LABQUALITY

External Quality Assessment Scheme

Hepatitis C virus, RNA
Round 1, 2023

Specimens
Please find enclosed 3 lyophilized human plasma samples S001, S002 and S003, each 1.2 mL.

Caution
Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e., as potential transmitters of serious diseases. The specimens may contain infectious viruses.

Examinations
Hepatitis C virus, RNA, quantitative
Hepatitis C virus, RNA, qualitative

Storage and use
After arrival, the samples should be stored at +2…8 °C. When disposing the samples, instructions concerning disposal of infectious specimens must be followed.

Handle the samples in a biological safety cabinet. Formation of aerosols and splashes as well as injuries and other contamination must be avoided.

1. Let the samples warm up to room temperature before rehydration.

2. Carefully add 1.2 mL of DNAse and RNAse free water into each vial.

3. Let the content of the vials to dissolve for 30 minutes and mix the vials gently from time to time. Ensure that the mixture is homogenous before performing the assay.

4. Perform the assay immediately after rehydration of the samples by following the instructions given by the manufacturer of your routine test method.

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your method from the registry, please contact the EQA Coordinator. Qualitative results will be scored.

S001

S002

S003

2023-03-07

INSTRUCTIONS

Product no. 5678
LQ778523011-013/US
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 **April 3, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 7, 2023.

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FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Only the qualitative analysis phase is accredited.

Quality Management
ISO 9001:2015

Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

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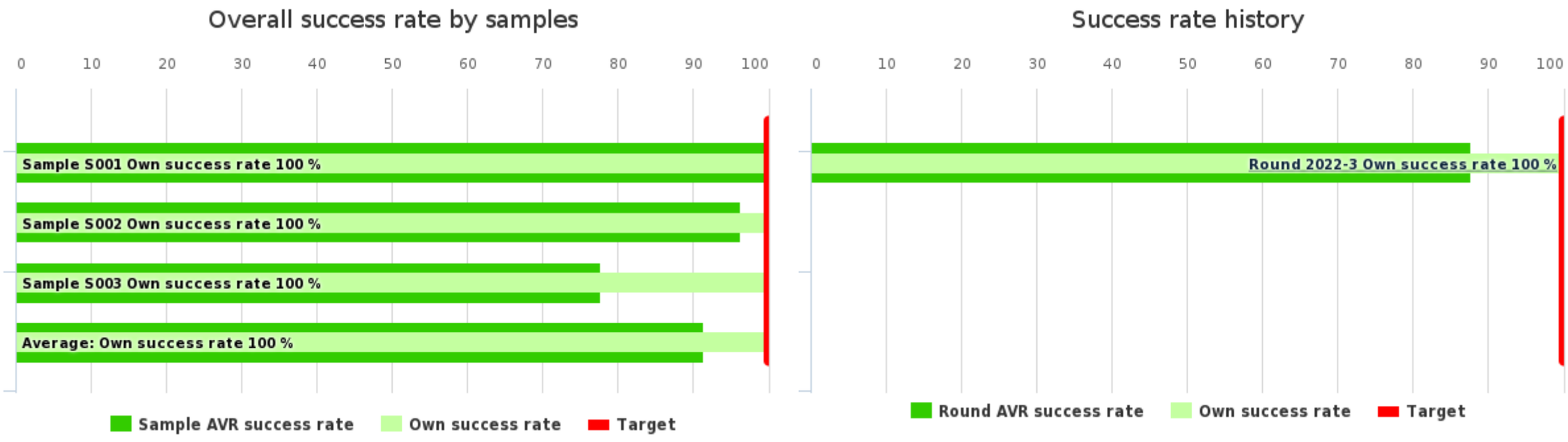
Qualitative scoring report

Client report

	No of participants	No of responded participants	Response percentage
Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023	29	27	93.1 %

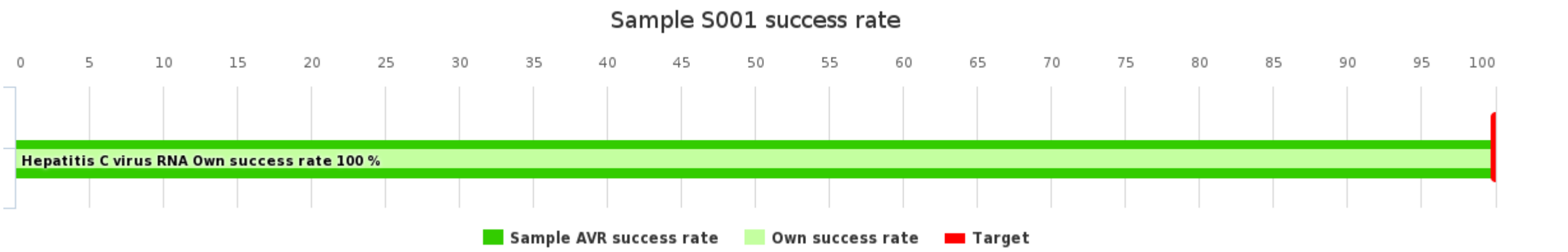
Summary



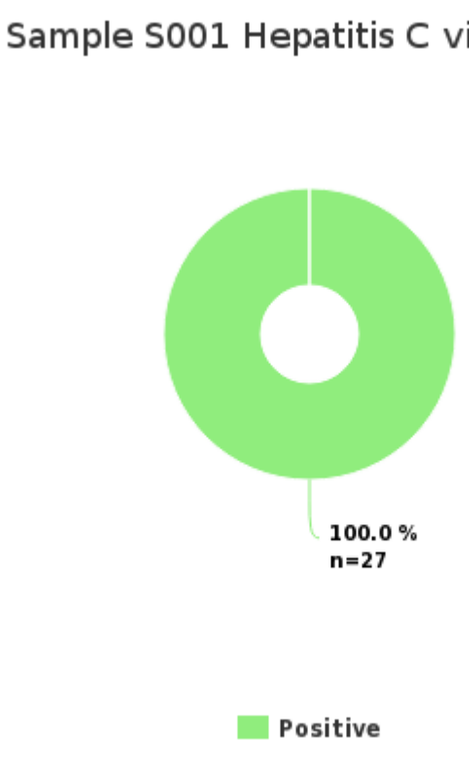
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	2	2	100 %	3.7 %	96.3 %
Sample S003	2	2	100 %	22.2 %	77.8 %
Average:			100 %	8.6 %	91.4 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-3	1-1	100 %	12.2 %	87.8 %

Sample S001

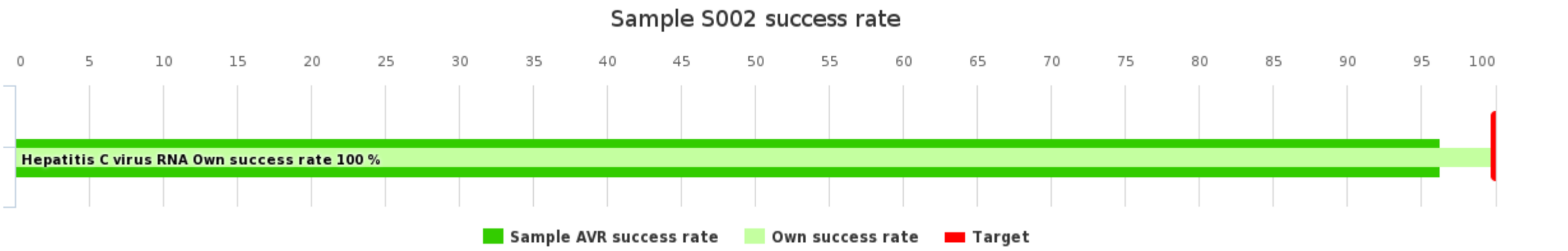


Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Hepatitis C virus RNA	2	2	100 %	0 %	100 %	27
Total:		2	2	100 %	0 %	100 %	27



Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		27		2	2	100 %	0 %	100 %
		◉ Abbott Alinity m HCV assay		3					
		Cepheid Xpert HCV Viral Load		8					
		DNA-Technology HCV Quantitative Real-Time PCR		1					
		GeneProof Hepatitis C Virus PCR Kit		1					
		Grifols Procleix Panther System		1					
		NeuMoDx HCV Quant Test Strip		1					
		Qiagen Artus HCV QS-RGQ kit		1					
		Qiagen Artus HCV RG RT-PCR Kit		1					
		Roche COBAS HCV		5					
		Roche COBAS MPX for 6800/8800 systems		4					
		Sacace HCV Real-TM Quant Dx		1					
	Total:		27		2	2	100 %	0 %	100 %

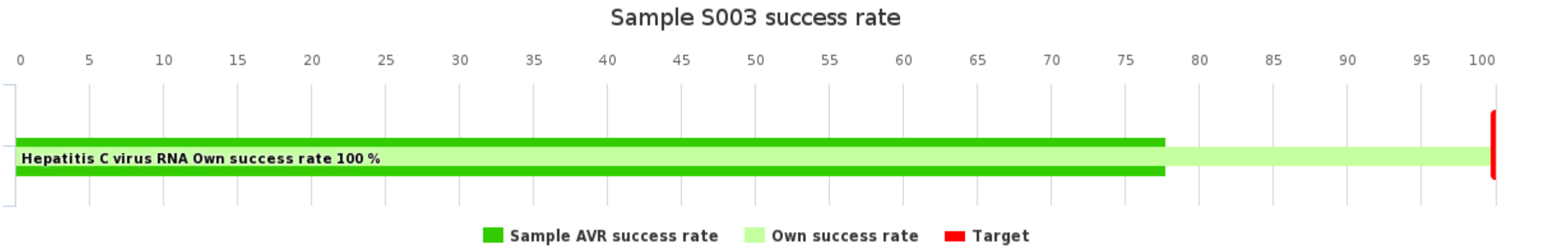
Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Hepatitis C virus RNA	2	2	100 %	3.7 %	96.3 %	27
Total:		2	2	100 %	3.7 %	96.3 %	27

Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Roche COBAS HCV		1					
	◉ Positive		26		2	2	100 %	0 %	100 %
		◉ Abbott Alinity m HCV assay		3					
		Cepheid Xpert HCV Viral Load		8					
		DNA-Technology HCV Quantitative Real-Time PCR		1					
		GeneProof Hepatitis C Virus PCR Kit		1					
		Grifols Procleix Panther System		1					
		NeuMoDx HCV Quant Test Strip		1					
		Qiagen Artus HCV QS-RGQ kit		1					
		Qiagen Artus HCV RG RT-PCR Kit		1					
		Roche COBAS HCV		4					
		Roche COBAS MPX for 6800/8800 systems		4					
		Sacace HCV Real-TM Quant Dx		1					
	Total:		27		2	2	100 %	3.7 %	96.3 %

Sample S003



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Hepatitis C virus RNA	2	2	100 %	22.2 %	77.8 %	27
Total:		2	2	100 %	22.2 %	77.8 %	27

Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		21		2	2	100 %	0 %	100 %
		◉ Abbott Alinity m HCV assay		2					
		Cepheid Xpert HCV Viral Load		5					
		DNA-Technology HCV Quantitative Real-Time PCR		1					
		GeneProof Hepatitis C Virus PCR Kit		1					
		NeuMoDx HCV Quant Test Strip		1					
		Qiagen Artus HCV QS-RGQ kit		1					
		Qiagen Artus HCV RG RT-PCR Kit		1					
		Roche COBAS HCV		4					
		Roche COBAS MPX for 6800/8800 systems		4					
		Sacace HCV Real-TM Quant Dx		1					
	Positive		6		-				0 %
		Abbott Alinity m HCV assay		1					
		Cepheid Xpert HCV Viral Load		3					
		Grifols Procleix Panther System		1					
		Roche COBAS HCV		1					
	Total:		27		2	2	100 %	22.2 %	77.8 %

Report Info

PARTICIPANTS

Altogether 29 laboratories from 14 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.

Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

Qualitative scoring report

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023	29	27	93.1 %

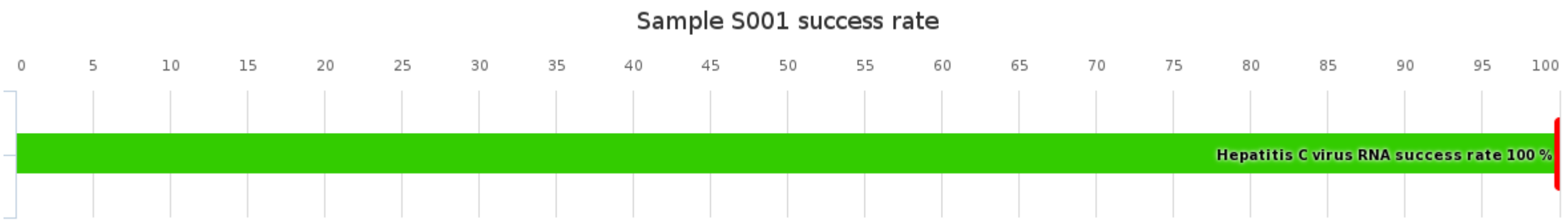
Summary

Summary	AVR success rate
Sample S001	100 %
Sample S002	96.3 %
Sample S003	77.8 %
Average:	91.4 %

Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

Qualitative scoring report

Sample S001



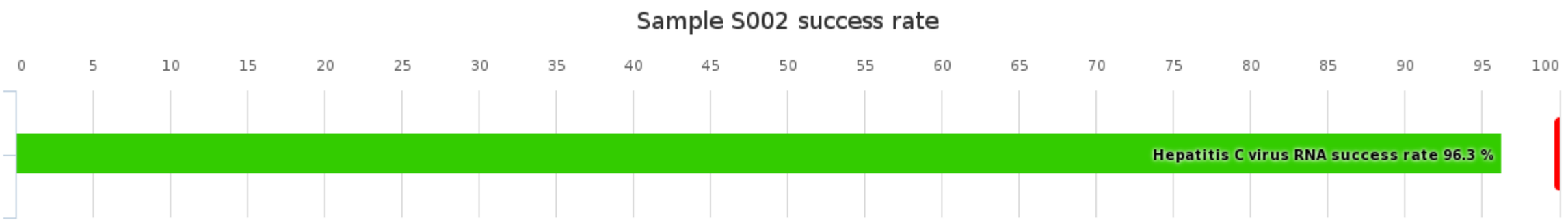
Sample S001 results	Responded	AVR success rate	Count
	Hepatitis C virus RNA	100 %	27
Total:		100 %	27

Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Positive		27		100 %	2
		Abbott Alinity m HCV assay		3		
		Cepheid Xpert HCV Viral Load		8		
		DNA-Technology HCV Quantitative Real-Time PCR		1		
		GeneProof Hepatitis C Virus PCR Kit		1		
		Grifols Procleix Panther System		1		
		NeuMoDx HCV Quant Test Strip		1		
		Qiagen Artus HCV QS-RGQ kit		1		
		Qiagen Artus HCV RG RT-PCR Kit		1		
		Roche COBAS HCV		5		
		Roche COBAS MPX for 6800/8800 systems		4		
		Sacace HCV Real-TM Quant Dx		1		
	Total:		27		100 %	

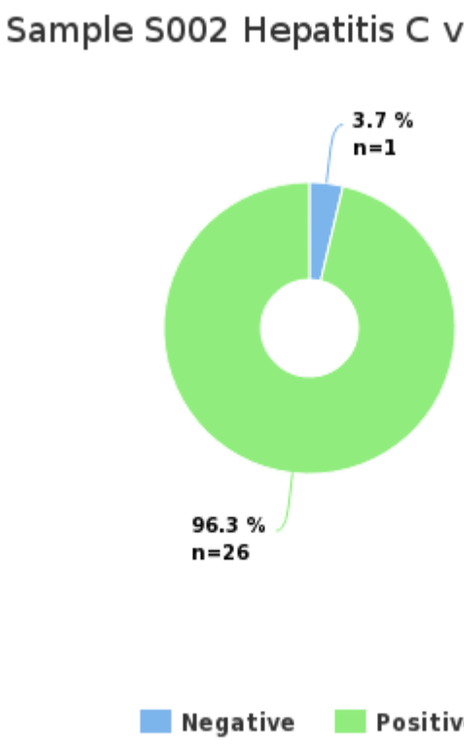
Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

Qualitative scoring report

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	Hepatitis C virus RNA	96.3 %	27
Total:		96.3 %	27

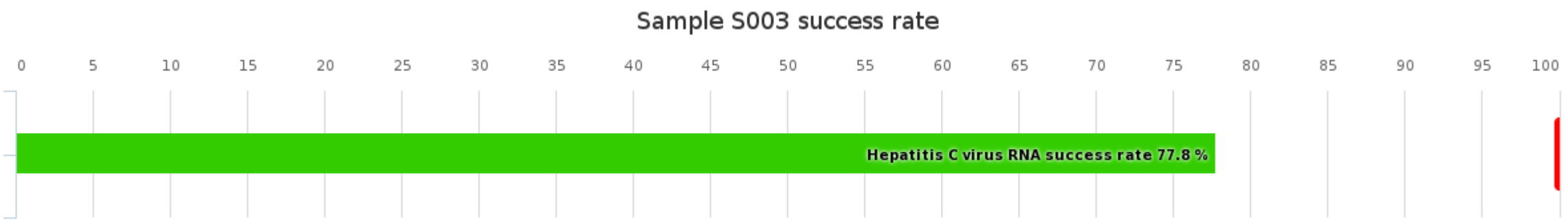


Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		1		0 %	0
		Roche COBAS HCV		1		
	Positive		26		100 %	2
		Abbott Alinity m HCV assay		3		
		Cepheid Xpert HCV Viral Load		8		
		DNA-Technology HCV Quantitative Real-Time PCR		1		
		GeneProof Hepatitis C Virus PCR Kit		1		
		Grifols Procleix Panther System		1		
		NeuMoDx HCV Quant Test Strip		1		
		Qiagen Artus HCV QS-RGQ kit		1		
		Qiagen Artus HCV RG RT-PCR Kit		1		
		Roche COBAS HCV		4		
		Roche COBAS MPX for 6800/8800 systems		4		
		Sacace HCV Real-TM Quant Dx		1		
	Total:		27		96.3 %	

Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

Qualitative scoring report

Sample S003



Sample S003 results	Responded	AVR success rate	Count
	Hepatitis C virus RNA	77.8 %	27
Total:		77.8 %	27

Hepatitis C virus RNA	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		21		100 %	2
		Abbott Alinity m HCV assay		2		
		Cepheid Xpert HCV Viral Load		5		
		DNA-Technology HCV Quantitative Real-Time PCR		1		
		GeneProof Hepatitis C Virus PCR Kit		1		
		NeuMoDx HCV Quant Test Strip		1		
		Qiagen Artus HCV QS-RGQ kit		1		
		Qiagen Artus HCV RG RT-PCR Kit		1		
		Roche COBAS HCV		4		
		Roche COBAS MPX for 6800/8800 systems		4		
		Sacace HCV Real-TM Quant Dx		1		
	Positive		6		0 %	0
		Abbott Alinity m HCV assay		1		
		Cepheid Xpert HCV Viral Load		3		
		Grifols Procleix Panther System		1		
		Roche COBAS HCV		1		
	Total:		27		77.8 %	

Hepatitis C virus, nucleic acid detection (RNA), March, 1-2023

Qualitative scoring report

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LABQUALITY

External Quality Assessment Scheme

Hepatitis C virus, RNA
Round 1, 2023

Specimens
Samples of this EQA round were lyophilized plasma. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable, and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ778523011)
HCV RNA: positive
Quantitative result according to the pre-testing was 1 250 000 IU/mL.

Sample S002 (LQ778523012)
HCV RNA: positive
Quantitative result according to the pre-testing was 32 IU/mL.

Sample S003 (LQ778523013)
HCV RNA: negative
Quantitative result according to the pre-testing was <15 IU/mL.

Pre-test method: Roche, cobas HCV

Report info
Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. The round is scored based on the qualitative results. The quantitative results from the HCV RNA positive samples, reported in unit IU/mL are presented in a separate laboratory-specific report as histograms as well as a numerical summary table. The quantitative results reported with < or > signs, or, if the HCV RNA level of the sample is >100 000 000 IU/mL, are not processed. The quantitative results cannot be compared statistically due to the low number of results. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – Expert
For samples S001 and S002 the round was problem-free. The expected result of the sample S003 was negative, which most laboratories did report. A few laboratories got a positive result, most probably due to either sample contamination or sample mix-up.

Exceptions in scoring
No exceptions.

End of report

2023-04-17

FINAL REPORT

Product no. 5678

Subcontracting: Sample pretesting

Samples sent	2023-03-07
Round closed	2023-04-03
Expected results	2023-04-06
Final report	2023-04-17

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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