LABQUALITY

External Quality Assessment Scheme

Human papillomavirus, nucleic acid detection
Round 1, 2023

Specimens
Please find enclosed 2 liquid samples S001 and S002, each 1 mL. The samples simulate clinical samples.

Caution
The samples are inactivated and should contain no infectious material. However, they should be handled with the same care as normal patient samples, capable of transmitting infectious disease. The buffer solution contains methanol as a preservative. Follow the standard operating procedure of your laboratory for disposal of the samples.

Examinations
Human papillomavirus, nucleic acid detection.

Storage and use
After arrival, the samples should be stored at +2…8 °C, and used as soon as possible, preferably within a week. The samples are ready for use. Mix the samples thoroughly by vortexing the vial for approximately 30 seconds prior to use. Analyse as patient samples and follow the instructions given by the test manufacturer.

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

2023-01-24

INSTRUCTIONS

Product no. 5086
LQ775423011-012/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 16, 2023**.

The expected results of the round are published in LabScala in the View Reports section by February 21, 2023.

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

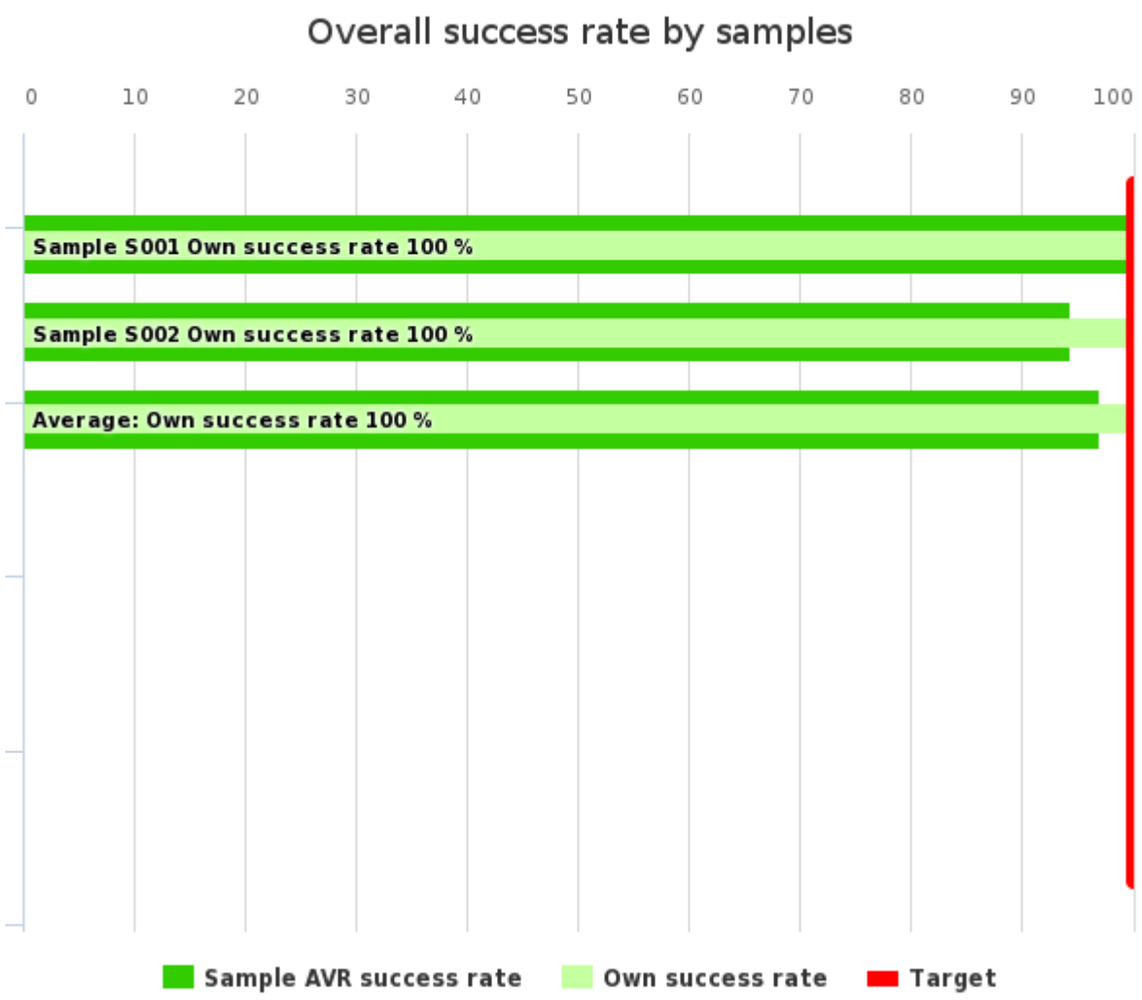
Quality Management
ISO 9001:2015

LABQUALITY Human papillomavirus,nucleic acid detection, January, 1-2023 XXXX

Client report

	No of participants	No of responded participants	Response percentage
Human papillomavirus,nucleic acid detection, January, 1-2023	31	31	100 %

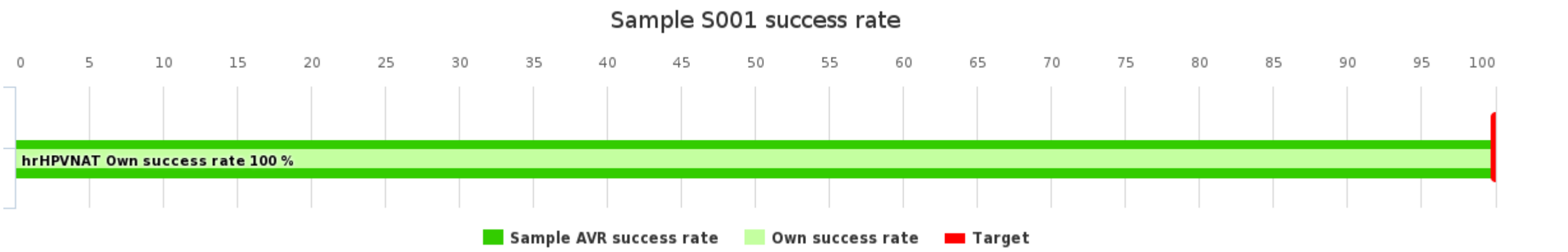
Summary



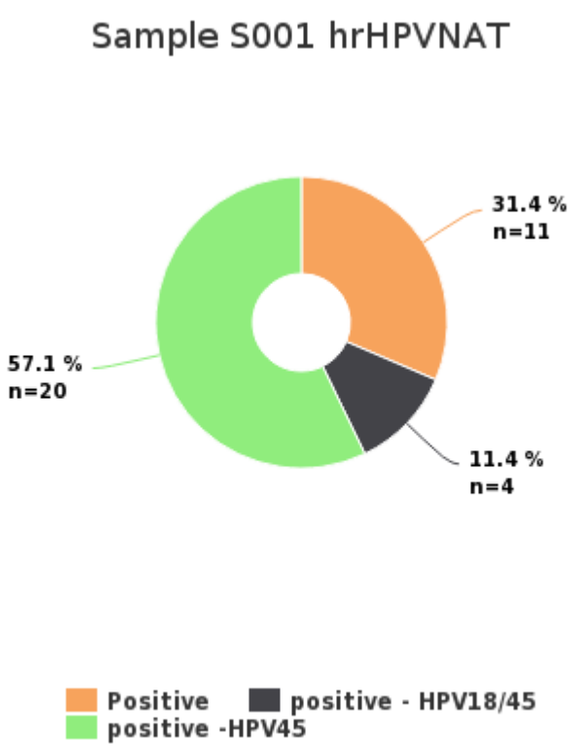
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	2	2	100 %	5.7 %	94.3 %
Average:			100 %	2.9 %	97.1 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	0 %	100 %
Round 2022-2	1-1	100 %	5.4 %	94.6 %
Round 2021-2	1-1	100 %	3.1 %	96.9 %
Round 2021-1	1-1	100 %	4.3 %	95.7 %
Round 2020-2	1-1	100 %	0 %	100 %
Round 2020-1	1-1	100 %	4.3 %	95.7 %
Round 2019-2	1-1	100 %	9.3 %	90.7 %
Round 2019-1	1-1	100 %	3.8 %	96.2 %

Sample S001



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	hrHPVNAT	2	2	100 %	0 %	100 %	35
Total:		2	2	100 %	0 %	100 %	35

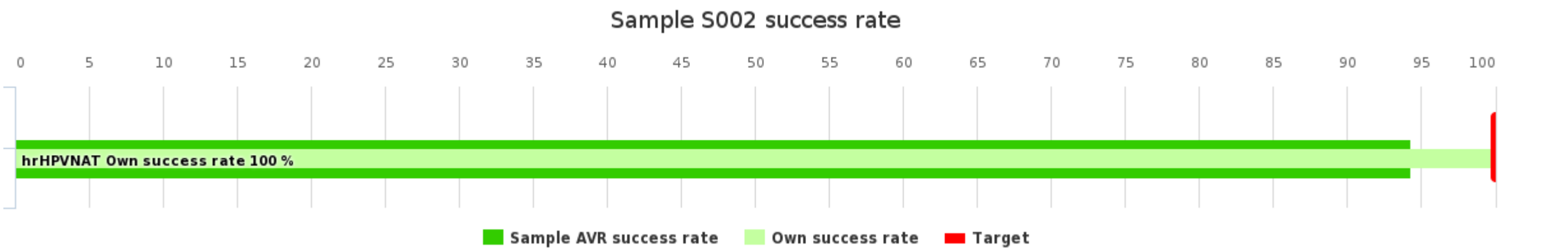


OWN DEVICE: HPV

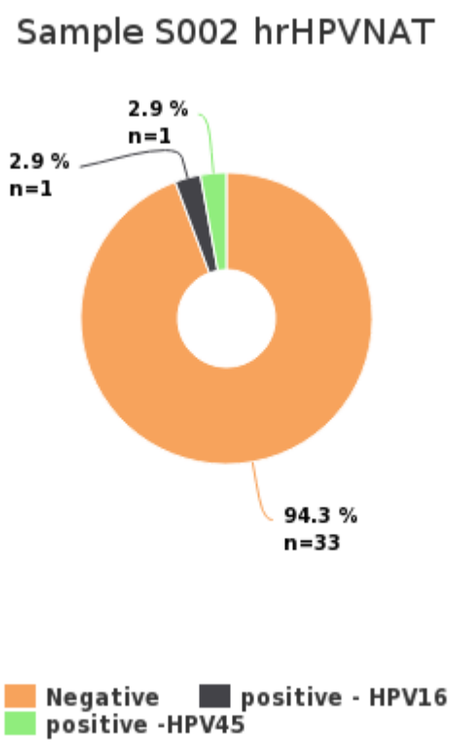
hrHPVNAT	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		11		-				100 %
		ELITe High Risk HPV Panel		1					
		Hologic Aptima HPV Assay		1					
		NeuMoDx HPV Test Strip		1					
		Roche cobas HPV		6					
		Sansure Biotech HPV Genotype		1					
		Sansure Biotech Human Papillomavirus DNA Diagnostic Kit (PCR-Fluorescence Probing)		1					
	positive - HPV18/45		4		-				100 %
		Cepheid Xpert HPV		3					
		Hologic Aptima HPV Assay		1					
	positive -HPV45		20		2	2	100 %	0 %	100 %
		Abbott Alinity m HR HPV		2					
		Abbott High Risk HPV Amplification		1					
		Amoy Diagnostics Human Papillomavirus (HPV) Genotyping Detection Kit		1					
		Anyplex II HPV HR Detection		2					
		BD Onclarity HPV Assay		3					
		BIORON RealLine HPV HCR Genotype (Fla-format)		1					
		Euroimmun EUROArray HPV		1					
		GeneProof Human Papilloma Virus (HPV) Screening PCR Kit		1					
		Genomica CLART HPV2		1					
		Genomica CLART HPV3		2					
		OSANTYS 15 HR-HPV qPCR KIT		1					

		Sacace Biotechnologies HPV Genotypes 21 Real-TM Quant		1					
		Seegene Anyplex II HPV28 Detection		3					
	Total:		35		2	2	100 %	0 %	100 %

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	hrHPVNAT	2	2	100 %	5.7 %	94.3 %	35
Total:		2	2	100 %	5.7 %	94.3 %	35



OWN DEVICE: HPV

hrHPVNAT	Result	Method	Result count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		33		2	2	100 %	0 %	100 %
		Abbott Alinity m HR HPV		2					
		◉ Abbott High Risk HPV Amplification		1					
		Amoy Diagnostics Human Papillomavirus (HPV) Genotyping Detection Kit		1					
		Anyplex II HPV HR Detection		1					
		BD Onclarity HPV Assay		3					
		BIORON RealLine HPV HCR Genotype (Fla-format)		1					
		Cepheid Xpert HPV		3					
		ELITe High Risk HPV Panel		1					
		Euroimmun EUROArray HPV		1					
		GeneProof Human Papilloma Virus (HPV) Screening PCR Kit		1					
		Genomica CLART HPV2		1					
		Genomica CLART HPV3		2					
		Hologic Aptima HPV Assay		2					
		NeuMoDx HPV Test Strip		1					
		OSANTYS 15 HR-HPV qPCR KIT		1					
		Roche cobas HPV		6					
		Sacace Biotechnologies HPV Genotypes 21 Real-TM Quant		1					
		Sansure Biotech HPV Genotype		1					
		Sansure Biotech Human Papillomavirus DNA Diagnostic Kit (PCR-Fluorescence Probing)		1					
		Seegene Anyplex II HPV28 Detection		2					
	positive - HPV16		1		-				0 %

		Seegene Anyplex II HPV28 Detection		1					
	positive -HPV45		1		-				0 %
		Anyplex II HPV HR Detection		1					
	Total:		35		2	2	100 %	5.7 %	94.3 %

Report Info

PARTICIPANTS

Altogether 31 laboratories from 12 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.
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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.

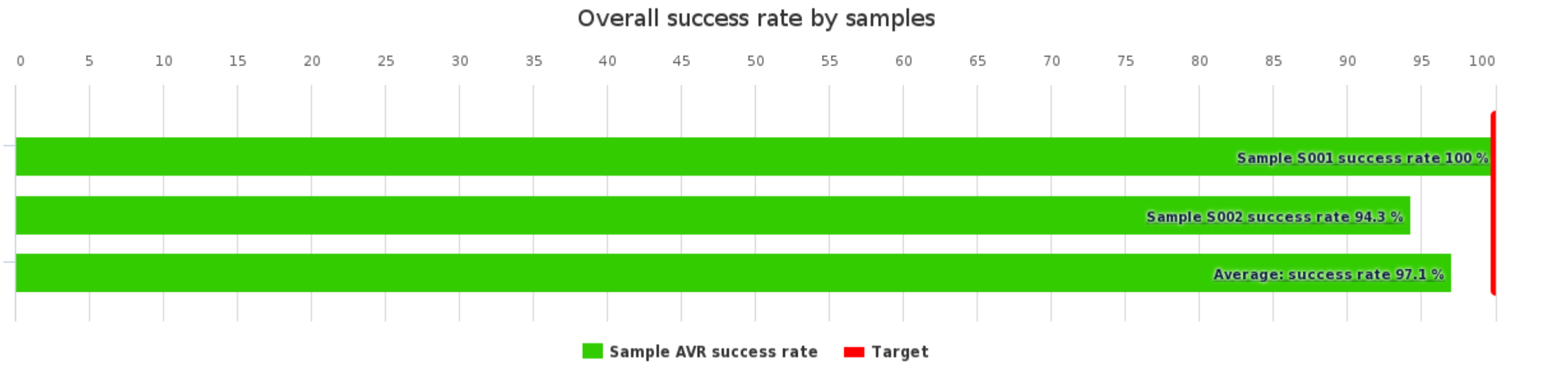
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

LABQUALITY Human papillomavirus,nucleic acid detection, January, 1-2023

GLOBAL REPORT

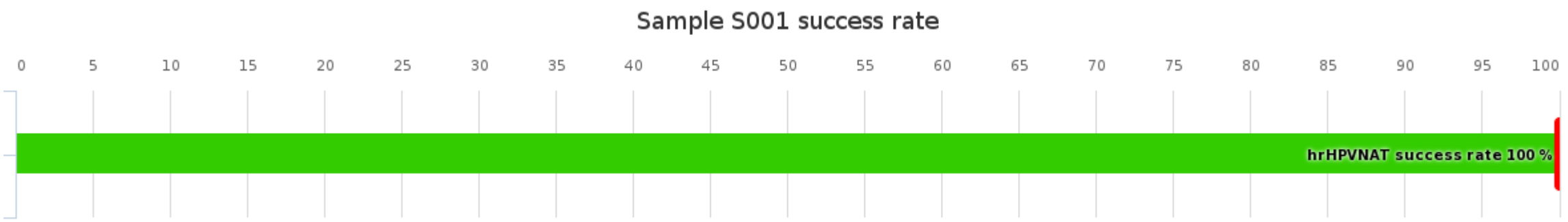
	No of participants	No of responded participants	Response percentage
Human papillomavirus,nucleic acid detection, January, 1-2023	31	31	100 %

Summary

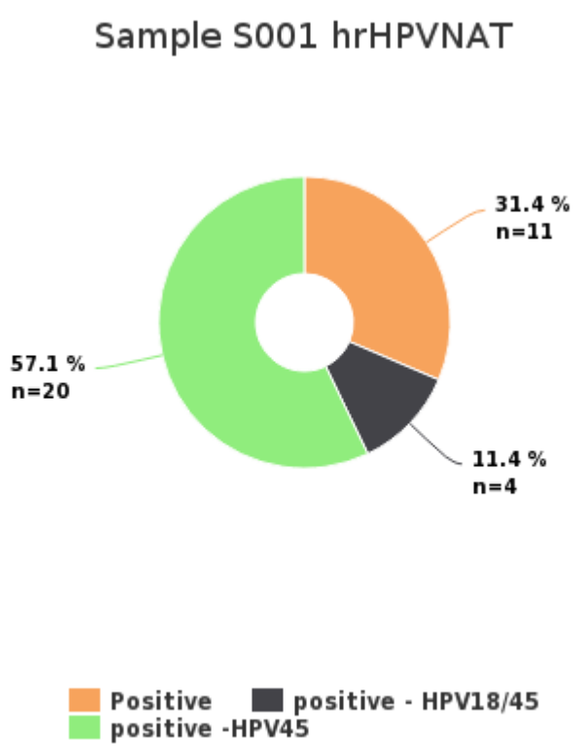


Summary	AVR success rate
Sample S001	100 %
Sample S002	94.3 %
Average:	97.1 %

Sample S001

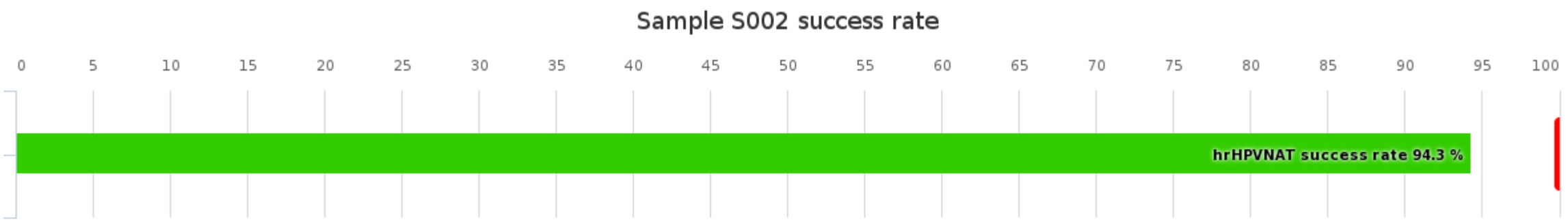


Sample S001 results	Responded	AVR success rate	Count
	hrHPVNAT	100 %	35
Total:		100 %	35

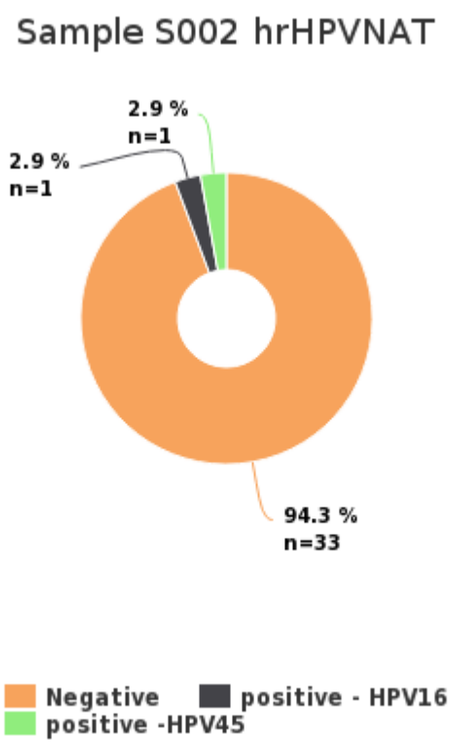


hrHPVNAT	Result	Method	Result count	Method count	AVR success rate	Result Score
	Positive		11		100 %	2
		ELITe High Risk HPV Panel		1		
		Hologic Aptima HPV Assay		1		
		NeuMoDx HPV Test Strip		1		
		Roche cobas HPV		6		
		Sansure Biotech HPV Genotype		1		
		Sansure Biotech Human Papillomavirus DNA Diagnostic Kit (PCR-Fluorescence Probing)		1		
	positive - HPV18/45		4		100 %	2
		Cepheid Xpert HPV		3		
		Hologic Aptima HPV Assay		1		
	positive -HPV45		20		100 %	2
		Abbott Alinity m HR HPV		2		
		Abbott High Risk HPV Amplification		1		
		Amoy Diagnostics Human Papillomavirus (HPV) Genotyping Detection Kit		1		
		Anyplex II HPV HR Detection		2		
		BD Onclarity HPV Assay		3		
		BIORON RealLine HPV HCR Genotype (Fla-format)		1		
		Euroimmun EUROArray HPV		1		
		GeneProof Human Papilloma Virus (HPV) Screening PCR Kit		1		
		Genomica CLART HPV2		1		
		Genomica CLART HPV3		2		
		OSANTYS 15 HR-HPV qPCR KIT		1		
		Sacace Biotechnologies HPV Genotypes 21 Real-TM Quant		1		
		Seegene Anyplex II HPV28 Detection		3		
	Total:		35		100 %	

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	hrHPVNAT	94.3 %	35
Total:		94.3 %	35



hrHPVNAT	Result	Method	Result count	Method count	AVR success rate	Result Score
	Negative		33		100 %	2
		Abbott Alinity m HR HPV		2		
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		OSANTYS 15 HR-HPV qPCR KIT		1		
		Roche cobas HPV		6		
		Sacace Biotechnologies HPV Genotypes 21 Real-TM Quant		1		
		Sansure Biotech HPV Genotype		1		
		Sansure Biotech Human Papillomavirus DNA Diagnostic Kit (PCR-Fluorescence Probing)		1		
		Seegene Anyplex II HPV28 Detection		2		
	positive - HPV16		1		0 %	0
		Seegene Anyplex II HPV28 Detection		1		
	positive -HPV45		1		0 %	0
		Anyplex II HPV HR Detection		1		
	Total:		35		94.3 %	

LABQUALITY Human papillomavirus,nucleic acid detection, January, 1-2023

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LABQUALITY

External Quality Assessment Scheme

Human papillomavirus, nucleic acid detection
Round 1, 2023

Specimens
Samples were liquid artificial samples containing human DNA. 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 accepted results were as follows:

Sample S001 (LQ775423011)
hrHPVNAT Positive
Positive, HPV 45
Positive, HPV 18/45

Sample S002 (LQ775423012)
hrHPVNAT 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
Altogether 31 laboratories participated in the first Papillomavirus (HPV) round in 2023, and 35 result reports were received from 31 participants. The round consisted of one HPV 45 positive sample (S001) and one HPV negative sample (S002).

Sample S001 was HPV 45 positive. All 35 results were correct (100%). Altogether 20 “positive – HPV 45” results, 4 “positive – HPV 18/45” results and 11 “positive” results were reported.

Sample S002 was HPV negative. Of all reported results 33 were correct (94.3%) and 2 were false. One participant reported a false “positive – HPV 16” result and one participant a false “positive – HPV 45” result.

The round was completed successfully. HPV 45 is one of the important high-risk HPV genotypes. All participants succeeded in detecting high risk HPV in sample S001. The responders had used 20 different HPV assays, most of which provided genotyping. On the HPV positive sample S001 altogether 24 of 35 replies (68.6%) reported either genotype HPV 45 or HPV 18/45.

Exceptions in scoring
No exceptions.

End of report

2023-03-02

FINAL REPORT

Product no. 5086

Samples sent	2023-01-24
Round closed	2023-02-16
Expected results	2023-02-17
Final report	2023-03-02

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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