

External Quality Assessment Scheme

Norovirus, nucleic acid detection Round 2, 2023

Specimens

Please find enclosed 3 artificial faecal samples S001, S002 and S003, each 1 mL.

Caution

Quality control samples 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 and the samples are found to be HBsAg, HCVAb and HIVAb negative when tested with licensed reagents. However, no known test method can offer complete assurance that the samples will not transmit these or other infectious diseases.

Examinations

Norovirus NAT, genogroups GI and GII.

Storage and use

After arrival, the samples should be stored at +2...8°C, and analysed as soon as possible, preferably within a week. The samples are ready for use and should be analysed as patient samples. Perform the analysis according to the manufacturer's instructions for a liquid specimen.

Result reporting

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

S001



S002



S003



2023-05-30

INSTRUCTIONS

Product no. 5675
LQ775223021-023/US

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 **June 23, 2023**.

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

Inquiries

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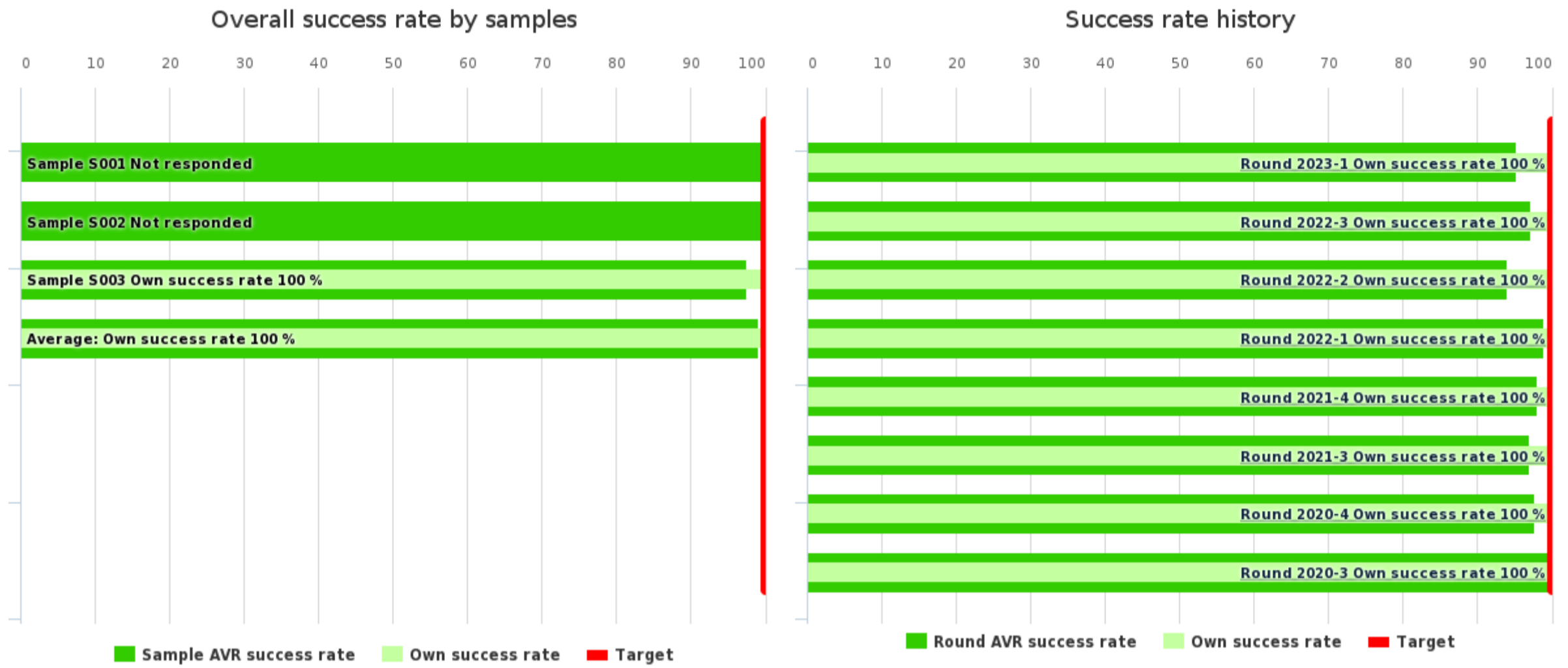
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Norovirus, nucleic acid detection, June, 2-2023	38	37	97.4 %

Summary

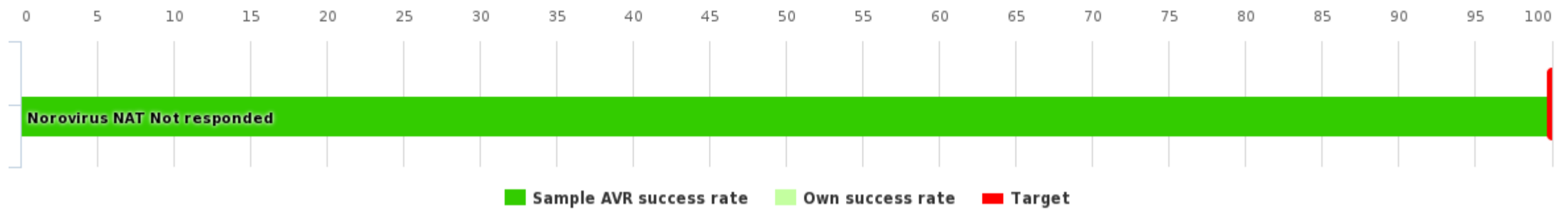


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	-	-	-	-	100 %
Sample S002	-	-	-	-	100 %
Sample S003	2	2	100 %	2.5 %	97.5 %
Average:			100 %	0.8 %	99.2 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2023-1	1-1	100 %	4.8 %	95.2 %
Round 2022-3	1-1	100 %	2.8 %	97.2 %
Round 2022-2	1-1	100 %	5.9 %	94.1 %
Round 2022-1	1-1	100 %	1 %	99 %
Round 2021-4	1-1	100 %	2 %	98 %
Round 2021-3	1-1	100 %	2.9 %	97.1 %
Round 2020-4	1-1	100 %	2.2 %	97.8 %
Round 2020-3	1-1	100 %	0 %	100 %

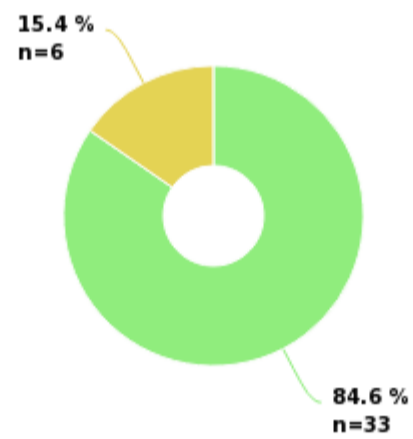
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Norovirus NAT	-	-	-	-	100 %	39
	Total:	-	-	-	-	100 %	39

Sample S001 Norovirus NAT

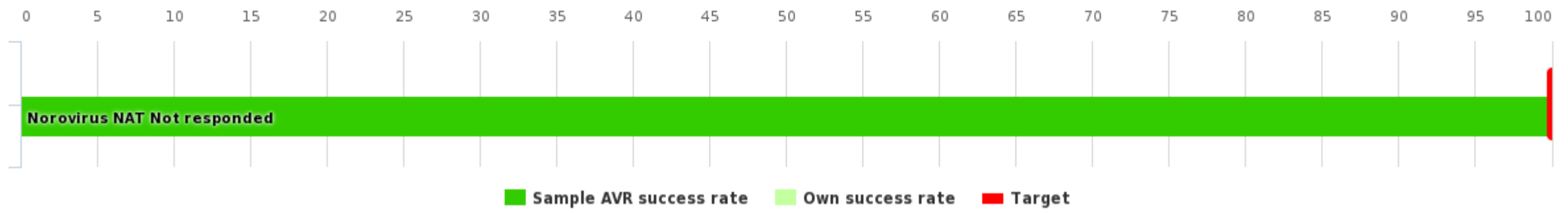


■ G2 positive
■ Norovirus positive, no genotyping

Norovirus NAT	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	G2 positive		33		-				100 %
		Abacus GenomEra Norovirus		4					
		Cepheid Xpert Norovirus		26					
		In-house Norovirus		1					
		Seegene Allplex GI-Virus Assay		1					
		Thermo Fisher QPCR		1					
	Norovirus positive, no genotyping		6		-				100 %
		Abacus GenomEra Norovirus		1					
		BD MAX Enteric Viral Panel		4					
		R-Biopharm RIDAGENE Norovirus		1					
	Total:		39		-	-	-	-	100 %

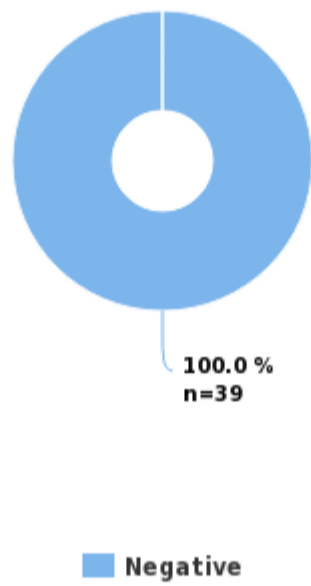
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Norovirus NAT	-	-	-	-	100 %	39
Total:		-	-	-	-	100 %	39

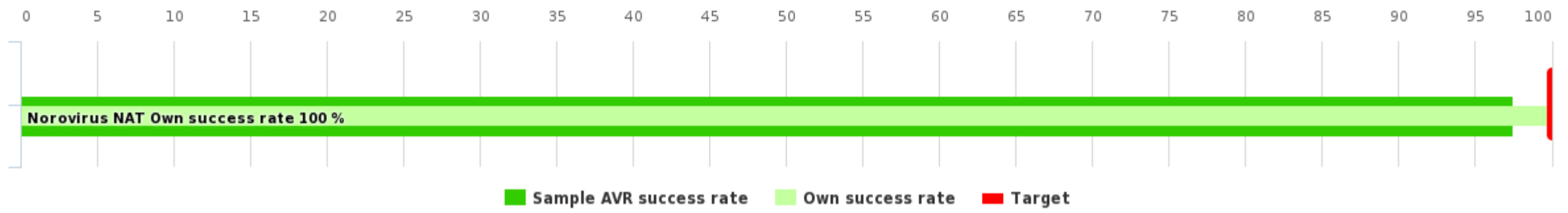
Sample S002 Norovirus NAT



Norovirus NAT	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		39		-				100 %
		Abacus GenomEra Norovirus		5					
		BD MAX Enteric Viral Panel		4					
		Cepheid Xpert Norovirus		26					
		In-house Norovirus		1					
		R-Biopharm RIDAGENE Norovirus		1					
		Seegene Allplex GI-Virus Assay		1					
		Thermo Fisher QPCR		1					
Total:			39		-	-	-	-	100 %

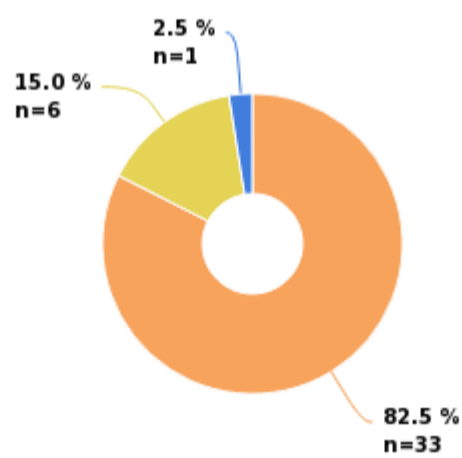
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Norovirus NAT	2	2	100 %	2.5 %	97.5 %	40
Total:		2	2	100 %	2.5 %	97.5 %	40

Sample S003 Norovirus NAT



- G1 positive
- Norovirus positive, no genotyping
- Indeterminate result

OWN DEVICE: GENEXPERT

Norovirus NAT	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> G1 positive		33		2	2	100 %	0 %	100 %
		Abacus GenomEra Norovirus		3					
		<input checked="" type="radio"/> Cepheid Xpert Norovirus		27					
		In-house Norovirus		1					
		Seegene Allplex GI-Virus Assay		1					
		Thermo Fisher QPCR		1					
	Norovirus positive, no genotyping		6		-				100 %
		Abacus GenomEra Norovirus		1					
		BD MAX Enteric Viral Panel		4					
		R-Biopharm RIDAGENE Norovirus		1					
	Indeterminate result		1		-				0 %
		Abacus GenomEra Norovirus		1					
Total:			40		2	2	100 %	2.5 %	97.5 %

Report Info

PARTICIPANTS

Altogether 38 laboratories from 8 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

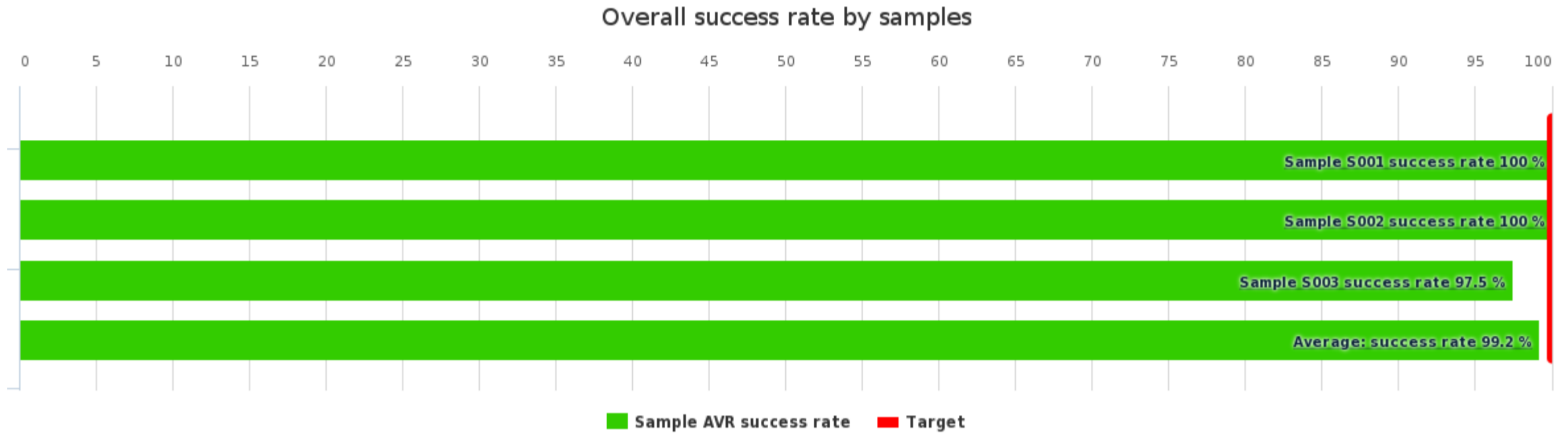
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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
Norovirus, nucleic acid detection, June, 2-2023	38	37	97.4 %

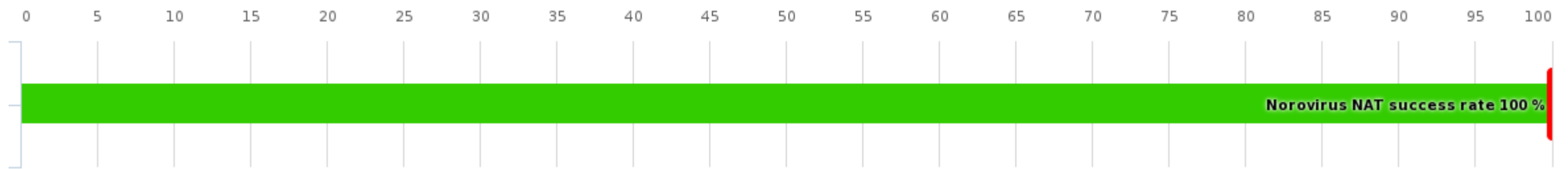
Summary



Summary	AVR success rate
Sample S001	100 %
Sample S002	100 %
Sample S003	97.5 %
Average:	99.2 %

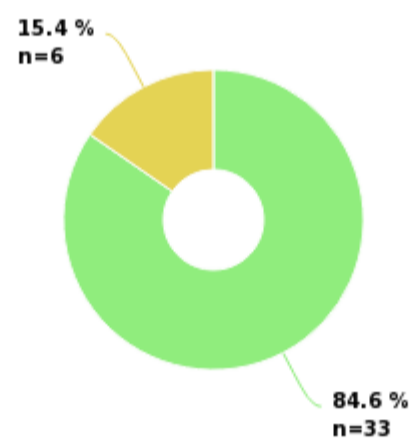
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Norovirus NAT	100 %	39
	Total:	100 %	39

Sample S001 Norovirus NAT

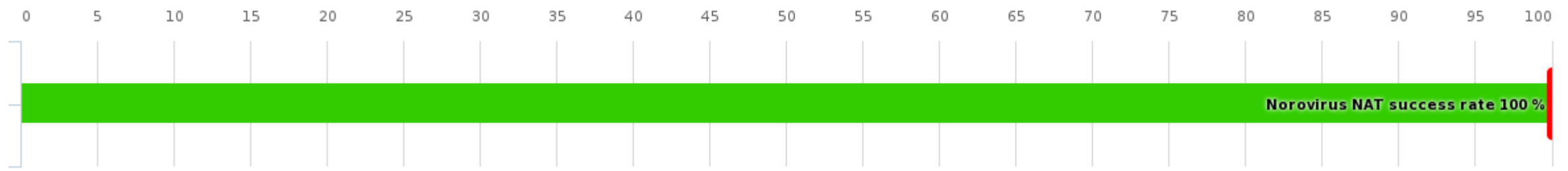


■ G2 positive
■ Norovirus positive, no genotyping

Norovirus NAT	Result	Method	Result count	Method count	AVR success rate	Result Score
	G2 positive		33		100 %	2
		Abacus GenomEra Norovirus		4		
		Cepheid Xpert Norovirus		26		
		In-house Norovirus		1		
		Seegene Allplex GI-Virus Assay		1		
		Thermo Fisher QPCR		1		
	Norovirus positive, no genotyping		6		100 %	2
		Abacus GenomEra Norovirus		1		
		BD MAX Enteric Viral Panel		4		
		R-Biopharm RIDAGENE Norovirus		1		
	Total:		39		100 %	

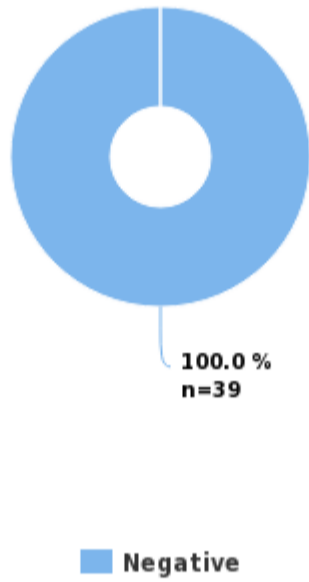
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Norovirus NAT	100 %	39
	Total:	100 %	39

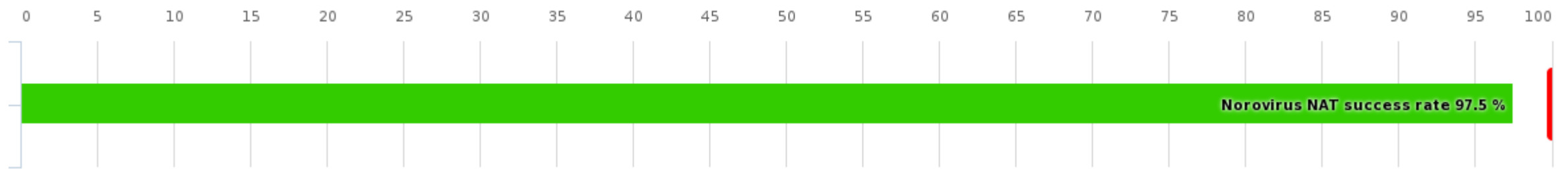
Sample S002 Norovirus NAT



Norovirus NAT	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		39		100 %	2
		Abacus GenomEra Norovirus		5		
		BD MAX Enteric Viral Panel		4		
		Cepheid Xpert Norovirus		26		
		In-house Norovirus		1		
		R-Biopharm RIDAGENE Norovirus		1		
		Seegene Allplex GI-Virus Assay		1		
		Thermo Fisher QPCR		1		
	Total:		39		100 %	

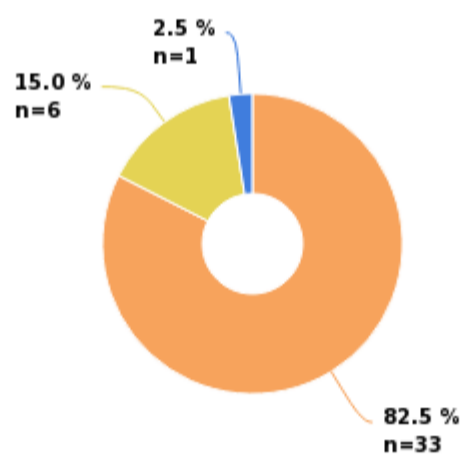
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Norovirus NAT	97.5 %	40
	Total:	97.5 %	40

Sample S003 Norovirus NAT



- G1 positive
- Norovirus positive, no genotyping
- Indeterminate result

Norovirus NAT	Result	Method	Result count	Method count	AVR success rate	Result Score
	G1 positive		33		100 %	2
		Abacus GenomEra Norovirus		3		
		Cepheid Xpert Norovirus		27		
		In-house Norovirus		1		
		Seegene Allplex GI-Virus Assay		1		
		Thermo Fisher QPCR		1		
	Norovirus positive, no genotyping		6		100 %	2
		Abacus GenomEra Norovirus		1		
		BD MAX Enteric Viral Panel		4		
		R-Biopharm RIDAGENE Norovirus		1		
	Indeterminate result		1		0 %	0
		Abacus GenomEra Norovirus		1		
	Total:		40		97.5 %	

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External Quality Assessment Scheme

Norovirus, nucleic acid detection Round 2, 2023

Specimens

Samples of this EQA round were artificial faecal samples. The sample lots were tested in an accredited Finnish reference 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 (LQ775223021)
Norovirus NAT GII positive, Ct value 30.4
Norovirus positive, no genotyping

Sample S002 (LQ775223022)
Norovirus NAT Negative

Sample S003 (LQ775223023)
Norovirus NAT GI positive, Ct value 34.3
Norovirus positive, no genotyping

Pre-test method: Cepheid Xpert Norovirus.

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 – EQA Coordinator

Participants performed very well in this EQA round. Only one indeterminate result was reported for sample S003. The median of the Ct values reported by the most used method in the round from sample S003 was 30.8 (n=16).

Exceptions in scoring

No exceptions.

End of report

2023-06-28

FINAL REPORT

Product no. 5675

Subcontracting: Sample pretesting

Samples sent	2023-05-30
Round closed	2023-06-23
Expected results	2023-06-28
Final report	2023-06-28

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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