LABQUALITY

External Quality Assessment Scheme

Urine culture, quantitative screening Round 1, 2023

Specimens
Please find enclosed 2 lyophilized samples S001 and S002, vials of rehydration fluid, each 1 mL and dilution buffer, each 99 mL.

Caution
The specimens simulate patient samples and should be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases.

Background information
Sample S001
Pyelonephritis of a toddler.

Sample S002
A 30-year-old female, sample taken in home, bladder time <4 hours.

Examinations
Urine culture, quantitation and evaluation of significance

Storage and use
After arrival, the samples should be stored at +2…8°C. The identification information of the sample is found in the Labquality label on the foil package. Possible markings located inside the foil package on the vials are to be ignored when processing the samples. Excessive shaking of the vials during the rehydration is not recommendable as it may produce foam and retard the dissolution process.

1. Warm the 99 mL bottles of dilution fluid to +35…37°C. Let the samples and rehydration fluids warn up to room temperature.
2. Discard the blue-coloured cap from the vial of rehydration fluid.
3. Transfer the colourless cap (on vial inside the foil package) to the vial of the rehydration fluid. The bacterial specimen is fixed in the black particles inside the colourless cap (the paper pad inside the vial with the colourless cap is a desiccant).
4. Invert the vial, tap to be sure the liquid is in contact with the inside of the cap and place it in an incubator at +35…37°C for 15 minutes to dissolve the preserved microbes.
5. Check that there are no black particles inside the cap to make certain that all the microbes have dissolved into the solution. If necessary, reinvert the vial and continue the rehydration process. Observe closely every 1 to 2 minutes for complete dissolution. Continue to dissolve the specimen until no black particles are left in the cap, however, note that a prolonged rehydration process may affect the bacterial count. To enhance the dissolution of the particles you may gently tap the bottom of the vial when keeping it in an inverted position. Excessive vigorous shaking will produce foam.
6. Decant the contents of the small vial completely into the 99 mL bottle of warm dilution fluid.
7. Immediately mix the contents of the bottle, culture and incubate as corresponding clinical specimens.

2023-03-07

INSTRUCTIONS

Product no. 5060
LQ761923011-012/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 4, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 6, 2023.

Inquiries
EQA Coordinator
Elina Tuovinen
elina.tuovinen@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

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

Only the analysis phase is accredited.

Quality Management
ISO 9001:2015

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your answer or method from the list, please contact the EQA Coordinator.

First report the urine culture method you use; dip-slide or plate culture. Note that only one option (culture method) can be reported. Report the quantity of bacteria present and the number of colonies on the plate culture. Next, report the type (significance) of growth. Finally, answer the question of further handling.

Results reported in the Extent of growth and Type of growth parts will be scored.

S001

S002

LABQUALITY

Urine culture, March, 1-2023

Extent and type of growth

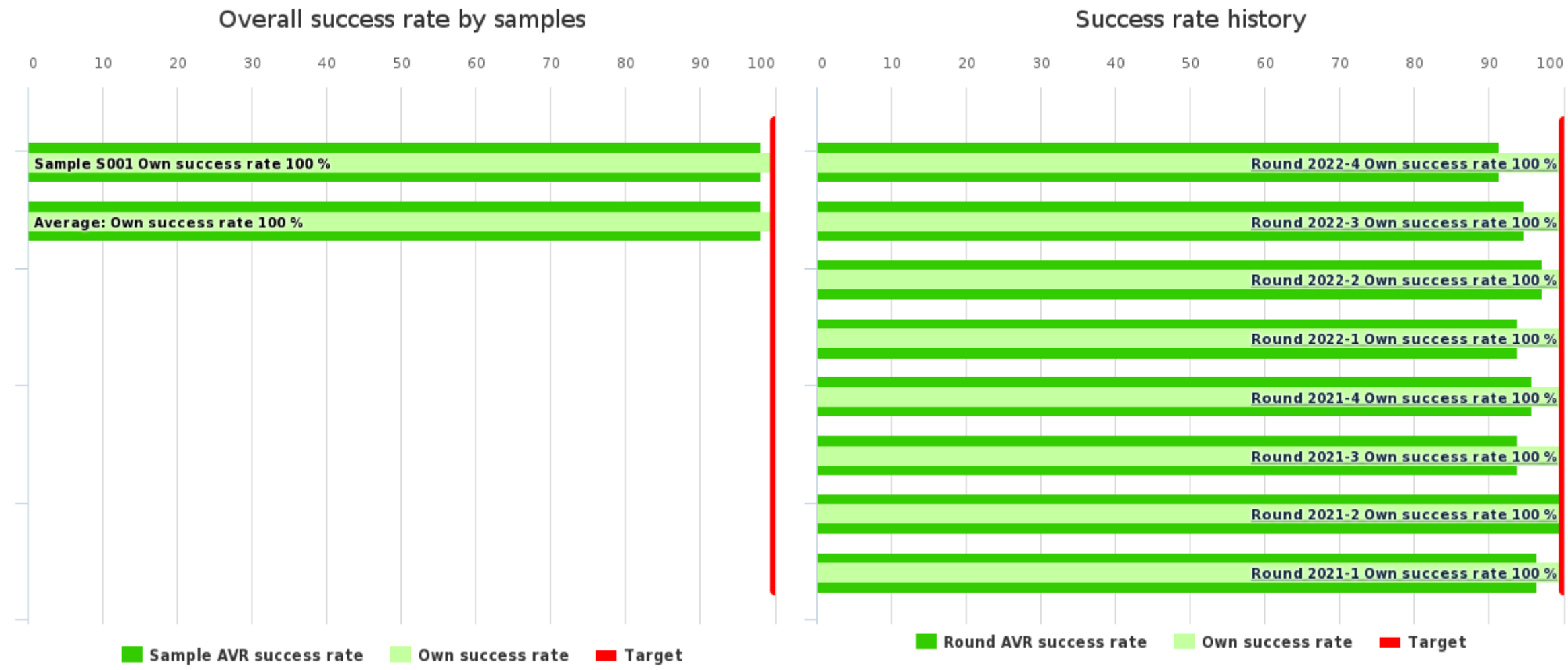
xxxxx

Client report

	No of participants	No of responded participants	Response percentage
Urine culture, quantitative screening, March, 1-2023	103	97	94.2 %

Summary

Urine culture, quantitative screening (5060)

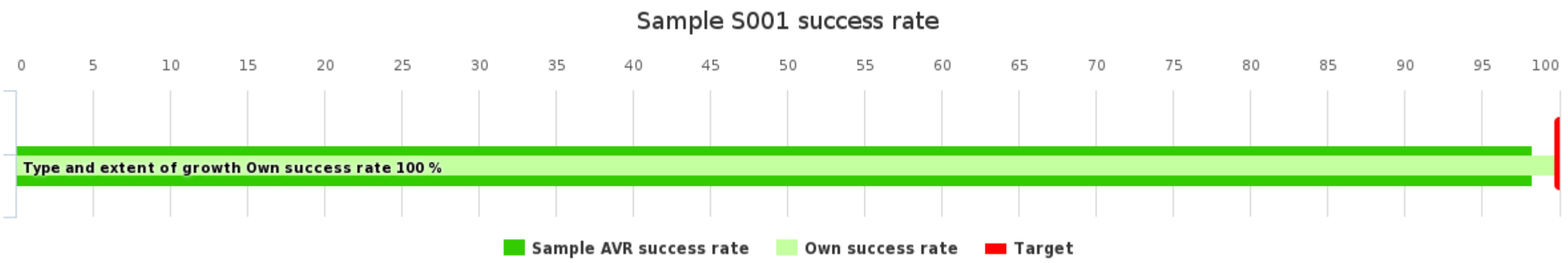


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	1.7 %	98.3 %
Sample S002	-	-	-	-	-
Average:			100 %	1.7 %	98.3 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	8.6 %	91.4 %
Round 2022-3	1-1	100 %	5.2 %	94.8 %
Round 2022-2	1-1	100 %	2.8 %	97.2 %
Round 2022-1	1-1	100 %	6.3 %	93.8 %
Round 2021-4	1-1	100 %	4.2 %	95.8 %
Round 2021-3	1-1	100 %	6.1 %	93.9 %
Round 2021-2	1-1	100 %	0.3 %	99.7 %
Round 2021-1	1-1	100 %	3.5 %	96.5 %

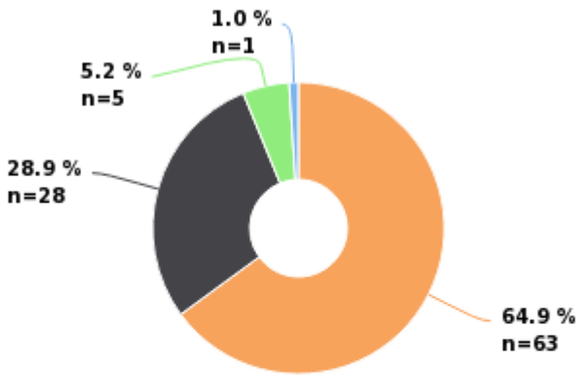
Sample S001 | Significant growth, >10^5 CFU/mL, E. coli

Urine culture, quantitative screening (5060)

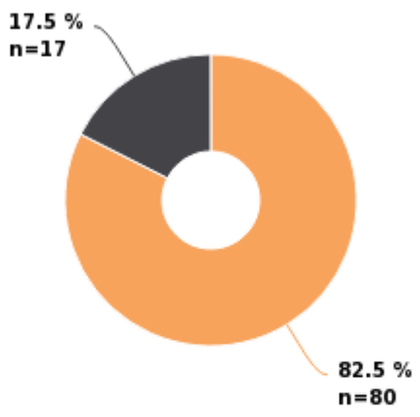


Type of growth	Extent of growth	Growth medium	count	Growth medium count	Own score	Max score	Own success rate	Difference	AVR success rate
Significant growth			80		4	4	100 %	1.9 %	98.1 %
	◉ >10^5		53		4	4	100 %	0 %	100 %
		◉ Chromogenic medium		43					
		Dipslide		3					
		Non-chromogenic medium		7					
	10^4 - 10^5		24		-				100 %
		Chromogenic medium		14					
		Dipslide		2					
		Non-chromogenic medium		8					
	10^3 - <10^4		2		-				50 %
		Chromogenic medium		1					
		Non-chromogenic medium		1					
	<10^3		1		-				50 %
		Chromogenic medium		1					
Significance not evaluated			17		-	-			100 %
	>10^5		10		-				100 %
		Chromogenic medium		7					
		Dipslide		1					
		Non-chromogenic medium		2					
	10^4 - 10^5		4		-				100 %
		Chromogenic medium		2					
		Dipslide		1					
		Non-chromogenic medium		1					
	10^3 - <10^4		3		-				100 %
		Chromogenic medium		3					
Total:			97		4	4	100 %	1.7 %	98.3 %

Sample S001 Growth extent



Sample S001 Growth type



Sample S001 Further action

>10E5 10E4 - 10E5 10E3 - <10E4 <10E3

Significant growth Significance not evaluated

Would be referred Would not be referred

GROWTH EXTENT

Extent of growth	count
◉ >10E5	63
10E4 - 10E5	28
10E3 - <10E4	5
<10E3	1
Total:	97

GROWTH TYPE

Type of growth	count
◉ Significant growth	80
Significance not evaluated	17
Total:	97

FURTHER ACTION

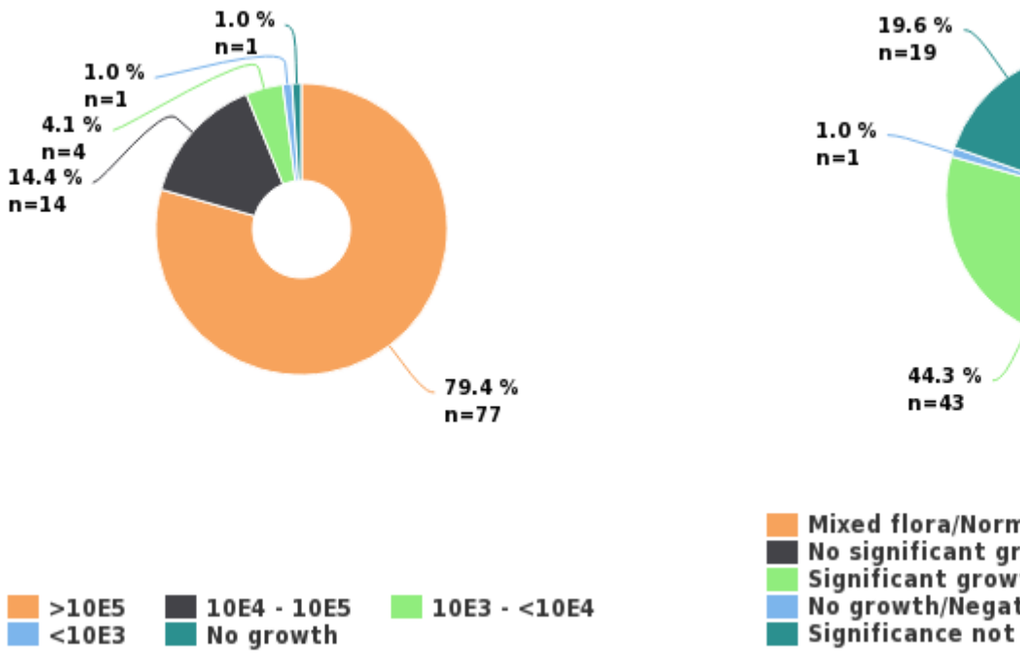
Result	count
Would be referred	56
◉ Would not be referred	41
Total:	97

Sample S002 | Mixed flora, >10^5 CFU/mL, E. faecalis, S. epidermidis, Acinetobacter sp.

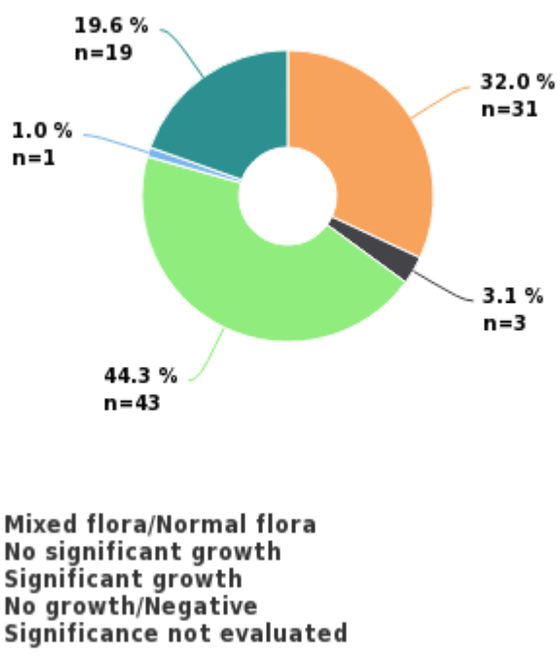
Urine culture, quantitative screening (5060)

Type of growth	Extent of growth	Growth medium	count	Growth medium count	Own score	Max score	Own success rate	Difference	AVR success rate
Mixed flora/Normal flora			31		-	-			-
	◉ >10^5		22		-				-
		◉ Chromogenic medium		20					
		Non-chromogenic medium		2					
	10^4 - 10^5		9		-				-
		Chromogenic medium		5					
		Non-chromogenic medium		4					
No growth/Negative			1		-	-			-
	No growth		1		-				-
		Chromogenic medium		1					
No significant growth			3		-	-			-
	>10^5		3		-				-
		Chromogenic medium		2					
		Non-chromogenic medium		1					
Significant growth			43		-	-			-
	>10^5		37		-				-
		Chromogenic medium		26					
		Dipslide		4					
		Non-chromogenic medium		7					
	10^4 - 10^5		4		-				-
		Chromogenic medium		3					
		Dipslide		1					
	10^3 - <10^4		1		-				-
		Chromogenic medium		1					
	<10^3		1		-				-
		Chromogenic medium		1					
Significance not evaluated			19		-	-			-
	>10^5		15		-				-
		Chromogenic medium		8					
		Dipslide		2					
		Non-chromogenic medium		5					
	10^4 - 10^5		1		-				-
		Chromogenic medium		1					
	10^3 - <10^4		3		-				-
		Chromogenic medium		3					
Total:			97		-	-	-	-	

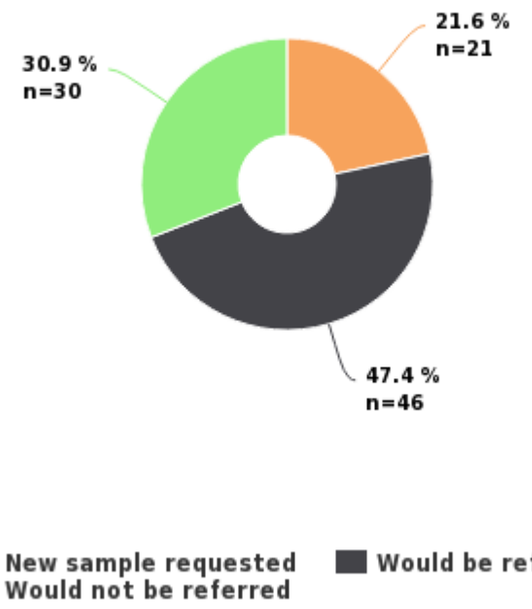
Sample S002 Growth extent



Sample S002 Growth type



Sample S002 Further action



GROWTH EXTENT

Extent of growth	count
◉ >10E5	77
10E4 - 10E5	14
10E3 - <10E4	4
<10E3	1
No growth	1
Total:	97

GROWTH TYPE

Type of growth	count
◉ Mixed flora/Normal flora	31
No significant growth	3
Significant growth	43
No growth/Negative	1
Significance not evaluated	19
Total:	97

FURTHER ACTION

Result	count
◉ New sample requested	21
Would be referred	46
Would not be referred	30
Total:	97

Report Info

PARTICIPANTS

Altogether 226 laboratories from 19 countries participated in this EQA round.

REPORT INFO

On the front page you can see summaries of overall success rate and sample specific success rates which have been calculated from the scores.
In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button ◉.
If you have not reported 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 results in the "Type of growth" and "Extent of growth" parts can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results. The report includes a sample specific scoring summary. Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

The following general rules are applied:
2 points is reached by reporting the expected extent of growth (CFU/mL)
2 points is reached by reporting the expected type of growth
Laboratories that routinely do not evaluate the observed growth but send all samples indicating any growth to the reference laboratory are given 2 points according to correctly identified growth.
For negative answers, the results are evaluated similarly to other screening laboratories

Urine culture, March, 1-2023

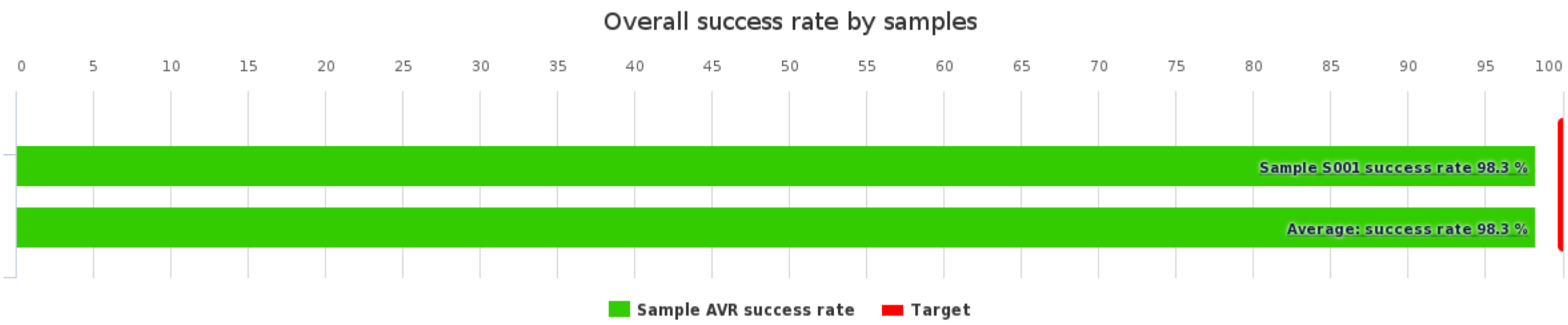
Extent and type of growth

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Urine culture, quantitative screening, identification and susceptibility, March, 1-2023	123	118	95.9 %
Urine culture, quantitative screening, March, 1-2023	103	97	94.2 %

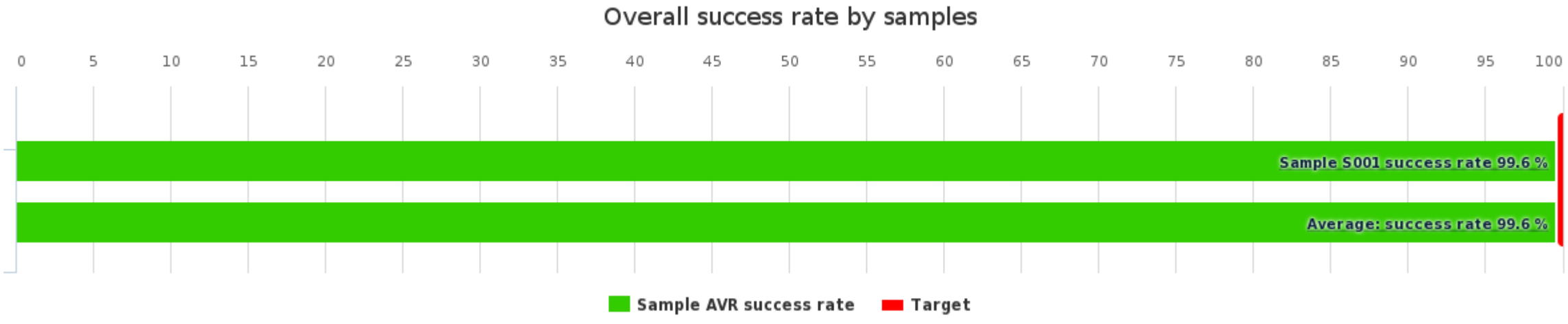
Summary

Urine culture, quantitative screening (5060)



Summary	AVR success rate
Sample S001	98.3 %
Sample S002	-
Average:	98.3 %

Urine culture, quantitative screening, identification and susceptibility (5065)



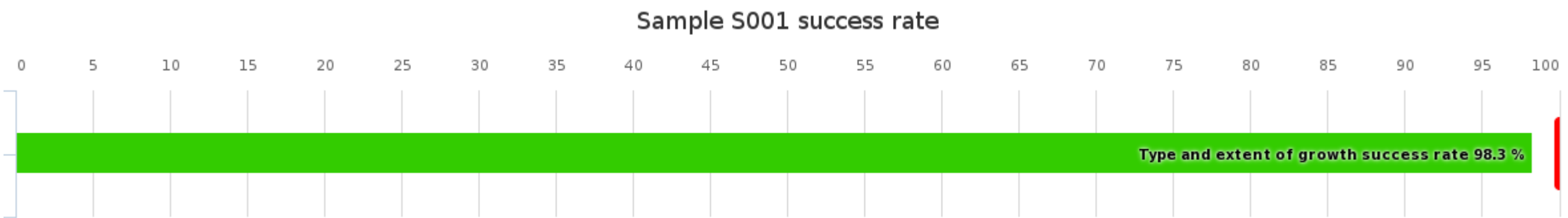
Summary	AVR success rate
Sample S001	99.6 %
Sample S002	-
Average:	99.6 %

Urine culture, March, 1-2023

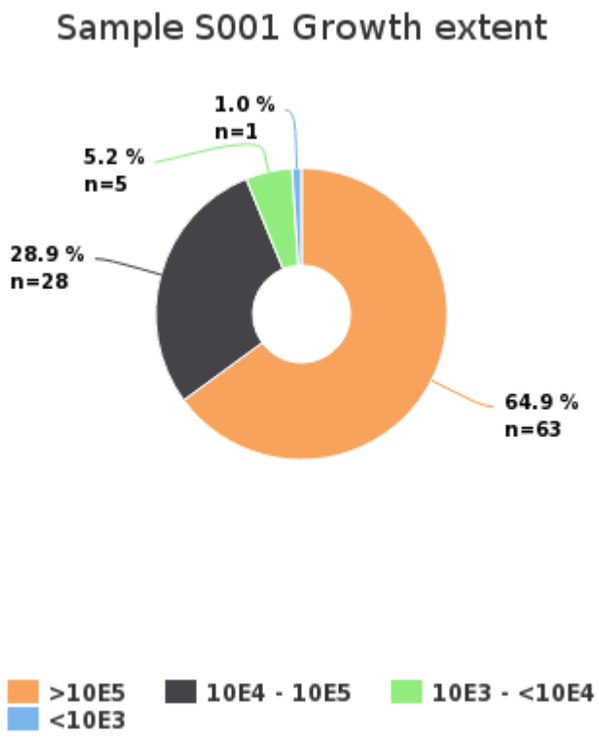
Extent and type of growth

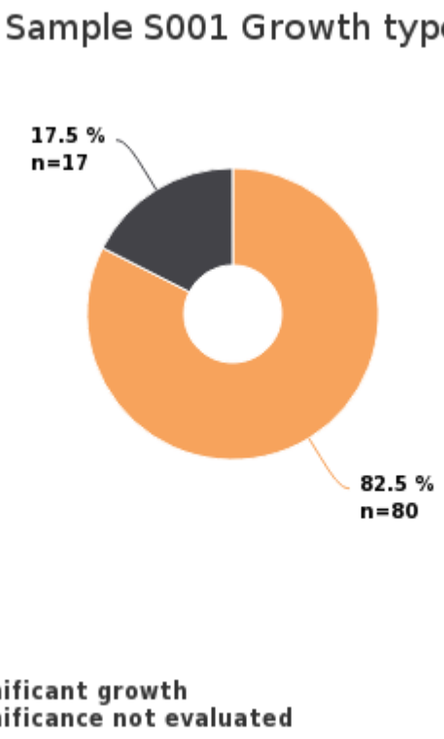
Sample S001 | Significant growth, >10E5 CFU/mL, E. coli

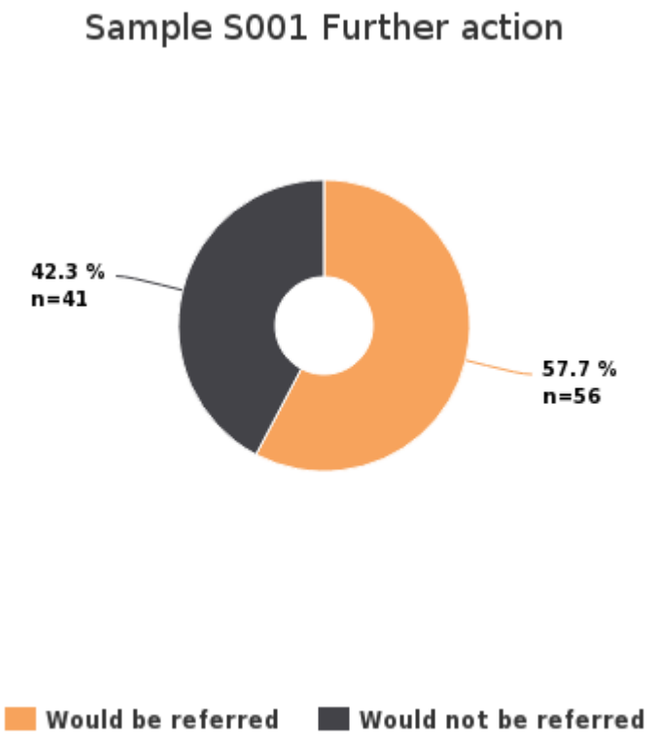
Urine culture, quantitative screening (5060)



Type of growth	Extent of growth	Growth medium	count	Growth medium count	AVR success rate	Score
Significant growth			80		98.1 %	
	>10E5		53		100 %	4
		Chromogenic medium		43		
		Dipslide		3		
		Non-chromogenic medium		7		
	10E4 - 10E5		24		100 %	4
		Chromogenic medium		14		
		Dipslide		2		
		Non-chromogenic medium		8		
	10E3 - <10E4		2		50 %	2
		Chromogenic medium		1		
		Non-chromogenic medium		1		
	<10E3		1		50 %	2
		Chromogenic medium		1		
Significance not evaluated			17		100 %	
	>10E5		10		100 %	2
		Chromogenic medium		7		
		Dipslide		1		
		Non-chromogenic medium		2		
	10E4 - 10E5		4		100 %	2
		Chromogenic medium		2		
		Dipslide		1		
		Non-chromogenic medium		1		
	10E3 - <10E4		3		100 %	2
		Chromogenic medium		3		
Total:			97		98.3 %	







Urine culture, March, 1-2023

Extent and type of growth

GROWTH EXTENT

Extent of growth	count
>10E5	63
10E4 - 10E5	28
10E3 - <10E4	5
<10E3	1
Total:	97

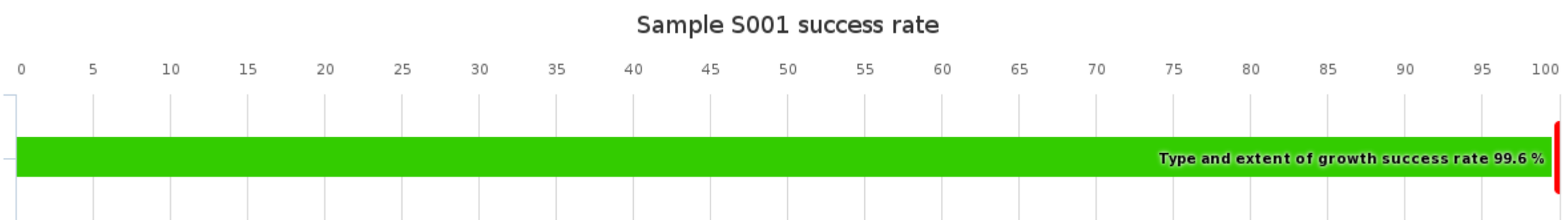
GROWTH TYPE

Type of growth	count
Significant growth	80
Significance not evaluated	17
Total:	97

FURTHER ACTION

Result	count
Would be referred	56
Would not be referred	41
Total:	97

Urine culture, quantitative screening, identification and susceptibility (5065)



Type of growth	Extent of growth	Growth medium	count	Growth medium count	AVR success rate	Score
Significant growth			116		99.6 %	
	>10E5		84		100 %	4
		Chromogenic medium		69		
		Non-chromogenic medium		15		
	10E4 - 10E5		31		100 %	4
		Chromogenic medium		24		
		Non-chromogenic medium		7		
	10E3 - <10E4		1		50 %	2
		Chromogenic medium		1		
Total:			116		99.6 %	

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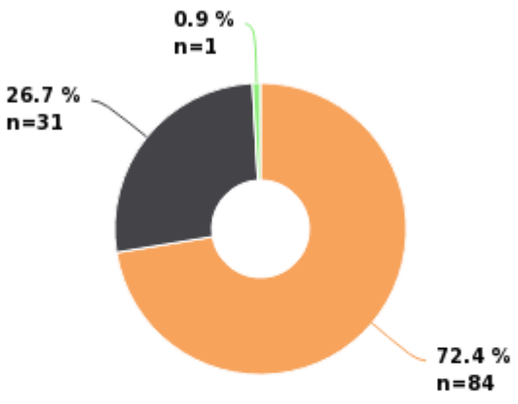
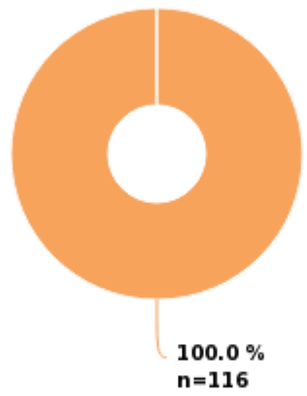
Urine culture, March, 1-2023

Extent and type of growth

Sample S001 Growth extent



Sample S001 Growth type



Sample S001 Further action

>10E5 10E4 - 10E5 10E3 - <10E4 Significant growth Would be referred Would not be referred

GROWTH EXTENT

Extent of growth	count
>10E5	84
10E4 - 10E5	31
10E3 - <10E4	1
Total:	116

GROWTH TYPE

Type of growth	count
Significant growth	116
Total:	116

FURTHER ACTION

Result	count
Would be referred	2
Would not be referred	114
Total:	116

Urine culture, March, 1-2023

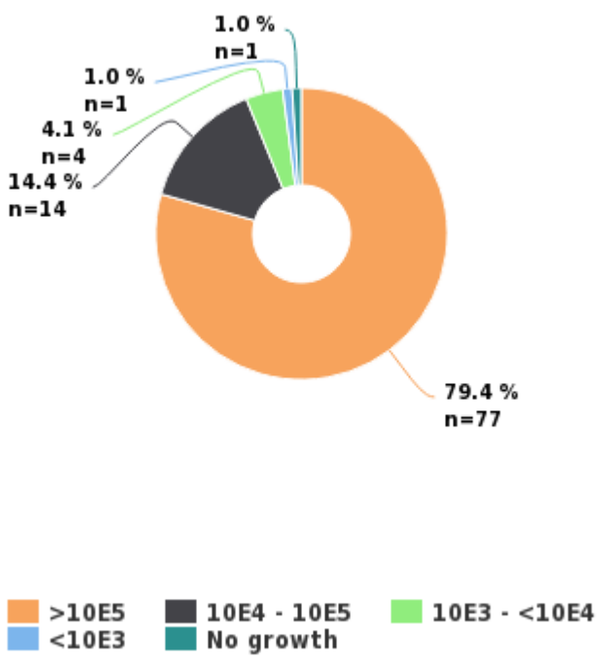
Extent and type of growth

Sample S002 | Mixed flora, >10E5 CFU/mL, E. faecalis, S. epidermidis, Acinetobacter sp.

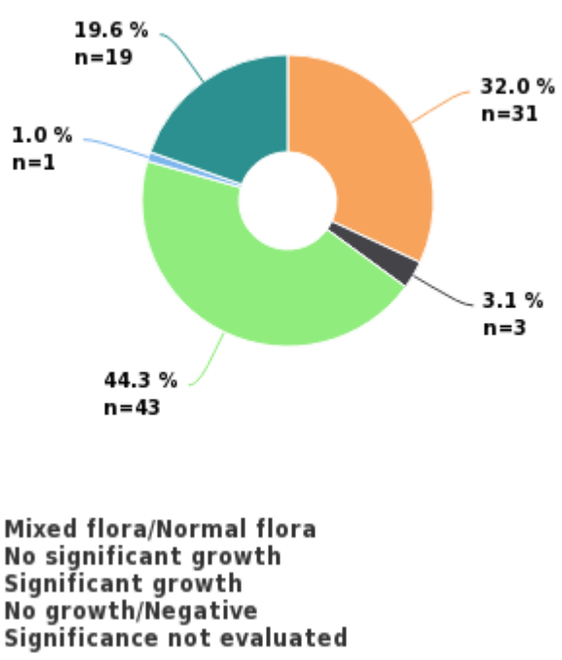
Urine culture, quantitative screening (5060)

Type of growth	Extent of growth	Growth medium	count	Growth medium count	AVR success rate	Score
Mixed flora/Normal flora			31		-	
	>10E5		22		-	-
		Chromogenic medium		20		
		Non-chromogenic medium		2		
	10E4 - 10E5		9		-	-
		Chromogenic medium		5		
		Non-chromogenic medium		4		
No growth/Negative			1		-	
	No growth		1		-	-
		Chromogenic medium		1		
No significant growth			3		-	
	>10E5		3		-	-
		Chromogenic medium		2		
		Non-chromogenic medium		1		
Significant growth			43		-	
	>10E5		37		-	-
		Chromogenic medium		26		
		Dipslide		4		
		Non-chromogenic medium		7		
	10E4 - 10E5		4		-	-
		Chromogenic medium		3		
		Dipslide		1		
	10E3 - <10E4		1		-	-
		Chromogenic medium		1		
	<10E3		1		-	-
		Chromogenic medium		1		
Significance not evaluated			19		-	
	>10E5		15		-	-
		Chromogenic medium		8		
		Dipslide		2		
		Non-chromogenic medium		5		
	10E4 - 10E5		1		-	-
		Chromogenic medium		1		
	10E3 - <10E4		3		-	-
		Chromogenic medium		3		
Total:			97			

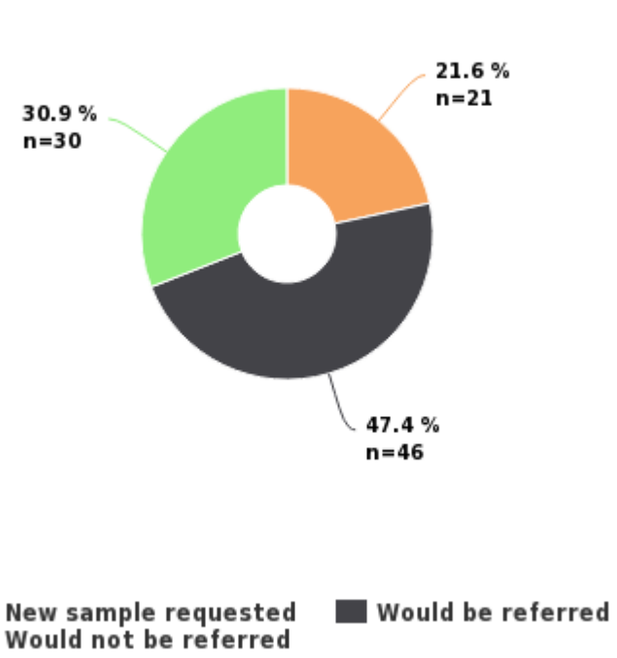
Sample S002 Growth extent



Sample S002 Growth type



Sample S002 Further action



Urine culture, March, 1-2023

Extent and type of growth

GROWTH EXTENT

Extent of growth	count
>10E5	77
10E4 - 10E5	14
10E3 - <10E4	4
<10E3	1
No growth	1
Total:	97

GROWTH TYPE

Type of growth	count
Mixed flora/Normal flora	31
No significant growth	3
Significant growth	43
No growth/Negative	1
Significance not evaluated	19
Total:	97

FURTHER ACTION

Result	count
New sample requested	21
Would be referred	46
Would not be referred	30
Total:	97

Urine culture, quantitative screening, identification and susceptibility (5065)

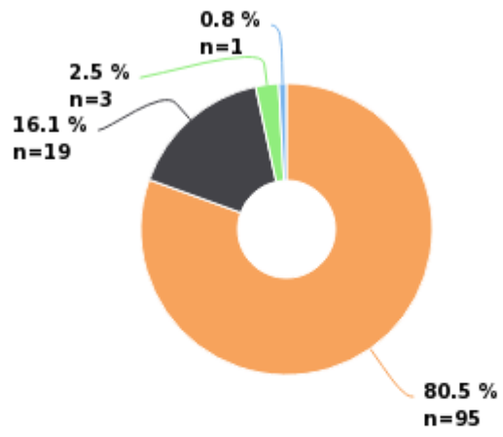
Type of growth	Extent of growth	Growth medium	count	Growth medium count	AVR success rate	Score
Mixed flora/Normal flora			52		-	
	>10E5		45		-	-
		Chromogenic medium		38		
		Non-chromogenic medium		7		
	10E4 - 10E5		6		-	-
		Chromogenic medium		4		
		Non-chromogenic medium		2		
	10E3 - <10E4		1		-	-
		Non-chromogenic medium		1		
No significant growth			6		-	
	>10E5		2		-	-
		Chromogenic medium		2		
	10E4 - 10E5		2		-	-
		Chromogenic medium		2		
	10E3 - <10E4		1		-	-
		Chromogenic medium		1		
	<10E3		1		-	-
		Non-chromogenic medium		1		
Significant growth			60		-	
	>10E5		48		-	-
		Chromogenic medium		41		
		Non-chromogenic medium		7		
	10E4 - 10E5		11		-	-
		Chromogenic medium		9		
		Non-chromogenic medium		2		
	10E3 - <10E4		1		-	-
		Chromogenic medium		1		
Total:			118			

LABQUALITY

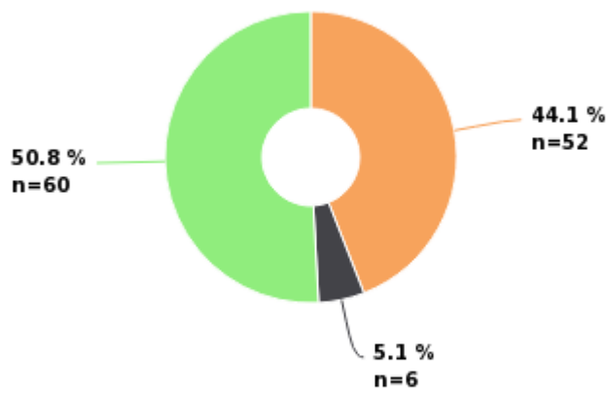
Urine culture, March, 1-2023

Extent and type of growth

Sample S002 Growth extent



Sample S002 Growth type



Sample S002 Further action

GROWTH EXTENT

Extent of growth	count
>10E5	95
10E4 - 10E5	19
10E3 - <10E4	3
<10E3	1
Total:	118

GROWTH TYPE

Type of growth	count
Mixed flora/Normal flora	52
No significant growth	6
Significant growth	60
Total:	118

FURTHER ACTION

Result	count
New sample requested	33
Would be referred	7
Would not be referred	78
Total:	118

LABQUALITY

Urine culture, March, 1-2023

Extent and type of growth

Report Info

PARTICIPANTS

Altogether 226 laboratories from 19 countries participated in this EQA round.

REPORT INFO

On the front page you can see summaries of overall success rate and sample specific success rates which have been calculated from the scores.
In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button ◉.
If you have not reported 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 results in the "Type of growth" and "Extent of growth" parts can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results. The report includes a sample specific scoring summary. Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

The following general rules are applied:
2 points is reached by reporting the expected extent of growth (CFU/mL)
2 points is reached by reporting the expected type of growth
Laboratories that routinely do not evaluate the observed growth but send all samples indicating any growth to the reference laboratory are given 2 points according to correctly identified growth.
For negative answers, the results are evaluated similarly to other screening laboratories

LABQUALITY

External Quality Assessment Scheme

Urine culture, quantitative screening Round 1, 2023

Specimens
Samples of this EQA round were lyophilized microbial samples. The sample lots were tested in two accredited Finnish reference laboratories 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 use of samples only for external quality assessment. The consent of Labquality must be requested for the use of the microbial strains contained in the samples for other purposes.

The content of the samples was as follows:

Sample S001 (LQ761923011)
Escherichia coli ATCC® 25922™, $>10^5$ CFU/mL

Sample S002 (LQ761923012)
Enterococcus faecalis C090604, $>10^5$ CFU/mL
Staphylococcus epidermidis C090609, $>10^5$ CFU/mL
Acinetobacter sp. C021239, $>10^5$ CFU/mL

Pre-test methods: the samples were cultured by loop method on CLED and/or chromogenic culture media. The number of microbes obtained in sample S001 was $>10^5$ CFU/mL in one of the pretest units and 10^4-10^5 CFU/mL in the other. For S002, the number of microbes obtained was $>10^5$ CFU/mL in both pretest units; one unit identified all three microbes whereas the other identified *E. faecalis* sekä *Acinetobacter* sp.

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 215 out of 226 laboratories reported their results before the closing date. 17 screening laboratories reported that they do not routinely interpret the clinical significance at all but refer all growing samples to another laboratory. These participants are scored according to correctly identified growth.

Sample S001
Background info: Pyelonephritis of a toddler. The sample contained *Escherichia coli,* significant growth, $>10^5$ CFU/mL.

Significant growth was detected by all of the laboratories. Both the expected amount of bacteria ($>10^5$ CFU/mL) and correct interpretation of the clinical significance (significant growth) was reported by 70% (137/196) of the participants. Significant growth with a lower quantity of 10^{4-5} CFU/mL was reported by 28% (55/196) of the participants. The lower category was accepted as well.

2023-05-17

FINAL REPORT

Product no. 5060

Subcontracting: Sample pretesting

Samples sent	2023-03-07
Round closed	2023-04-04
Expected results	2023-04-06
Final report	2023-05-17

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
EQA Coordinator
Elina Tuovinen
elina.tuovinen@labquality.fi

Expert
M.Sc., Clinical Microbiologist
Päivi Suomala,
ISLAB, South Savo, 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

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Quality Management
ISO 9001:2015

Sample S002
Background info: A 30-year-old female, sample taken at home, bladder time <4 hours. The sample contained *Enterococcus faecalis, Staphylococcus epidermidis* and *Acinetobacter* sp., mixed flora, $>10^5$ CFU/mL.

Mixed flora was reported by 42% (83/196) of the laboratories, whereas 53% (103/196) interpreted the growth as significant. The expected extent of growth ($>10^5$ CFU/mL) was reported by 80% (172/215) of the laboratories. Sample S002 contained three bacterial species belonging to normal urogenital and skin microbiome. The pathogenicity of all these species is very low and there were no such special details in background info based on which identification and susceptibility testing would have been necessary. Interpretation of the results varied as expected, thus the sample is left unscored.

Exceptions in scoring
Sample S002 was not scored.

End of report