

External Quality Assessment Scheme

## HSV1&2/VZV/*T.pallidum*, nucleic acid detection Round 1, 2023

### Specimens

Please find enclosed 2 samples, S001 and S002, that simulate swab samples taken from genital lesions.

### 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

Herpes Simplex Virus type 1 (HSV1 NAT)  
Herpes Simplex Virus type 2 (HSV2 NAT)  
Varicella Zoster Virus (VZV NAT)  
*Treponema pallidum* (*T. pallidum* NAT)

### Storage and use

After arrival, the samples should be stored unopened at +2...30°C until use.

1. Elute the swabs described in the assay instructions for use (usually 1-3 mL).
2. From the eluted swab, use the appropriate volume for the nucleic acid extraction step according to the assay instructions for use (usually 100-1000 µL).
3. After extraction, proceed with the NAT by using the eluted nucleic acid test volume specified in the assay instructions for use (usually 5-20 µL). Perform the analysis according to the assay instructions.

### Result reporting

Please enter the results and methods via LabScala ([www.labscala.com](http://www.labscala.com)). If you cannot find your test from the registry, please contact the EQA Coordinator. Report only the results of examinations that are in use in your laboratory. All reported examinations will be scored.

S001



S002



2023-04-25

### INSTRUCTIONS

Product no. 5556  
LQ776423011-012/CA

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi).

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The results should be reported no later than **May 18, 2023.**

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The expected results of the round are published in LabScala in the View Reports section by May 23, 2023.

### Inquiries

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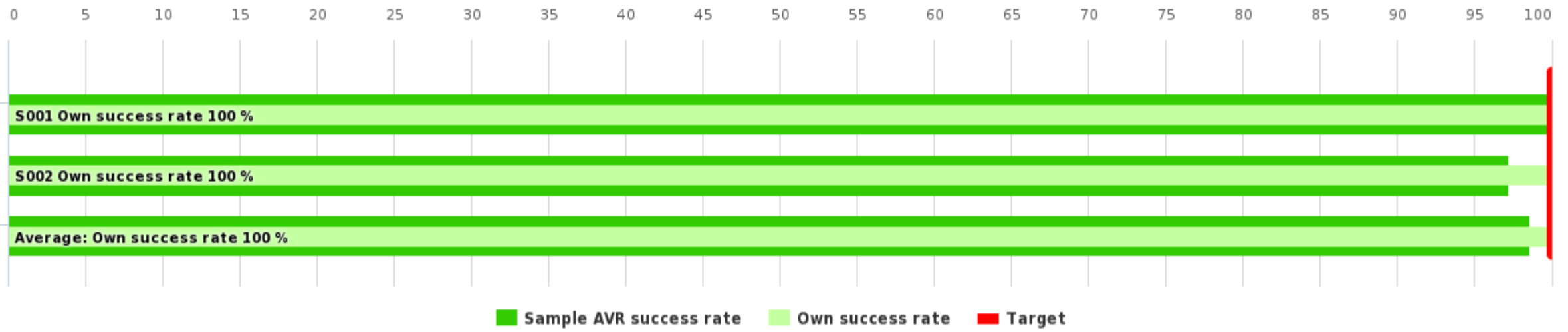


Client report

	No of participants	No of responded participants	Response percentage
HSV1&2/VZV/T.pallidum, nucleic acid detection, April, 1-2023	23	23	100 %

Summary

Overall success rate by samples

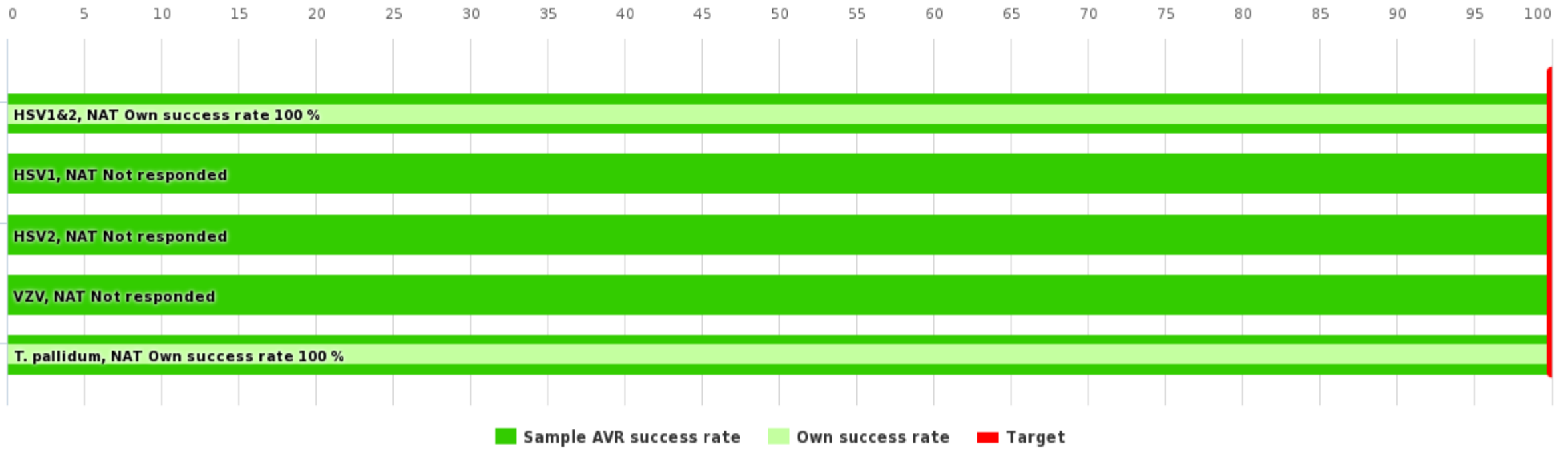


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
S001	4	4	100 %	0 %	100 %
S002	4	4	100 %	2.8 %	97.2 %
Average:			100 %	1.4 %	98.6 %

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

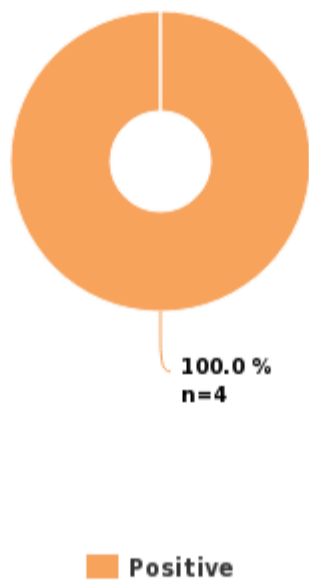
S001 | HSV-1

S001 success rate

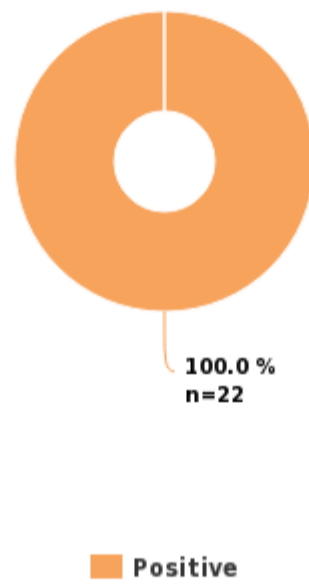


S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HSV1&2, NAT	2	2	100 %	0 %	100 %	4
	HSV1, NAT	-	-	-	-	100 %	22
	HSV2, NAT	-	-	-	-	100 %	21
	VZV, NAT	-	-	-	-	100 %	16
	T. pallidum, NAT	2	2	100 %	0 %	100 %	8
Total:		4	4	100 %	0 %	100 %	71

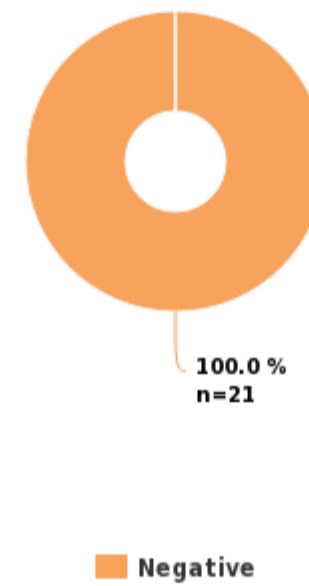
S001 HSV1&2, NAT



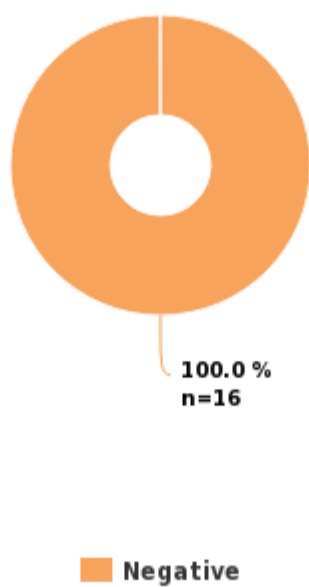
S001 HSV1, NAT



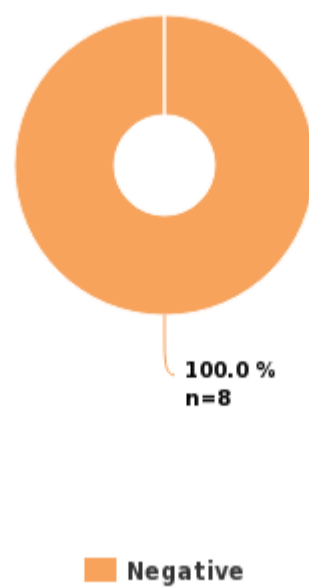
S001 HSV2, NAT



S001 VZV, NAT



S001 T. pallidum, NAT



HSV1&2, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		4		2	2	100 %	0 %	100 %
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1					
		DNA-Technology HSV 1,2		2					
		<input checked="" type="radio"/> Sacace Biotechnologies HSV I/II Real-TM		1					
	Total:		4		2	2	100 %	0 %	100 %

HSV1, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		22		-				100 %
		AmpliSens HSV-typing-FRT PCR kit		1					
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1					
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2					
		ELITechGroup HSV1 ELITe MGB Kit		1					
		In-house PCR		8					
		Luminex ARIES HSV 1&2 Assay		1					
		Meridian Bioscience Alethia HSV 1&2		1					
		Qiagen artus HSV-1/2		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		22		-	-	-	-	100 %

HSV2, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		21		-				100 %
		AmpliSens HSV-typing-FRT PCR kit		1					
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1					
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2					
		In-house PCR		8					
		Luminex ARIES HSV 1&2 Assay		1					
		Meridian Bioscience Alethia HSV 1&2		1					
		Qiagen artus HSV-1/2		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		21		-	-	-	-	100 %

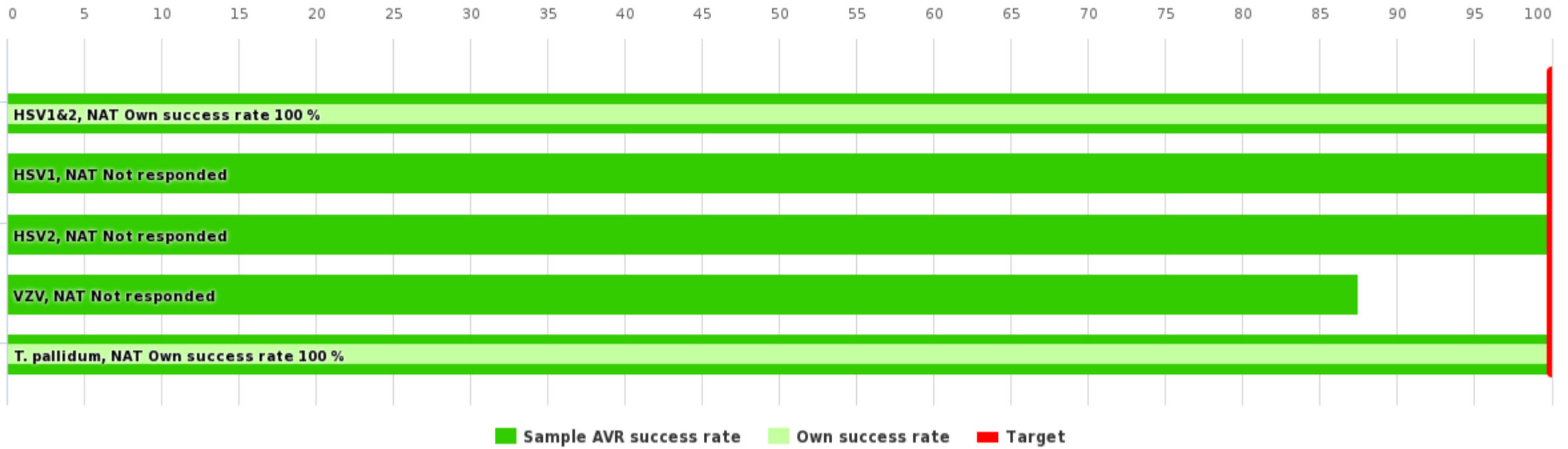
VZV, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		16		-				100 %
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1					
		DiaSorin Simplexa VZV Swab Direct Kit		2					
		In-house PCR		6					
		Qiagen artus VZV		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		16		-	-	-	-	100 %

T. pallidum, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		8		2	2	100 %	0 %	100 %
		AmpliSens Treponema pallidum-FRT PCR kit		1					
		GeneProof Treponema pallidum PCR Kit		1					
		In-house PCR		1					
		<input checked="" type="radio"/> Sacace Biotechnologies Treponema pallidum Real-TM		1					

		Seegene Allplex Genital ulcer Assay		4					
	Total:		8		2	2	100 %	0 %	100 %

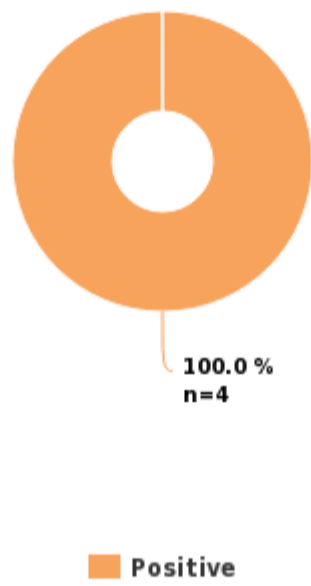
S002 | HSV-1, HSV-2, VZV, Treponema pallidum

S002 success rate

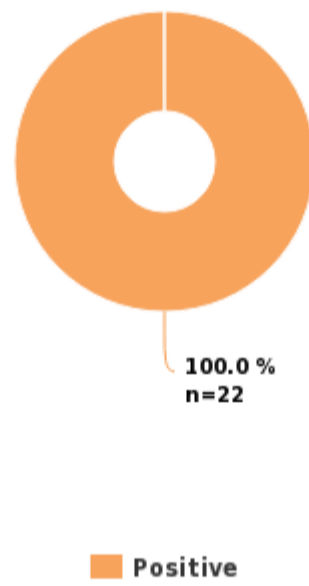


S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HSV1&2, NAT	2	2	100 %	0 %	100 %	4
	HSV1, NAT	-	-	-	-	100 %	22
	HSV2, NAT	-	-	-	-	100 %	21
	VZV, NAT	-	-	-	-	87.5 %	16
	T. pallidum, NAT	2	2	100 %	0 %	100 %	8
	Total:	4	4	100 %	2.8 %	97.2 %	71

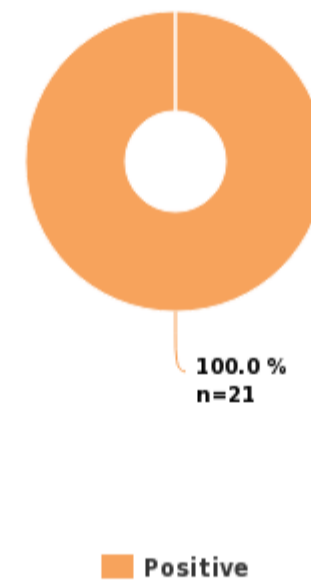
S002 HSV1&2, NAT



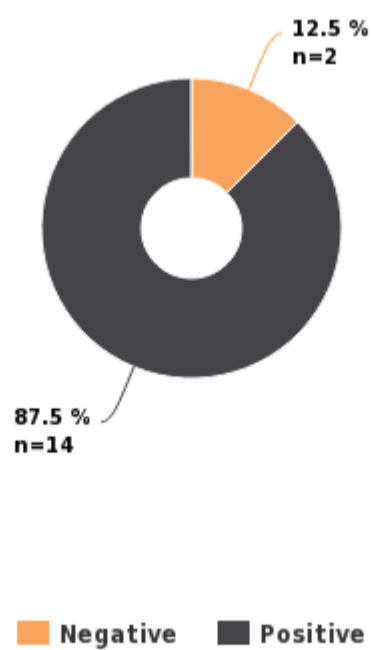
S002 HSV1, NAT



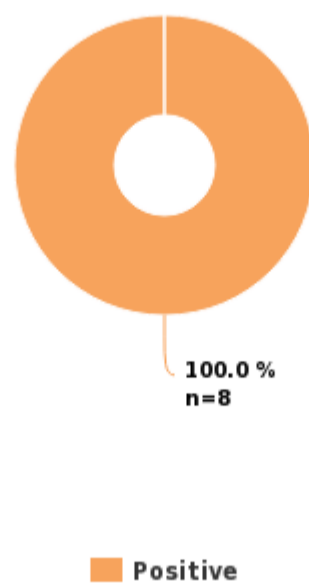
S002 HSV2, NAT



S002 VZV, NAT



S002 T. pallidum, NAT



HSV1&2, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		4		2	2	100 %	0 %	100 %
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1					
		DNA-Technology HSV 1,2		2					
		<input checked="" type="radio"/> Sacace Biotechnologies HSV I/II Real-TM		1					
	Total:		4		2	2	100 %	0 %	100 %

HSV1, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		22		-				100 %
		AmpliSens HSV-typing-FRT PCR kit		1					
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1					
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2					
		ELITechGroup HSV1 ELITe MGB Kit		1					
		In-house PCR		8					
		Luminex ARIES HSV 1&2 Assay		1					
		Meridian Bioscience Alethia HSV 1&2		1					
		Qiagen artus HSV-1/2		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		22		-	-	-	-	100 %

HSV2, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		21		-				100 %
		AmpliSens HSV-typing-FRT PCR kit		1					
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1					
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2					
		In-house PCR		8					
		Luminex ARIES HSV 1&2 Assay		1					
		Meridian Bioscience Alethia HSV 1&2		1					
		Qiagen artus HSV-1/2		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		21		-	-	-	-	100 %

VZV, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		In-house PCR		1					
		Seegene Allplex Genital ulcer Assay		1					
	Positive		14		-				100 %
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2					
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1					
		DiaSorin Simplexa VZV Swab Direct Kit		2					
		In-house PCR		5					
		Qiagen artus VZV		1					
		Seegene Allplex Genital ulcer Assay		3					
	Total:		16		-	-	-	-	87.5 %

T. pallidum, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		8		2	2	100 %	0 %	100 %
		AmpliSens Treponema pallidum-FRT PCR kit		1					

		GeneProof Treponema pallidum PCR Kit		1					
		In-house PCR		1					
		<input checked="" type="radio"/> Sacace Biotechnologies Treponema pallidum Real-TM		1					
		Seegene Allplex Genital ulcer Assay		4					
	Total:		8		2	2	100 %	0 %	100 %



## Report Info

### PARTICIPANTS

Altogether 23 laboratories from 9 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.

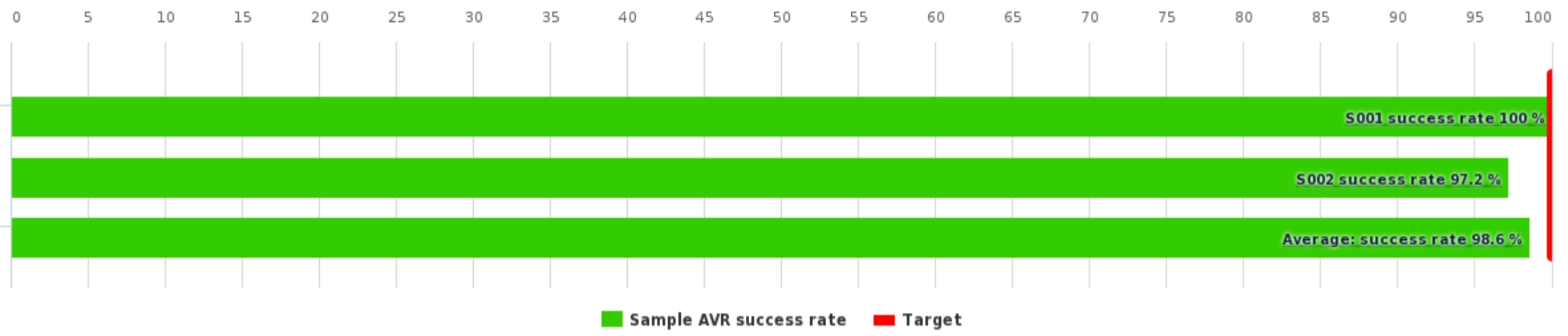
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores\*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success 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
HSV1&2/VZV/T.pallidum, nucleic acid detection, April, 1-2023	23	23	100 %

**Summary**

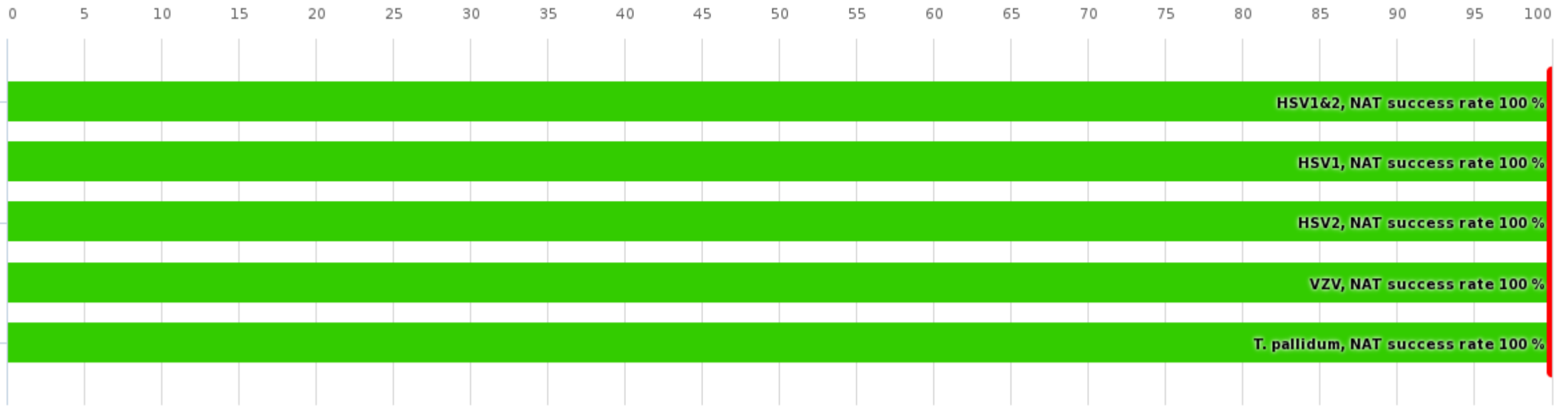
Overall success rate by samples



Summary	AVR success rate
S001	100 %
S002	97.2 %
Average:	98.6 %

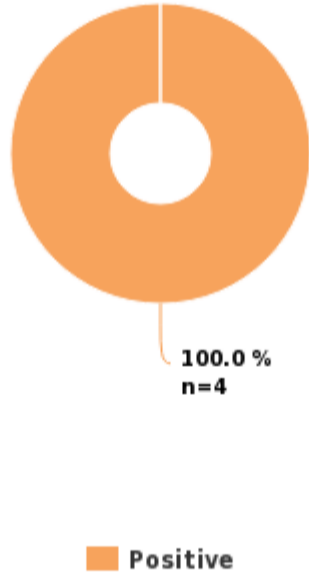
S001 | HSV-1

S001 success rate

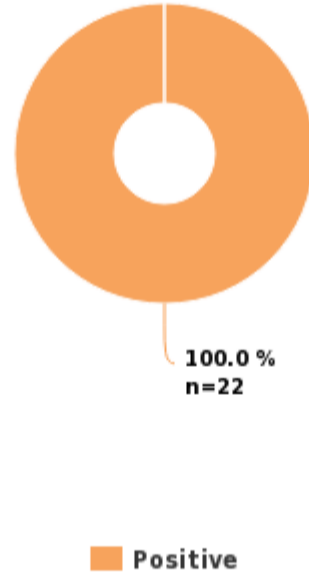


S001 results	Responded	AVR success rate	Count
	HSV1&2, NAT	100 %	4
	HSV1, NAT	100 %	22
	HSV2, NAT	100 %	21
	VZV, NAT	100 %	16
	T. pallidum, NAT	100 %	8
	Total:	100 %	71

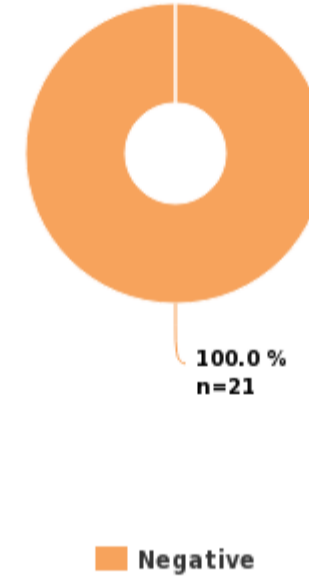
S001 HSV1&2, NAT



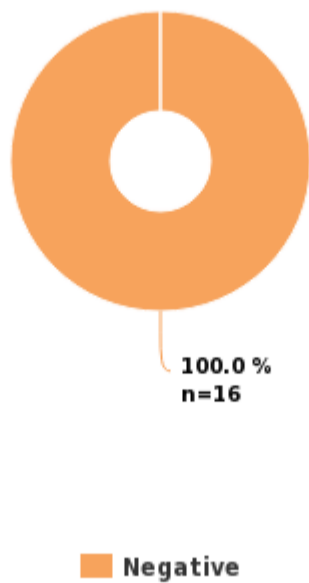
S001 HSV1, NAT



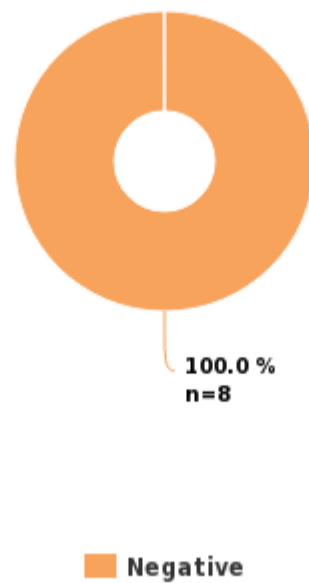
S001 HSV2, NAT



S001 VZV, NAT



S001 T. pallidum, NAT



HSV1&2, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		4		100 %	2
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1		
		DNA-Technology HSV 1,2		2		
		Sacace Biotechnologies HSV I/II Real-TM		1		
	Total:		4		100 %	

HSV1, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		22		100 %	2
		AmpliSens HSV-typing-FRT PCR kit		1		
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1		
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2		
		ELITechGroup HSV1 ELITe MGB Kit		1		
		In-house PCR		8		
		Luminex ARIES HSV 1&2 Assay		1		
		Meridian Bioscience Alethia HSV 1&2		1		
		Qiagen artus HSV-1/2		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		22		100 %	

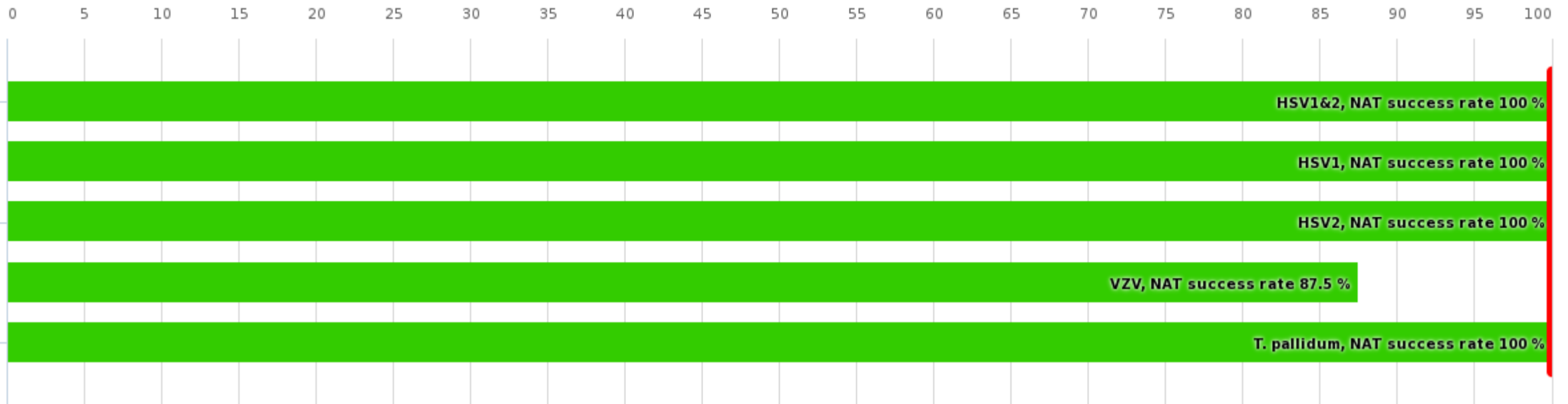
HSV2, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		21		100 %	2
		AmpliSens HSV-typing-FRT PCR kit		1		
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1		
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2		
		In-house PCR		8		
		Luminex ARIES HSV 1&2 Assay		1		
		Meridian Bioscience Alethia HSV 1&2		1		
		Qiagen artus HSV-1/2		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		21		100 %	

VZV, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		16		100 %	2
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1		
		DiaSorin Simplexa VZV Swab Direct Kit		2		
		In-house PCR		6		
		Qiagen artus VZV		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		16		100 %	

T. pallidum, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		8		100 %	2
		AmpliSens Treponema pallidum-FRT PCR kit		1		
		GeneProof Treponema pallidum PCR Kit		1		
		In-house PCR		1		
		Sacace Biotechnologies Treponema pallidum Real-TM		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		8		100 %	

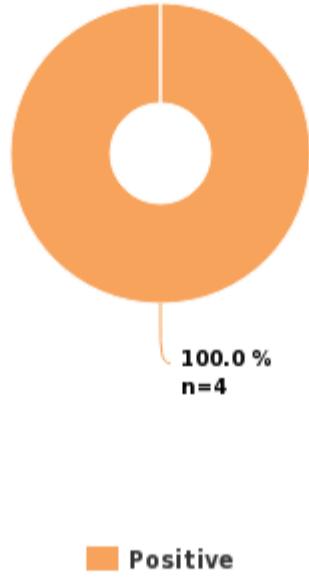
**S002 | HSV-1, HSV-2, VZV, Treponema pallidum**

S002 success rate

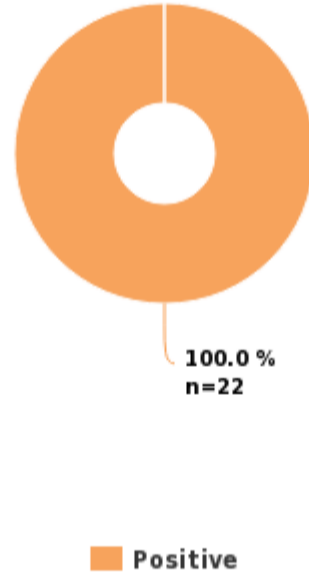


S002 results	Responded	AVR success rate	Count
	HSV1&2, NAT	100 %	4
	HSV1, NAT	100 %	22
	HSV2, NAT	100 %	21
	VZV, NAT	87.5 %	16
	T. pallidum, NAT	100 %	8
	<b>Total:</b>	<b>97.2 %</b>	<b>71</b>

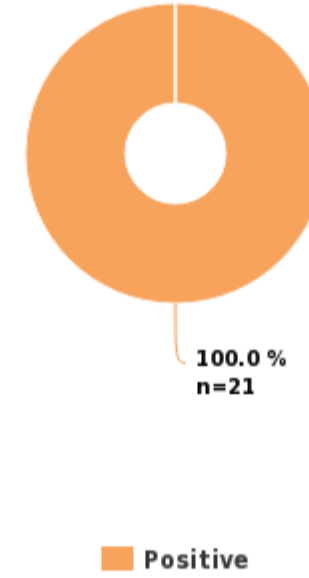
S002 HSV1&2, NAT



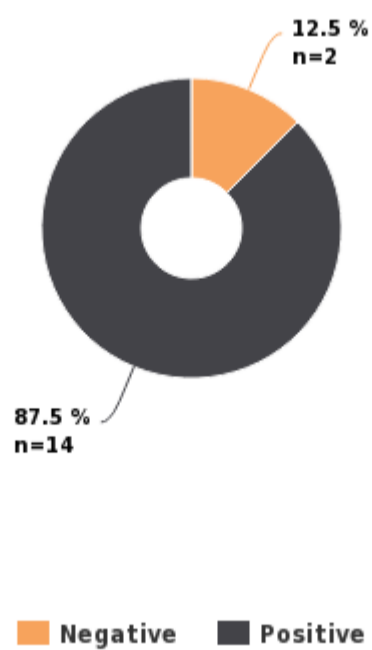
S002 HSV1, NAT



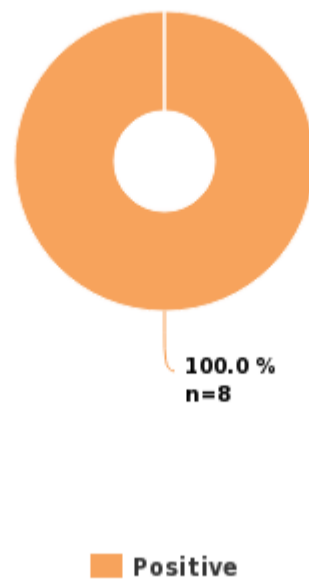
S002 HSV2, NAT



S002 VZV, NAT



S002 T. pallidum, NAT



# LABQUALITY HSV1&2/VZV/T.pallidum, nucleic acid detection, April, 1-2023

HSV1&2, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		4		100 %	2
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1		
		DNA-Technology HSV 1,2		2		
		Sacace Biotechnologies HSV I/II Real-TM		1		
	Total:		4		100 %	

HSV1, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		22		100 %	2
		AmpliSens HSV-typing-FRT PCR kit		1		
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1		
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2		
		ELITechGroup HSV1 ELITe MGB Kit		1		
		In-house PCR		8		
		Luminex ARIES HSV 1&2 Assay		1		
		Meridian Bioscience Alethia HSV 1&2		1		
		Qiagen artus HSV-1/2		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		22		100 %	

HSV2, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		21		100 %	2
		AmpliSens HSV-typing-FRT PCR kit		1		
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1 HSV2 R-GENE		1		
		DiaSorin Simplexa HSV 1 & 2 Direct Kit		2		
		In-house PCR		8		
		Luminex ARIES HSV 1&2 Assay		1		
		Meridian Bioscience Alethia HSV 1&2		1		
		Qiagen artus HSV-1/2		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		21		100 %	

VZV, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		2		0 %	0
		In-house PCR		1		
		Seegene Allplex Genital ulcer Assay		1		
	Positive		14		100 %	2
		BioGX Viral Meningitis HSV/VZV - OSR for BD MAX		2		
		bioMerieux ARGENE HSV1&2 VZV R-GENE		1		
		DiaSorin Simplexa VZV Swab Direct Kit		2		
		In-house PCR		5		
		Qiagen artus VZV		1		
		Seegene Allplex Genital ulcer Assay		3		
	Total:		16		87.5 %	

T. pallidum, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		8		100 %	2
		AmpliSens Treponema pallidum-FRT PCR kit		1		
		GeneProof Treponema pallidum PCR Kit		1		
		In-house PCR		1		
		Sacace Biotechnologies Treponema pallidum Real-TM		1		
		Seegene Allplex Genital ulcer Assay		4		
	Total:		8		100 %	

## Report Info

### PARTICIPANTS

Altogether 23 laboratories from 9 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

## HSV1&2/VZV/*T. pallidum*, nucleic acid detection Round 1, 2023

### Specimens

For this EQA round, samples simulating swab samples taken from genital lesions were used. 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 (LQ776423011)

HSV1 NAT	Positive
HSV2 NAT	Negative
VZV NAT	Negative
<i>T. pallidum</i> NAT	Negative

#### Sample S002 (LQ776423012)

HSV1 NAT	Positive
HSV2 NAT	Positive
VZV NAT	Positive
<i>T. pallidum</i> NAT	Positive

### 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 combination round of type 1 and 2 Herpes simplex viruses (HSV-1 and HSV-2), Varicella zoster virus (VZV) and *Treponema pallidum* (*T. pallidum*) had 23 participants and all participants responded, giving a response rate of 100%.

There were two samples in the round, of which sample S001 was positive for HSV-1 and all participants had found HSV-1 nicely in the sample. Sample S002 contained all the analytes, so the sample was positive for HSV-1, HSV-2, VZV and *T. Pallidum*. For sample S002, HSV-1 and HSV-2 had been found by all participants. Likewise, all those who responded to *T. pallidum* had found it. A couple of false negative VZV results were reported from VZV respondents.

Overall, the round went very well, and the various tests were well represented.

### Exceptions in scoring

No exceptions.

### End of report

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2023-05-29

### FINAL REPORT

Product no. 5556

Samples sent	2023-04-25
Round closed	2023-05-18
Expected results	2023-05-23
Final report	2023-05-29

### 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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