LABQUALITY

External Quality Assessment Scheme

Streptococcus agalactiae (GBS), nucleic acid detection Round 1, 2023

Specimens
Please find enclosed 2 simulated swab samples S001 and S002.

Caution
The specimens simulate clinical samples and should therefore be handled with the same care as normal patient samples, capable of transmitting infectious disease.

Not for patient use

Examinations
Streptococcus agalactiae (GBS), direct nucleic acid detection

Storage and use
After arrival, the samples should be stored at +2…8 °C.

Handling instructions

1. Open the foil package. Pay attention to avoid contamination.

For test kits without transport medium (e.g. Xpert GBS (Cepheid)):

2. Remove the swab from the foil package and place the swab into the sample chamber of the cartridge. Snap or cut off the shaft so that the swab fits into the sample chamber.
3. Close the cartridge lid.
4. Perform the analysis according to the manufacturer's instructions.

For test kits with transport medium:

2. Remove the swab from the foil package and place the swab into a sample collection tube / transport medium (supplied by your kit manufacturer) and rotate to dislodge as much material as possible. Snap off or cut the shaft of the swab to fit into the tube.
3. Recap the collection tube and mix thoroughly to ensure that all the test material is mixed with the transport medium.
4. Perform the analysis according to the manufacturer's instructions.

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

S001

S002

2023-03-28

INSTRUCTIONS

Product no. 5599
LQ762323011-012/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 24, 2023**.

The expected results of the round are published in LabScala in the View reports section by April 26, 2023.

Inquiries
EQA Coordinator
Yvonne Björkman
yvonne.bjorkman@labquality.fi

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com

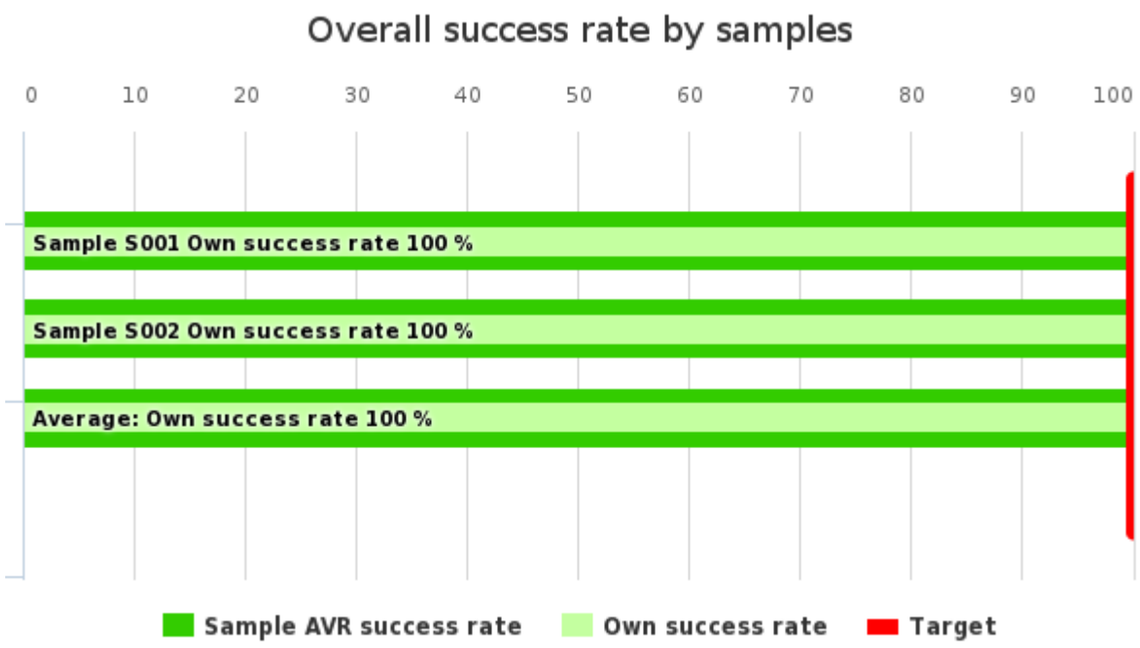
Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023

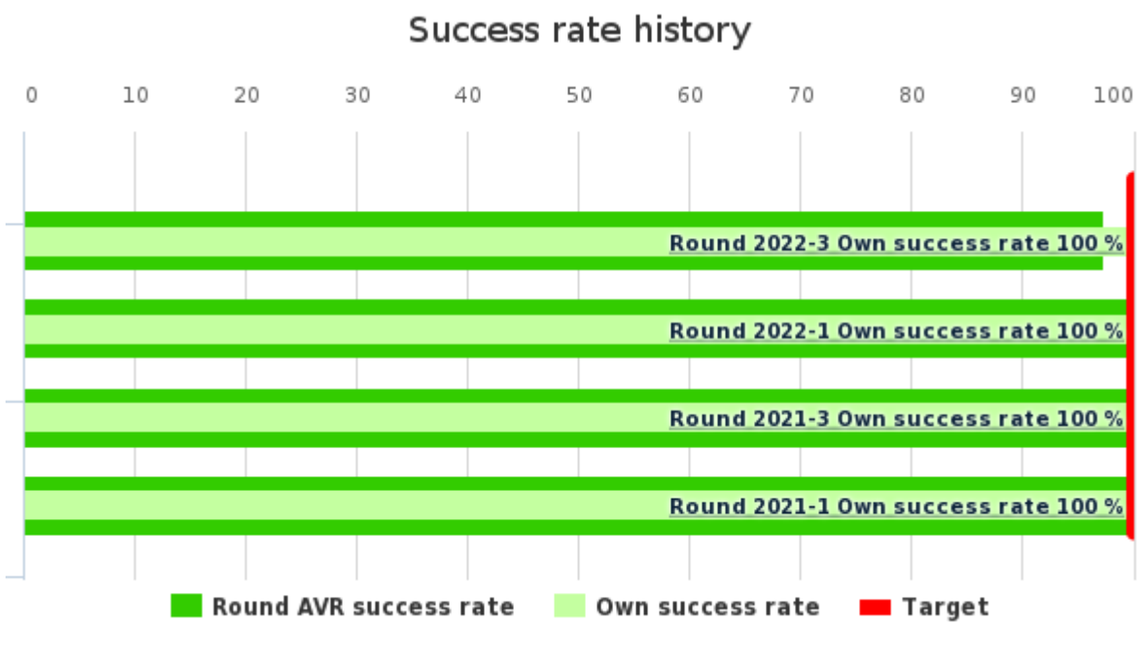
xxxx

Client report

	No of participants	No of responded participants	Response percentage
Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023	75	72	96 %

Summary

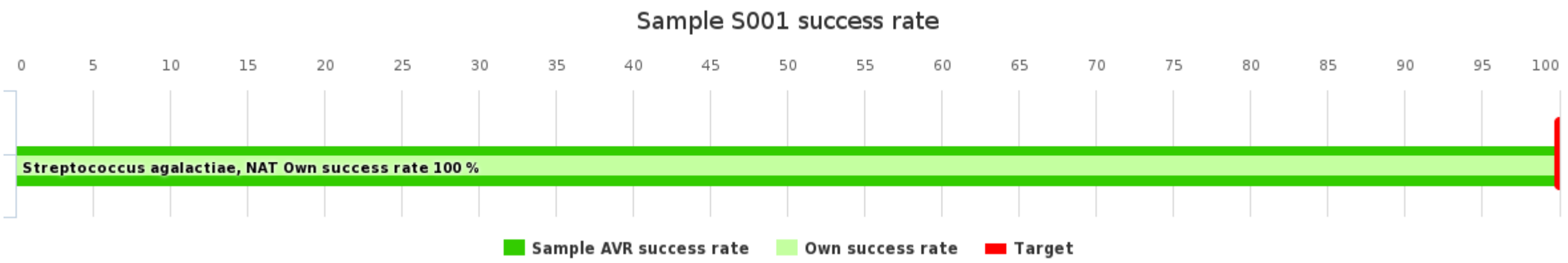




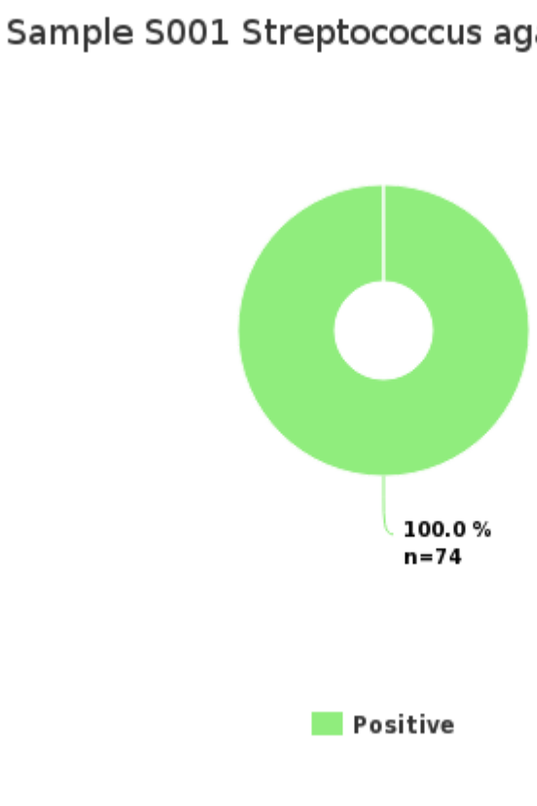
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	2	2	100 %	0 %	100 %
Average:			100 %	0 %	100 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-3	1-1	100 %	2.6 %	97.4 %
Round 2022-1	1-1	100 %	0 %	100 %
Round 2021-3	1-1	100 %	0 %	100 %
Round 2021-1	1-1	100 %	0 %	100 %

Sample S001 | Streptococcus agalactiae (GBS): positive

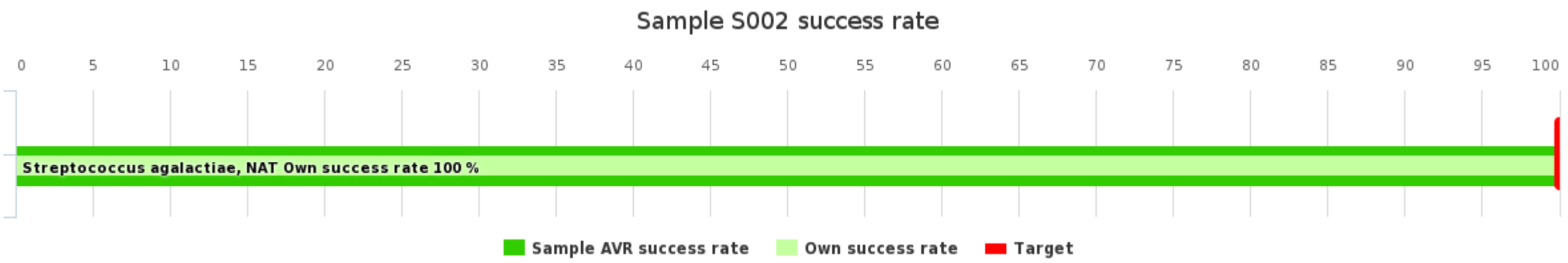


Sample S001 results	Responded	AVR success rate	Count
	Streptococcus agalactiae, NAT	100 %	74

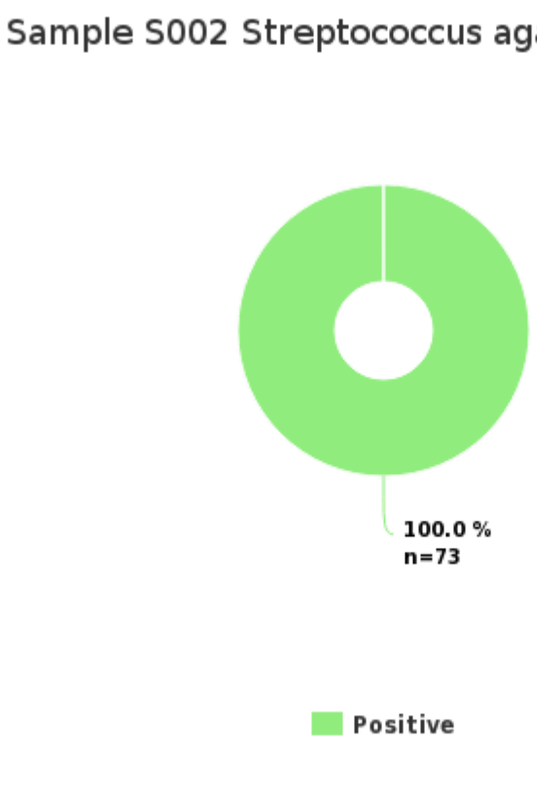


Streptococcus agalactiae, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		74		2	2	100 %	0 %	100 %
		BD MAX GBS assay (Becton Dickinson)		1					
		GenomEra CDX GBS (Abacus Diagnostica)		1					
		PCR (In-house)		1					
		Revogene GBS DS (Meridian Bioscience)		1					
		◉ Xpert GBS (Cepheid)		61					
		Xpert Xpress GBS (Cepheid)		9					
	Total:		74		2	2	100 %	0 %	100 %

Sample S002 | Streptococcus agalactiae (GBS): positive



Sample S002 results	Responded	AVR success rate	Count
	Streptococcus agalactiae, NAT	100 %	73



Streptococcus agalactiae, NAT	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Positive		73		2	2	100 %	0 %	100 %
		BD MAX GBS assay (Becton Dickinson)		1					
		GenomEra CDX GBS (Abacus Diagnostica)		1					
		Revogene GBS DS (Meridian Bioscience)		1					
		◉ Xpert GBS (Cepheid)		60					
		Xpert GBS LB (Cepheid)		1					
		Xpert Xpress GBS (Cepheid)		9					
	Total:		73		2	2	100 %	0 %	100 %

Report Info

PARTICIPANTS

Altogether 75 laboratories from 7 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.

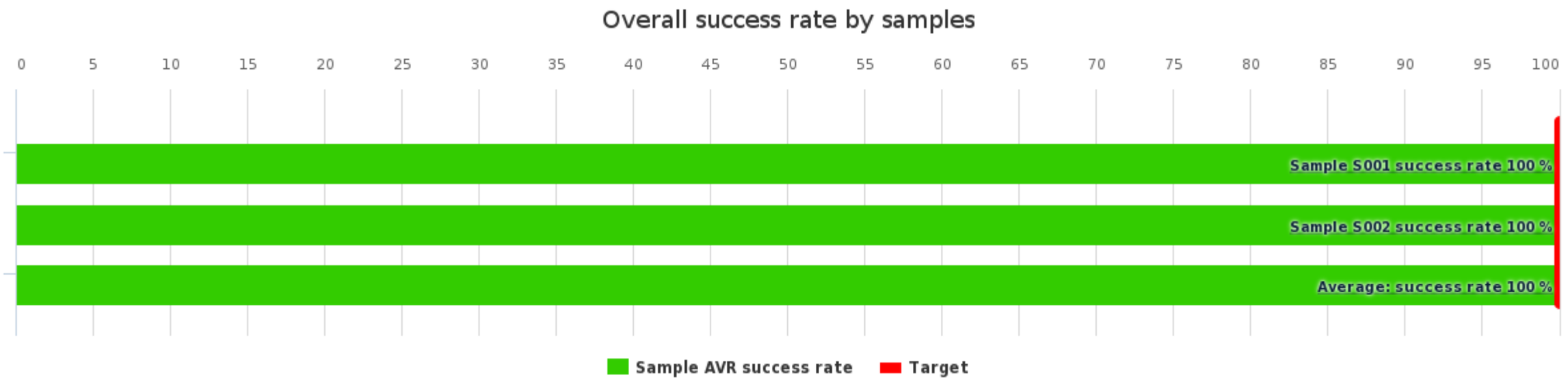
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate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

Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023	75	72	96 %

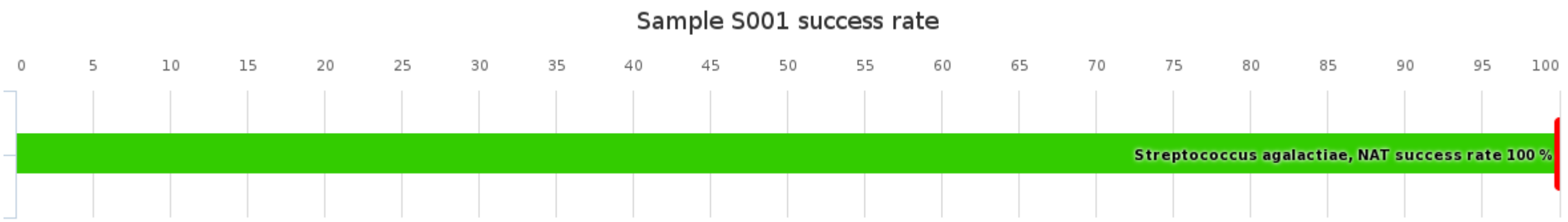
Summary



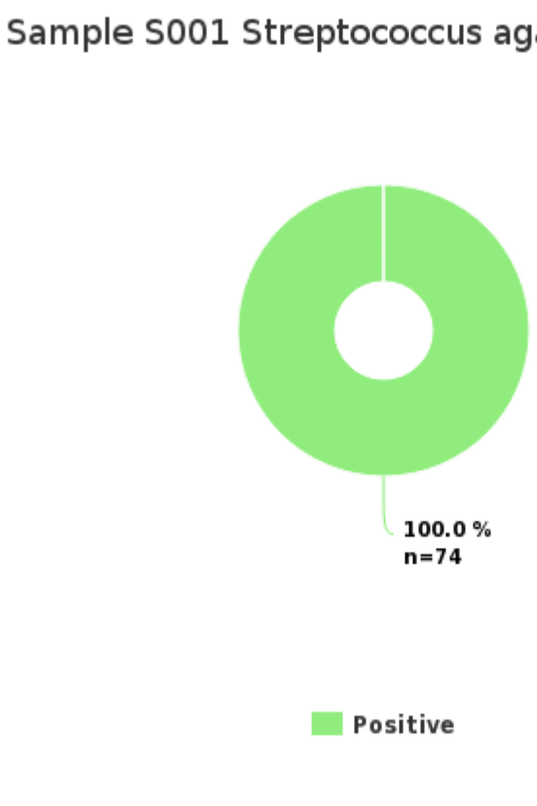
Summary	AVR success rate
Sample S001	100 %
Sample S002	100 %
Average:	100 %

Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023

Sample S001 | Streptococcus agalactiae (GBS): positive



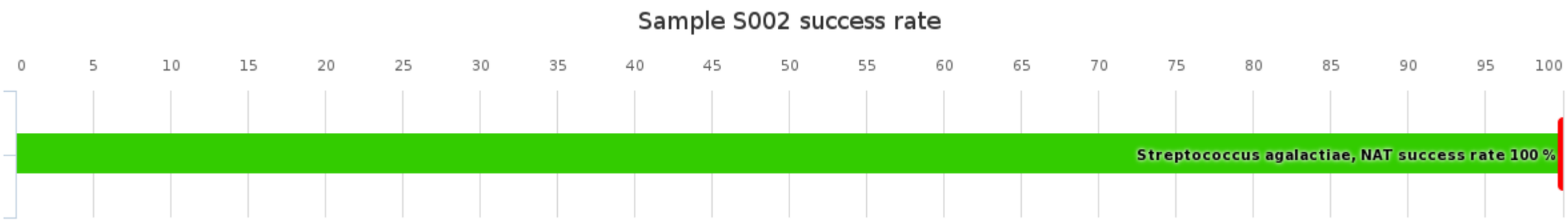
Sample S001 results	Responded	AVR success rate	Count
	Streptococcus agalactiae, NAT	100 %	74



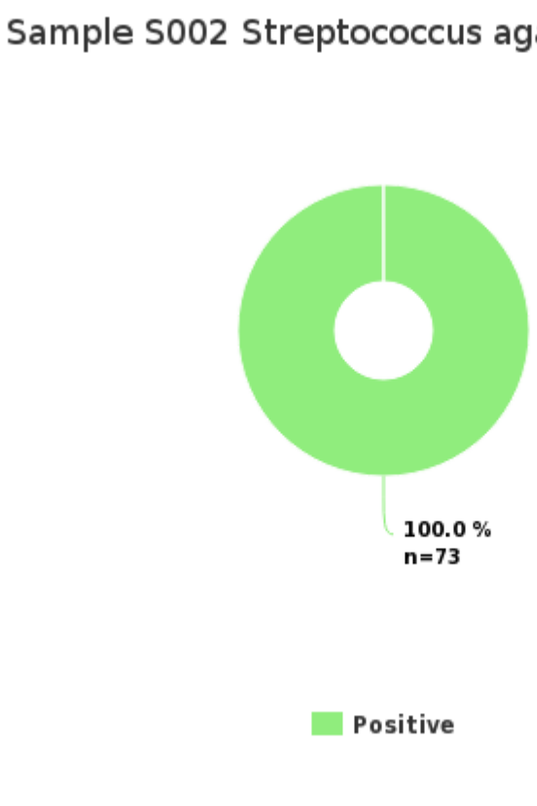
Streptococcus agalactiae, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		74		100 %	2
		BD MAX GBS assay (Becton Dickinson)		1		
		GenomEra CDX GBS (Abacus Diagnostica)		1		
		PCR (In-house)		1		
		Revogene GBS DS (Meridian Bioscience)		1		
		Xpert GBS (Cepheid)		61		
		Xpert Xpress GBS (Cepheid)		9		
	Total:		74		100 %	

Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023

Sample S002 | Streptococcus agalactiae (GBS): positive



Sample S002 results	Responded	AVR success rate	Count
	Streptococcus agalactiae, NAT	100 %	73



Streptococcus agalactiae, NAT	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		73		100 %	2
		BD MAX GBS assay (Becton Dickinson)		1		
		GenomEra CDX GBS (Abacus Diagnostica)		1		
		Revogene GBS DS (Meridian Bioscience)		1		
		Xpert GBS (Cepheid)		60		
		Xpert GBS LB (Cepheid)		1		
		Xpert Xpress GBS (Cepheid)		9		
	Total:		73		100 %	

Streptococcus agalactiae (GBS), nucleic acid detection, April, 1-2023

Report Info

PARTICIPANTS

Altogether 75 laboratories from 7 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.

LABQUALITY

External Quality Assessment Scheme

Streptococcus agalactiae (GBS), nucleic acid detection Round 1, 2023

Specimens
The samples were artificial swab samples. The sample lots were tested in the scheme expert´s 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 (LQ762323011)
Streptococcus agalactiae, nucleic acid detection positive
Obtained C_t value in the pre-testing: 25.0

Sample S002 (LQ762323012)
Streptococcus agalactiae, nucleic acid detection positive
Obtained C_t value in the pre-testing: 27.2

Pre-test method: Xpert Xpress GBS (Cepheid).

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
Altogether 96% (72/75) of the participants reported their results before the closing date. In all 26% (19/72) of the participants were maternity wards. Two participants reported results for two sample sets, therefore the number of results reported to the clinician are higher than the number of laboratories that returned their results. Altogether 22 laboratories reported C_t values, and 19 out of these used the Xpert GBS (Cepheid) test.

Sample S001 was positive, and all participants reported the expected result. The C_t values (n=19) reported for the Xpert GBS (Cepheid) test varied between C_t 16.0–34.0, the mean being C_t 29.1 (SD 3.53 and CV 12.12%).

Sample S002 was also positive, and it was reported as successfully as sample S001. The C_t values (n=19) reported for the Xpert GBS (Cepheid) test varied between C_t 16.0–37.0, the mean being C_t 30.3 (SD 4.01 and CV 13.25%).

The samples were correctly reported by all participants, well done!

Exceptions in scoring
No exceptions.

End of report

2023-05-02

FINAL REPORT

Product no. 5599

Subcontracting: Sample pretesting

Samples sent	2023-03-28
Round closed	2023-04-24
Expected results	2023-04-26
Final report	2023-05-02

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
EQA Coordinator
Yvonne Björkman
yvonne.bjorkman@labquality.fi

Expert
Clinical Microbiologist, Ph.D.,
Joanna Peltola, Nordlab, Finland.

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com