LABQUALITY

External Quality Assessment Scheme

Monkeypox virus, nucleic acid detection Round 1, 2022 (pilot)

Specimens
Please find enclosed 2 simulated swab samples S001 and S002. Samples do not need to be inactivated.

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
Monkeypox virus (MPXV) NAT

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 (1-3 mL) and rotate to dislodge as much material as possible. You can also cut the swab into the sample collection tube.
3. Recap the collection tube and mix thoroughly to ensure that all of the sample material is mixed with the transport media.
4. Follow the test manufacturer's instructions for sample extraction and detection.

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. Please also report on the e-form the elution buffer and volume used to elute the sample swabs, as well as the quantitative results of the samples (Ct value). Scoring is based on the qualitative results (interpretation).

It is possible to report three results from the same sample, if the sample volume is sufficient for several analyses. To open a new result form, press the "Add result +" button on the right side of the blue bar for each sample in LabScala.

S001

LQ776522011

S002

LQ776522012

2022-11-29

INSTRUCTIONS

Product no. 5683
LQ776522011-012/CA

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 **December 22, 2022**.

The expected results of the round are published in LabScala in the View Reports section by December 27, 2022.

Inquiries
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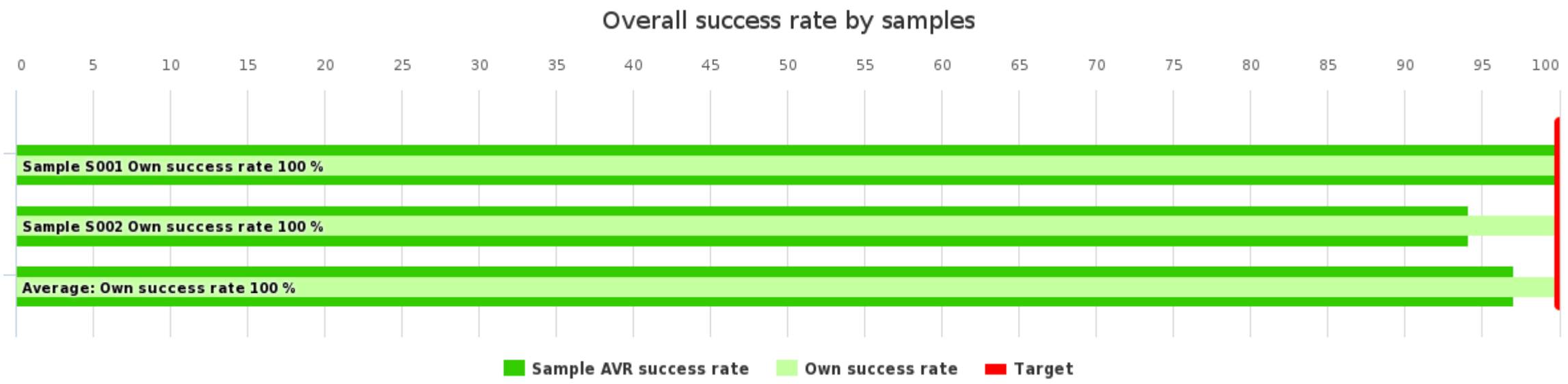
Client report

	No of participants	No of responded participants	Response percentage
PILOT ROUND: Monkeypox virus, nucleic acid detection, November, 1-2022	33	29	87.9 %

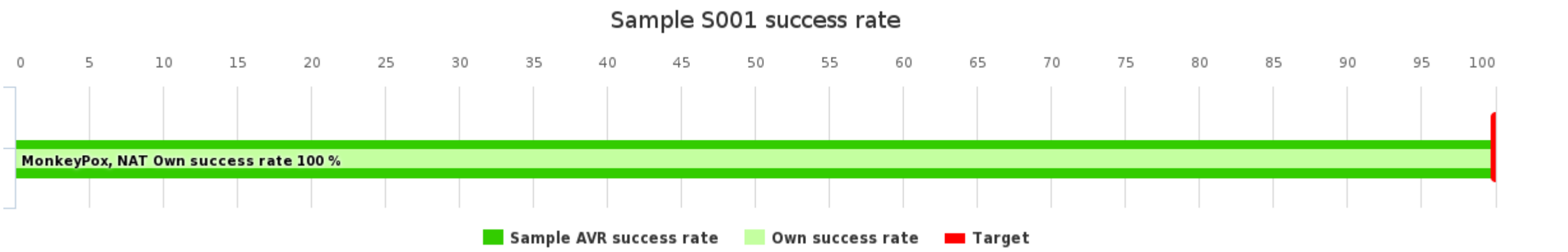
Summary



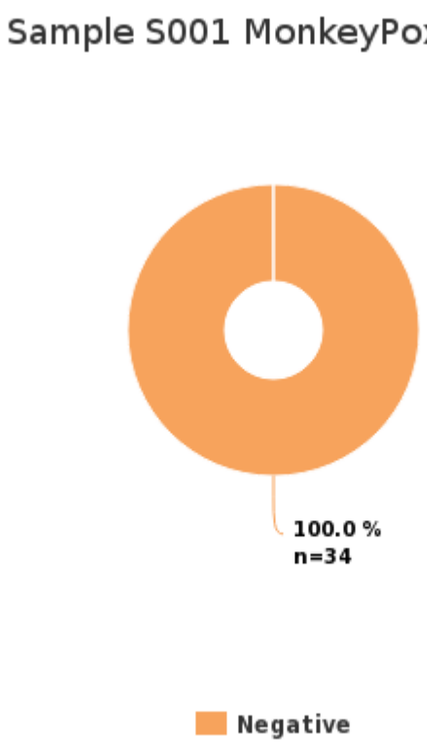
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	2	2	100 %	5.9 %	94.1 %
Average:			100 %	2.9 %	97.1 %

History	Test nr.	Own success rate	Difference	AVR success rate
History not found				

Sample S001

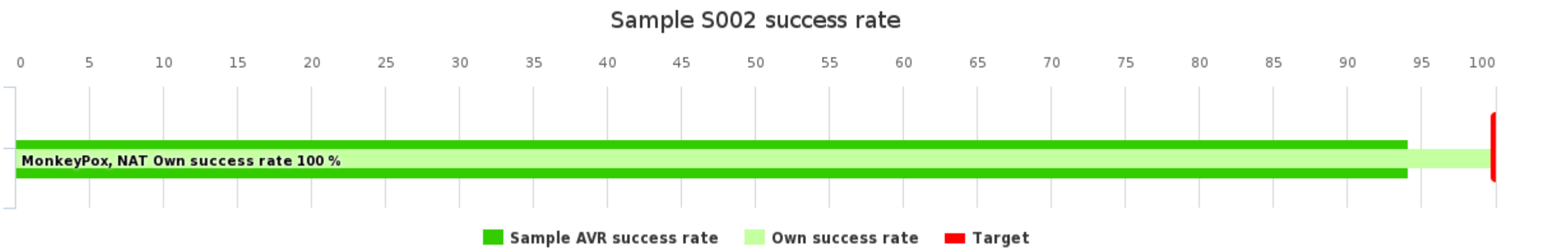


Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	MonkeyPox, NAT	2	2	100 %	0 %	100 %	34
Total:		2	2	100 %	0 %	100 %	34

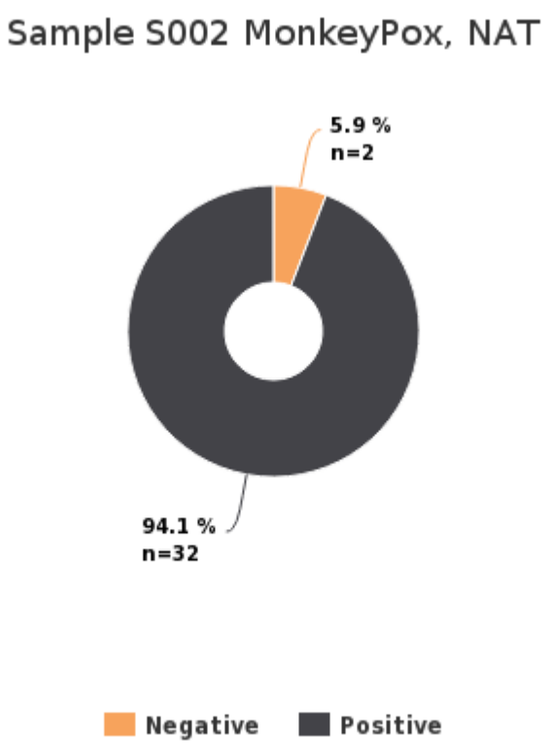


MonkeyPox, NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		34		2	2	100 %	0 %	100 %
		Abiom Monkeypox Virus Detection Kit		4					
		Altona Diagnostics RealStar® Orthopoxvirus PCR Kit 1.0		1					
		AMD ZENA Max Monkeypox Virus (MPXV) PCR Kit		1					
		BioPerfectus Monkeypox Virus Genotyping Real Time PCR Kit		5					
		Bosphore Monkeypox Detection Kit v1		1					
		ID Solutions iSolutions™ Monkeypox Fullplex qPCR kit		1					
		In house		9					
		Mole Bioscience Monkeypox Virus Nucleic Acid Detection Kit		3					
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		2					
		TIB Molbiol/Roche LightMix Modular Orthopox Virus		2					
		◉ VIASURE Monkeypox virus Real Time PCR Detection Kits		4					
		Vircell MONKEYPOX Real-time PCR		1					
	Total:		34		2	2	100 %	0 %	100 %

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	MonkeyPox, NAT	2	2	100 %	5.9 %	94.1 %	34
Total:		2	2	100 %	5.9 %	94.1 %	34



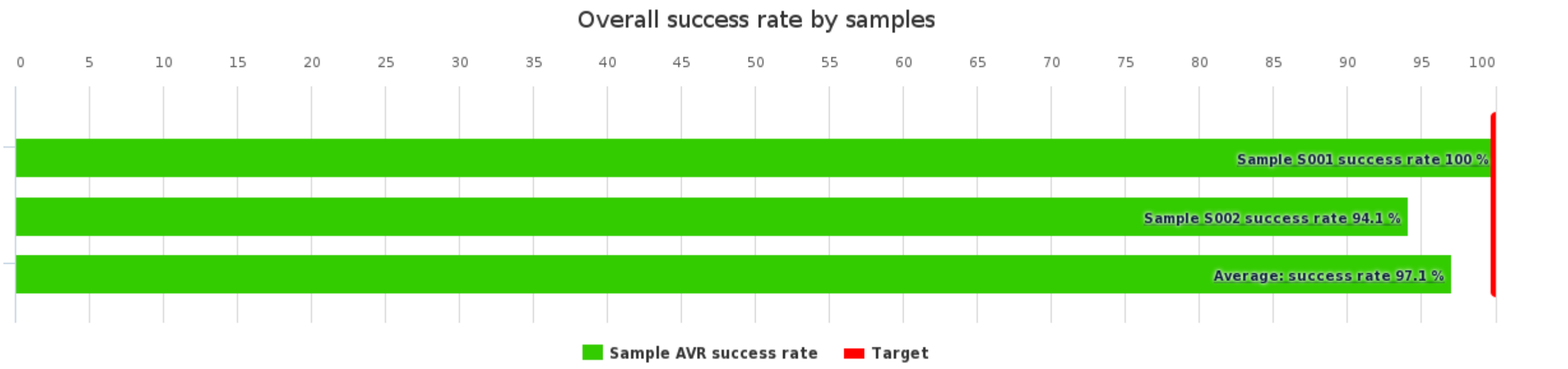
MonkeyPox, NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		In house		1					
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		1					
	◉ Positive		32		2	2	100 %	0 %	100 %
		Abiom Monkeypox Virus Detection Kit		4					
		Altona Diagnostics RealStar® Orthopoxvirus PCR Kit 1.0		1					
		AMD ZENA Max Monkeypox Virus (MPXV) PCR Kit		1					
		BioPerfectus Monkeypox Virus Genotyping Real Time PCR Kit		5					
		Bosphore Monkeypox Detection Kit v1		1					
		ID Solutions iSolutions™ Monkeypox Fullplex qPCR kit		1					
		In house		8					
		Mole Bioscience Monkeypox Virus Nucleic Acid Detection Kit		3					
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		1					
		TIB Molbiol/Roche LightMix Modular Orthopox Virus		2					
		◉ VIASURE Monkeypox virus Real Time PCR Detection Kits		4					
		Vircell MONKEYPOX Real-time PCR		1					
	Total:		34		2	2	100 %	5.9 %	94.1 %

Monkeypox virus, nucleic acid detection, November, 1-2022

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
PILOT ROUND: Monkeypox virus, nucleic acid detection, November, 1-2022	33	29	87.9 %

Summary



Summary	AVR success rate
Sample S001	100 %
Sample S002	94.1 %
Average:	97.1 %

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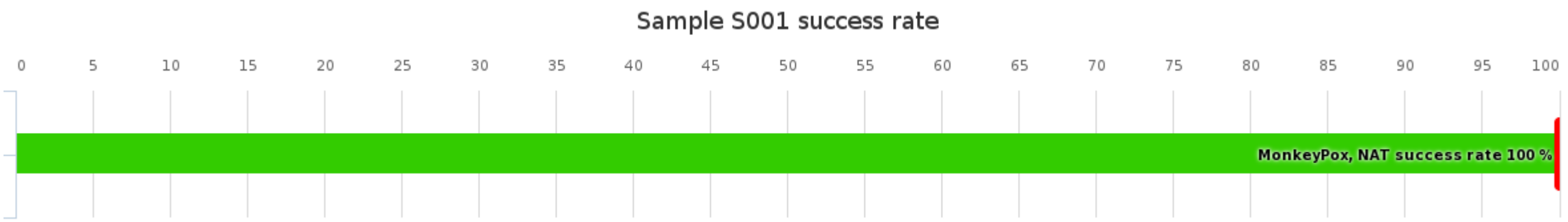
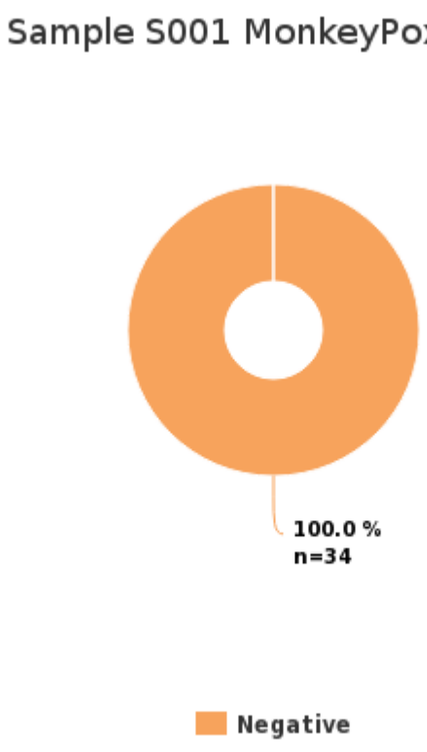
Monkeypox virus, nucleic acid detection, November, 1-2022

Sample S001



Sample S001 results	Responded	AVR success rate	Count
	MonkeyPox, NAT	100 %	34
Total:		100 %	34



MonkeyPox, NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		34		100 %	2
		Abiom Monkeypox Virus Detection Kit		4		
		Altona Diagnostics RealStar® Orthopoxvirus PCR Kit 1.0		1		
		AMD ZENA Max Monkeypox Virus (MPXV) PCR Kit		1		
		BioPerfectus Monkeypox Virus Genotyping Real Time PCR Kit		5		
		Bosphore Monkeypox Detection Kit v1		1		
		ID Solutions iSolutions™ Monkeypox Fullplex qPCR kit		1		
		In house		9		
		Mole Bioscience Monkeypox Virus Nucleic Acid Detection Kit		3		
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		2		
		TIB Molbiol/Roche LightMix Modular Orthopox Virus		2		
		VIASURE Monkeypox virus Real Time PCR Detection Kits		4		
		Vircell MONKEYPOX Real-time PCR		1		
	Total:		34		100 %	

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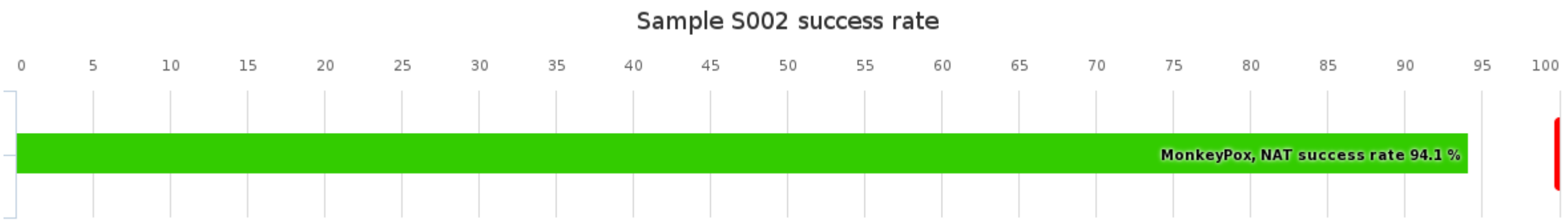
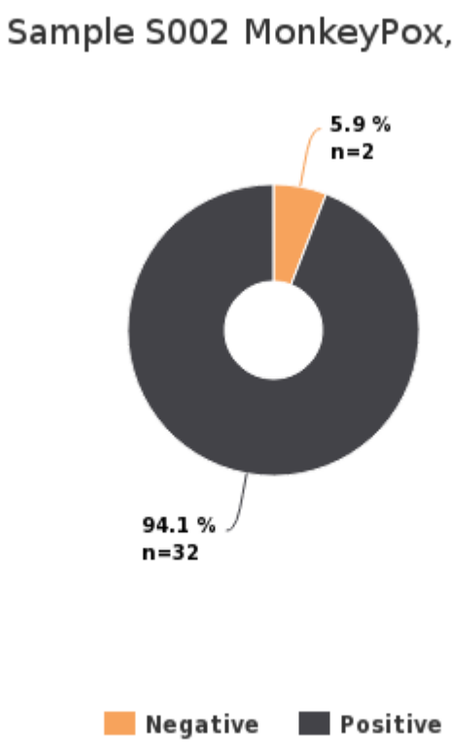
Monkeypox virus, nucleic acid detection, November, 1-2022

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	MonkeyPox, NAT	94.1 %	34
Total:		94.1 %	34



MonkeyPox, NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		2		0 %	0
		In house		1		
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		1		
	Positive		32		100 %	2
		Abiom Monkeypox Virus Detection Kit		4		
		Altona Diagnostics RealStar® Orthopoxvirus PCR Kit 1.0		1		
		AMD ZENA Max Monkeypox Virus (MPXV) PCR Kit		1		
		BioPerfectus Monkeypox Virus Genotyping Real Time PCR Kit		5		
		Bosphore Monkeypox Detection Kit v1		1		
		ID Solutions iSolutions™ Monkeypox Fullplex qPCR kit		1		
		In house		8		
		Mole Bioscience Monkeypox Virus Nucleic Acid Detection Kit		3		
		Shanghai ZJ BIO-TECH Monkeypox Virus Real Time PCR Kit		1		
		TIB Molbiol/Roche LightMix Modular Orthopox Virus		2		
		VIASURE Monkeypox virus Real Time PCR Detection Kits		4		
		Vircell MONKEYPOX Real-time PCR		1		
	Total:		34		94.1 %	

LABQUALITY

External Quality Assessment Scheme

Monkeypox virus, nucleic acid detection Round 1, 2022 (pilot)

Thank you for participating in the pilot round. For further development of Monkeypox virus EQA we kindly ask you to fill in the short survey in this link. In 2023, one Monkeypox virus EQA round will be performed in October. Please register as soon as possible in LabScala or through your local distributor.

Specimens
The samples of this EQA round were simulated swab 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 and stable. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ776522011)
Monkeypox virus (MPXV) NAT Negative

Sample S002 (LQ776522012)
Monkeypox virus (MPXV) NAT Positive, Ct value 29.45 (average Ct value of pre-test methods)

Pre-test methods: Mole Bioscience Monkeypox Virus Nucleic Acid Detection Kit, Promotor Monkeypox Virus Real Time PCR Test Kit and three laboratory developed tests (in-house).

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
33 participants had signed up for the pilot round of monkeypox virus nucleic acid detection and the response rate was 87.9%. Of the participants, 25 had used a commercial test, which were a total of 11 different groups. Nine of the respondents had used laboratory developed test (in-house).

The round went well overall. The success rate for sample S001 was 100% and for sample S002 94.1%. The average Ct value for the positive sample S002 was 31.35 and standard deviation was 2.08. The differences between Ct values with different test may be explained by the pretreatment of the sample, i.e., the dissolving volume (1-3 mL) or elution volume of the nucleic acids. In addition to this, different tests use different amounts of nucleic acid in their rection.

Exceptions in scoring
No exceptions.

End of report

2023-01-17

FINAL REPORT

Product no. 5683

Subcontracting: Sample pretesting

Samples sent	2022-11-29
Round closed	2022-12-22
Expected results	2023-01-09
Final report	2023-01-17

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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