

External Quality Assessment Scheme

SARS-CoV-2, 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.

Not for patient use.

Examinations

SARS-CoV-2 antigen detection

Storage and use

After arrival, the samples should be stored at +2...30 °C and used as soon as possible.

1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a specimen collection tube / transport media and rotate to dislodge as much material as possible. You can also cut the swab into the sample tube.
3. Recap the collection tube and mix thoroughly to ensure that all of the test material is mixed with the transport media.
4. Perform the analysis according to the test manufacturer's instructions.

Result reporting

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

S001



S002



S003



2023-01-24

INSTRUCTIONS

Product no. 5681
LQ776023011-013/CA

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 20, 2023.**

The expected results of the round are published in LabScala in the View Reports section by February 24, 2023.

Inquiries

EQA Coordinator
Marsa Järvenpää
marsa.jarvenpaa@labquality.fi

Labquality Oy

Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

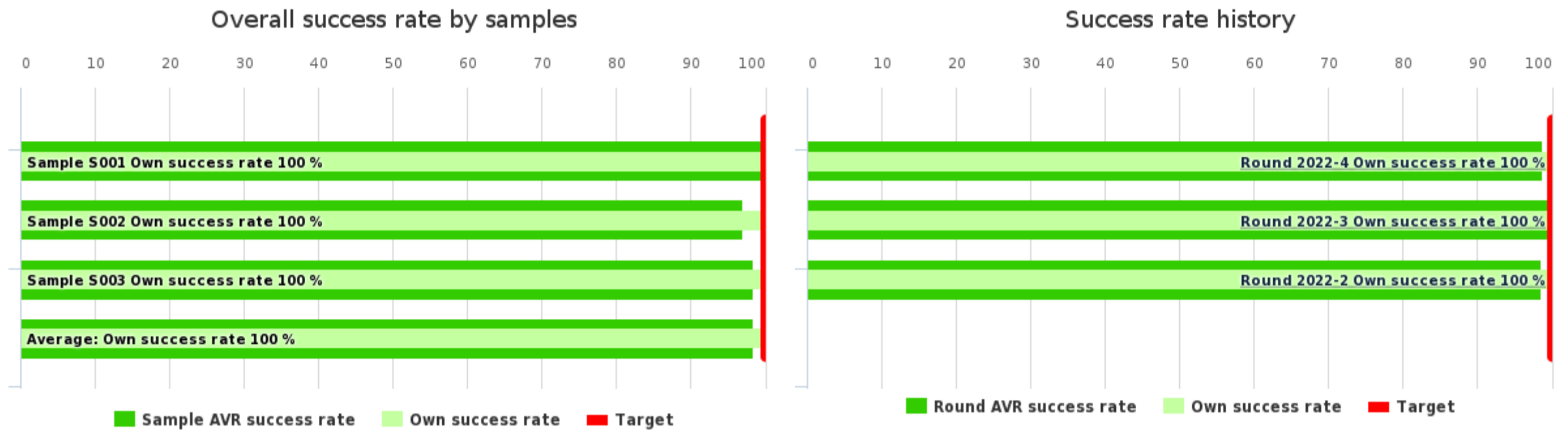
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
SARS-CoV-2, antigen detection, January, 1-2023	407	370	90.9 %

Summary

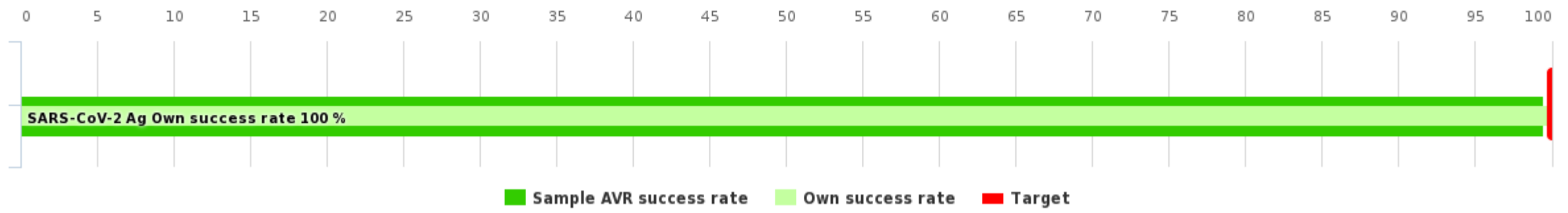


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0.5 %	99.5 %
Sample S002	2	2	100 %	2.9 %	97.1 %
Sample S003	2	2	100 %	1.5 %	98.5 %
Average:			100 %	1.6 %	98.4 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	1.3 %	98.7 %
Round 2022-3	1-1	100 %	0.4 %	99.6 %
Round 2022-2	1-1	100 %	1.4 %	98.6 %

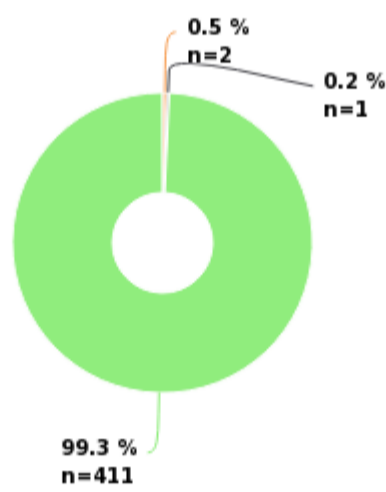
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	SARS-CoV-2 Ag	2	2	100 %	0.5 %	99.5 %	414
Total:		2	2	100 %	0.5 %	99.5 %	414

Sample S001 SARS-CoV-2 Ag



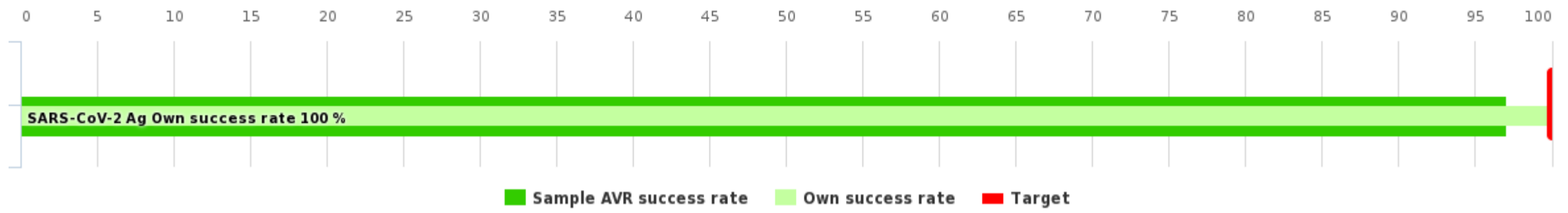
■ Negative
 ■ Weak positive
 ■ Positive

SARS-CoV-2 Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		AMP Rapid Test SARS-CoV-2 Ag		1					
		SD Biosensor STANDARD Q COVID-19 Ag Test		1					
	Weak positive		1		-				100 %
		SD Biosensor STANDARD Q COVID-19 Ag Test		1					
	<input checked="" type="radio"/> Positive		411		2	2	100 %	0 %	100 %
		AAZ-LMB COVID-VIRO		1					
		Abbott Panbio COVID-19 Ag Rapid Test Device		16					
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1					
		Aidian LF SARS-CoV-2 Ag Test		1					
		AMP Rapid Test SARS-CoV-2 Ag		2					
		ArcDia mariPOC Quick Flu+		23					
		ArcDia mariPOC Respi+		17					
		ArcDia SARS-CoV-2		3					
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1					
		BioMaxima SARS-CoV-2 Ag Rapid Test		2					
		Biosynex COMBO COVID-FLU-RSV BSS		1					
		Biosynex COVID-19 Ag BSS		20					
		Biosynex COVID-19 Ag+ BSS		28					
		CerTest CLIA SARS-CoV-2 Ag		1					
		CerTest SARS-CoV-2 one step card test		1					
		Core Technology Coretests COVID-19 Ag Test		2					
		Coris BioConcept COVID-19 Ag K-Set		1					
		CTK Biotech OnSite COVID-19 Ag Rapid Test		2					
		Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		4					

	Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		2					
	● Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test		5					
	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
	Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)		1					
	LumiraDx SARS-CoV-2 Ag Test		2					
	Nal von Minden NADAL COVID-19 Ag Rapid Test		2					
	Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection		3					
	NanoEntek FRENED COVID-19 Ag		1					
	New Gene Bioengineering COVID-19 Antigen Detection Kit		6					
	Quidel Sofia SARS Antigen (FIA)		1					
	Roche Elecsys SARS-CoV-2 Antigen		2					
	Roche SARS-CoV-2 Rapid Antigen Test		72					
	Romed SARS-CoV-2 Antigen Rapid Test		2					
	SD Biosensor STANDARD F COVID-19 Ag FIA		1					
	SD Biosensor STANDARD Q COVID-19 Ag Test		172					
	Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test		3					
	Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)		1					
	Siemens CLINITEST Rapid COVID-19 Antigen Test		2					
	Vitassay SARS-CoV-2		1					
	Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit		1					
	Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit		1					
	Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)		1					
	Total:		414	2	2	100 %	0.5 %	99.5 %

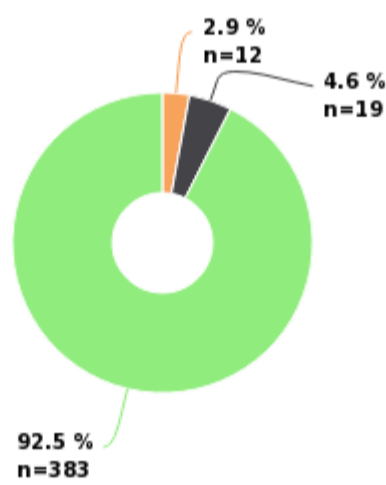
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	SARS-CoV-2 Ag	2	2	100 %	2.9 %	97.1 %	414
Total:		2	2	100 %	2.9 %	97.1 %	414

Sample S002 SARS-CoV-2 Ag



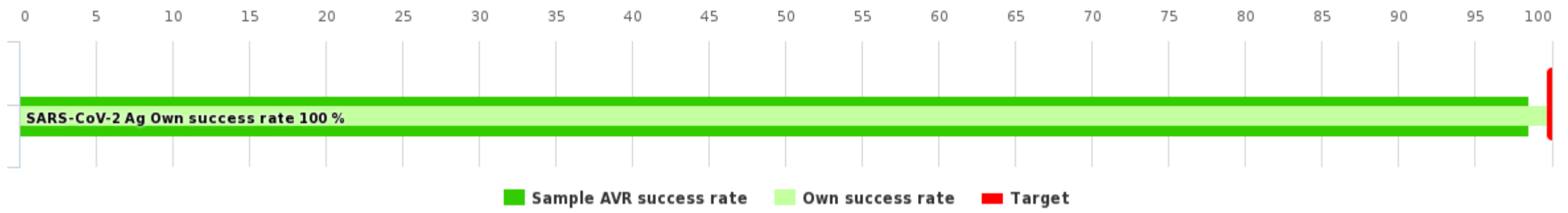
Negative Weak positive Positive

SARS-CoV-2 Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		12		-				0 %
		Abbott Panbio COVID-19 Ag Rapid Test Device		1					
		Acro Biotech COVID-19 Antigen Rapid Test		1					
		ArcDia mariPOC Quick Flu+		3					
		Biosynex COVID-19 Ag BSS		1					
		Roche SARS-CoV-2 Rapid Antigen Test		3					
		SD Biosensor STANDARD Q COVID-19 Ag Test		3					
	Weak positive		19		-				100 %
		Abbott Panbio COVID-19 Ag Rapid Test Device		5					
		Biosynex COVID-19 Ag BSS		3					
		CerTest CLIA SARS-CoV-2 Ag		1					
		Roche SARS-CoV-2 Rapid Antigen Test		2					
		SD Biosensor STANDARD Q COVID-19 Ag Test		8					
	Positive		383		2	2	100 %	0 %	100 %
		AAZ-LMB COVID-VIRO		1					
		Abbott Panbio COVID-19 Ag Rapid Test Device		10					
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1					
		Aidian LF SARS-CoV-2 Ag Test		1					
		AMP Rapid Test SARS-CoV-2 Ag		2					
		ArcDia mariPOC Quick Flu+		20					
		ArcDia mariPOC Respi+		17					
		ArcDia SARS-CoV-2		3					
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1					
		BioMaxima SARS-CoV-2 Ag Rapid Test		2					
		Biosynex COMBO COVID-FLU-RSV BSS		1					
		Biosynex COVID-19 Ag BSS		16					

	Biosynex COVID-19 Ag+ BSS		28						
	CerTest SARS-CoV-2 one step card test		1						
	Core Technology Coretests COVID-19 Ag Test		2						
	Coris BioConcept COVID-19 Ag K-Set		1						
	CTK Biotech OnSite COVID-19 Ag Rapid Test		2						
	Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		2						
	Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		3						
	Hangzhou Clongene Biotech COVID-19 Antigen Rapid Test		1						
	● Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test		5						
	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2						
	Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)		1						
	LumiraDx SARS-CoV-2 Ag Test		2						
	Nal von Minden NADAL COVID-19 Ag Rapid Test		2						
	Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection		3						
	NanoEntek FREND COVID-19 Ag		1						
	New Gene Bioengineering COVID-19 Antigen Detection Kit		6						
	Quidel Sofia SARS Antigen (FIA)		1						
	Roche Elecsys SARS-CoV-2 Antigen		2						
	Roche SARS-CoV-2 Rapid Antigen Test		68						
	Romed SARS-CoV-2 Antigen Rapid Test		1						
	SD Biosensor STANDARD F COVID-19 Ag FIA		2						
	SD Biosensor STANDARD Q COVID-19 Ag Test		162						
	Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test		3						
	Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)		1						
	Siemens CLINITEST Rapid COVID-19 Antigen Test		2						
	Vitassay SARS-CoV-2		1						
	Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit		1						
	Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit		1						
	Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)		1						
	Total:		414		2	2	100 %	2.9 %	97.1 %

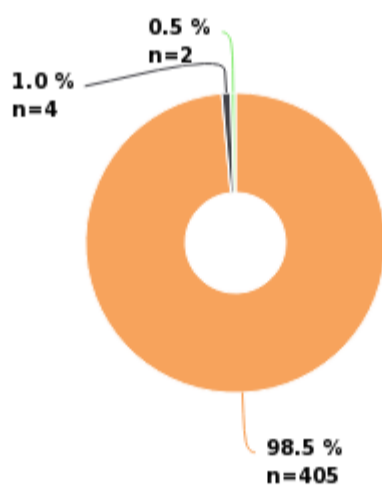
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	SARS-CoV-2 Ag	2	2	100 %	1.5 %	98.5 %	411
Total:		2	2	100 %	1.5 %	98.5 %	411

Sample S003 SARS-CoV-2 Ag



■ Negative
 ■ Positive
 ■ Invalid result

SARS-CoV-2 Ag	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		405		2	2	100 %	0 %	100 %
		AAZ-LMB COVID-VIRO		1					
		Abbott BinaxNOW COVID-19 Ag Card		1					
		Abbott Panbio COVID-19 Ag Rapid Test Device		15					
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1					
		Acro Biotech COVID-19 Antigen Rapid Test		1					
		Aidian LF SARS-CoV-2 Ag Test		1					
		AMP Rapid Test SARS-CoV-2 Ag		2					
		ArcDia mariPOC Quick Flu+		23					
		ArcDia mariPOC Respi+		17					
		ArcDia SARS-CoV-2		2					
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1					
		BioMaxima SARS-CoV-2 Ag Rapid Test		2					
		Biosynex COMBO COVID-FLU-RSV BSS		1					
		Biosynex COVID-19 Ag BSS		19					
		Biosynex COVID-19 Ag+ BSS		28					
		CerTest CLIA SARS-CoV-2 Ag		1					
		CerTest SARS-CoV-2 one step card test		1					
		Core Technology Coretests COVID-19 Ag Test		2					
		Coris BioConcept COVID-19 Ag K-Set		1					
		CTK Biotech OnSite COVID-19 Ag Rapid Test		2					
		Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		3					
		Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		2					
		Hangzhou Clongene Biotech COVID-19 Antigen Rapid Test		1					

	◎ Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test		5					
	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2					
	Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)		1					
	LumiraDx SARS-CoV-2 Ag Test		2					
	Nal von Minden NADAL COVID-19 Ag Rapid Test		2					
	Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection		3					
	NanoEntek FRENED COVID-19 Ag		1					
	New Gene Bioengineering COVID-19 Antigen Detection Kit		5					
	Quidel Sofia SARS Antigen (FIA)		1					
	Roche Elecsys SARS-CoV-2 Antigen		2					
	Roche SARS-CoV-2 Rapid Antigen Test		69					
	Romed SARS-CoV-2 Antigen Rapid Test		2					
	SD Biosensor STANDARD F COVID-19 Ag FIA		2					
	SD Biosensor STANDARD Q COVID-19 Ag Test		170					
	Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test		3					
	Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)		1					
	Siemens CLINITEST Rapid COVID-19 Antigen Test		2					
	Vitassay SARS-CoV-2		1					
	Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit		1					
	Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit		1					
	Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)		1					
Positive		4		-				0 %
	Biosynex COVID-19 Ag BSS		1					
	Roche SARS-CoV-2 Rapid Antigen Test		1					
	SD Biosensor STANDARD Q COVID-19 Ag Test		2					
Invalid result		2		-				0 %
	Roche SARS-CoV-2 Rapid Antigen Test		2					
Total:		411		2	2	100 %	1.5 %	98.5 %

Report Info

PARTICIPANTS

Altogether 407 laboratories from 15 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

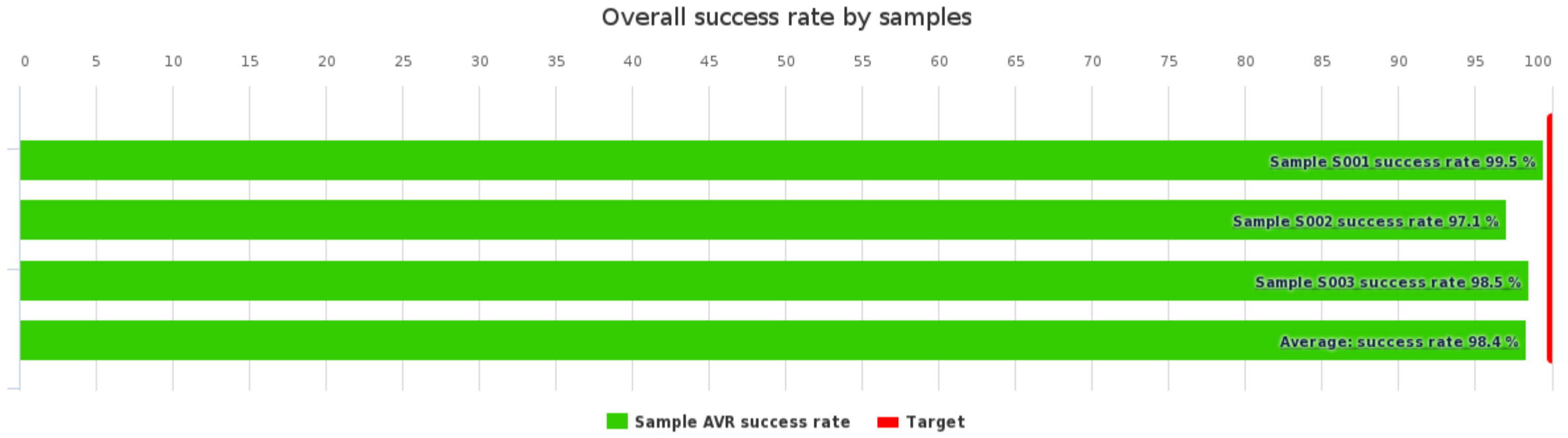
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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
SARS-CoV-2, antigen detection, January, 1-2023	407	370	90.9 %

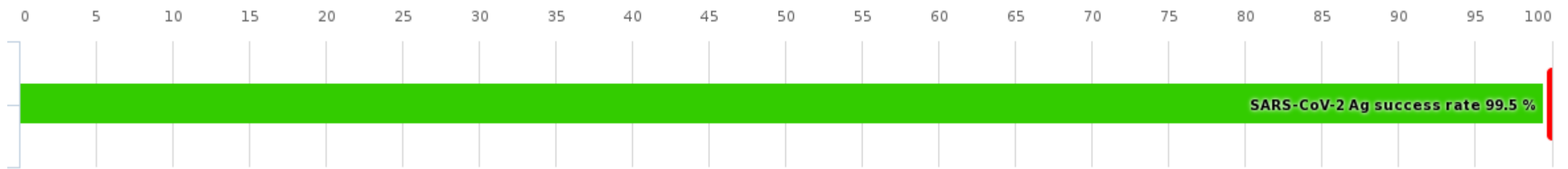
Summary



Summary	AVR success rate
Sample S001	99.5 %
Sample S002	97.1 %
Sample S003	98.5 %
Average:	98.4 %

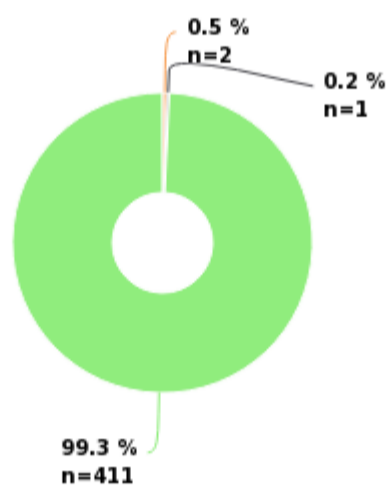
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	SARS-CoV-2 Ag	99.5 %	414
	Total:	99.5 %	414

Sample S001 SARS-CoV-2 Ag



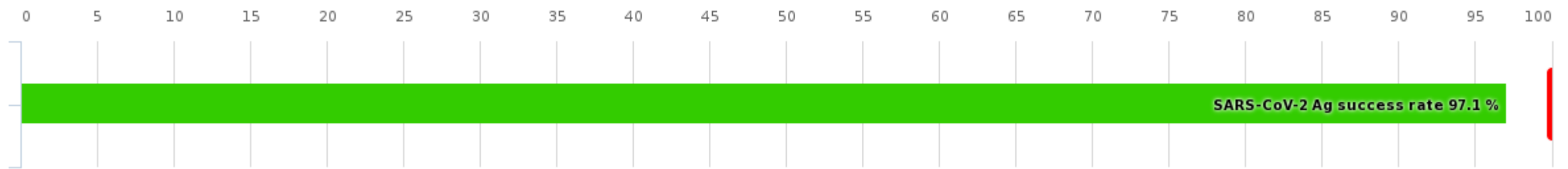
■ Negative
 ■ Weak positive
 ■ Positive

SARS-CoV-2 Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		2		0 %	0
		AMP Rapid Test SARS-CoV-2 Ag		1		
		SD Biosensor STANDARD Q COVID-19 Ag Test		1		
	Weak positive		1		100 %	2
		SD Biosensor STANDARD Q COVID-19 Ag Test		1		
	Positive		411		100 %	2
		AAZ-LMB COVID-VIRO		1		
		Abbott Panbio COVID-19 Ag Rapid Test Device		16		
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1		
		Aidian LF SARS-CoV-2 Ag Test		1		
		AMP Rapid Test SARS-CoV-2 Ag		2		
		ArcDia mariPOC Quick Flu+		23		
		ArcDia mariPOC Respi+		17		
		ArcDia SARS-CoV-2		3		
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1		
		BioMaxima SARS-CoV-2 Ag Rapid Test		2		
		Biosynex COMBO COVID-FLU-RSV BSS		1		
		Biosynex COVID-19 Ag BSS		20		
		Biosynex COVID-19 Ag+ BSS		28		
		CerTest CLIA SARS-CoV-2 Ag		1		
		CerTest SARS-CoV-2 one step card test		1		
		Core Technology Coretests COVID-19 Ag Test		2		
		Coris BioConcept COVID-19 Ag K-Set		1		
		CTK Biotech OnSite COVID-19 Ag Rapid Test		2		
		Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		4		
		Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		2		

	Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test	5		
	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)	2		
	Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	1		
	LumiraDx SARS-CoV-2 Ag Test	2		
	Nal von Minden NADAL COVID-19 Ag Rapid Test	2		
	Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection	3		
	NanoEntek FRENED COVID-19 Ag	1		
	New Gene Bioengineering COVID-19 Antigen Detection Kit	6		
	Quidel Sofia SARS Antigen (FIA)	1		
	Roche Elecsys SARS-CoV-2 Antigen	2		
	Roche SARS-CoV-2 Rapid Antigen Test	72		
	Romed SARS-CoV-2 Antigen Rapid Test	2		
	SD Biosensor STANDARD F COVID-19 Ag FIA	1		
	SD Biosensor STANDARD Q COVID-19 Ag Test	172		
	Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test	3		
	Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)	1		
	Siemens CLINITEST Rapid COVID-19 Antigen Test	2		
	Vitassay SARS-CoV-2	1		
	Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit	1		
	Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit	1		
	Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)	1		
	Total:	414	99.5 %	

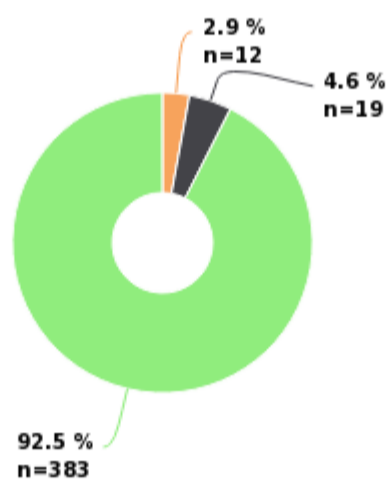
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	SARS-CoV-2 Ag	97.1 %	414
	Total:	97.1 %	414

Sample S002 SARS-CoV-2 Ag



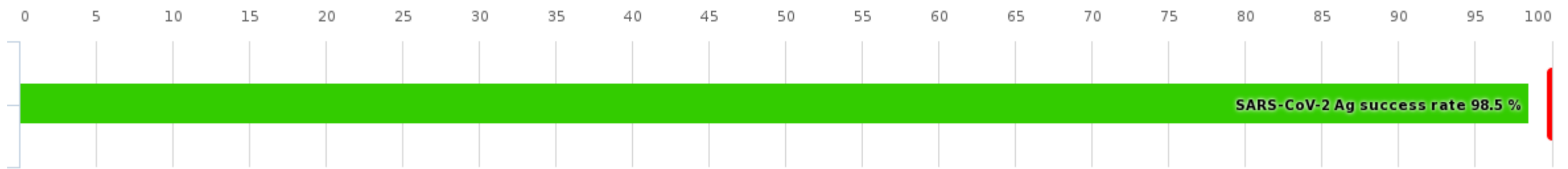
■ Negative
 ■ Weak positive
 ■ Positive

SARS-CoV-2 Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		12		0 %	0
		Abbott Panbio COVID-19 Ag Rapid Test Device		1		
		Acro Biotech COVID-19 Antigen Rapid Test		1		
		ArcDia mariPOC Quick Flu+		3		
		Biosynex COVID-19 Ag BSS		1		
		Roche SARS-CoV-2 Rapid Antigen Test		3		
		SD Biosensor STANDARD Q COVID-19 Ag Test		3		
	Weak positive		19		100 %	2
		Abbott Panbio COVID-19 Ag Rapid Test Device		5		
		Biosynex COVID-19 Ag BSS		3		
		CerTest CLIA SARS-CoV-2 Ag		1		
		Roche SARS-CoV-2 Rapid Antigen Test		2		
		SD Biosensor STANDARD Q COVID-19 Ag Test		8		
	Positive		383		100 %	2
		AAZ-LMB COVID-VIRO		1		
		Abbott Panbio COVID-19 Ag Rapid Test Device		10		
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1		
		Aidian LF SARS-CoV-2 Ag Test		1		
		AMP Rapid Test SARS-CoV-2 Ag		2		
		ArcDia mariPOC Quick Flu+		20		
		ArcDia mariPOC Respi+		17		
		ArcDia SARS-CoV-2		3		
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1		
		BioMaxima SARS-CoV-2 Ag Rapid Test		2		
		Biosynex COMBO COVID-FLU-RSV BSS		1		
		Biosynex COVID-19 Ag BSS		16		
		Biosynex COVID-19 Ag+ BSS		28		

	CerTest SARS-CoV-2 one step card test		1		
	Core Technology Coretests COVID-19 Ag Test		2		
	Coris BioConcept COVID-19 Ag K-Set		1		
	CTK Biotech OnSite COVID-19 Ag Rapid Test		2		
	Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		2		
	Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		3		
	Hangzhou Clongene Biotech COVID-19 Antigen Rapid Test		1		
	Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test		5		
	Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
	Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)		1		
	LumiraDx SARS-CoV-2 Ag Test		2		
	Nal von Minden NADAL COVID-19 Ag Rapid Test		2		
	Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection		3		
	NanoEntek FRENED COVID-19 Ag		1		
	New Gene Bioengineering COVID-19 Antigen Detection Kit		6		
	Quidel Sofia SARS Antigen (FIA)		1		
	Roche Elecsys SARS-CoV-2 Antigen		2		
	Roche SARS-CoV-2 Rapid Antigen Test		68		
	Romed SARS-CoV-2 Antigen Rapid Test		1		
	SD Biosensor STANDARD F COVID-19 Ag FIA		2		
	SD Biosensor STANDARD Q COVID-19 Ag Test		162		
	Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test		3		
	Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)		1		
	Siemens CLINITEST Rapid COVID-19 Antigen Test		2		
	Vitassay SARS-CoV-2		1		
	Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit		1		
	Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit		1		
	Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)		1		
	Total:		414		97.1 %

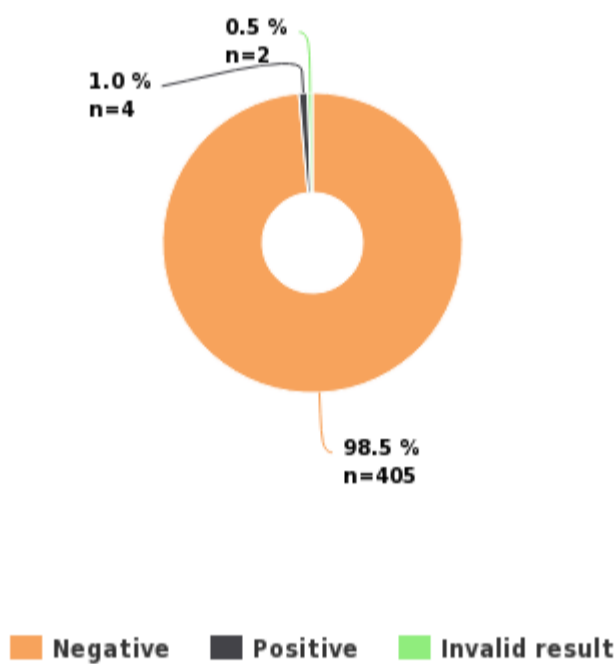
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	SARS-CoV-2 Ag	98.5 %	411
	Total:	98.5 %	411

Sample S003 SARS-CoV-2 Ag



SARS-CoV-2 Ag	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		405		100 %	2
		AAZ-LMB COVID-VIRO		1		
		Abbott BinaxNOW COVID-19 Ag Card		1		
		Abbott Panbio COVID-19 Ag Rapid Test Device		15		
		ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test		1		
		Acro Biotech COVID-19 Antigen Rapid Test		1		
		Aidian LF SARS-CoV-2 Ag Test		1		
		AMP Rapid Test SARS-CoV-2 Ag		2		
		ArcDia mariPOC Quick Flu+		23		
		ArcDia mariPOC Respi+		17		
		ArcDia SARS-CoV-2		2		
		Beijing Hotgen Biotech Novel Coronavirus 2019-nCoV Antigen Test		1		
		BioMaxima SARS-CoV-2 Ag Rapid Test		2		
		Biosynex COMBO COVID-FLU-RSV BSS		1		
		Biosynex COVID-19 Ag BSS		19		
		Biosynex COVID-19 Ag+ BSS		28		
		CerTest CLIA SARS-CoV-2 Ag		1		
		CerTest SARS-CoV-2 one step card test		1		
		Core Technology Coretests COVID-19 Ag Test		2		
		Coris BioConcept COVID-19 Ag K-Set		1		
		CTK Biotech OnSite COVID-19 Ag Rapid Test		2		
		Hangzhou AllTest Biotech COVID-19 Antigen Rapid Test		3		
		Hangzhou AllTest Biotech GSD NovaGen SARS-CoV-2 Ag Rapid Test (NP swab)		2		
		Hangzhou Clongene Biotech COVID-19 Antigen Rapid Test		1		
		Hangzhou Clongene Biotech Lungene COVID-19 Antigen Rapid Test		5		

		Healgen Influenza & COVID-19 Ag Combo Rapid Test Cassette (Swab)		2		
		Jiangsu Konsung Bio-Medical Science And Technology COVID-19 Antigen Rapid Test Kit (Colloidal Gold)		1		
		LumiraDx SARS-CoV-2 Ag Test		2		
		Nal von Minden NADAL COVID-19 Ag Rapid Test		2		
		Nanjing Vazyme Biotech SARS-CoV-2 Antigen Detection		3		
		NanoEntek FRENED COVID-19 Ag		1		
		New Gene Bioengineering COVID-19 Antigen Detection Kit		5		
		Quidel Sofia SARS Antigen (FIA)		1		
		Roche Elecsys SARS-CoV-2 Antigen		2		
		Roche SARS-CoV-2 Rapid Antigen Test		69		
		Romed SARS-CoV-2 Antigen Rapid Test		2		
		SD Biosensor STANDARD F COVID-19 Ag FIA		2		
		SD Biosensor STANDARD Q COVID-19 Ag Test		170		
		Shenzhen YHLO Biotech GLINE-2019-nCoV Rapid Antigen Test		3		
		Siemens Atellica IM SARS-CoV-2 Antigen (CoV2Ag)		1		
		Siemens CLINITEST Rapid COVID-19 Antigen Test		2		
		Vitassay SARS-CoV-2		1		
		Vitrosens Biotechnology RapidFor SARS-CoV-2 Rapid Antigen Test Kit		1		
		Wuhan Easy Diagnosis BioMedicine COVID-19 (SARS-CoV-2) Antigen Test Kit		1		
		Zybio SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)		1		
	Positive		4		0 %	0
		Biosynex COVID-19 Ag BSS		1		
		Roche SARS-CoV-2 Rapid Antigen Test		1		
		SD Biosensor STANDARD Q COVID-19 Ag Test		2		
	Invalid result		2		0 %	0
		Roche SARS-CoV-2 Rapid Antigen Test		2		
	Total:		411		98.5 %	

Report Info

PARTICIPANTS

Altogether 407 laboratories from 15 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.

External Quality Assessment Scheme

SARS-CoV-2, antigen detection Round 1, 2023

Specimens

Samples of this EQA round were artificial samples. Based on the quality controls conducted by the sample material manufacturer 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 (LQ776023011)
SARS-CoV-2 Ag Positive

Sample S002 (LQ776023012)
SARS-CoV-2 Ag Low positive

Sample S003 (LQ776023013)
SARS-CoV-2 Ag Negative

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 overall success rate on this round was high, 98.4%. False results in samples S001 and S003 had several different error types. The low positive sample S002 (success rate 97.1%) was only slightly more difficult than S001 (99.5%). For tests that had more than 10 users, the test specific success rate in sample S002 was 87–100%, and below 95% for only two tests.

Exceptions in scoring

No exceptions.

End of report

2023-03-07

FINAL REPORT

Product no. 5681

Samples sent	2023-01-24
Round closed	2023-02-20
Expected results	2023-02-21
Final report	2023-03-07

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
Marsa Järvenpää
marsa.jarvenpaa@labquality.fi

Expert

Docent Matti Waris,
University of Turku, Finland

Labquality Oy

Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com



Copyright © Labquality Oy

Labquality does not permit any reproduction for commercial purposes of any portion of the material subject to this copyright. Labquality prohibits any use of its name, or reference to Labquality EQA program, or material in this report in any advertising, brochures or other commercial publications. Labquality EQA data do not necessarily indicate the superiority of instruments, reagents, testing equipments or materials used by participating laboratories. Use of Labquality EQA data to suggest superiority or inferiority of equipments or materials may be deceptive and misleading. Proficiency test results are handled confidentially. Labquality will not issue any statements to third parties of the performance of laboratories in external quality assessment schemes unless otherwise agreed.