LABQUALITY

External Quality Assessment Scheme

Fungal infections, nucleic acid detection Round 1, 2023

Specimens
Please find enclosed three simulated swab samples S001-S003, one simulated pellet sample S004 and one vial of rehydration fluid intended for sample S004.

Caution
Each specimen simulates a clinical specimen and should therefore be handled with the same care as normal patient samples, capable of transmitting infectious disease.

Not for patient use.

Examinations
Fungal nucleic acid detection (yeasts, dermatophytes, molds) according to laboratory's own test selection.

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

Swab samples S001-S003:

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 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 tube.
3. Recap the collection tube and mix thoroughly to ensure that all of the test material is mixed with the transport medium.
4. Perform the analysis according to the manufacturer's instructions.

Pellet sample S004:

1. Let the sample (blue-capped vial inside the foil package) and the rehydration fluid warm up to room temperature.
2. Aseptically remove the pellet with sterile forceps from the blue-capped vial and place it in the rehydration fluid vial. Alternatively, you may add the rehydration fluid directly into the blue-capped vial.
3. Crush the pellet with a sterile loop until the suspension is homogenous.
4. Incubate the vial for 30 minutes in +35…37 °C.
5. Check that the pellet has dissolved properly.
6. Mix well the contents of the vial and proceed immediately with the examination similar to a patient sample. 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 answer or method from the list, please contact the EQA Coordinator.

Indicate in the Test selection tab of the result form which findings belong to your laboratory's test selection and with what accuracy (check the boxes). Test selection is taken into account in the result processing. You can also add information about your test selection in the comment field.

2023-04-04

INSTRUCTIONS

Product no. 5261
LQ765223011-014/US

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 **May 2, 2023**.

The expected results of the round are published in LabScala in the View Reports section by May 5, 2023.

Inquiries
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Any comments regarding the samples or the result form are most welcome. We especially hope for feedback on the suitability of swab and pellet sample types. You can use the comment field on the result form to provide additional information and feedback, or you can contact the EQA coordinator directly.

S001

S002

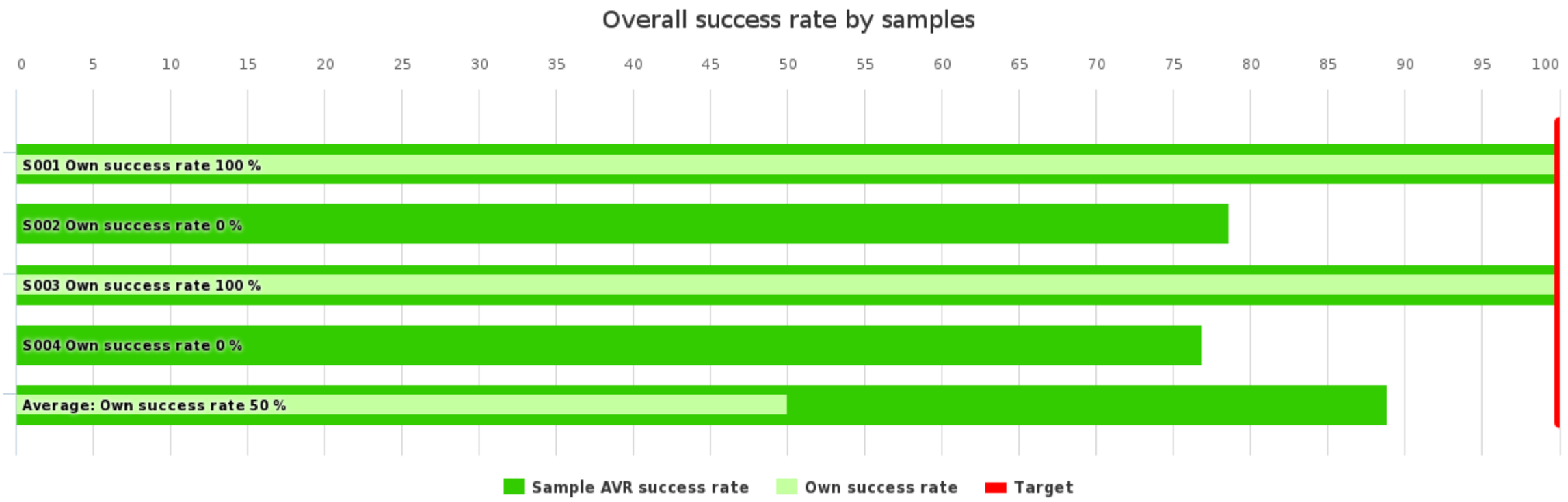
S003

S004

Client report

	No of participants	No of responded participants	Response percentage
Fungal infections, nucleic acid detection, April, 1-2023	16	14	87.5 %

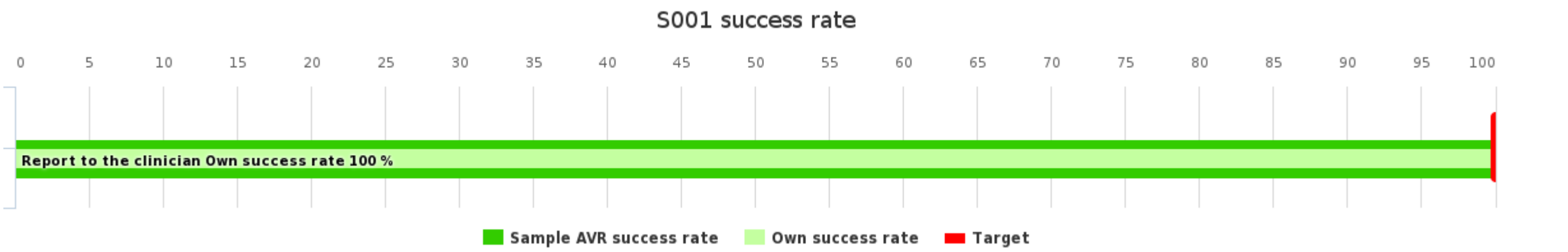
Summary



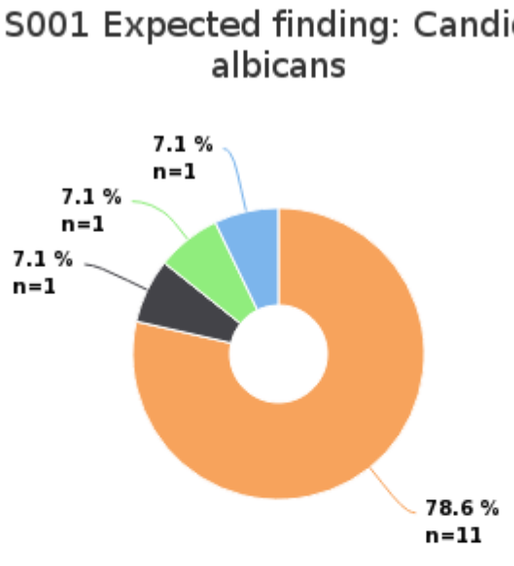
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
S001	2	2	100 %	0 %	100 %
S002	0	2	0 %	-78.6 %	78.6 %
S003	2	2	100 %	0 %	100 %
S004	0	2	0 %	-76.9 %	76.9 %
Average:			50 %	-38.9 %	88.9 %

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

S001 | Candida albicans



S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	2	2	100 %	0 %	100 %	14
	Identification tests	-	-	-	-	-	18
Total:		2	2	100 %	0 %	100 %	32



LABORATORY SPECIFIC SCORING TABLE

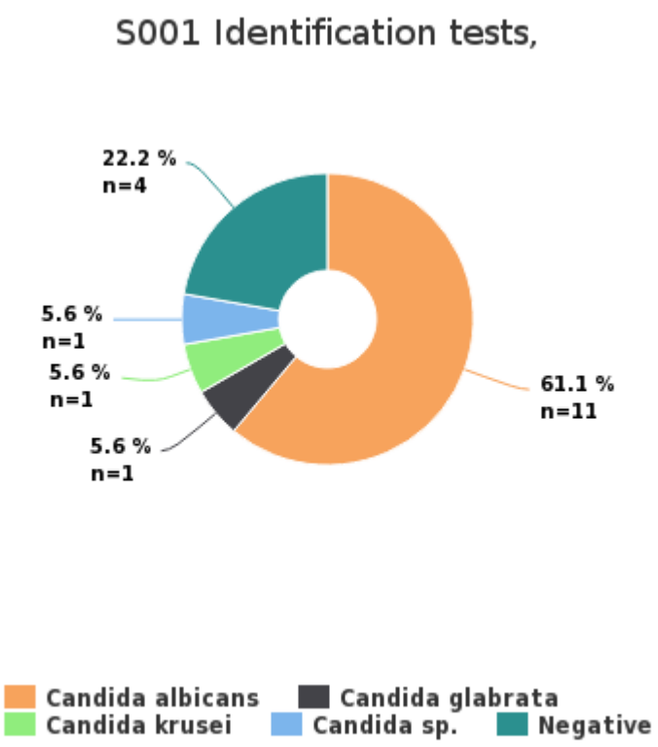
Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
Expected finding: Candida albicans	Candida albicans		2	2	100 %	0 %	100 %
Total:			2	2	100 %	0 %	100 %

REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Candida albicans		**14**	**100 %**
	◉ Candida albicans	11	
	Candida sp.	1	
	Negative (finding not in test selection)	1	
	No result	1	
Total:		14	100 %

SCORING SUMMARY

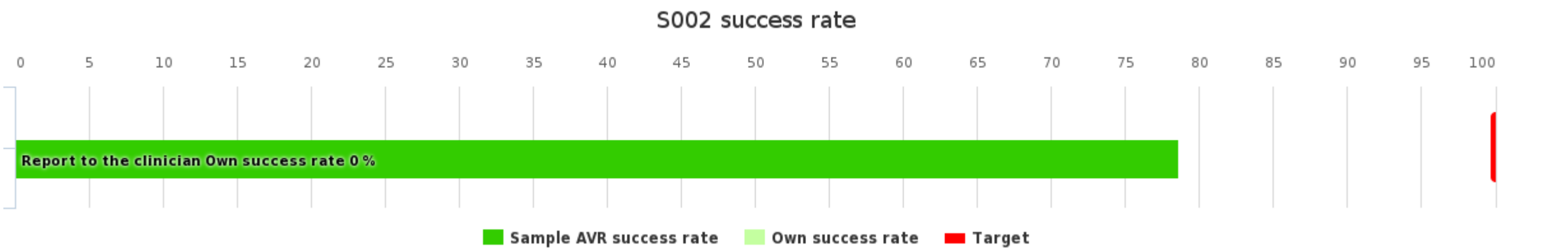
Finding group	Finding	Finding score	Max score
Expected finding: Candida albicans			**2**
	Candida albicans	2	2
	Candida sp.	2	2
	Negative (finding not in test selection)	2	2
	No result	-	-



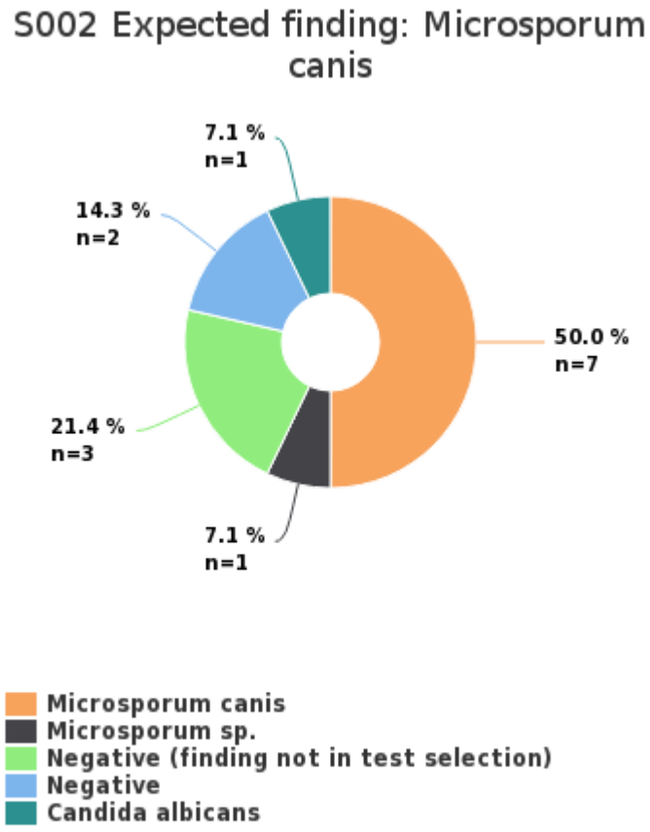
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Candida albicans	2
In-house PCR test	Candida albicans	2
	Candida sp.	1
	Negative	2
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Candida albicans	3
PathoNostics DermaGenius 3.0 Complete	Candida albicans	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	2
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Candida albicans	1
Total:		18

S002 | Microsporum canis



S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	0	2	0 %	-78.6 %	78.6 %	14
	Identification tests	-	-	-	-	-	20
Total:		0	2	0 %	-78.6 %	78.6 %	34



LABORATORY SPECIFIC SCORING TABLE

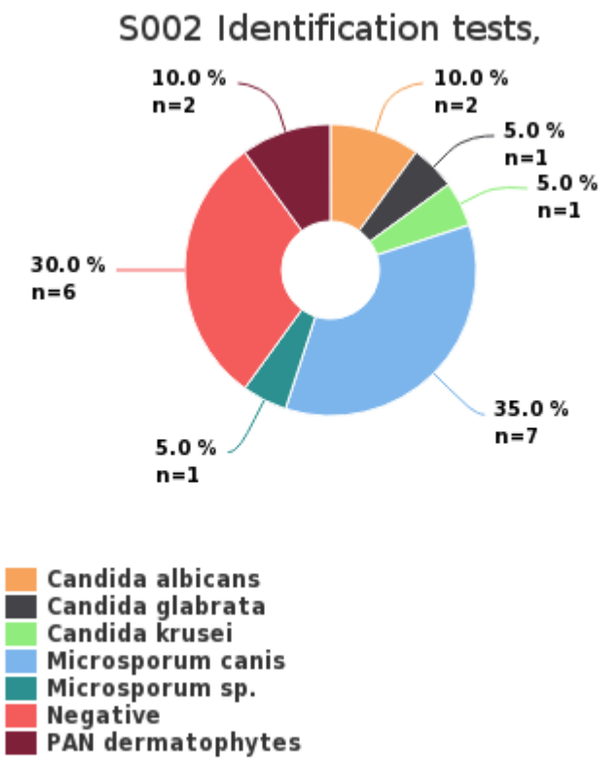
Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
Expected finding: Microsporum canis	Negative		0	2	0 %	-78.6 %	78.6 %
Total:			0	2	0 %	-78.6 %	78.6 %

REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Microsporum canis		**14**	**78.6 %**
	Microsporum canis	7	
	Microsporum sp.	1	
	Negative (finding not in test selection)	3	
	Negative	2	
	Candida albicans	1	
Total:		14	78.6 %

SCORING SUMMARY

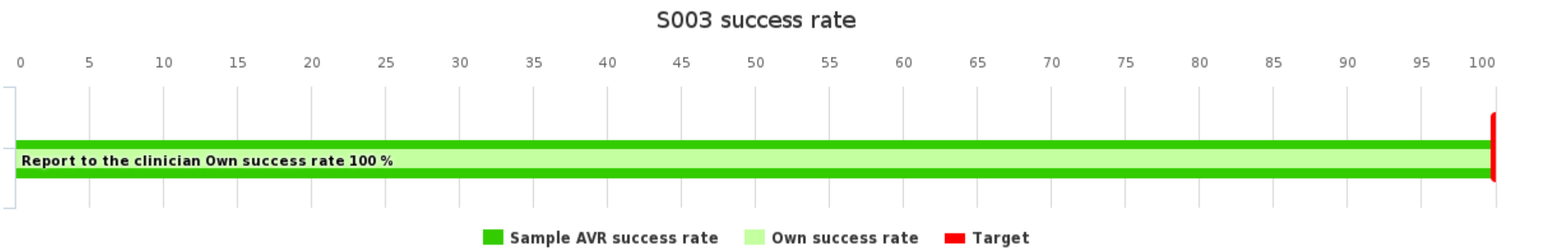
Finding group	Finding	Finding score	Max score
Expected finding: Microsporum canis			**2**
	Microsporum canis	2	2
	Microsporum sp.	2	2
	Negative (finding not in test selection)	2	2
	Negative	0	2
	Candida albicans	0	2



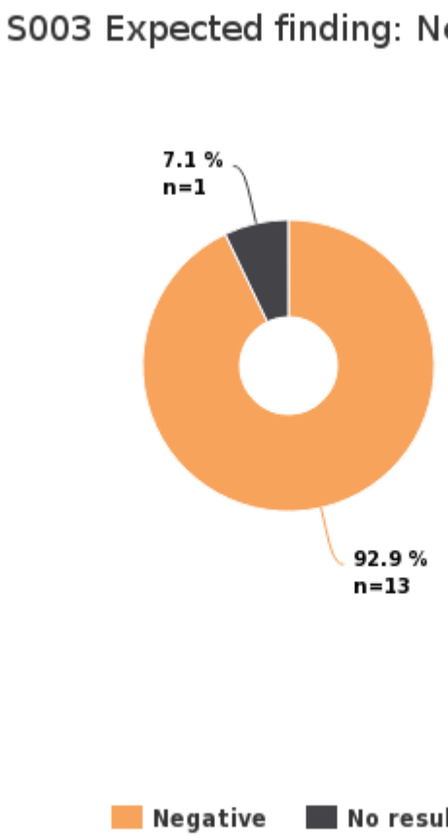
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Microsporum canis	2
	PAN dermatophytes	1
In-house PCR test	Candida albicans	1
	Microsporum canis	1
	◉ Negative	3
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Microsporum canis	3
	Microsporum sp.	1
PathoNostics DermaGenius 3.0 Complete	Microsporum canis	1
	PAN dermatophytes	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		20

S003 | Negative



S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	2	2	100 %	0 %	100 %	14
	Identification tests	-	-	-	-	-	18
Total:		2	2	100 %	0 %	100 %	32



LABORATORY SPECIFIC SCORING TABLE

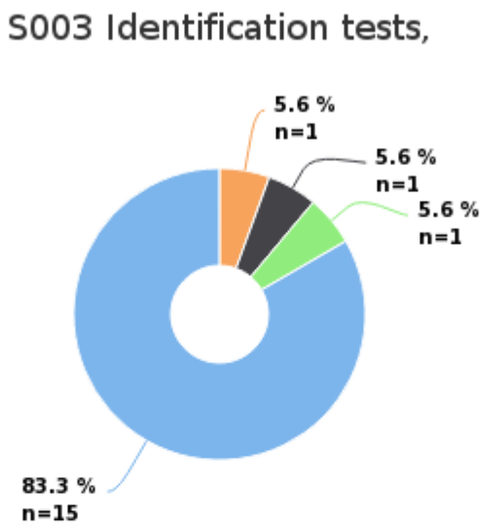
Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
Expected finding: Negative	Negative		2	2	100 %	0 %	100 %
Total:			2	2	100 %	0 %	100 %

REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Negative		**14**	**100 %**
	◉ Negative	13	
	No result	1	
Total:		14	100 %

SCORING SUMMARY

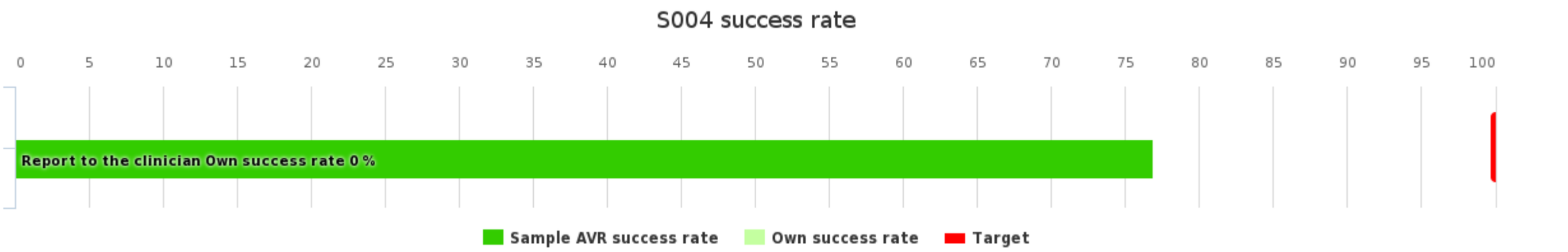
Finding group	Finding	Finding score	Max score
Expected finding: Negative			**2**
	Negative	2	2
	No result	-	-



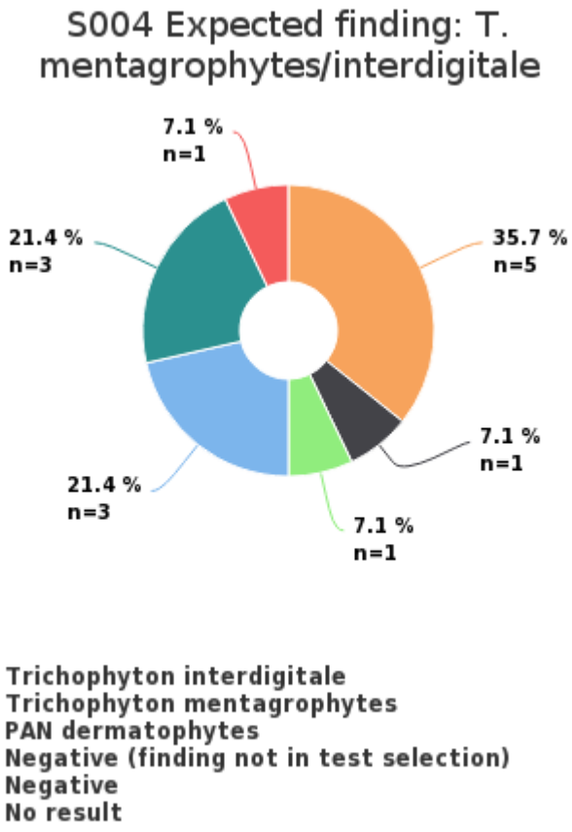
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Negative	2
In-house PCR test	◉ Negative	5
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Negative	4
PathoNostics DermaGenius 3.0 Complete	Negative	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		18

S004 | Trichophyton mentagrophytes/interdigitale



S004 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	0	2	0 %	-76.9 %	76.9 %	14
	Identification tests	-	-	-	-	-	19
Total:		0	2	0 %	-76.9 %	76.9 %	33



LABORATORY SPECIFIC SCORING TABLE

Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
Expected finding: T. mentagrophytes/interdigitale	Negative		0	2	0 %	-76.9 %	76.9 %
Total:			0	2	0 %	-76.9 %	76.9 %

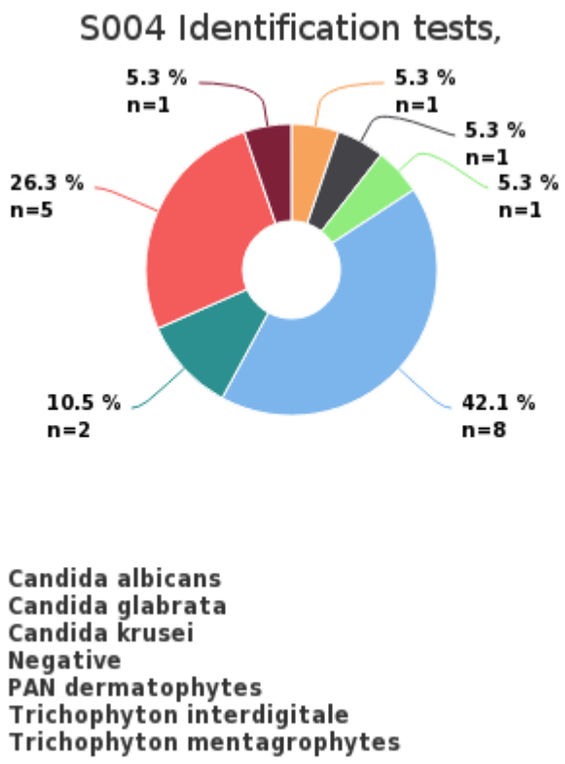
REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: T. mentagrophytes/interdigitale		**14**	**76.9 %**
	Trichophyton interdigitale	5	
	Trichophyton mentagrophytes	1	
	PAN dermatophytes	1	
	Negative (finding not in test selection)	3	
	◉ Negative	3	
	No result	1	
Total:		14	76.9 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
Expected finding: T. mentagrophytes/interdigitale			**2**
	Trichophyton interdigitale	2	2
	Trichophyton mentagrophytes	2	2
	PAN dermatophytes	2	2
	Negative (finding not in test selection)	2	2
	Negative	0	2

	No result	-	-



IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	PAN dermatophytes	1
	Trichophyton interdigitale	2
In-house PCR test	◉ Negative	4
	Trichophyton interdigitale	1
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Negative	1
	Trichophyton interdigitale	2
	Trichophyton mentagrophytes	1
PathoNostics DermaGenius 3.0 Complete	PAN dermatophytes	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		19

Report Info

PARTICIPANTS

Altogether 16 laboratories from 10 countries participated in this EQA round.

REPORT INFO

On the front page you can see summary of overall success rate and sample specific success rates which have been calculated from the scores.
The results are presented in laboratory-specific tables. In general, the expected results are marked with green color. Accepted results, taking into account the participant's test selection, may also be indicated with yellow color. Negative report to clinician is considered correct when the finding in question is not in the reported test selection. 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 "Report to the clinician" part can be scored when at least 60% of the participants, whose test selection includes the finding in question, have reported the correct/expected result and when there are at least three reported results.
The following general rules are applied:

2/2 points is given to results that are correct/accepted regarding the expected result, taking into account the participant's test selection
1/2 point can be given to results that are partly correct/insufficient regarding the expected result
0/2 point is given to results that are incorrect/false regarding the expected result

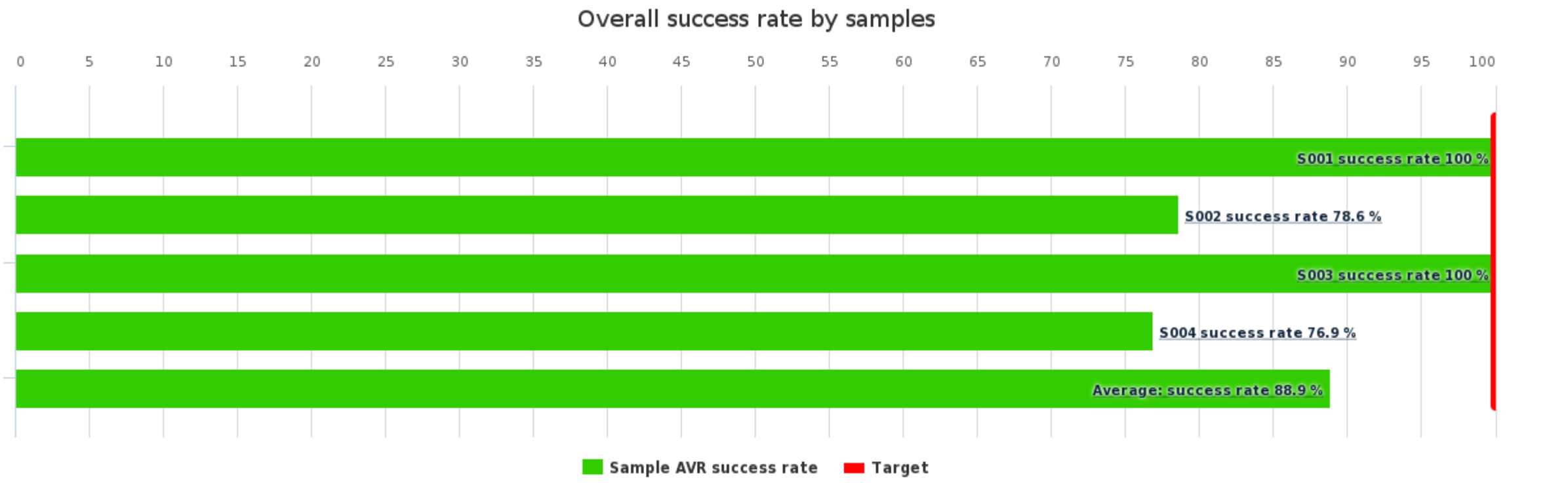
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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

Fungal infections, nucleic acid detection, April, 1-2023

GLOBAL REPORT

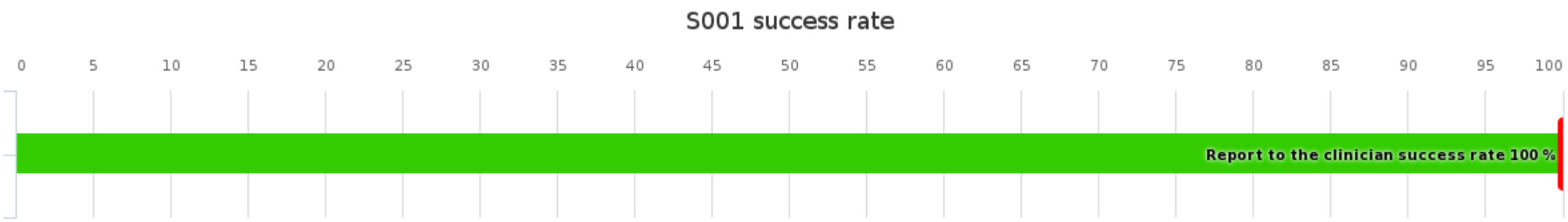
	No of participants	No of responded participants	Response percentage
Fungal infections, nucleic acid detection, April, 1-2023	16	14	87.5 %

Summary

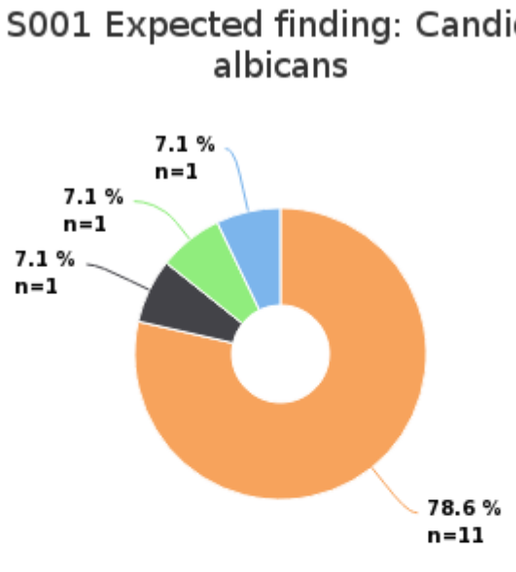


Summary	AVR success rate
S001	100 %
S002	78.6 %
S003	100 %
S004	76.9 %
Average:	88.9 %

S001 | Candida albicans



S001 results	Responded	AVR success rate	Count
	Report to the clinician	100 %	14
	Identification tests	-	18
Total:		100 %	32



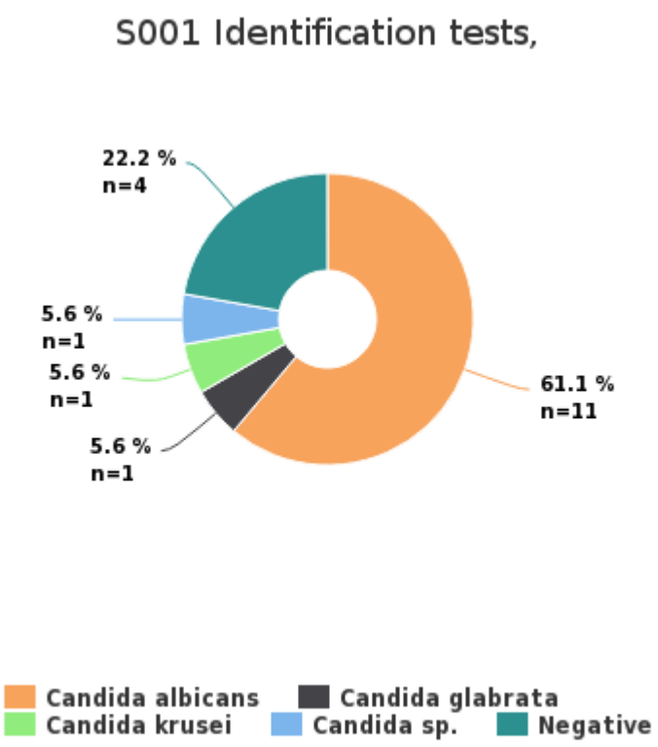
REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Candida albicans		**14**	**100 %**
	Candida albicans	11	
	Candida sp.	1	
	Negative (finding not in test selection)	1	
	No result	1	
Total:		14	100 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
Expected finding: Candida albicans			**2**
	Candida albicans	2	2
	Candida sp.	2	2
	Negative (finding not in test selection)	2	2
	No result	-	-

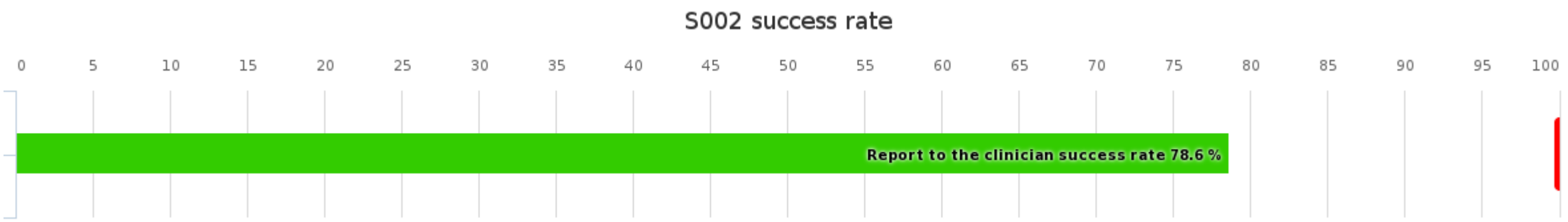
Fungal infections, nucleic acid detection, April, 1-2023



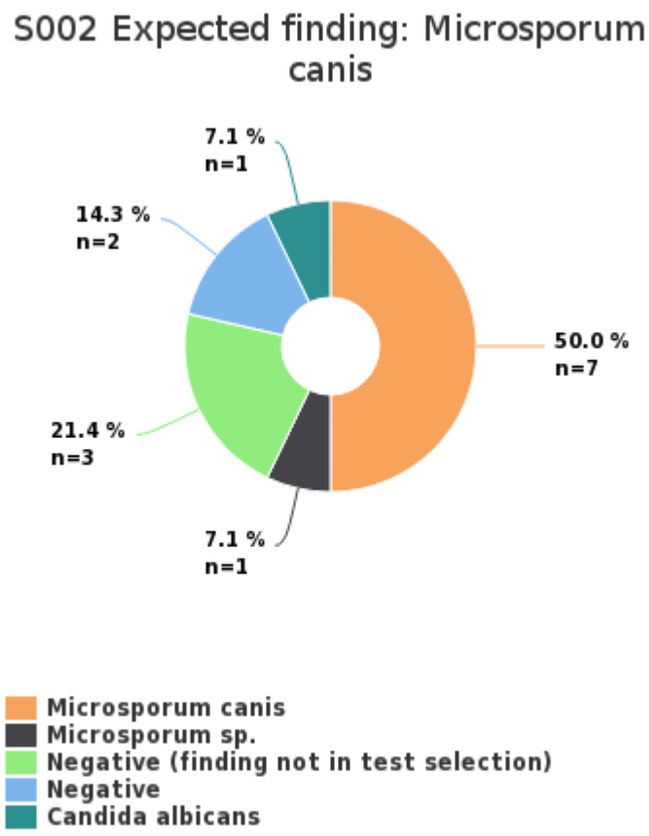
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Candida albicans	2
In-house PCR test	Candida albicans	2
	Candida sp.	1
	Negative	2
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Candida albicans	3
PathoNostics DermaGenius 3.0 Complete	Candida albicans	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	2
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Candida albicans	1
Total:		18

S002 | Microsporum canis



S002 results	Responded	AVR success rate	Count
	Report to the clinician	78.6 %	14
	Identification tests	-	20
Total:		78.6 %	34



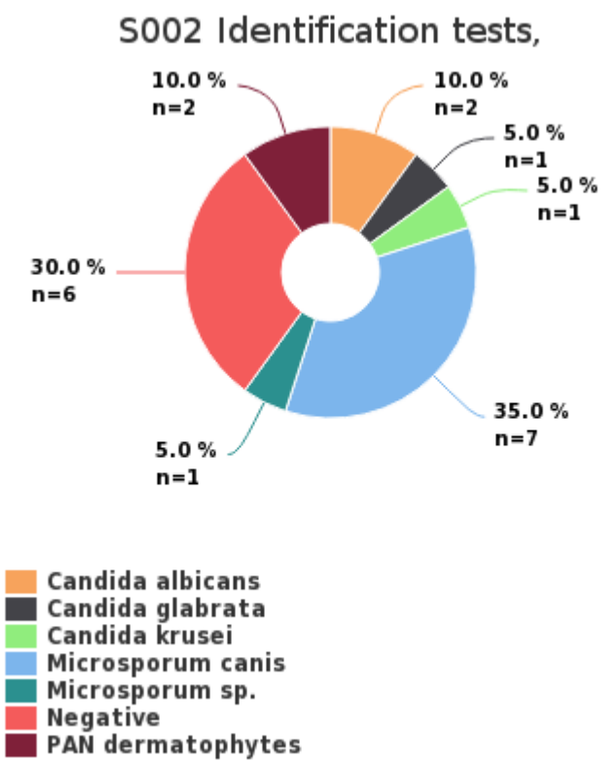
REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Microsporum canis		**14**	**78.6 %**
	Microsporum canis	7	
	Microsporum sp.	1	
	Negative (finding not in test selection)	3	
	Negative	2	
	Candida albicans	1	
Total:		14	78.6 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
Expected finding: Microsporum canis			**2**
	Microsporum canis	2	2
	Microsporum sp.	2	2
	Negative (finding not in test selection)	2	2
	Negative	0	2
	Candida albicans	0	2

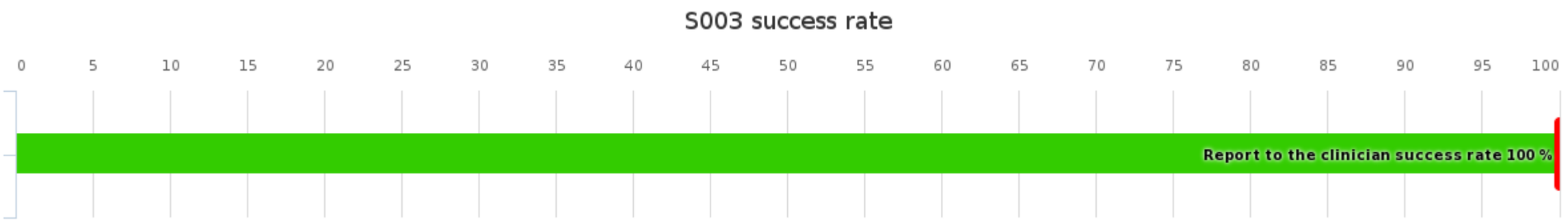
Fungal infections, nucleic acid detection, April, 1-2023



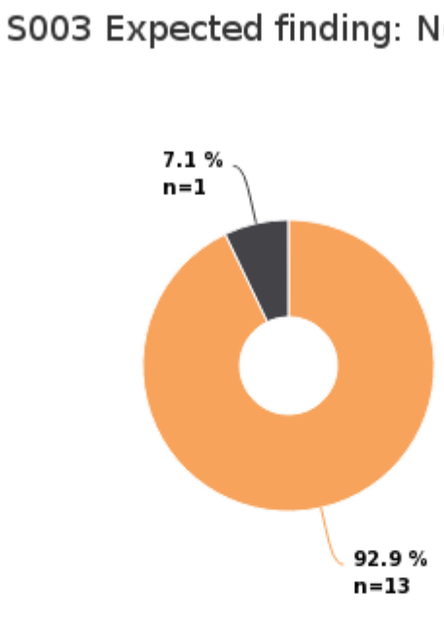
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Microsporum canis	2
	PAN dermatophytes	1
In-house PCR test	Candida albicans	1
	Microsporum canis	1
	Negative	3
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Microsporum canis	3
	Microsporum sp.	1
PathoNostics DermaGenius 3.0 Complete	Microsporum canis	1
	PAN dermatophytes	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		20

S003 | Negative



S003 results	Responded	AVR success rate	Count
	Report to the clinician	100 %	14
	Identification tests	-	18
Total:		100 %	32

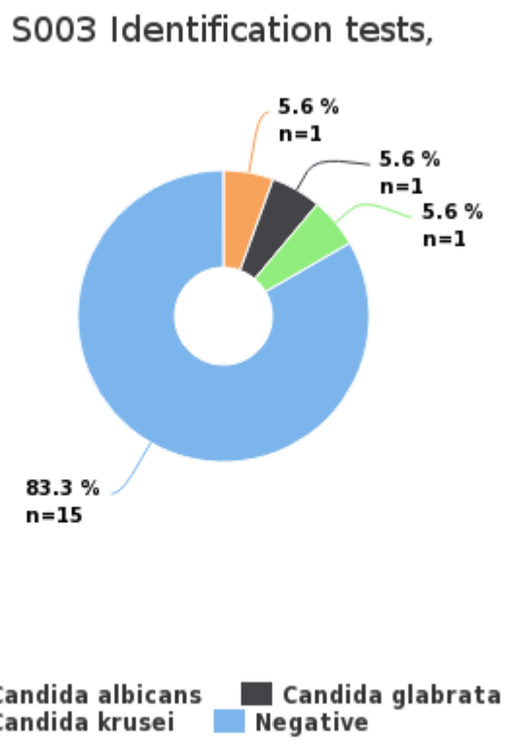


REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: Negative		**14**	**100 %**
	Negative	13	
	No result	1	
Total:		14	100 %

SCORING SUMMARY

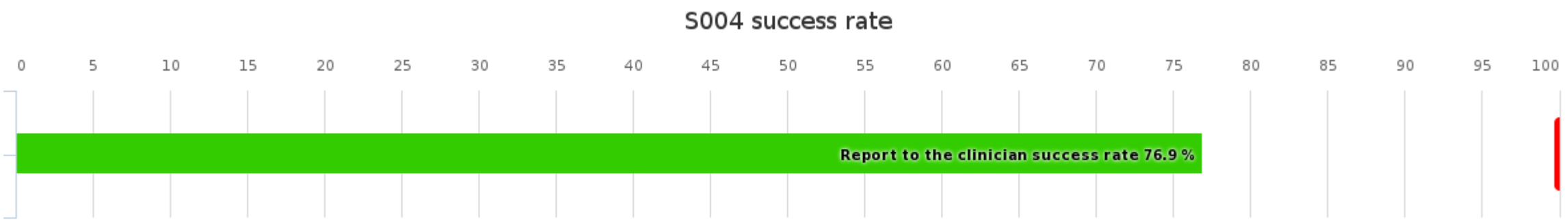
Finding group	Finding	Finding score	Max score
Expected finding: Negative			**2**
	Negative	2	2
	No result	-	-



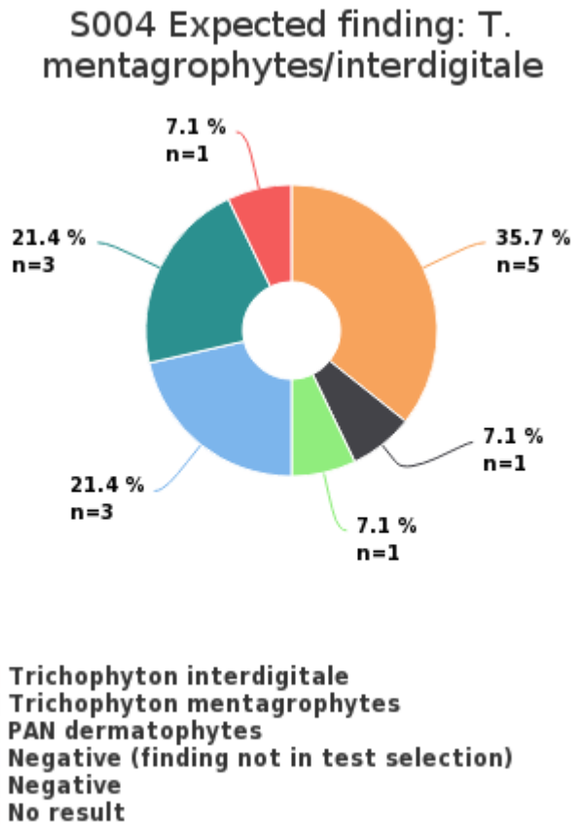
IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	Negative	2
In-house PCR test	Negative	5
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Negative	4
PathoNostics DermaGenius 3.0 Complete	Negative	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		18

S004 | Trichophyton mentagrophytes/interdigitale



S004 results	Responded	AVR success rate	Count
	Report to the clinician	76.9 %	14
	Identification tests	-	19
Total:		76.9 %	33



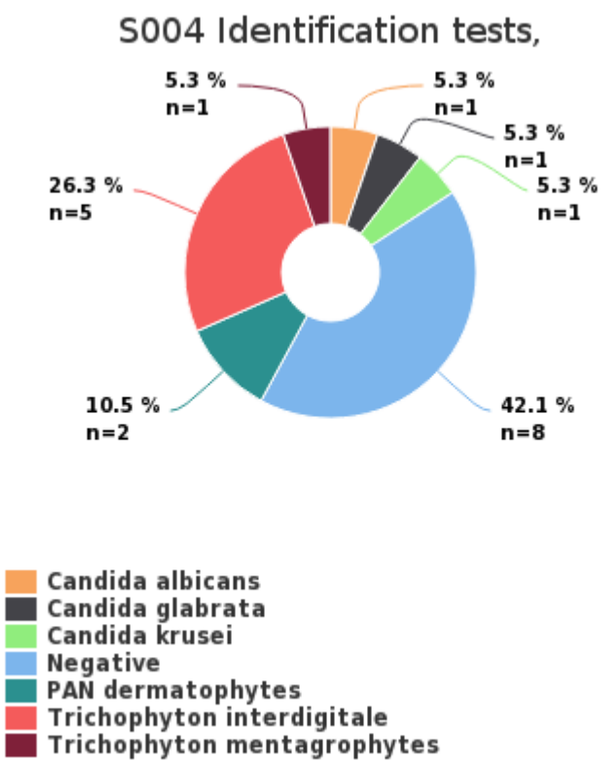
REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	AVR success rate
Expected finding: T. mentagrophytes/interdigitale		**14**	**76.9 %**
	Trichophyton interdigitale	5	
	Trichophyton mentagrophytes	1	
	PAN dermatophytes	1	
	Negative (finding not in test selection)	3	
	Negative	3	
	No result	1	
Total:		14	76.9 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
Expected finding: T. mentagrophytes/interdigitale			**2**
	Trichophyton interdigitale	2	2
	Trichophyton mentagrophytes	2	2
	PAN dermatophytes	2	2
	Negative (finding not in test selection)	2	2
	Negative	0	2
	No result	-	-

Fungal infections, nucleic acid detection, April, 1-2023



IDENTIFICATION TESTS

Method	Result	Result count
EUROIMMUN EUROArray Dermatomycosis	PAN dermatophytes	1
	Trichophyton interdigitale	2
In-house PCR test	Negative	4
	Trichophyton interdigitale	1
PathoNostics AsperGenius® Species	Negative	1
PathoNostics DermaGenius 2.0 Complete	Negative	1
	Trichophyton interdigitale	2
	Trichophyton mentagrophytes	1
PathoNostics DermaGenius 3.0 Complete	PAN dermatophytes	1
PathoNostics MucorGenius	Negative	1
Sacace Candida albicans/glabrata/krusei Real-TM	Candida albicans	1
	Candida glabrata	1
	Candida krusei	1
Sacace Candidosis Real-TM Quant	Negative	1
Total:		19

Report Info

PARTICIPANTS

Altogether 16 laboratories from 10 countries participated in this EQA round.

REPORT INFO

On the front page you can see summary of overall success rate and sample specific success rates which have been calculated from the scores.
The results are presented in laboratory-specific tables. In general, the expected results are marked with green color. Accepted results, taking into account the participant's test selection, may also be indicated with yellow color. Negative report to clinician is considered correct when the finding in question is not in the reported test selection. 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 "Report to the clinician" part can be scored when at least 60% of the participants, whose test selection includes the finding in question, have reported the correct/expected result and when there are at least three reported results.
The following general rules are applied:

2/2 points is given to results that are correct/accepted regarding the expected result, taking into account the participant's test selection
1/2 point can be given to results that are partly correct/insufficient regarding the expected result
0/2 point is given to results that are incorrect/false regarding the expected result

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

Fungal infections, nucleic acid detection Round 1, 2023

Specimens
The samples S001-S003 were simulated swab samples and S004 was a simulated pellet sample, all 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 content of the samples was as follows:

Sample S001 (LQ765223011)
Candida albicans

Sample S002 (LQ765223012)
Microsporum canis

Sample S003 (LQ765223013)
Negative

Sample S004 (LQ765223014)
Trichophyton interdigitale/mentagrophytes

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
This was the first official Fungal infections, nucleic acid detection round and this is the first report. Unfortunately, the background information for the samples was not yet given for this round, however, they are planned to be included in the future as well. The round will make more sense if the laboratory has background information for the samples. Anyway, the round went relatively well. The average success, considering all samples, was 88.9%. The first and the third samples were the easiest in terms of success percentages, and the second and the fourth samples were slightly more challenging. Next, let's see the sample specific comments.

Sample S001 *Candida albicans*
The first sample contained *Candida albicans* yeast. The correct species/genus name was reported by all laboratories who reported that their library (test selection) included this yeast. The success for this sample was therefore 100%, which can be considered as an excellent success. Great!

Sample S002 *Microsporum canis*
The second sample contained *Microsporum canis* fungus. The average success rate taking into account the test selection was 73%. One laboratory reported incorrectly *C. albicans* from this sample. Moreover, two laboratories reported a negative result although PAN dermatophytes were reported to be included in their test selection. However, most commonly the reason for a negative response resulted from the limitation of the library which the laboratory uses and these negative responses were considered as correct.

2023-06-13

FINAL REPORT

Product no. 5261

Samples sent	2032-04-04
Round closed	2023-05-02
Expected results	2023-05-05
Final report	2023-06-13

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.

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Sample S003 Negative

The third sample was negative. This was easy for all laboratories, as no one reported any fungus from this sample. One laboratory reported their answer to clinician as *No result.* The background for this type of answer in this case was not clear, whether there has been some technical problem with this sample or not. Anyway, it is necessary to differentiate the negative and *no result* responses from each other. A negative result indicates a negative PCR result, but *no result* indicates that there has been a problem with the analytics.

Sample S004 *Trichophyton interdigitale/mentagrophytes*

In this round, there was also another dermatophyte: *T. interdigitale/mentagrophytes.* This sample turned out to be even more challenging than the other dermatophyte (S002). Taking into account the test selection, 70% of the laboratories reported the expected result. A positive PAN dermatophyte result was also considered as correct. Often the reason for a negative response resulted from the limitation of the library which the laboratory uses, therefore these negative responses were also considered correct. However, there were some laboratories who reported a negative result, although the PAN dermatophytes were reported to be included in their PCR library panel.

In summary, both the yeast, and the negative sample were easier than the samples containing dermatophytes. We started with these fungi and let's see what is included next time. Hopefully, we can provide also some background information for the samples in future rounds.

Exceptions in scoring

No exceptions.

End of report