LABQUALITY

External Quality Assessment Scheme

Mycobacterium tuberculosis, drug resistance
Round 1, 2023

Specimens
Please find enclosed 2 artificial sputum samples (primary samples) S001 and S002, each 1 mL.

Caution
Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. According to the sample manufacturer the specimens do not contain viable microbes and the specimens are found to be HBsAg, HCVAb and HIVAb negative when tested with licensed reagents. However, no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations
Mycobacterium tuberculosis, nucleic acid detection
Rifampicin susceptibility
Isoniazid susceptibility

Storage and use
After arrival, the samples should be stored at +2 … 8 °C, and used as soon as possible, preferably within a week. The samples are artificial primary samples (do not contain viable microbes) and cannot be enriched by culturing. The samples should not be decontaminated. Perform the analysis according to the manufacturer's instructions for a liquid specimen.

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your test kit from the registry, please contact the EQA Coordinator. This round has the possibility to report three results from the same sample, if the sample volume is sufficient for several analyses. To open a new result form, press the "Add result +" button on the right side of the blue bar for each sample in LabScala. Report only the results of examinations that are in use in your laboratory. All reported examinations will be scored.

S001

LQ762523011

S002

LQ762523012

2023-03-14

INSTRUCTIONS

Product no. 5230
LQ762523011-012/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 **April 6, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 12, 2023.

Inquiries
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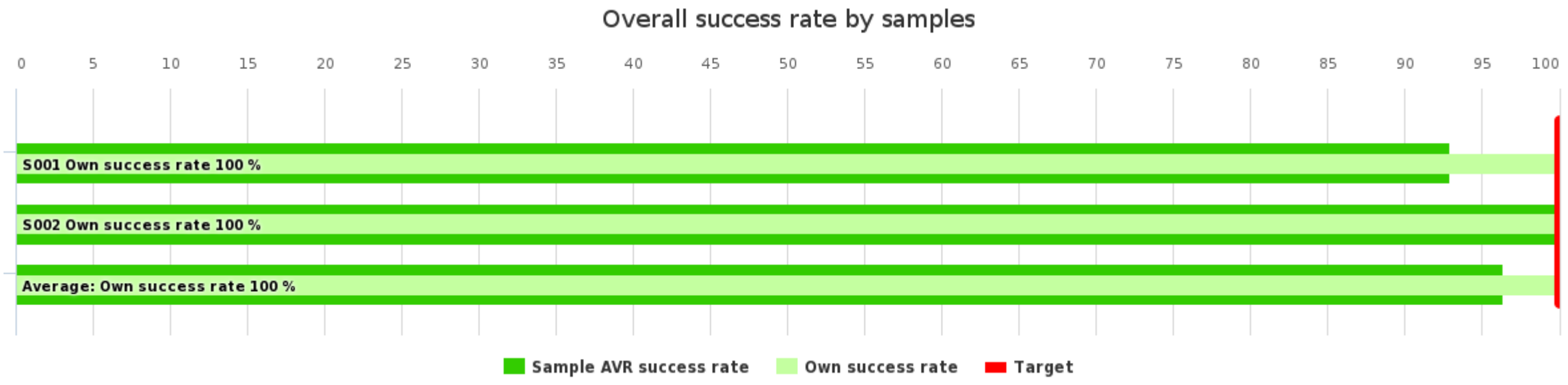
Client report

	No of participants	No of responded participants	Response percentage
Mycobacterium tuberculosis, drug resistance, March, 1-2023	21	19	90.5 %

Summary



Summary	Own score	Max score	Own success rate	Difference	AVR success rate
S001	2	2	100 %	7.1 %	92.9 %
S002	4	4	100 %	0 %	100 %
Average:			100 %	3.6 %	96.4 %

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

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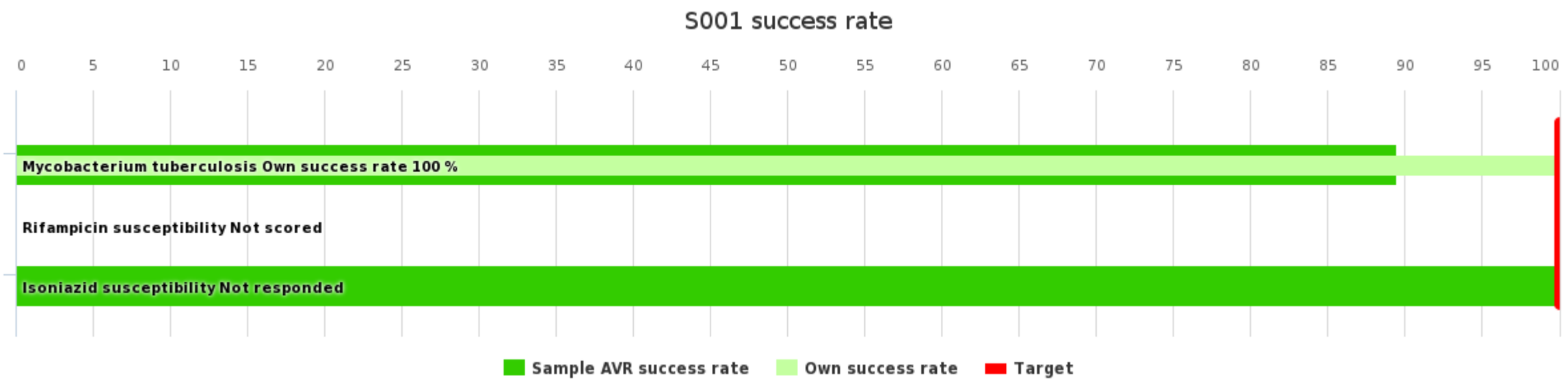
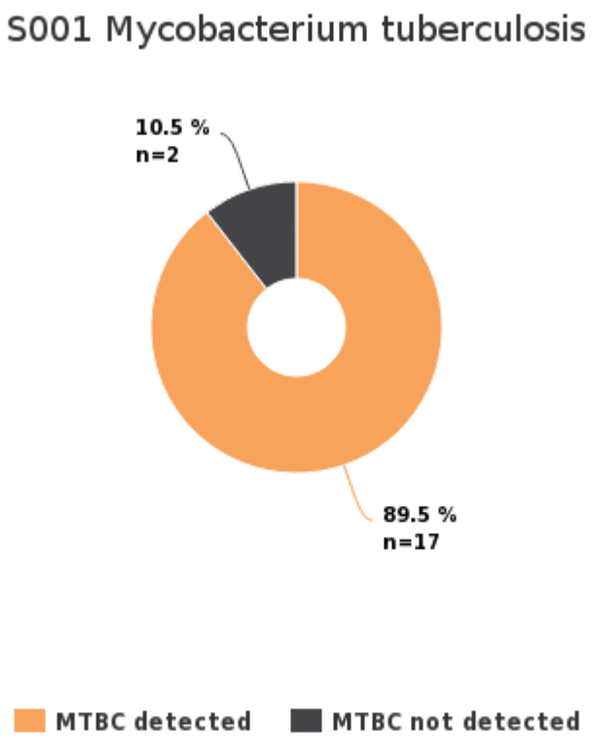
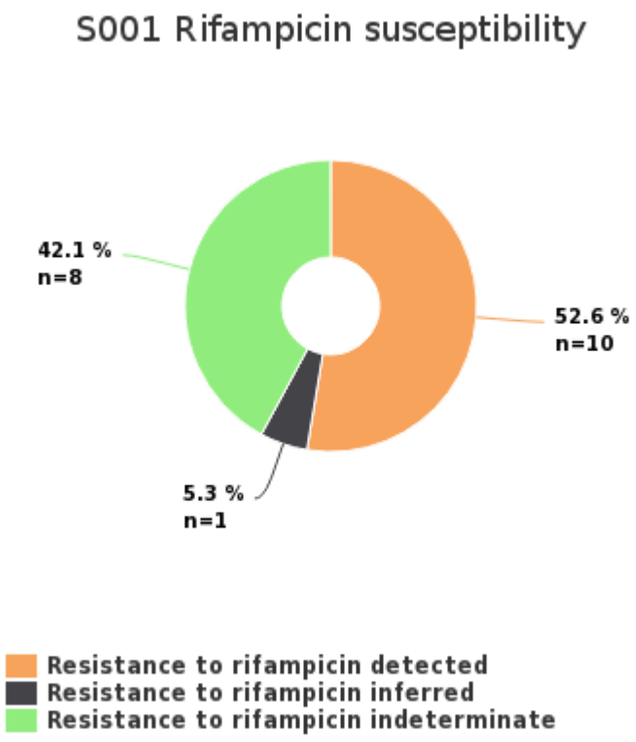
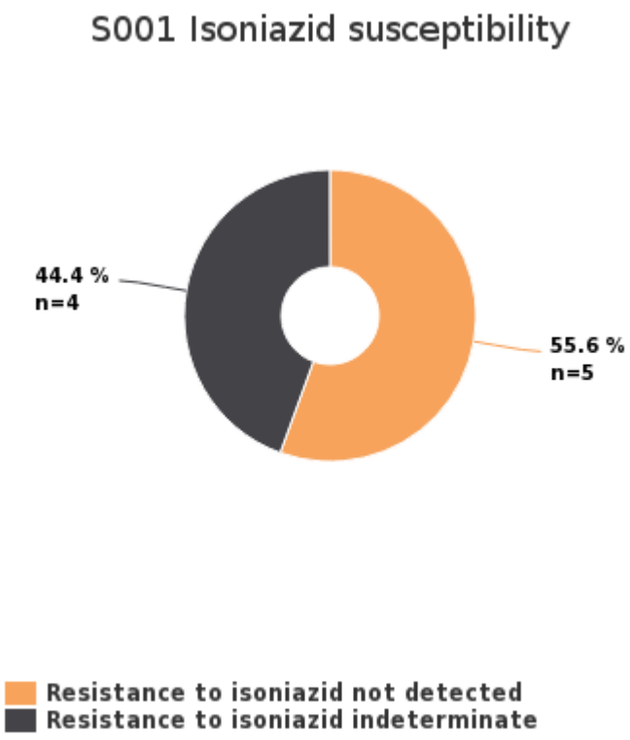
S001



S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Mycobacterium tuberculosis	2	2	100 %	10.5 %	89.5 %	19
	Rifampicin susceptibility	-	-	-	-	-	19
	Isoniazid susceptibility	-	-	-	-	100 %	9
Total:		2	2	100 %	7.1 %	92.9 %	47







Mycobacterium tuberculosis	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ MTBC detected		17		2	2	100 %	0 %	100 %
		Xpert MTB/RIF (Cepheid)		1					
		◉ Xpert MTB/RIF Ultra (Cepheid)		16					
	MTBC not detected		2		-				0 %
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2					
	Total:		19		2	2	100 %	10.5 %	89.5 %

Rifampicin susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Resistance to rifampicin detected		10		-				-
		Xpert MTB/RIF (Cepheid)		1					
		◉ Xpert MTB/RIF Ultra (Cepheid)		9					
	Resistance to rifampicin inferred		1		-				-
		Xpert MTB/RIF Ultra (Cepheid)		1					
	Resistance to rifampicin indeterminate		8		-				-
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2					
		Xpert MTB/RIF (Cepheid)		1					
		Xpert MTB/RIF Ultra (Cepheid)		5					
	Total:		19		-	-	-	-	

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Isoniazid susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Resistance to isoniazid not detected		5		-				100 %
		GenoType MTBDRplus 2.0 (Hain Lifescience)		1					
		Xpert MTB/XDR (Cepheid)		4					
	Resistance to isoniazid indeterminate		4		-				100 %
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2					
		Xpert MTB/XDR (Cepheid)		2					
	Total:		9		-	-	-	-	100 %

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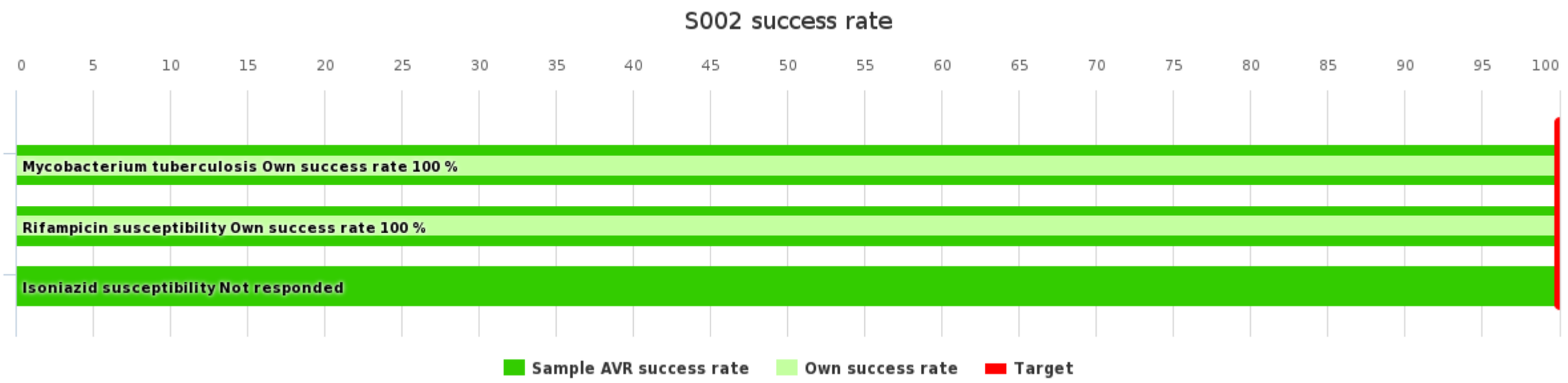
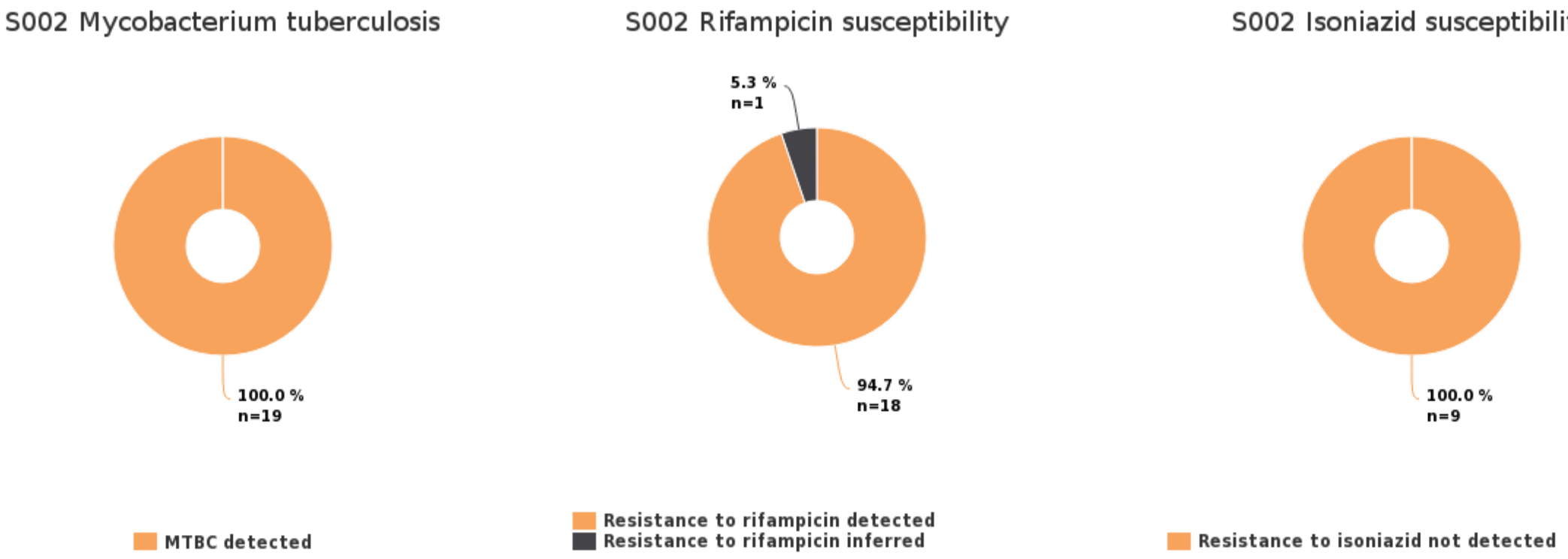
S002



S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Mycobacterium tuberculosis	2	2	100 %	0 %	100 %	19
	Rifampicin susceptibility	2	2	100 %	0 %	100 %	19
	Isoniazid susceptibility	-	-	-	-	100 %	9
Total:		4	4	100 %	0 %	100 %	47



Mycobacterium tuberculosis	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ MTBC detected		19		2	2	100 %	0 %	100 %
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2					
		Xpert MTB/RIF (Cepheid)		2					
		◉ Xpert MTB/RIF Ultra (Cepheid)		15					
	Total:		19		2	2	100 %	0 %	100 %

Rifampicin susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Resistance to rifampicin detected		18		2	2	100 %	0 %	100 %
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2					
		Xpert MTB/RIF (Cepheid)		2					
		◉ Xpert MTB/RIF Ultra (Cepheid)		14					
	Resistance to rifampicin inferred		1		-				100 %
		Xpert MTB/RIF Ultra (Cepheid)		1					
	Total:		19		2	2	100 %	0 %	100 %

Isoniazid susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Resistance to isoniazid not detected		9		-				100 %

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		GenoType MTBDRplus 2.0 (Hain Lifescience)		3					
		Xpert MTB/XDR (Cepheid)		6					
	Total:		9		-	-	-	-	100 %

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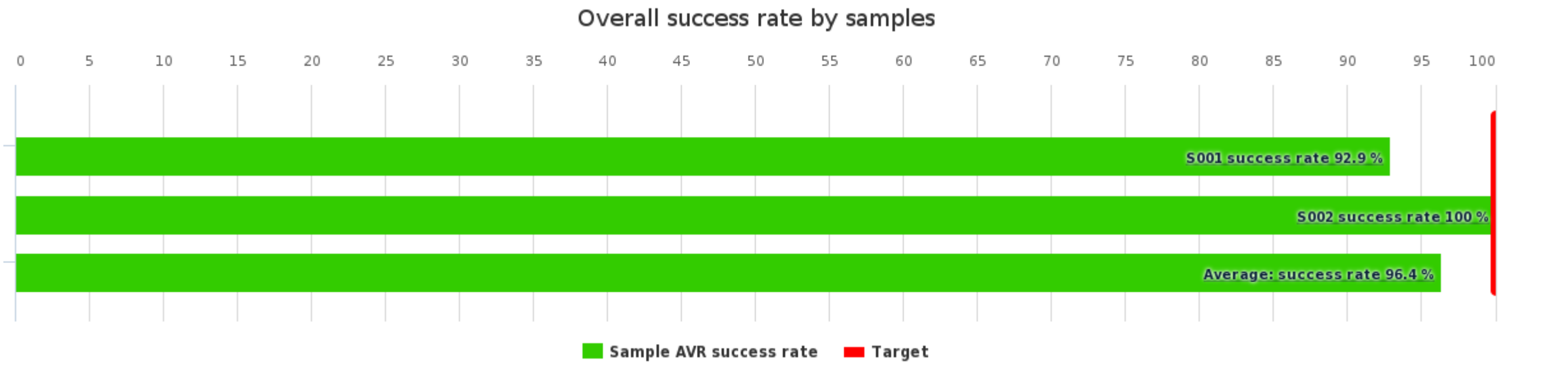
Mycobacterium tuberculosis, drug resistance, March, 1-2023

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Mycobacterium tuberculosis, drug resistance, March, 1-2023	21	19	90.5 %

Summary



Summary	AVR success rate
S001	92.9 %
S002	100 %
Average:	96.4 %

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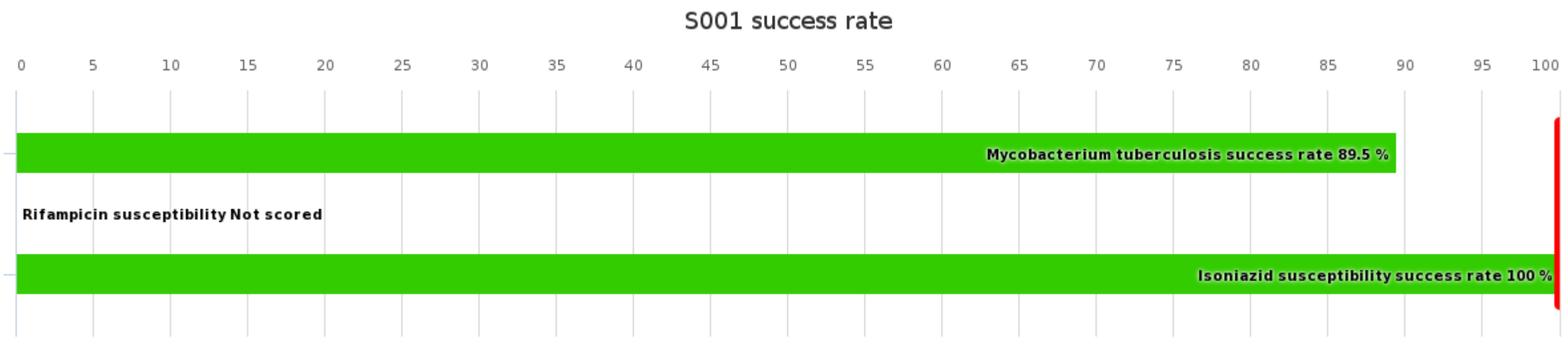
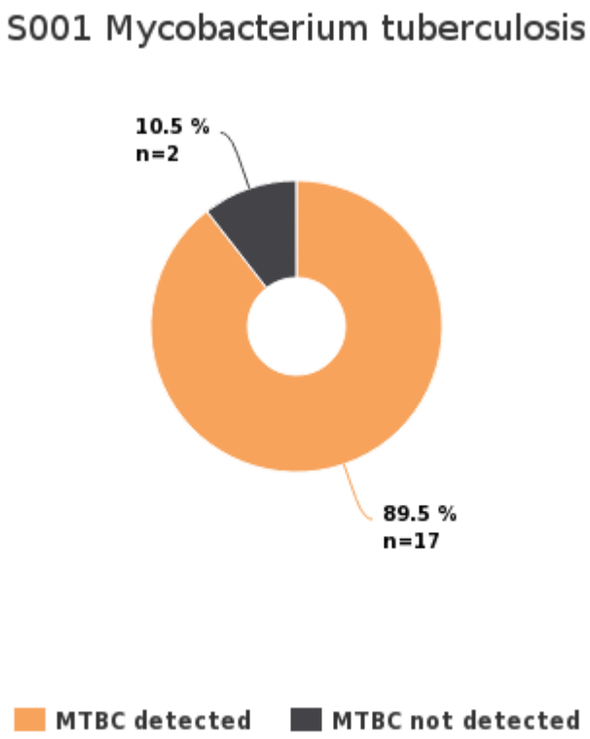
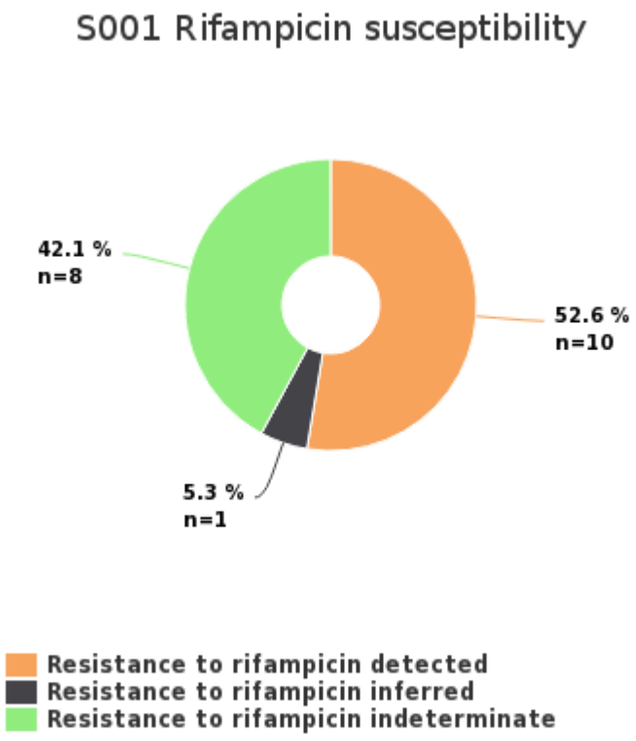
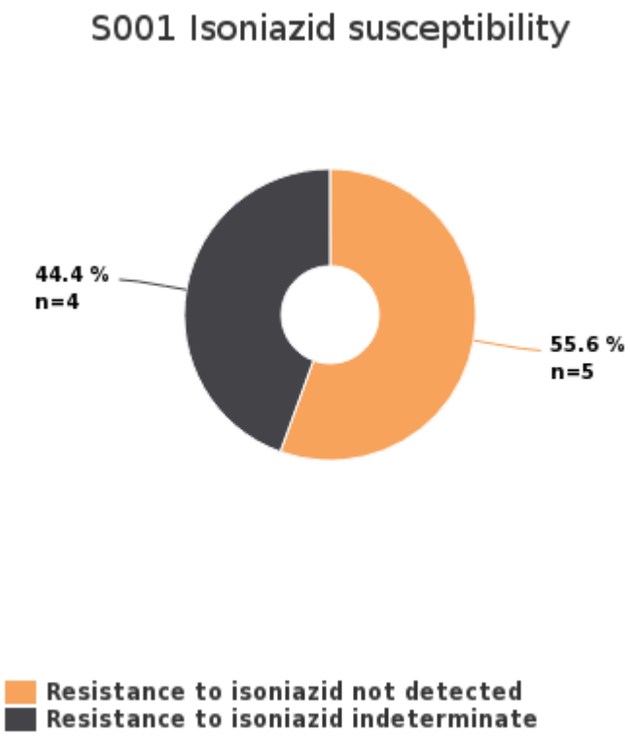
S001



S001 results	Responded	AVR success rate	Count
	Mycobacterium tuberculosis	89.5 %	19
	Rifampicin susceptibility	-	19
	Isoniazid susceptibility	100 %	9
Total:		92.9 %	47







Mycobacterium tuberculosis	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	MTBC detected		17		100 %	2
		Xpert MTB/RIF (Cepheid)		1		
		Xpert MTB/RIF Ultra (Cepheid)		16		
	MTBC not detected		2		0 %	0
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2		
	Total:		19		89.5 %	

Rifampicin susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to rifampicin detected		10		-	-
		Xpert MTB/RIF (Cepheid)		1		
		Xpert MTB/RIF Ultra (Cepheid)		9		
	Resistance to rifampicin inferred		1		-	-
		Xpert MTB/RIF Ultra (Cepheid)		1		
	Resistance to rifampicin indeterminate		8		-	-
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2		
		Xpert MTB/RIF (Cepheid)		1		
		Xpert MTB/RIF Ultra (Cepheid)		5		
	Total:		19			

Isoniazid susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score

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	Resistance to isoniazid not detected		5		100 %	2
		GenoType MTBDRplus 2.0 (Hain Lifescience)		1		
		Xpert MTB/XDR (Cepheid)		4		
	Resistance to isoniazid indeterminate		4		100 %	2
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2		
		Xpert MTB/XDR (Cepheid)		2		
	Total:		9		100 %	

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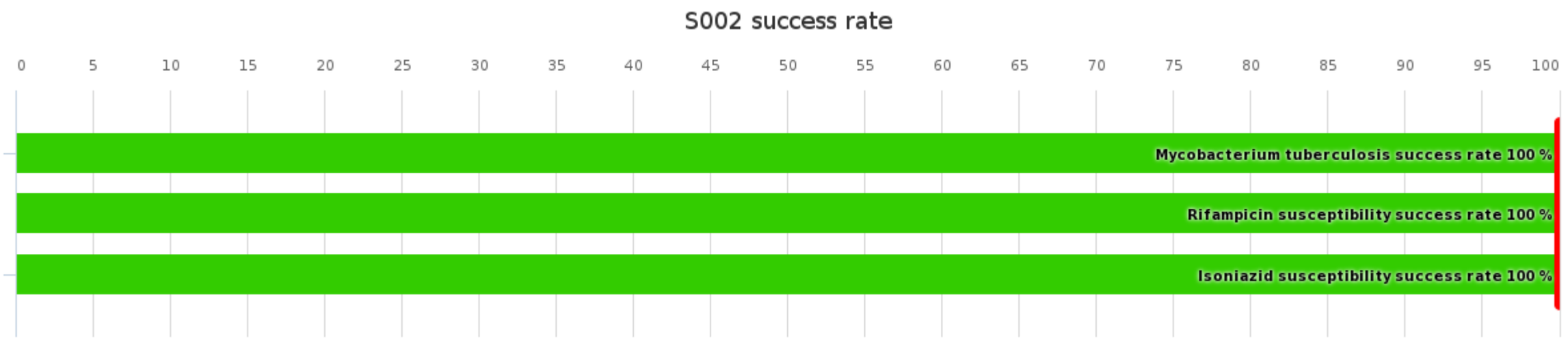
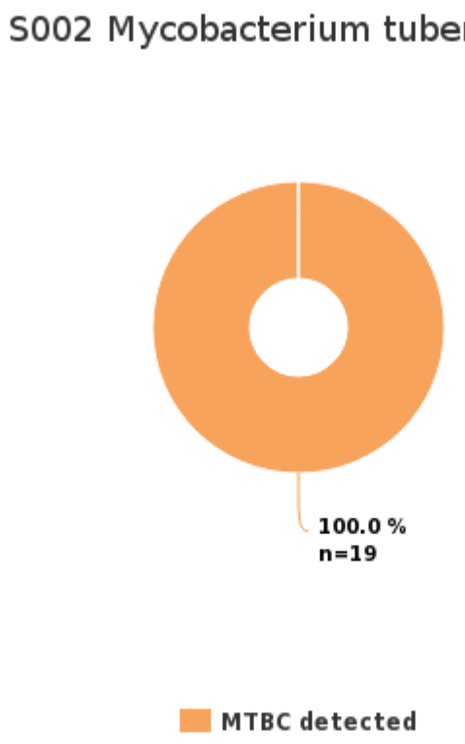
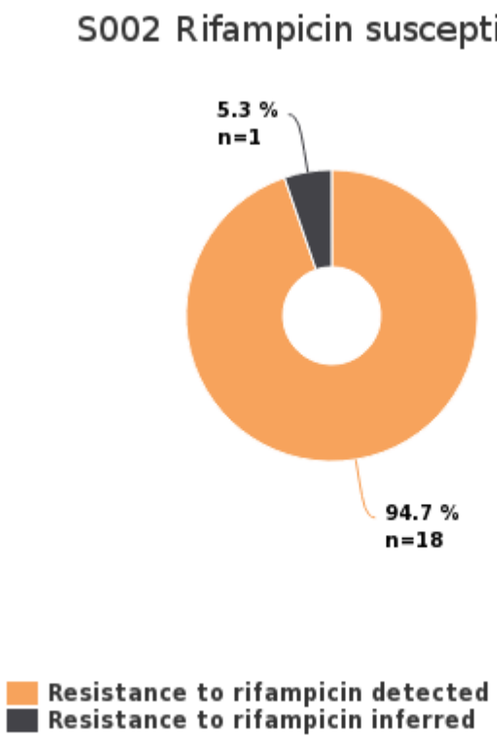
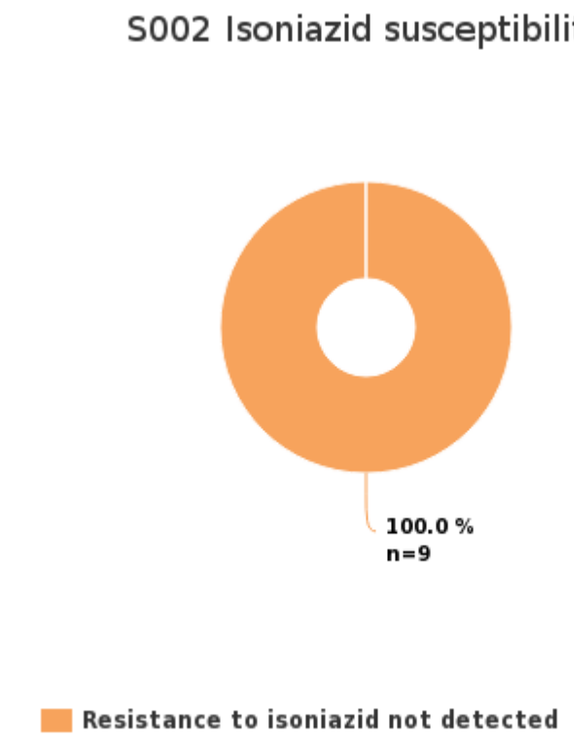
S002



S002 results	Responded	AVR success rate	Count
	Mycobacterium tuberculosis	100 %	19
	Rifampicin susceptibility	100 %	19
	Isoniazid susceptibility	100 %	9
Total:		100 %	47







Mycobacterium tuberculosis	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	MTBC detected		19		100 %	2
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2		
		Xpert MTB/RIF (Cepheid)		2		
		Xpert MTB/RIF Ultra (Cepheid)		15		
	Total:		19		100 %	

Rifampicin susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to rifampicin detected		18		100 %	2
		GenoType MTBDRplus 2.0 (Hain Lifescience)		2		
		Xpert MTB/RIF (Cepheid)		2		
		Xpert MTB/RIF Ultra (Cepheid)		14		
	Resistance to rifampicin inferred		1		100 %	2
		Xpert MTB/RIF Ultra (Cepheid)		1		
	Total:		19		100 %	

Isoniazid susceptibility	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to isoniazid not detected		9		100 %	2
		GenoType MTBDRplus 2.0 (Hain Lifescience)		3		
		Xpert MTB/XDR (Cepheid)		6		
	Total:		9		100 %	

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LABQUALITY

External Quality Assessment Scheme

Mycobacterium tuberculosis, drug resistance
Round 1, 2023

Specimens
Samples of this EQA round were artificial sputum samples (primary samples). 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 expected results were as follows:

Sample S001 (LQ762523011)	
Mycobacterium tuberculosis	MTBC detected
Rifampicin susceptibility	Resistance to rifampicin detected (low)
Isoniazid susceptibility	Resistance to isoniazid not detected

Sample S002 (LQ762523012)	
Mycobacterium tuberculosis	MTBC detected
Rifampicin susceptibility	Resistance to rifampicin detected (high)
Isoniazid susceptibility	Resistance to isoniazid not detected

Pre-test methods: Xpert MTB/RIF (Cepheid) and GenoType MTBDRplus 2.0 (Hain Lifescience).

Report info
Please see the description of the data analysis on the last page of this letter as an annex (Annex 1). 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 a single rifampicin resistant and isoniazid susceptible sample in low (sample S001) and high (sample S002) concentration.

The performance for the high concentration sample S002 was excellent with 100% success rates for all targets (MTBC detection, susceptibility to rifampicin and isoniazid). For the low concentration sample S001, the results varied, which was expected due to low template number. There were 2/19 false negative results for MTBC detection and 8/19 indeterminate results for rifampicin and 4/9 for isoniazid compared with none in sample S002. The high proportion of indeterminate results by all used tests refers to proximity to the limit of detection, where result may remain unavailable. For samples that are close to the limit of detection, optimal testing conditions are crucial.

The pretesting with GenoType MTBDRplus was performed with PCR cycle number 50 as instructed for primary samples, instead of 30 cycles for cultures. Testing yielded expected results, though inhA WT1 was weak, and on re-testing there was no katG or inhA product at all (competition in PCR).

Exceptions in scoring
Rifampicin susceptibility in sample S001 was not scored as the success rate was below 60%.

Annex
Annex 1. Report info.

2023-04-13

FINAL REPORT

Product no. 5230

Subcontracting: Sample pretesting

Samples sent	2023-03-14
Round closed	2023-04-06
Expected results	2023-04-12
Final report	2023-04-13

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.

Authorized by
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End of report

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Annex 1.

Participants
Altogether 21 laboratories from 8 countries participated in this EQA round.

Report info
The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. In general, the expected results are marked with green color. Laboratory's own result is marked with a black radio button (⊙). In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available."

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

Scoring
The round is scored based on test results when 60% or more of the participants report the expected/correct result and when at least three results are reported.

The following general rules are applied:

- 2/2 points is given to results that are correct/accepted regarding the expected result
- 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.