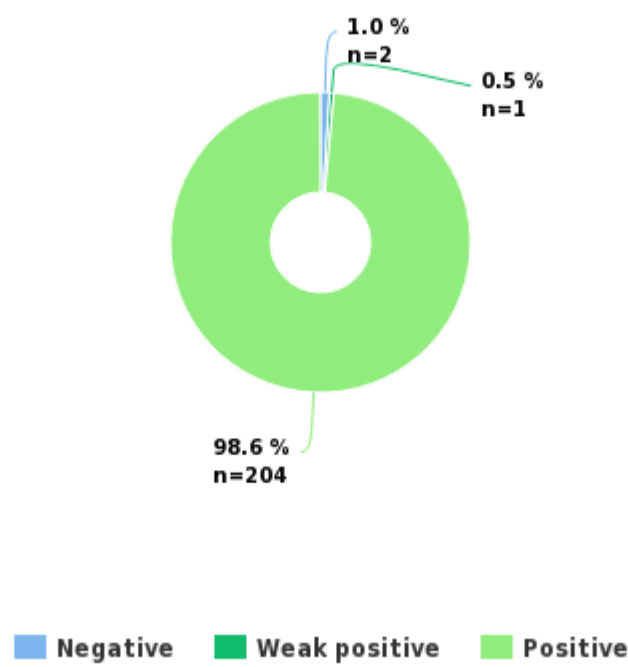
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	RSV Ag	2	2	100 %	1 %	99 %	207
	Total:	2	2	100 %	1 %	99 %	207

Sample S001 RSV Ag

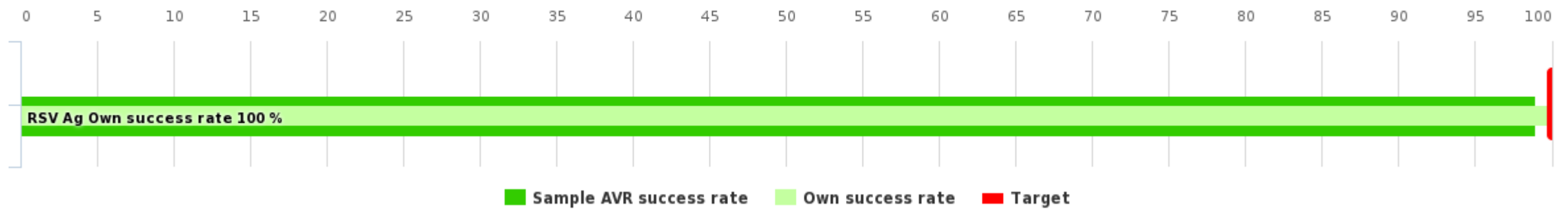


RSV Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Abbott BinaxNOW RSV		1					
		Hangzhou Alltest RSV Rapid Test Cassette		1					
	Weak positive		1		-				100 %
		Biosynex RSVTOP		1					
	Positive		204		2	2	100 %	0 %	100 %
		Abbott BinaxNOW RSV		41					
		Abbott Bioline RSV		1					
		Acro Biotech Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette		2					
		ArcDia mariPOC Quick Flu+		9					
		ArcDia mariPOC Quick Flu/RSV		22					
		ArcDia mariPOC Respi		1					
		ArcDia mariPOC Respi+		19					
		BD Veritor System RSV		16					
		Biosynex COMBO COVID-FLU-RSV BSS		10					
		Biosynex RSVTOP		10					
		CerTest Biotec RSV		3					
		CerTest Biotec RSV-Adeno		1					
		Coris BioConcept RSV K-SeT		2					
		Coris BioConcept RSV Respi-Strip		4					
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1					
		Hangzhou Alltest RSV Rapid Test Cassette		1					
		LumiraDx SARS-CoV-2 & RSV		2					
		Mascia Brunelli RSV RESPI CARD		1					
		Meridian Bioscience TRU RSV		2					

	nal von minden Nadal RSV test		1					
	Operon Simple RSV-RespirAdeno		1					
	Quidel Sofia RSV FIA		31					
	SD Biosensor Standard F RSV Ag FIA		11					
	Sekisui Diagnostics OSOM RSV/Adeno Test		6					
	Servibio VRS Color		2					
	Vidia Rapid-VIDITEST RSV Card		2					
	Vitassay RSV Single Card		2					
Total:		207		2	2	100 %	1 %	99 %

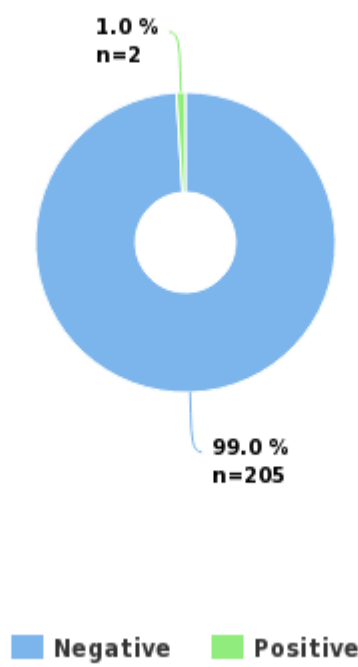
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	RSV Ag	2	2	100 %	1 %	99 %	207
Total:		2	2	100 %	1 %	99 %	207

Sample S002 RSV Ag

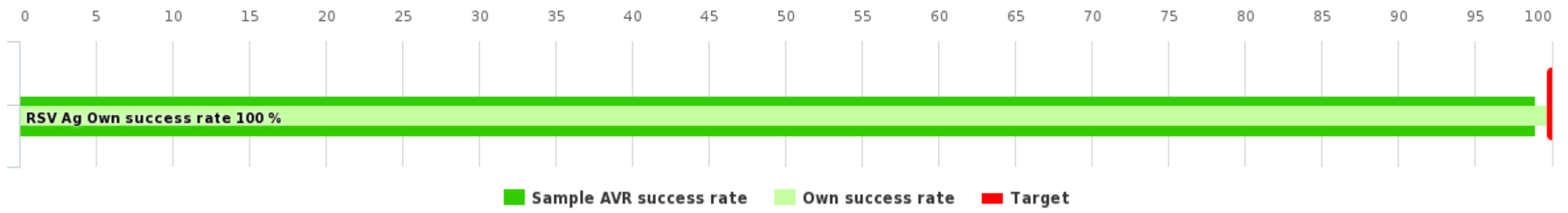


RSV Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		205		2	2	100 %	0 %	100 %
		Abbott BinaxNOW RSV		42					
		Abbott Bioline RSV		1					
		<input checked="" type="radio"/> Acro Biotech Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette		2					
		ArcDia mariPOC Quick Flu+		8					
		ArcDia mariPOC Quick Flu/RSV		22					
		ArcDia mariPOC Respi		1					
		ArcDia mariPOC Respi+		20					
		BD Veritor System RSV		16					
		Biosynex COMBO COVID-FLU-RSV BSS		10					
		Biosynex RSVTOP		10					
		CerTest Biotec RSV		3					
		CerTest Biotec RSV-Adeno		1					
		Coris BioConcept RSV K-SeT		2					
		Coris BioConcept RSV Respi-Strip		4					
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1					
		Hangzhou Alltest RSV Rapid Test Cassette		1					
		LumiraDx SARS-CoV-2 & RSV		2					
		Mascia Brunelli RSV RESPI CARD		1					
		Meridian Bioscience TRU RSV		2					
		nal von minden Nadal RSV test		1					
		Operon Simple RSV-RespirAdeno		1					
		Quidel Sofia RSV FIA		31					
		SD Biosensor Standard F RSV Ag FIA		11					
		Sekisui Diagnostics OSOM RSV/Adeno Test		6					

		Servibio VRS Color		2					
		Vidia Rapid-VIDITEST RSV Card		2					
		Vitassay RSV Single Card		2					
	Positive		2		-				0 %
		Biosynex RSVTOP		1					
		Hangzhou Alltest RSV Rapid Test Cassette		1					
	Total:		207		2	2	100 %	1 %	99 %

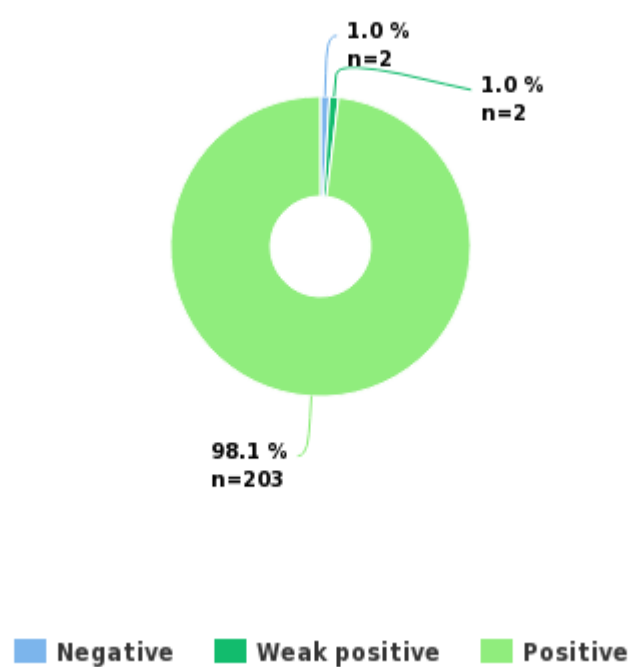
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	RSV Ag	2	2	100 %	1 %	99 %	207
	Total:	2	2	100 %	1 %	99 %	207

Sample S003 RSV Ag



RSV Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Biosynex RSVTOP		1					
		Meridian Bioscience TRU RSV		1					
	Weak positive		2		-				100 %
		Abbott BinaxNOW RSV		1					
		Biosynex RSVTOP		1					
	<input checked="" type="radio"/> Positive		203		2	2	100 %	0 %	100 %
		Abbott BinaxNOW RSV		41					
		Abbott Bioline RSV		1					
		<input checked="" type="radio"/> Acro Biotech Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette		2					
		ArcDia mariPOC Quick Flu+		9					
		ArcDia mariPOC Quick Flu/RSV		22					
		ArcDia mariPOC Respi		2					
		ArcDia mariPOC Respi+		18					
		BD Veritor System RSV		16					
		Biosynex COMBO COVID-FLU-RSV BSS		10					
		Biosynex RSVTOP		9					
		CerTest Biotec RSV		3					
		CerTest Biotec RSV-Adeno		1					
		Coris BioConcept RSV K-SeT		2					
		Coris BioConcept RSV Respi-Strip		4					
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1					
		Hangzhou Alltest RSV Rapid Test Cassette		2					
		LumiraDx SARS-CoV-2 & RSV		2					
		Mascia Brunelli RSV RESPI CARD		1					

	Meridian Bioscience TRU RSV		1						
	nal von minden Nadal RSV test		1						
	Operon Simple RSV-RespirAdeno		1						
	Quidel Sofia RSV FIA		31						
	SD Biosensor Standard F RSV Ag FIA		11						
	Sekisui Diagnostics OSOM RSV/Adeno Test		6						
	Servibio VRS Color		2						
	Vidia Rapid-VIDITEST RSV Card		2						
	Vitassay RSV Single Card		2						
	Total:		207		2	2	100 %	1 %	99 %

Report Info**PARTICIPANTS**

Altogether 187 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

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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
RS virus, antigen detection, February, 1-2023	187	181	96.8 %

Summary

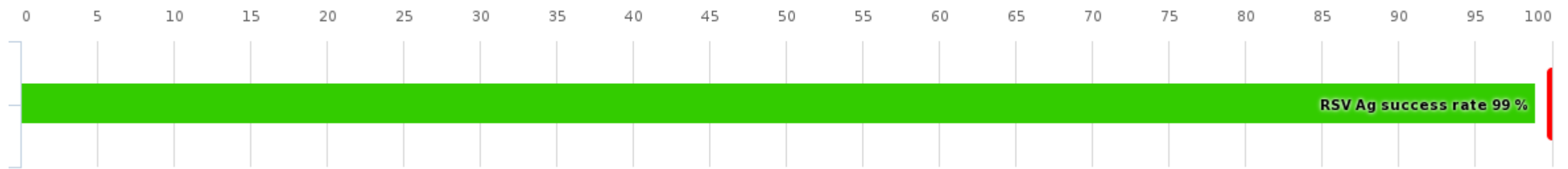
Overall success rate by samples



Summary	AVR success rate
Sample S001	99 %
Sample S002	99 %
Sample S003	99 %
Average:	99 %

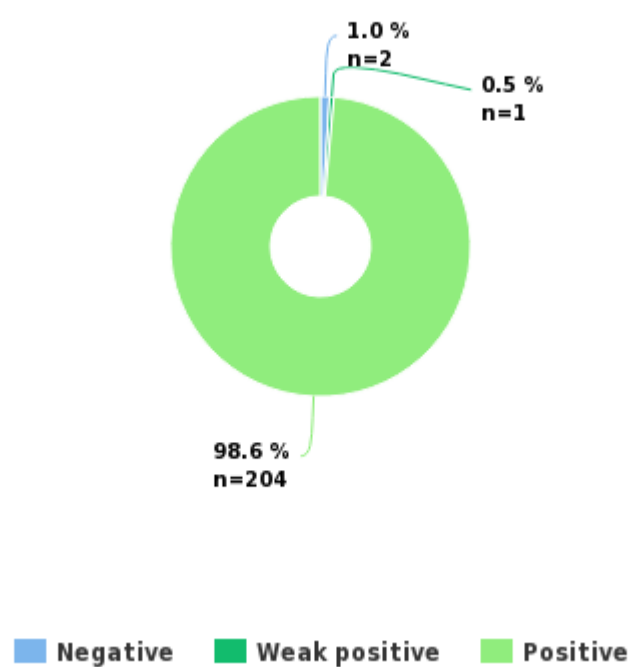
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	RSV Ag	99 %	207
	Total:	99 %	207

Sample S001 RSV Ag

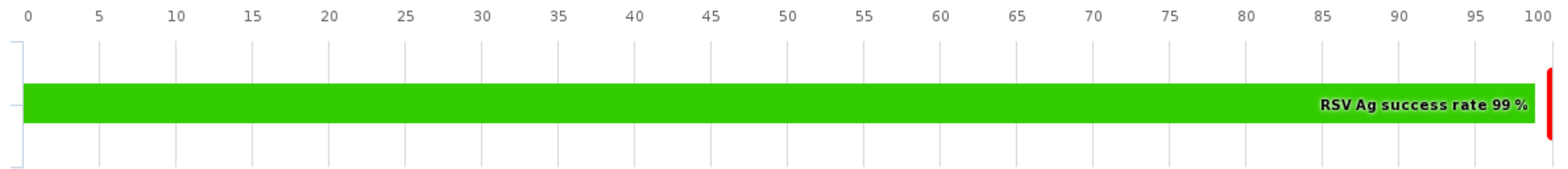


RSV Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		2		0 %	0
		Abbott BinaxNOW RSV		1		
		Hangzhou Alltest RSV Rapid Test Cassette		1		
	Weak positive		1		100 %	2
		Biosynex RSVTOP		1		
	Positive		204		100 %	2
		Abbott BinaxNOW RSV		41		
		Abbott Bioline RSV		1		
		Acro Biotech Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette		2		
		ArcDia mariPOC Quick Flu+		9		
		ArcDia mariPOC Quick Flu/RSV		22		
		ArcDia mariPOC Respi		1		
		ArcDia mariPOC Respi+		19		
		BD Veritor System RSV		16		
		Biosynex COMBO COVID-FLU-RSV BSS		10		
		Biosynex RSVTOP		10		
		CerTest Biotec RSV		3		
		CerTest Biotec RSV-Adeno		1		
		Coris BioConcept RSV K-Set		2		
		Coris BioConcept RSV Respi-Strip		4		
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1		
		Hangzhou Alltest RSV Rapid Test Cassette		1		
		LumiraDx SARS-CoV-2 & RSV		2		
		Mascia Brunelli RSV RESPI CARD		1		
		Meridian Bioscience TRU RSV		2		
		nal von minden Nadal RSV test		1		
		Operon Simple RSV-RespirAdeno		1		

		Quidel Sofia RSV FIA		31		
		SD Biosensor Standard F RSV Ag FIA		11		
		Sekisui Diagnostics OSOM RSV/Adeno Test		6		
		Servibio VRS Color		2		
		Vidia Rapid-VIDITEST RSV Card		2		
		Vitassay RSV Single Card		2		
	Total:		207		99 %	

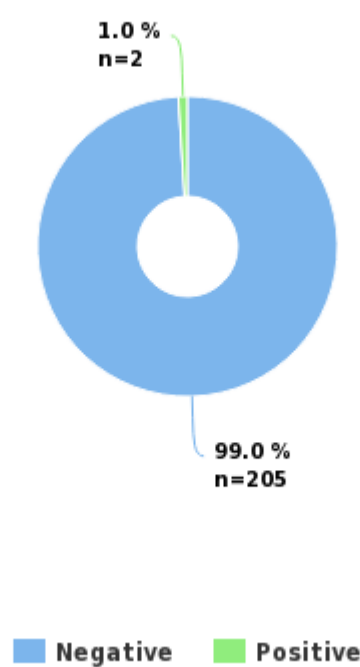
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	RSV Ag	99 %	207
Total:		99 %	207

Sample S002 RSV Ag

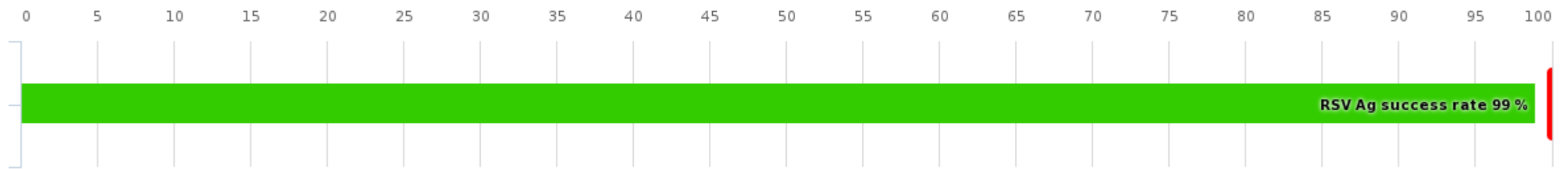


RSV Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		205		100 %	2
		Abbott BinaxNOW RSV		42		
		Abbott Bioline RSV		1		
		Acro Biotech Adenovirus, RSV and Influenza A+B Combo Rapid Test Cassette		2		
		ArcDia mariPOC Quick Flu+		8		
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		Biosynex RSVTOP		10		
		CerTest Biotec RSV		3		
		CerTest Biotec RSV-Adeno		1		
		Coris BioConcept RSV K-Set		2		
		Coris BioConcept RSV Respi-Strip		4		
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1		
		Hangzhou Alltest RSV Rapid Test Cassette		1		
		LumiraDx SARS-CoV-2 & RSV		2		
		Mascia Brunelli RSV RESPI CARD		1		
		Meridian Bioscience TRU RSV		2		
		nal von minden Nadal RSV test		1		
		Operon Simple RSV-RespirAdeno		1		
		Quidel Sofia RSV FIA		31		
		SD Biosensor Standard F RSV Ag FIA		11		
		Sekisui Diagnostics OSOM RSV/Adeno Test		6		
		Servibio VRS Color		2		
		Vidia Rapid-VIDITEST RSV Card		2		

		Vitassay RSV Single Card		2		
	Positive		2		0 %	0
		Biosynex RSVTOP		1		
		Hangzhou Alltest RSV Rapid Test Cassette		1		
	Total:		207		99 %	

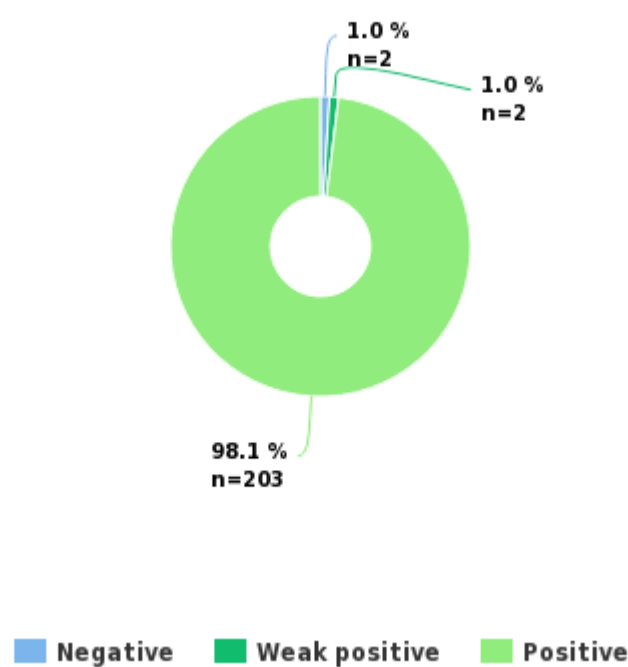
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	RSV Ag	99 %	207
	Total:	99 %	207

Sample S003 RSV Ag



RSV Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		2		0 %	0
		Biosynex RSVTOP		1		
		Meridian Bioscience TRU RSV		1		
	Weak positive		2		100 %	2
		Abbott BinaxNOW RSV		1		
		Biosynex RSVTOP		1		
	Positive		203		100 %	2
		Abbott BinaxNOW RSV		41		
		Abbott Bioline RSV		1		
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		Biosynex RSVTOP		9		
		CerTest Biotec RSV		3		
		CerTest Biotec RSV-Adeno		1		
		Coris BioConcept RSV K-SeT		2		
		Coris BioConcept RSV Respi-Strip		4		
		Hangzhou Alltest Beright Adenovirus and RSV Combo Rapid Test Cassette		1		
		Hangzhou Alltest RSV Rapid Test Cassette		2		
		LumiraDx SARS-CoV-2 & RSV		2		
		Mascia Brunelli RSV RESPI CARD		1		
		Meridian Bioscience TRU RSV		1		
		nal von minden Nadal RSV test		1		

		Operon Simple RSV-RespirAdeno		1		
		Quidel Sofia RSV FIA		31		
		SD Biosensor Standard F RSV Ag FIA		11		
		Sekisui Diagnostics OSOM RSV/Adeno Test		6		
		Servibio VRS Color		2		
		Vidia Rapid-VIDITEST RSV Card		2		
		Vitassay RSV Single Card		2		
	Total:		207		99 %	

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External Quality Assessment Scheme

RS virus, antigen detection Round 1, 2023

Specimens

Samples of this EQA round were artificial nasopharyngeal samples. The samples were suitable for antigen detection methods. 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 and pre-test laboratory C_t values were as follows:

Sample S001 (LQ773823011)
RSV A positive, C_t 17.8

Sample S002 (LQ773823012)
Negative

Sample S003 (LQ773823013)
RSV A positive, C_t 17.8

Pre-test methods: Seegene Allplex Respiratory Panel 1 (C_t values) and laboratory developed test (RT-PCR)

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

The positive samples on this EQA round were of the same batch and had a high virus content according to the C_t values. There were only 6 erroneous results including 4 apparent sample mix-ups.

Exceptions in scoring

No exceptions.

End of report

2023-03-24

FINAL REPORT

Product no. 5672

Subcontracting: Sample pretesting

Samples sent	2023-01-31
Round closed	2023-02-27
Expected results	2023-02-28
Final report	2023-03-24

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

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Expert

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