LABQUALITY

External Quality Assessment Scheme

Mycobacterial culture and stain Round 1, 2023

Specimens

Please find enclosed 2 lyophilized samples S001 and S002 and 2 smears on slides S003 and S004. The shipment also includes vials of rehydration fluid for S001 and S002, each 0.5 mL.

Caution

Specimens simulate patient specimens and they should be handled in the same way as corresponding specimens capable of transmitting infectious disease.

Background information

Specimen S001 Simulated sputum

Specimen S002 Simulated sputum

Examinations

Mycobacterial culture and stain Mycobacterial nucleic acid detection

Storage and use

After arrival, the samples should be stored at +2...8 °C.

- 1. Let the specimens and the rehydration fluids warm up to room temperature.
- 2. Cut the foil package open at the end where you can feel the thicker part of the loop.
- 3. Remove the plastic sheath from the loop. Break the loop shaft off from handle directly into the tube containing warm rehydration fluid (blue cap). If the volume in one rehydration liquid (à 0.5 mL) tube is not enough for your method, there are two extra tubes included in the package.
- 4. Incubate the tube for 30 minutes in +35...37 °C incubator.
- 5. Check that the black film inside the loop (containing the lyophilized specimen) has dissolved completely.
- 6. Mix well the content of the tube and handle similar to a clinical specimen.

After rehydration specimens S001 and S002 are to be cultured by the method that you routinely use in your laboratory. The specimens should not be decontaminated. After rehydration specimens S001 and S002 are also suitable to be examined by direct nucleic acid detection methods. Specimens S003 and S004 are ready-fixed preparations. They are to be stained by the staining method that you routinely use. Note that the identification number is on the foil package and the slide is not marked.

Result reporting

Please enter the results via LabScala (www.labscala.com). Report to the clinician and Interpretation parts will be scored.

2023-02-28

INSTRUCTIONS

Product no. 5220 LQ760923011-014/US UN3373

Subcontracting: Sample testing

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 26, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 28, 2023.

Inquiries

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Mycobacterial culture and stain

S001



S002



S003



S004



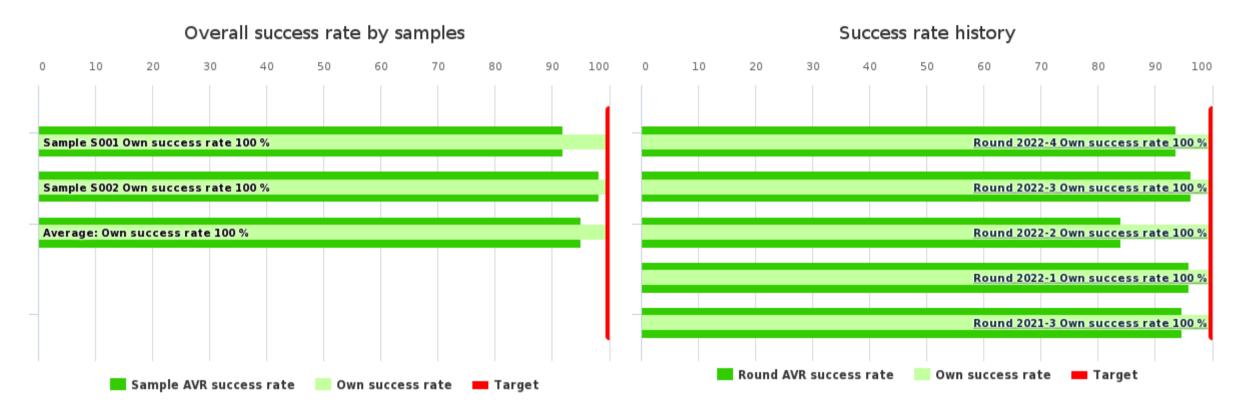


Report to the clinician

Client report

	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	87	94.6 %
Mycobacterial nucleic acid detection, March, 1-2023	23	21	91.3 %

Summary



Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	8 %	92 %
Sample S002	4	4	100 %	1.8 %	98.2 %
Average:			100 %	4.9 %	95.1 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1	100 %	6.3 %	93.7 %
Round 2022-3	1	100 %	3.7 %	96.3 %
Round 2022-2	1	100 %	15.9 %	84.1 %
Round 2022-1	1	100 %	4.1 %	95.9 %
Round 2021-3	1	100 %	5.3 %	94.7 %

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100



10

Report to the clinician

Sample S001 | Mycobacterium intracellulare

15

Report to the clinician Own success rate 100 %

20

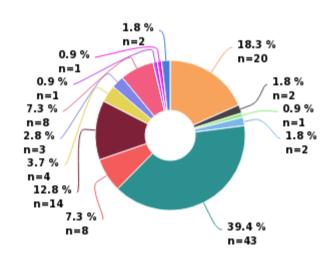
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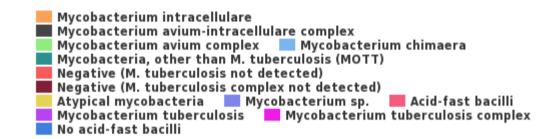




Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	4	4	100 %	8 %	92 %	109
Total:		4	4	100 %	8 %	92 %	109

Sample S001 Mycobacterium intracellulare





LABORATORY SPECIFIC SCORING TABLE

Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
Mycobacterium intracellulare	Mycobacteria, other than M. tuberculosis (MOTT)	Referred for further action	4	4	100 %	8 %	92 %
Total:			4	4	100 %	8 %	92 %

REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	Referred	Not referred	AVR success rate
Mycobacterium intracellulare		109			92 %
	Mycobacterium intracellulare	20	8	12	
	Mycobacterium avium-intracellulare complex	2	1	1	
	Mycobacterium avium complex	1		1	
	Mycobacterium chimaera	2		2	
	Mycobacteria, other than M. tuberculosis (MOTT)	43	26	17	
	Negative (M. tuberculosis not detected)	8	1	7	
	Negative (M. tuberculosis complex not detected)	14	4	10	
	Atypical mycobacteria	4	4		
	Mycobacterium sp.	3	3		
	Acid-fast bacilli	8	5	3	
	Mycobacterium tuberculosis	1	1		
	Mycobacterium tuberculosis complex	1	1		
	No acid-fast bacilli	2		2	

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Report to the clinician

Total:	109		92 %

SCORING SUMMARY

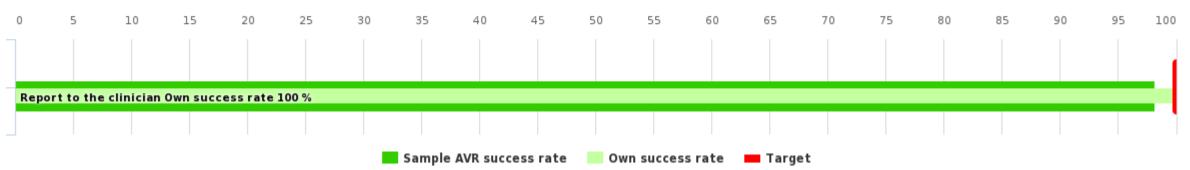
Finding group	Finding	Finding score	Referred	Max score
Mycobacterium intracellulare				4
	Mycobacterium intracellulare	4		4
	Mycobacterium avium-intracellulare complex	4		4
	Mycobacterium avium complex	4		4
	Mycobacterium chimaera	4		4
	Mycobacteria, other than M. tuberculosis (MOTT)	4		4
	Negative (M. tuberculosis not detected)	4		4
	Negative (M. tuberculosis complex not detected)	4		4
	Atypical mycobacteria	4		4
	Mycobacterium sp.	4		4
	Acid-fast bacilli	1	1	4
	Mycobacterium tuberculosis	0		4
	Mycobacterium tuberculosis complex	0		4
	No acid-fast bacilli	0		4
Total:				4



Report to the clinician

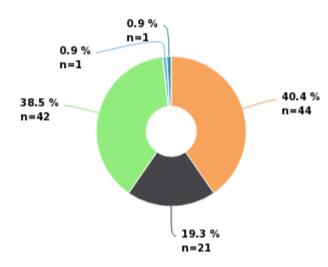
Sample S002 | No acid-fast bacilli





Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Report to the clinician	4	4	100 %	1.8 %	98.2 %	109
Total:		4	4	100 %	1.8 %	98.2 %	109

Sample S002 No acid-fast bacilli





LABORATORY SPECIFIC SCORING TABLE

Finding group	Finding	Further action	Own score	Max score	Own success rate	Difference	AVR success rate
No acid-fast bacilli	Negative (M. tuberculosis complex not detected)	Not referred for further action	4	4	100 %	1.8 %	98.2 %
Total:			4	4	100 %	1.8 %	98.2 %

REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	Referred	Not referred	AVR success rate
No acid-fast bacilli		109			98.2 %
	No acid-fast bacilli	44	1	43	
	Negative (M. tuberculosis not detected)	21	7	14	
	 Negative (M. tuberculosis complex not detected) 	42	2	40	
	Mycobacterium tuberculosis	1	1		
	Mycobacterium tuberculosis complex	1	1		
Total:		109			98.2 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
No acid-fast bacilli			4
	No acid-fast bacilli	4	4
	Negative (M. tuberculosis not detected)	4	4
	Negative (M. tuberculosis complex not detected)	4	4
	Mycobacterium tuberculosis	0	4
	Mycobacterium tuberculosis complex	0	4
otal:			4



Report to the clinician

XXXXX

Report Info

PARTICIPANTS

Altogether 115 laboratories from 14 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. The reported results and the scores are presented in the same report but in separate tables.

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 . In the participant specific report there is also a laboratory specific scoring table for each sample, where you can find your own result and the scores given.

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

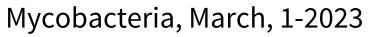
The results in the "Report to the clinician" part can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results. The report includes a sample specific scoring summary.

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: 4 points is reached by reporting the expected result
1-3 points is given to results that are partly correct/insufficient regarding the expected finding
0 points is given for an incorrect/false result

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Culture media and identification tests

Client report

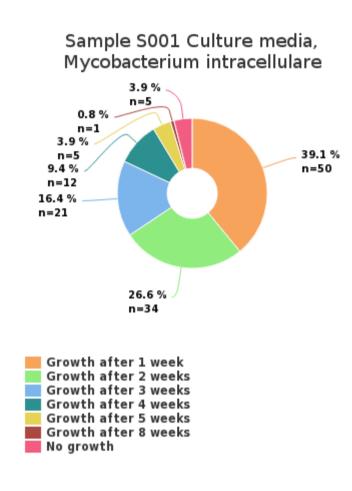
	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	86	93.5 %
Mycobacterial nucleic acid detection, March, 1-2023	23	21	91.3 %



Culture media and identification tests

Sample S001 | Mycobacterium intracellulare

Sample S001 results	Responded	Count
	Culture media	128
	Identification tests: NAT	92
	Identification tests: Other	56
	Identification tests: MALDI-TOF	8
Total:		284



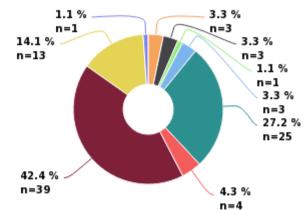
CULTURE MEDIA

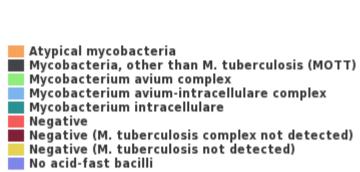
Finding group	Method	Growth after 1 week	Growth after 2 weeks	Growth after 3 weeks	Growth after 4 weeks	Growth after 5 weeks	Growth after 8 weeks	No growth	Total:
Mycobacterium intracellulare									128
	BacT/ALERT MP (bioMerieux)	1	-	-	-	-	-	-	1
	Bactec MGIT (BD)	36	1	2	-	-	-	2	41
	Bactec Myco/F Lytic Culture Vials (BD)	-	1	-	-	-	-	-	1
	Coletsos medium	1	3	3	2	1	-	2	12
	Finlayson medium	-	-	1	-	-	-	-	1
	Löwenstein-Jensen	10	28	15	9	2	1	1	66
	Löwenstein-Jensen+pyruvic acid	-	1	-	1	1	-	-	3
	MiddleBrooks	1	-	-	-	-	-	-	1
	Stonebrink medium	-	-	-	-	1	-	-	1
	VersaTREK Myco medium	1	-	-	-	-	-	-	1
	Total:	50	34	21	12	5	1	5	128



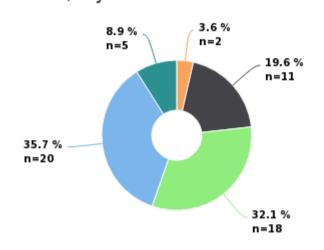
Culture media and identification tests

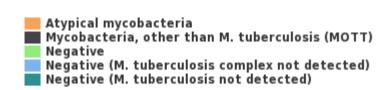






Sample S001 Identification tests: Other, Mycobacterium intracellulare





IDENTIFICATION TESTS: NAT

Finding group	Method	Result	Result count
Mycobacterium intracellulare	BD MAX MDR-TB panel (BD)	Negative	1
		Negative (M. tuberculosis complex not detected)	1
	GenoType MTBC (Hain Lifescience)	Mycobacterium intracellulare	1
	GenoType MTBDRplus 2.0 (Hain Lifescience)	Atypical mycobacteria	1
	GenoType mycobacterium AS (Hain Lifescience)	Mycobacteria, other than M. tuberculosis (MOTT)	1
	GenoType mycobacterium CM (Hain Lifescience)	Atypical mycobacteria	1
		Mycobacterium avium complex	1
		Mycobacterium avium-intracellulare complex	2
		Mycobacterium intracellulare	13
	GenoType NTM-DR (Hain Lifescience)	Mycobacterium intracellulare	6
	In-house hsp65 gene sequencing	Mycobacterium avium-intracellulare complex	1
		Mycobacterium intracellulare	4
	In-house PCR	Mycobacterium intracellulare	1
	MDR/MTB ELITe MGB Kit (ELITechGroup)	Negative (M. tuberculosis complex not detected)	1
	Seegene Anyplex MTB/NTM Real-time Detection	Atypical mycobacteria	1
	Xpert MTB/RIF (Cepheid)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	6
		Negative (M. tuberculosis not detected)	3
	Xpert MTB/RIF Ultra (Cepheid)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	2
		Negative (M. tuberculosis complex not detected)	31
		Negative (M. tuberculosis not detected)	10
		No acid-fast bacilli	1
Total:			92

IDENTIFICATION TESTS: OTHER

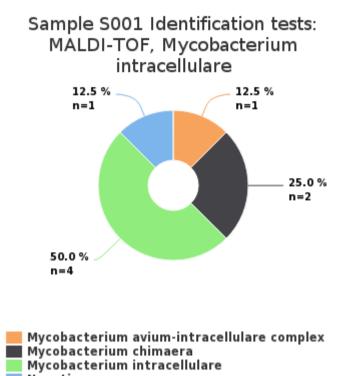
Finding group	Method	Result	Result count
Mycobacterium intracellulare	BD MGIT TBc Identification test (BD)	Atypical mycobacteria	1
		Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	5
	In-house Nitrate test	Negative (M. tuberculosis complex not detected)	1
	SD BIOLINE TB Ag MPT64 (SD)	Atypical mycobacteria	1
		Mycobacteria, other than M. tuberculosis (MOTT)	7
		Negative	15
		 Negative (M. tuberculosis complex not detected) 	13
		Negative (M. tuberculosis not detected)	3
	TB MPT 64 Ag test (ubio Biotechnology Systems)	Mycobacteria, other than M. tuberculosis (MOTT)	2
		Negative	2
		Negative (M. tuberculosis not detected)	2



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Culture media and identification tests

	TBCheck MPT64 (Hain Lifescience)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative (M. tuberculosis complex not detected)	1
Total:			56



IDENTIFICATION TESTS: MALDI-TOF

Négative

Finding group	Method	Result	Score / Probability	Score / Probability % count
Mycobacterium intracellulare	MALDI Biotyper (Bruker)	Mycobacterium avium-intracellulare complex	≥2	1
		Mycobacterium chimaera	≥2	2
		Mycobacterium intracellulare	≥2	1
			≥1.7<2	1
		Negative	N/A	1
	VITEK MS (bioMérieux)	Mycobacterium intracellulare	99,9 %	1
			99,5 %	1
Total:				8

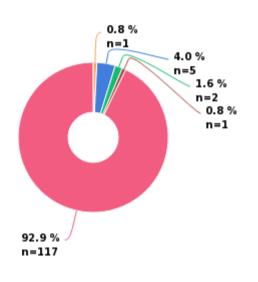


Culture media and identification tests

Sample S002 | No acid-fast bacilli

Sample S002 results	Responded	Count
	Culture media	126
	Identification tests: NAT	58
	Identification tests: Other	4
Total:		188

Sample S002 Culture media, No acidfast bacilli





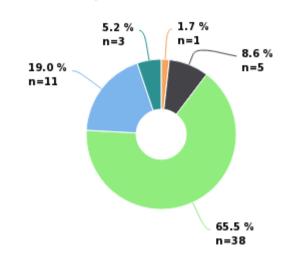
CULTURE MEDIA

Finding group	Method	Growth after 1 week	Growth after 6 weeks	Growth after 7 weeks	Growth after 8 weeks	No growth	Total:
No acid-fast bacilli							126
	BacT/ALERT MP (bioMerieux)	-	-	-	-	1	1
	Bactec MGIT (BD)	1	-	-	-	38	39
	Bactec Myco/F Lytic Culture Vials (BD)	-	-	-	-	1	1
	Coletsos medium	-	-	-	-	11	11
	Finlayson medium	-	-	-	-	1	1
	Löwenstein-Jensen	-	4	1	1	61	67
	Löwenstein-Jensen+pyruvic acid	-	-	-	-	3	3
	MiddleBrooks	-	1	-	-	-	1
	Stonebrink medium	-	-	1	-	-	1
	VersaTREK Myco medium	-	-	-	-	1	1
	Total:	1	5	2	1	117	126

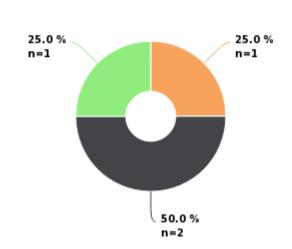
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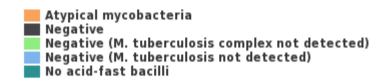
Culture media and identification tests

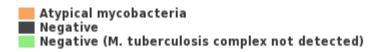
Sample S002 Identification tests: NAT, No acid-fast bacilli



Sample S002 Identification tests: Other, No acid-fast bacilli







IDENTIFICATION TESTS: NAT

Finding group	Method	Result	Result count
No acid-fast bacilli	BD MAX MDR-TB panel (BD)	Negative	1
		Negative (M. tuberculosis complex not detected)	1
	GenoType MTBDRplus 2.0 (Hain Lifescience)	Atypical mycobacteria	1
	GenoType mycobacterium CM (Hain Lifescience)	No acid-fast bacilli	2
	Seegene Anyplex MTB/NTM Real-time Detection	Negative	1
	Xpert MTB/RIF (Cepheid)	Negative	1
		Negative (M. tuberculosis complex not detected)	6
		Negative (M. tuberculosis not detected)	2
	Xpert MTB/RIF Ultra (Cepheid)	Negative	2
		Negative (M. tuberculosis complex not detected)	31
		Negative (M. tuberculosis not detected)	9
		No acid-fast bacilli	1
otal:			58

IDENTIFICATION TESTS: OTHER

Finding group	Method	Result	Result count
No acid-fast bacilli	SD BIOLINE TB Ag MPT64 (SD)	Atypical mycobacteria	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	1
	TB MPT 64 Ag test (ubio Biotechnology Systems)	Negative	1
Total:			4

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Mycobacterial staining

Client report

	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	90	97.8 %
Mycobacterial stain, March, 1-2023	37	35	94.6 %

Summary



Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S003	2	2	100 %	3.8 %	96.2 %
Sample S004	2	2	100 %	6.9 %	93.1 %
Average:			100 %	5.4 %	94.6 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	0 %	-92 %	92 %
Round 2022-3	1-1	100 %	8.2 %	91.8 %
Round 2022-2	1-1	100 %	5.6 %	94.4 %
Round 2022-1	1-1	100 %	6.7 %	93.3 %
Round 2021-3	1-1	100 %	8.6 %	91.4 %

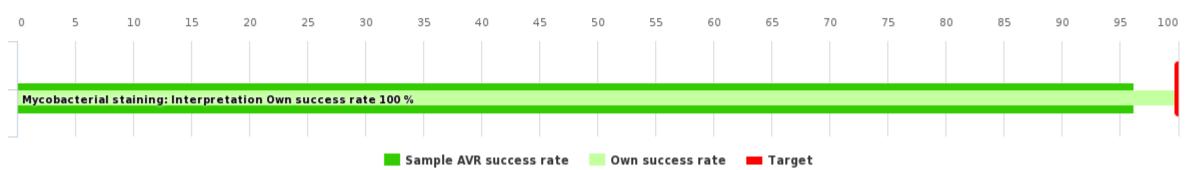
1/4



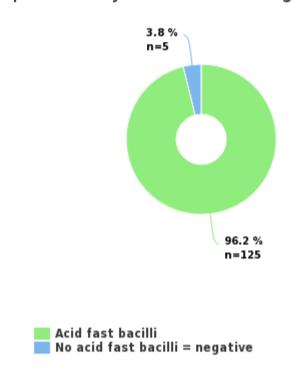
Mycobacterial staining

Sample S003 | Positive / AFB, +++

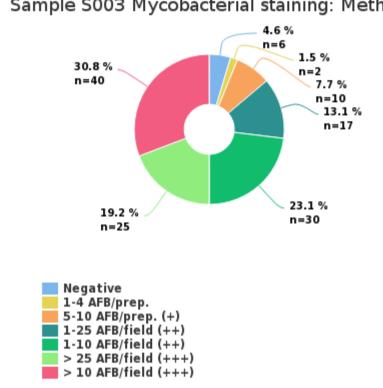




Sample S003 Mycobacterial staining: Interpretation



Sample S003 Mycobacterial staining: Method



MYCOBACTERIAL STAINING: INTERPRETATION

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Acid fast bacilli	125	2	2	100 %	0 %	100 %
No acid fast bacilli = negative	5	-				0 %
Total:	130	2	2	100 %	3.8 %	96.2 %

MYCOBACTERIAL STAINING: METHOD

Method	Negative	1-4 AFB/prep.	5-10 AFB/prep. (+)	1-25 AFB/field (++)	1-10 AFB/field (++)	> 25 AFB/field (+++)	> 10 AFB/field (+++)	Total:
Acridine orange	-	-	-	1	-	2	-	3
Auramine	2	1	1	5	3	14	7	33
Auramine-Rodamine	-	_	-	3	1	4	1	9
Kinyoun	-	-	3	2	3	-	1	9
Tan-Thiam-Hok	-	-	-	-	1	-	-	1
Ziehl-Neelsen	4	1	6	6	22	5	31	75
Total:	6	2	10	17	30	25	40	130

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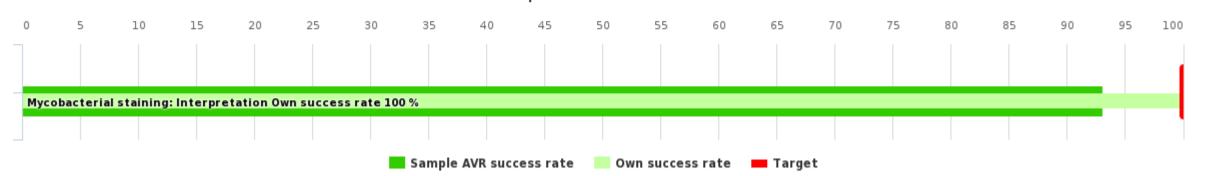
2/4 10.05.2023



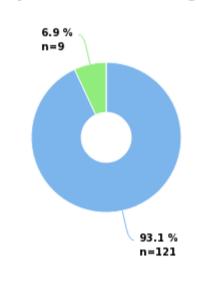
Mycobacterial staining

Sample S004 | No acid-fast bacilli

Sample S004 success rate

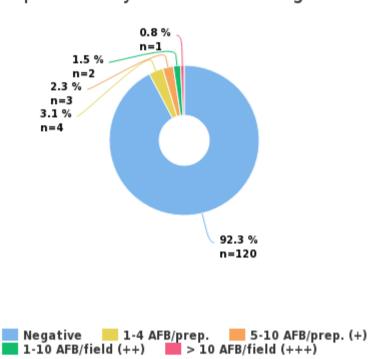


Sample S004 Mycobacterial staining: Interpretation





Sample S004 Mycobacterial staining: Method



MYCOBACTERIAL STAINING: INTERPRETATION

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
● No acid fast bacilli = negative	121	2	2	100 %	0 %	100 %
Acid fast bacilli	9	-				0 %
Total:	130	2	2	100 %	6.9 %	93.1 %

MYCOBACTERIAL STAINING: METHOD

Method	Negative	1-4 AFB/prep.	5-10 AFB/prep. (+)	1-10 AFB/field (++)	> 10 AFB/field (+++)	Total:
Acridine orange	3	-	-	-	-	3
Auramine	37	1	-	-	-	38
Auramine-Rodamine	7	-	-	-	-	7
Kinyoun	8	-	-	1	-	9
Tan-Thiam-Hok	1	-	-	-	-	1
Ziehl-Neelsen	• 64	3	3	1	1	72
Total:	120	4	3	2	1	130

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Mycobacterial staining

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Report Info

PARTICIPANTS

Altogether 127 laboratories from 14 countries participated in this EQA round.

REPORT INFO

On the front page you can see a summary of the overall average 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 . In the participant specific report there is also a laboratory specific scoring table for each sample, where you can find your own result and the scores given..

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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 "Interpretation" part 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. 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 correct result 0 points is given for an incorrect/false result

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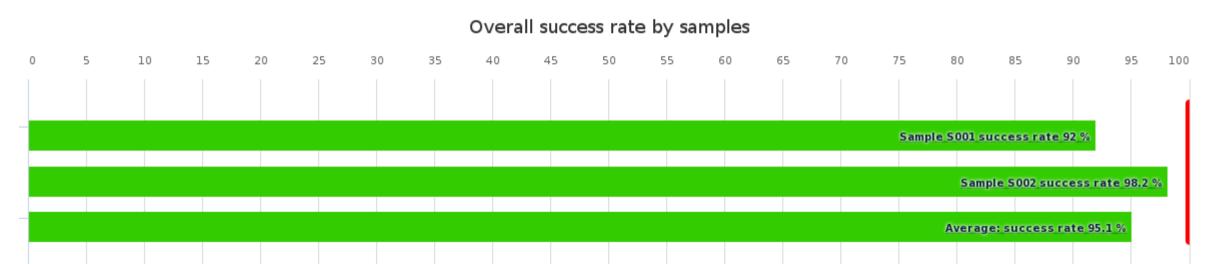


Report to the clinician

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	87	94.6 %
Mycobacterial nucleic acid detection, March, 1-2023	23	21	91.3 %

Summary



Sample AVR success rate Target

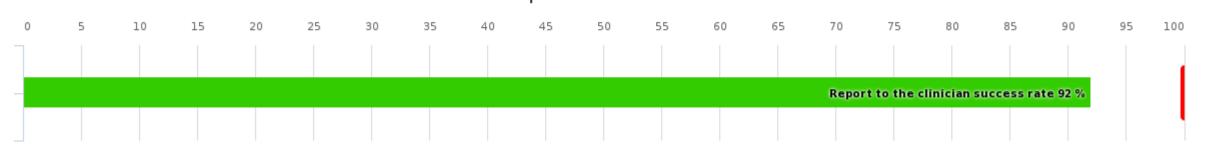




Report to the clinician

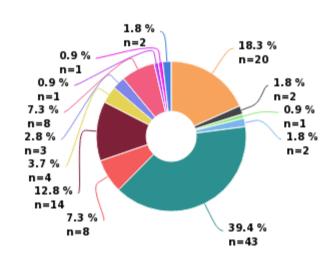
Sample S001 | Mycobacterium intracellulare

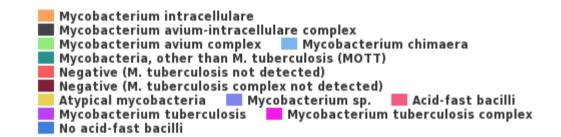
Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Report to the clinician	92 %	109
Total:		92 %	109

Sample S001 Mycobacterium intracellulare





REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	Referred	Not referred	AVR success rate
Mycobacterium intracellulare		109			92 %
	Mycobacterium intracellulare	20	8	12	
	Mycobacterium avium-intracellulare complex	2	1	1	
	Mycobacterium avium complex	1		1	
	Mycobacterium chimaera	2		2	
	Mycobacteria, other than M. tuberculosis (MOTT)	43	26	17	
	Negative (M. tuberculosis not detected)	8	1	7	
	Negative (M. tuberculosis complex not detected)	14	4	10	
	Atypical mycobacteria	4	4		
	Mycobacterium sp.	3	3		
	Acid-fast bacilli	8	5	3	
	Mycobacterium tuberculosis	1	1		
	Mycobacterium tuberculosis complex	1	1		
	No acid-fast bacilli	2		2	
Total:		109			92 %

SCORING SUMMARY

Finding group	Finding	Finding score	Referred	Max score
Mycobacterium intracellulare				4
	Mycobacterium intracellulare	4		4
	Mycobacterium avium-intracellulare complex	4		4

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Report to the clinician

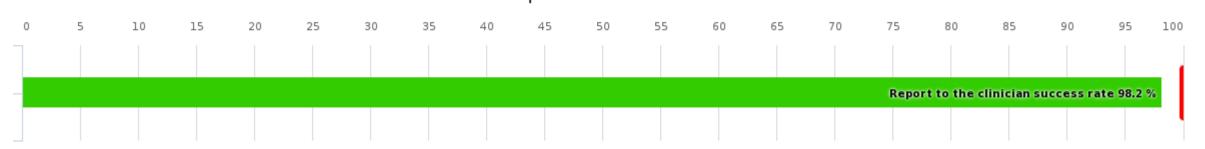
Mycobacterium avium complex	4		4
Mycobacterium chimaera	4		4
Mycobacteria, other than M. tuberculosis (MOTT)	4		4
Negative (M. tuberculosis not detected)	4		4
Negative (M. tuberculosis complex not detected)	4		4
Atypical mycobacteria	4		4
Mycobacterium sp.	4		4
Acid-fast bacilli	1	1	4
Mycobacterium tuberculosis	0		4
Mycobacterium tuberculosis complex	0		4
No acid-fast bacilli	0		4
Total:			4



Report to the clinician

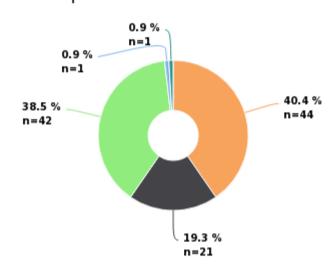
Sample S002 | No acid-fast bacilli

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Report to the clinician	98.2 %	109
	Total:	98.2 %	109

Sample S002 No acid-fast bacilli





REPORT TO THE CLINICIAN

Finding group	Finding	Finding count	Referred	Not referred	AVR success rate
No acid-fast bacilli		109			98.2 %
	No acid-fast bacilli	44	1	43	
	Negative (M. tuberculosis not detected)	21	7	14	
	Negative (M. tuberculosis complex not detected)	42	2	40	
	Mycobacterium tuberculosis	1	1		
	Mycobacterium tuberculosis complex	1	1		
Total:		109			98.2 %

SCORING SUMMARY

Finding group	Finding	Finding score	Max score
No acid-fast bacilli			4
	No acid-fast bacilli	4	4
	Negative (M. tuberculosis not detected)	4	4
	Negative (M. tuberculosis complex not detected)	4	4
	Mycobacterium tuberculosis	0	4
	Mycobacterium tuberculosis complex	0	4
Total:			4

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Report to the clinician

Report Info

PARTICIPANTS

Altogether 115 laboratories from 14 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. The reported results and the scores are presented in the same report but in separate tables.

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 . In the participant specific report there is also a laboratory specific scoring table for each sample, where you can find your own result and the scores given.

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 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: 4 points is reached by reporting the expected result
1-3 points is given to results that are partly correct/insufficient regarding the expected finding
0 points is given for an incorrect/false result

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09.05.2023 5/5



Culture media and identification tests

GLOBAL REPORT

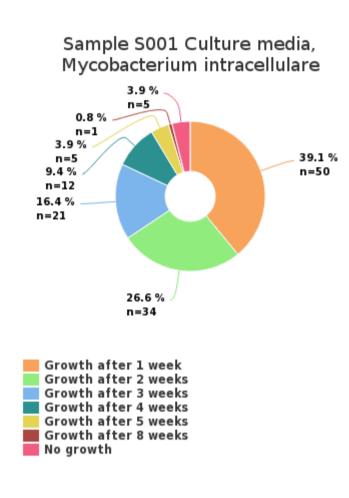
	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	86	93.5 %
Mycobacterial nucleic acid detection, March, 1-2023	23	21	91.3 %



Culture media and identification tests

Sample S001 | Mycobacterium intracellulare

Sample S001 results	Responded	Count
	Culture media	128
	Identification tests: NAT	92
	Identification tests: Other	56
	Identification tests: MALDI-TOF	8
Total:		284

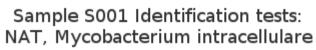


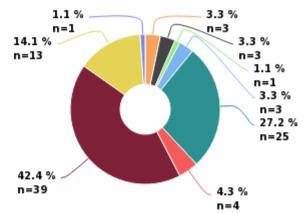
CULTURE MEDIA

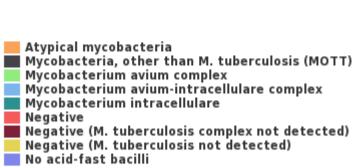
Finding group	Method	Growth after 1 week	Growth after 2 weeks	Growth after 3 weeks	Growth after 4 weeks	Growth after 5 weeks	Growth after 8 weeks	No growth	Total:
Mycobacterium intracellulare									128
	BacT/ALERT MP (bioMerieux)	1	-	-	-	-	-	-	1
	Bactec MGIT (BD)	36	1	2	-	-	-	2	41
	Bactec Myco/F Lytic Culture Vials (BD)	-	1	-	-	-	-	-	1
	Coletsos medium	1	3	3	2	1	-	2	12
	Finlayson medium	-	-	1	-	-	-	-	1
	Löwenstein-Jensen	10	28	15	9	2	1	1	66
	Löwenstein-Jensen+pyruvic acid	-	1	-	1	1	-	-	3
	MiddleBrooks	1	-	-	-	-	-	-	1
	Stonebrink medium	-	-	-	-	1	-	-	1
	VersaTREK Myco medium	1	-	-	-	-	-	-	1
	Total:	50	34	21	12	5	1	5	128



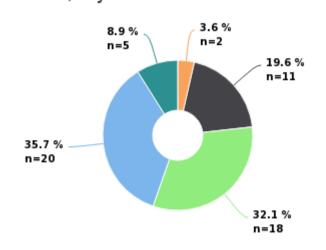
Culture media and identification tests

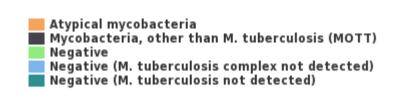






Sample S001 Identification tests: Other, Mycobacterium intracellulare





IDENTIFICATION TESTS: NAT

Finding group	Method	Result	Result count
Mycobacterium intracellulare	BD MAX MDR-TB panel (BD)	Negative	1
		Negative (M. tuberculosis complex not detected)	1
	GenoType MTBC (Hain Lifescience)	Mycobacterium intracellulare	1
	GenoType MTBDRplus 2.0 (Hain Lifescience)	Atypical mycobacteria	1
	GenoType mycobacterium AS (Hain Lifescience)	Mycobacteria, other than M. tuberculosis (MOTT)	1
	GenoType mycobacterium CM (Hain Lifescience)	Atypical mycobacteria	1
		Mycobacterium avium complex	1
		Mycobacterium avium-intracellulare complex	2
		Mycobacterium intracellulare	13
	GenoType NTM-DR (Hain Lifescience)	Mycobacterium intracellulare	6
	In-house hsp65 gene sequencing	Mycobacterium avium-intracellulare complex	1
		Mycobacterium intracellulare	4
	In-house PCR	Mycobacterium intracellulare	1
	MDR/MTB ELITe MGB Kit (ELITechGroup)	Negative (M. tuberculosis complex not detected)	1
	Seegene Anyplex MTB/NTM Real-time Detection	Atypical mycobacteria	1
	Xpert MTB/RIF (Cepheid)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	6
		Negative (M. tuberculosis not detected)	3
	Xpert MTB/RIF Ultra (Cepheid)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	2
		Negative (M. tuberculosis complex not detected)	31
		Negative (M. tuberculosis not detected)	10
		No acid-fast bacilli	1
Total:			92

IDENTIFICATION TESTS: OTHER

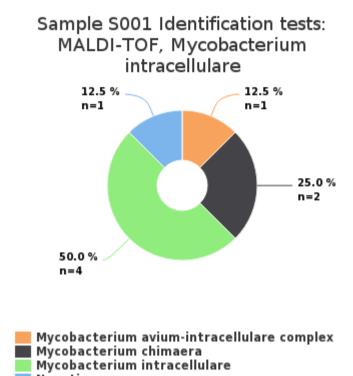
Finding group	Method	Result	Result count
Mycobacterium intracellulare	BD MGIT TBc Identification test (BD)	Atypical mycobacteria	1
		Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	5
	In-house Nitrate test	Negative (M. tuberculosis complex not detected)	1
	SD BIOLINE TB Ag MPT64 (SD)	Atypical mycobacteria	1
		Mycobacteria, other than M. tuberculosis (MOTT)	7
		Negative	15
		Negative (M. tuberculosis complex not detected)	13
		Negative (M. tuberculosis not detected)	3
	TB MPT 64 Ag test (ubio Biotechnology Systems)	Mycobacteria, other than M. tuberculosis (MOTT)	2
		Negative	2
		Negative (M. tuberculosis not detected)	2

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Culture media and identification tests

	TBCheck MPT64 (Hain Lifescience)	Mycobacteria, other than M. tuberculosis (MOTT)	1
		Negative (M. tuberculosis complex not detected)	1
Total:			56



IDENTIFICATION TESTS: MALDI-TOF

Négative

Finding group	Method	Result	Score / Probability	Score / Probability % count
Mycobacterium intracellulare	MALDI Biotyper (Bruker)	Mycobacterium avium-intracellulare complex	≥2	1
		Mycobacterium chimaera	≥2	2
		Mycobacterium intracellulare	≥2	1
			≥1.7<2	1
		Negative	N/A	1
	VITEK MS (bioMérieux)	Mycobacterium intracellulare	99,9 %	1
			99,5 %	1
Total:				8

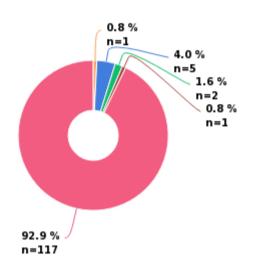


Culture media and identification tests

Sample S002 | No acid-fast bacilli

Sample S002 results	Responded	Count
	Culture media	126
	Identification tests: NAT	58
	Identification tests: Other	4
Total:		188

Sample S002 Culture media, No acidfast bacilli





CULTURE MEDIA

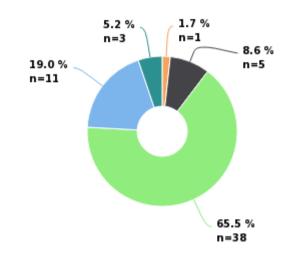
Finding group	Method	Growth after 1 week	Growth after 6 weeks	Growth after 7 weeks	Growth after 8 weeks	No growth	Total:
No acid-fast bacilli							126
	BacT/ALERT MP (bioMerieux)	-	-	-	-	1	1
	Bactec MGIT (BD)	1	-	-	-	38	39
	Bactec Myco/F Lytic Culture Vials (BD)	-	-	-	-	1	1
	Coletsos medium	-	-	-	-	11	11
	Finlayson medium	-	-	-	-	1	1
	Löwenstein-Jensen	-	4	1	1	61	67
	Löwenstein-Jensen+pyruvic acid	-	-	-	-	3	3
	MiddleBrooks	-	1	-	-	-	1
	Stonebrink medium	-	-	1	-	-	1
	VersaTREK Myco medium	-	-	-	-	1	1
	Total:	1	5	2	1	117	126

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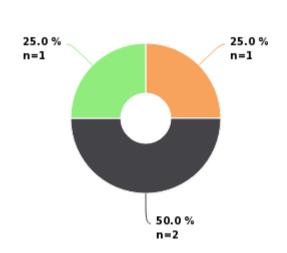


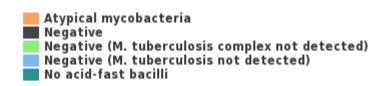
Culture media and identification tests

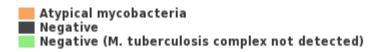
Sample S002 Identification tests: NAT, No acid-fast bacilli



Sample S002 Identification tests: Other, No acid-fast bacilli







IDENTIFICATION TESTS: NAT

Finding group	Method	Result	Result count
No acid-fast bacilli	BD MAX MDR-TB panel (BD)	Negative	1
		Negative (M. tuberculosis complex not detected)	1
	GenoType MTBDRplus 2.0 (Hain Lifescience)	Atypical mycobacteria	1
	GenoType mycobacterium CM (Hain Lifescience)	No acid-fast bacilli	2
	Seegene Anyplex MTB/NTM Real-time Detection	Negative	1
	Xpert MTB/RIF (Cepheid)	Negative	1
		Negative (M. tuberculosis complex not detected)	6
		Negative (M. tuberculosis not detected)	2
	Xpert MTB/RIF Ultra (Cepheid)	Negative	2
		Negative (M. tuberculosis complex not detected)	31
		Negative (M. tuberculosis not detected)	9
		No acid-fast bacilli	1
Γotal:			58

IDENTIFICATION TESTS: OTHER

Finding group	Method	Result	Result count
No acid-fast bacilli	SD BIOLINE TB Ag MPT64 (SD)	Atypical mycobacteria	1
		Negative	1
		Negative (M. tuberculosis complex not detected)	1
	TB MPT 64 Ag test (ubio Biotechnology Systems)	Negative	1
Total:			4

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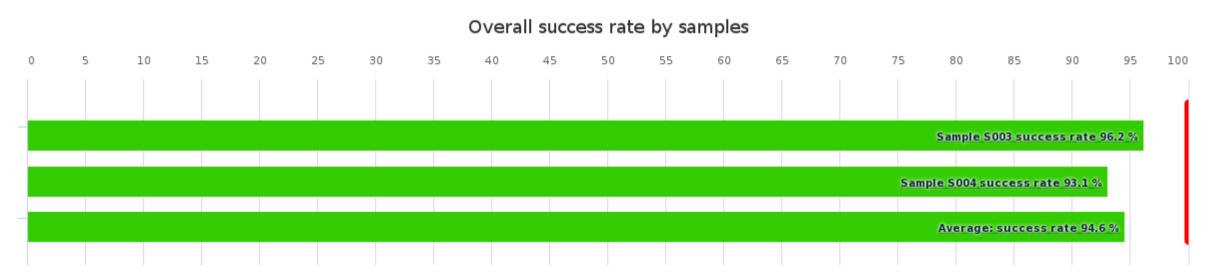


Mycobacterial staining

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Mycobacterial culture and stain, March, 1-2023	92	90	97.8 %
Mycobacterial stain, March, 1-2023	37	35	94.6 %

Summary



Sample AVR success rate Target

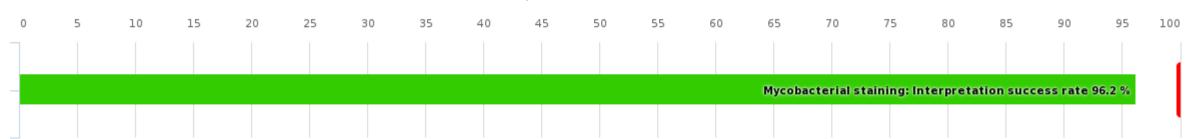
Summary	AVR success rate
Sample S003	96.2 %
Sample S004	93.1 %
Average:	94.6 %



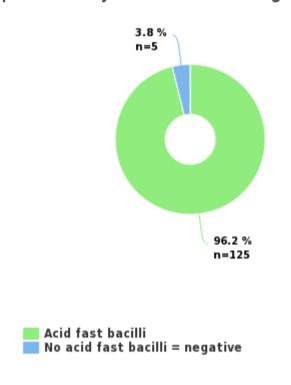
Mycobacterial staining

Sample S003 | Positive / AFB, +++

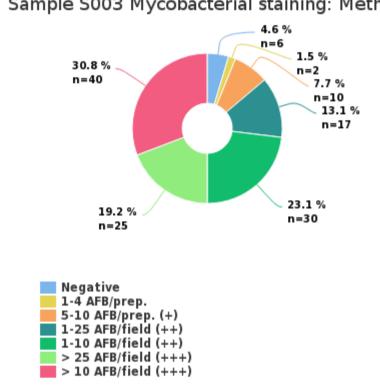
Sample S003 success rate



Sample S003 Mycobacterial staining: Interpretation



Sample S003 Mycobacterial staining: Method



MYCOBACTERIAL STAINING: INTERPRETATION

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Acid fast bacilli	125	100 %	2
No acid fast bacilli = negative	5	0 %	0
Total:	130	96.2 %	

MYCOBACTERIAL STAINING: METHOD

Method	Negative	1-4 AFB/prep.	5-10 AFB/prep. (+)	1-25 AFB/field (++)	1-10 AFB/field (++)	> 25 AFB/field (+++)	> 10 AFB/field (+++)	Total:
Acridine orange	-	-	-	1	-	2	-	3
Auramine	2	1	1	5	3	14	7	33
Auramine-Rodamine	-	-	-	3	1	4	1	9
Kinyoun	-	-	3	2	3	-	1	9
Tan-Thiam-Hok	-	-	-	-	1	-	-	1
Ziehl-Neelsen	4	1	6	6	22	5	31	75
Total:	6	2	10	17	30	25	40	130

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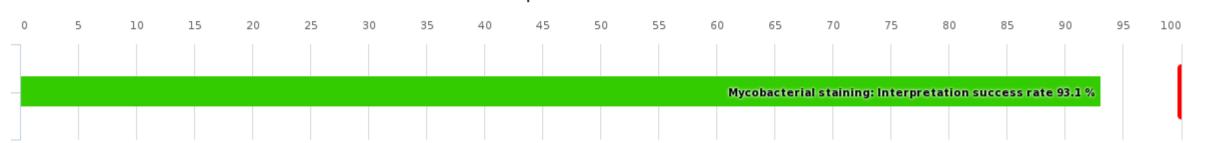
2/4 09.05.2023



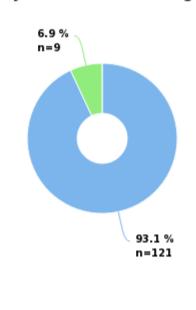
Mycobacterial staining

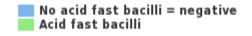
Sample S004 | No acid-fast bacilli

Sample S004 success rate

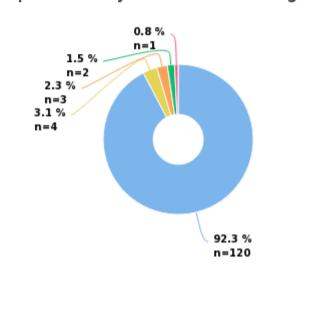


Sample S004 Mycobacterial staining: Interpretation





Sample S004 Mycobacterial staining: Method





MYCOBACTERIAL STAINING: INTERPRETATION

Interpretation	Interpretation count	AVR success rate	Interpretation Score
No acid fast bacilli = negative	121	100 %	2
Acid fast bacilli	9	0 %	0
Total:	130	93.1 %	

MYCOBACTERIAL STAINING: METHOD

Method	Negative	1-4 AFB/prep.	5-10 AFB/prep. (+)	1-10 AFB/field (++)	> 10 AFB/field (+++)	Total:
Acridine orange	3	-	-	-	-	3
Auramine	37	1	-	-	-	38
Auramine-Rodamine	7	-	-	-	-	7
Kinyoun	8	-	-	1	-	9
Tan-Thiam-Hok	1	-	-	-	-	1
Ziehl-Neelsen	64	3	3	1	1	72
Total:	120	4	3	2	1	130

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Mycobacterial staining

Report Info

PARTICIPANTS

Altogether 127 laboratories from 14 countries participated in this EQA round.

REPORT INFO

On the front page you can see a summary of the overall average 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 . In the participant specific report there is also a laboratory specific scoring table for each sample, where you can find your own result and the scores given.. 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 "Interpretation" part 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. 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 correct result 0 points is given for an incorrect/false result

09.05.2023 4/4

LABQUALITY

External Quality Assessment Scheme

Mycobacterial culture and stain (5220) Mycobacterial nucleic acid detection (5221) Mycobacterial stain (5240) Rounds 1, 2023

Specimens

The round included two lyophilized samples and/or two smears on slides. The sample lots were tested in an accredited Finnish reference 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, 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 (LQ760923011)

Mycobacterium intracellulare N000062

Background information: simulated sputum

Sample S002 (LQ760923012) No acid-fast bacilli

Background information: simulated sputum

Sample S003 (LQ760923013) Positive / AFB, +++

Sample S004 (LQ760923014) No acid-fast bacilli

Test method: Reference laboratory stained the slides with the direct auramin method.

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 round consisted of *Mycobacterium intracellulare* in sample S001 and a negative sample S002. Slide S003 was strong positive and slide S004 was negative.

Staining

The average success rate for the positive slide S003 was 96.2% with 5/130 false negative results, and for the negative slide S004 the success rate was 93.1% with 9/130 false positive results, of which 4 were weak positives (1-4 cells/slide). Three laboratories had possibly mixed up the samples and reported crosswise correct results. Additionally, two laboratories had discrepancies between parallel initial results and/or final reports.

2023-05-09

FINAL REPORT

Product no. 5220, 5221, 5240

Subcontracting: Sample testing

 Samples sent
 2023-02-28

 Round closed
 2023-04-26

 Expected results
 2023-04-28

 Final report
 2023-05-09

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 Jaana Paakkanen jaana.paakkanen@labquality.fi

Expert

Microbiologist, Ph.D, Docent Silja Mentula, National Institute for Health and Welfare, 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





Culture and identification

Sample S001

The average success rate for sample S001 was 92% with 25/109 (23%) species level identifications, 50 NTM identifications, TB was ruled out by 22 participants, 8 reported acid-fast bacilli, 2 false TB findings and 2 false negative results. All species in the *avium-intracellulare* complex were accepted as correct result (*M. avium, M. intracellulare, M. chimaera*). Species level identification was performed by Hain Genotype in 22, by In-house PCR / sequencing in 6 and by MALDI-TOF in 8 laboratories. Some of the laboratories used multiple methods. "No growth" was reported by 5 laboratories. There were altogether 92 nucleic acid amplification test results, 55 immunologic test results, 8 MALDI-TOF results and 1 nitrate result. Culture was performed by 82 laboratories.

One laboratory reported "no acid-fast bacilli" after a negative result from TB detection test, hence, the correct reporting option would have been "negative (*M. tuberculosis* not detected)". There were also two reporting errors with correct initial TB negative result but false final TB positive report.

Sample S002

The average success rate for the negative sample S002 was 98.2% with TB ruled out by 63 participants, 44 reported no acid-fast bacilli and 2/109 reported false TB findings. Growth was reported by 5 laboratories.

Conclusions

The round went well though the cell counts in staining scattered somewhat and there were some reporting errors.

Exceptions in scoring

No exceptions.

End of report

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