LABQUALITY

External Quality Assessment Scheme

Helicobacter pylori, nucleic acid detection Round 1, 2023 (pilot)

Thank you for participating in the pilot round. There will be a feedback survey attached to the reports. Please respond to the survey and give us important information on how we can make the EQA scheme better for you.

Specimens
Please find enclosed 2 artificial swab samples S001 and S002 and 1 lyophilized faecal sample S003.

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
Helicobacter pylori, nucleic acid detection
Clarithromycin susceptibility

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

Handling instructions for swabs (S001, S002):
1. Open the foil package. Pay attention to avoid contamination.
2. Remove the swab from the foil package and place the swab into a sample collection tube / transport media (1-3 mL). Rotate the swab several times in the tube to dislodge as much material as possible. Remove the swab by pressing it towards the walls of the elution vial. You can also cut the swab into the sample collection tube.
3. Recap the collection tube and mix thoroughly.
4. Follow the test manufacturer's instructions for sample extraction and detection.

Handling instructions for lyophilized sample (S003):
1. Let the sample vial warm up to room temperature before rehydration.
2. Carefully add 500 µL of distilled or deionized water into sample vial.
3. Let the content of the vial to dissolve for 10 minutes in room temperature and vortex the vial for 30 seconds. Ensure that the mixture is homogenous before performing the assay.
4. Follow the test manufacturer's instructions for sample extraction and detection.

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.

2023-10-17

INSTRUCTIONS

Product no. 5253
LQ763323011-013/CA, DE
UN3373

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **November 8, 2023**.

Inquiries
EQA Coordinator
Kati Luiro
kati.luiro@labquality.fi

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200

info@labquality.fi
www.labquality.com

Helicobacter pylori, nucleic acid detection

S001

S002

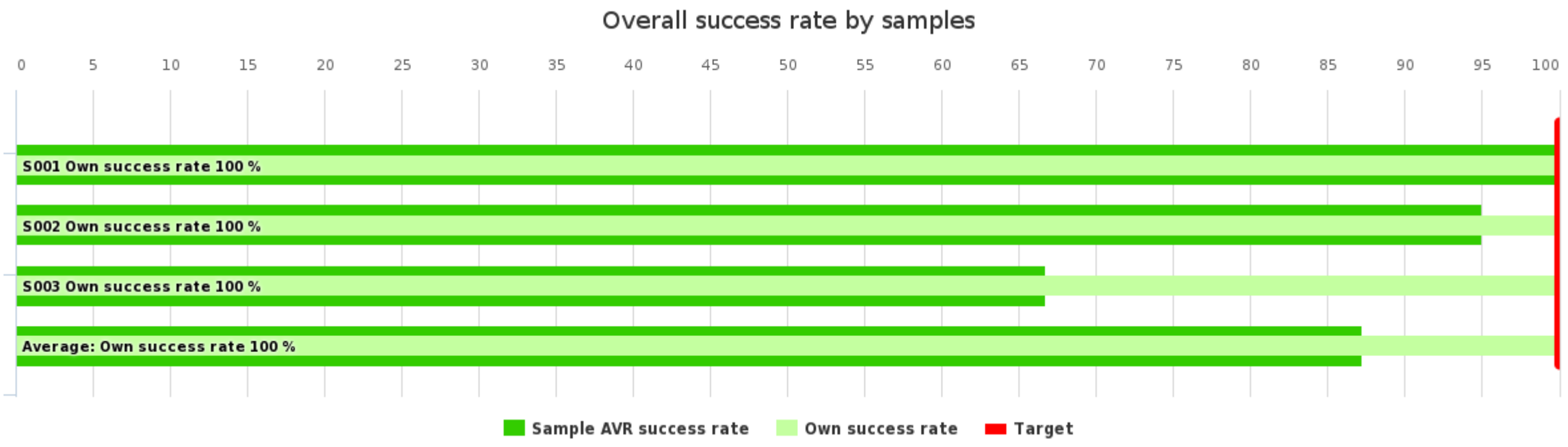
S003

Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

Client report

	No of participants	No of responded participants	Response percentage
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023	17	13	76.5 %

Summary

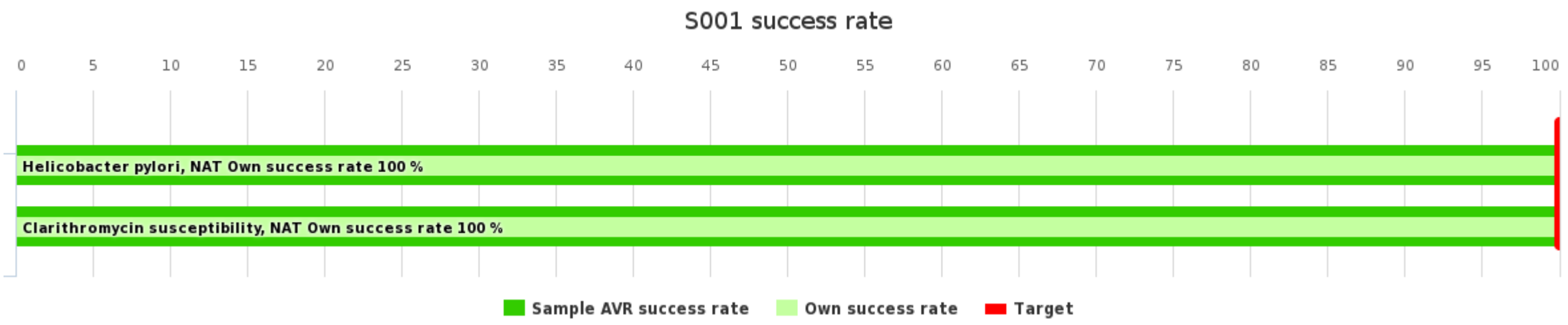


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
S001	4	4	100 %	0 %	100 %
S002	2	2	100 %	5 %	95 %
S003	2	2	100 %	33.3 %	66.7 %
Average:			100 %	12.8 %	87.2 %

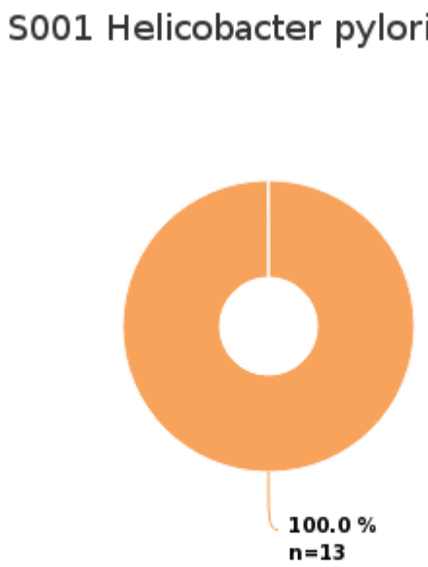
History	Test nr.	Own success rate	Difference	AVR success rate
History not found				

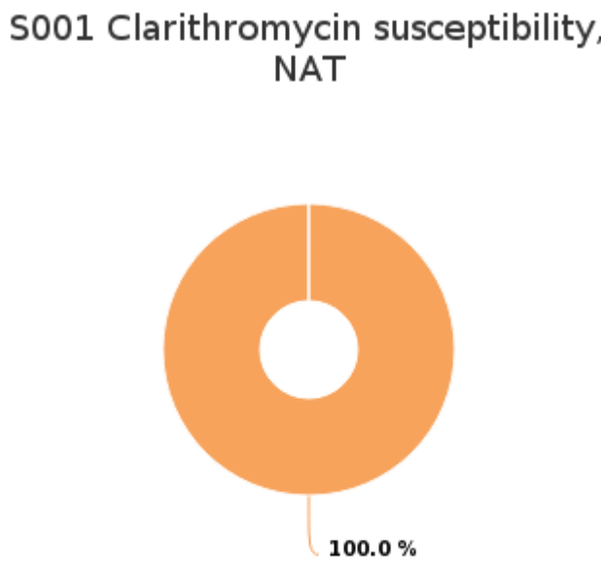
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S001



S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori, NAT	2	2	100 %	0 %	100 %	13
	Clarithromycin susceptibility, NAT	2	2	100 %	0 %	100 %	9
Total:		4	4	100 %	0 %	100 %	34



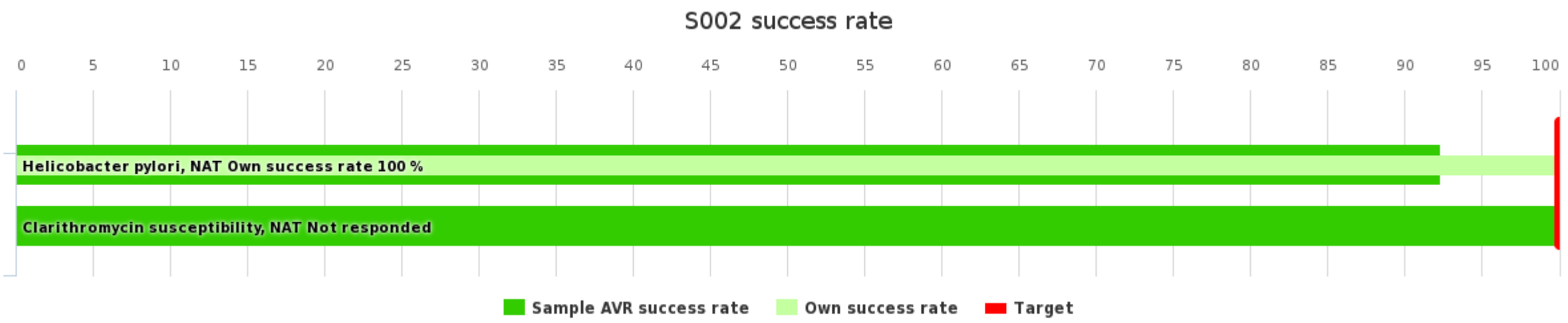


Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ H. pylori detected		13		2	2	100 %	0 %	100 %
		BioCorp BC-H. pylori		2					
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1					
		In house		2					
		LightGene H. pylori		1					
		Mobidiag Amplidiag® H. pylori+ClariR		3					
		◉ R-Biopharm RIDAGENE Helicobacter pylori		3					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Total:		13		2	2	100 %	0 %	100 %

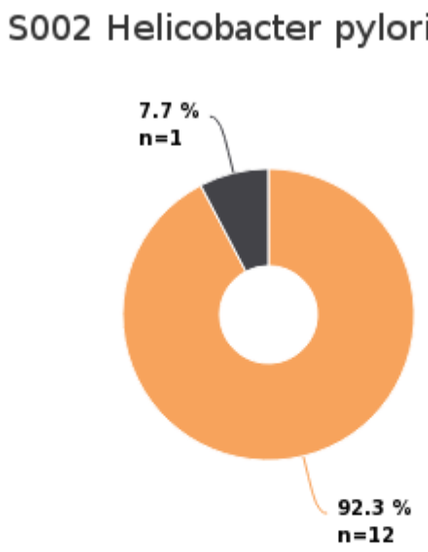
Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Resistance to clarithromycin not detected		9		2	2	100 %	0 %	100 %
		In house		2					
		Mobidiag Amplidiag® H. pylori+ClariR		3					
		◉ R-Biopharm RIDAGENE Helicobacter pylori		3					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Total:		9		2	2	100 %	0 %	100 %

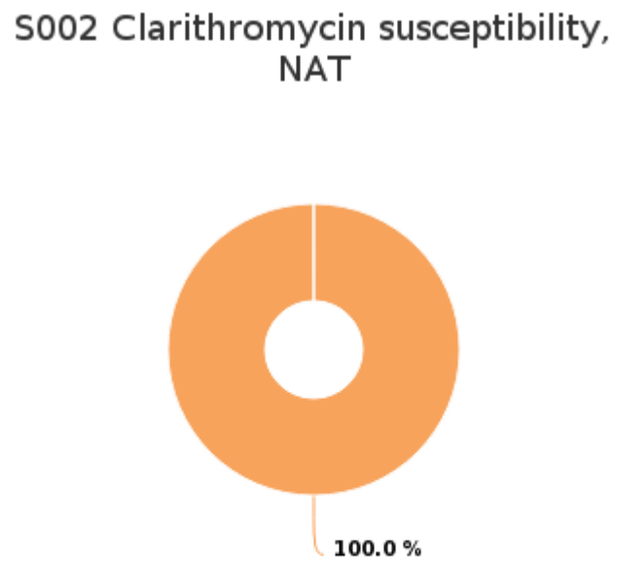
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S002



S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori, NAT	2	2	100 %	7.7 %	92.3 %	13
	Clarithromycin susceptibility, NAT	-	-	-	-	100 %	7
Total:		2	2	100 %	5 %	95 %	31



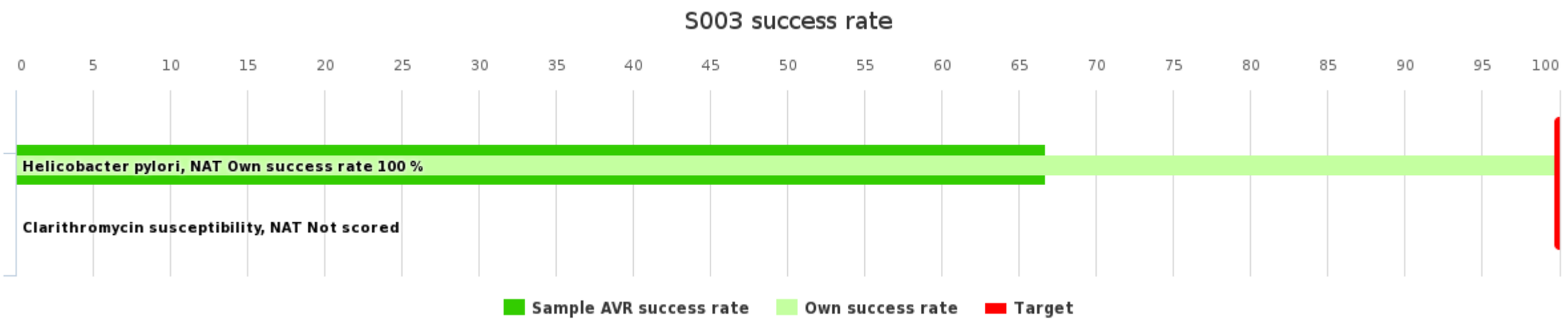


Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ H. pylori not detected		12		2	2	100 %	0 %	100 %
		BioCorp BC-H. pylori		1					
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1					
		In house		2					
		LightGene H. pylori		1					
		Mobidiag Amplidiag® H. pylori+ClariR		3					
		◉ R-Biopharm RIDAGENE Helicobacter pylori		3					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Invalid/unclear test result		1		-				0 %
		BioCorp BC-H. pylori		1					
	Total:		13		2	2	100 %	7.7 %	92.3 %

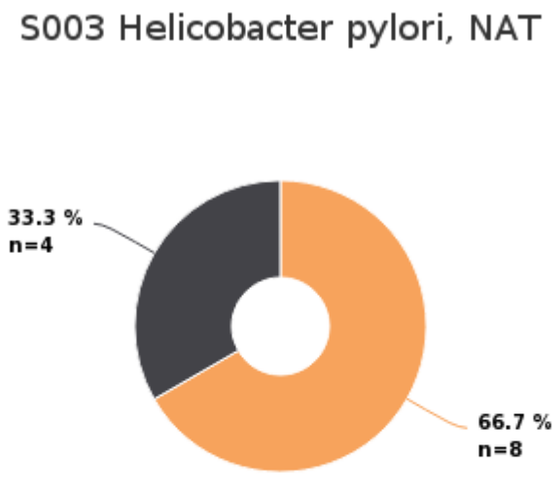
Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Resistance to clarithromycin not detected		7		-				100 %
		In house		1					
		Mobidiag Amplidiag® H. pylori+ClariR		3					
		R-Biopharm RIDAGENE Helicobacter pylori		2					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Total:		7		-	-	-	-	100 %

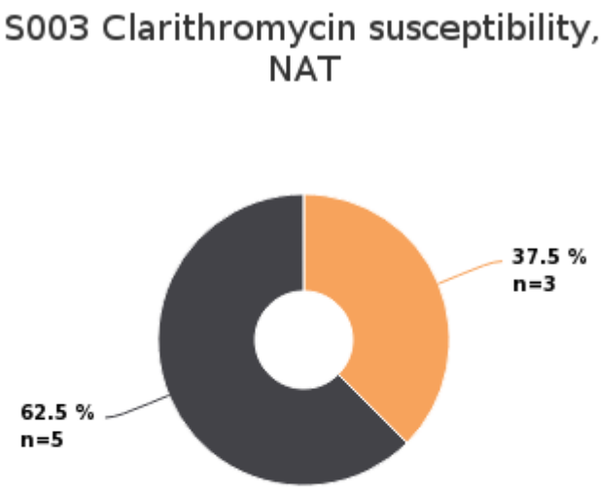
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S003



S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori, NAT	2	2	100 %	33.3 %	66.7 %	12
	Clarithromycin susceptibility, NAT	-	-	-	-	-	8
Total:		2	2	100 %	33.3 %	66.7 %	20





Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ H. pylori detected		8		2	2	100 %	0 %	100 %
		BioCorp BC-H. pylori		1					
		In house		2					
		LightGene H. pylori		1					
		Mobidiag Amplidiag® H. pylori+ClariR		3					
		◉ R-Biopharm RIDAGENE Helicobacter pylori		1					
	H. pylori not detected		4		-				0 %
		BioCorp BC-H. pylori		1					
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1					
		R-Biopharm RIDAGENE Helicobacter pylori		1					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Total:		12		2	2	100 %	33.3 %	66.7 %

Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Resistance to clarithromycin detected		3		-				-
		Mobidiag Amplidiag® H. pylori+ClariR		2					
		◉ R-Biopharm RIDAGENE Helicobacter pylori		1					
	Resistance to clarithromycin not detected		5		-				-

		In house		2					
		Mobidiag Amplidiag® H. pylori+ClariR		1					
		R-Biopharm RIDAGENE Helicobacter pylori		1					
		Seegene Allplex™ H. pylori & ClariR Assay		1					
	Total:		8		-	-	-	-	

Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

GLOBAL REPORT

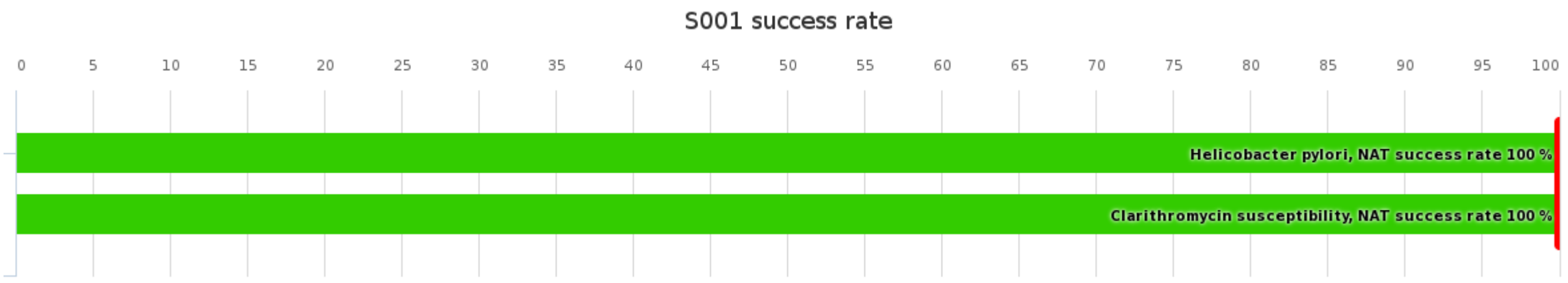
	No of participants	No of responded participants	Response percentage
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023	17	13	76.5 %

Summary

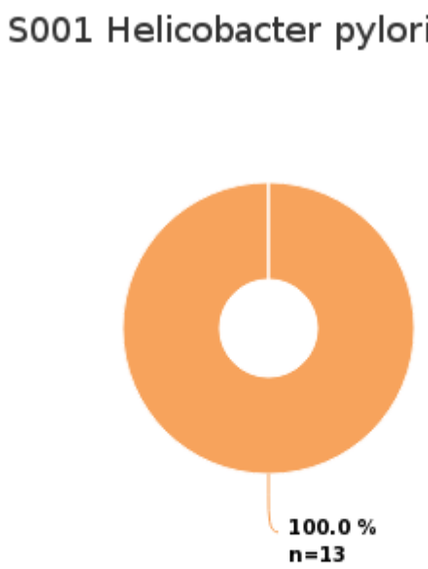
Summary	AVR success rate
S001	100 %
S002	95 %
S003	66.7 %
Average:	87.2 %

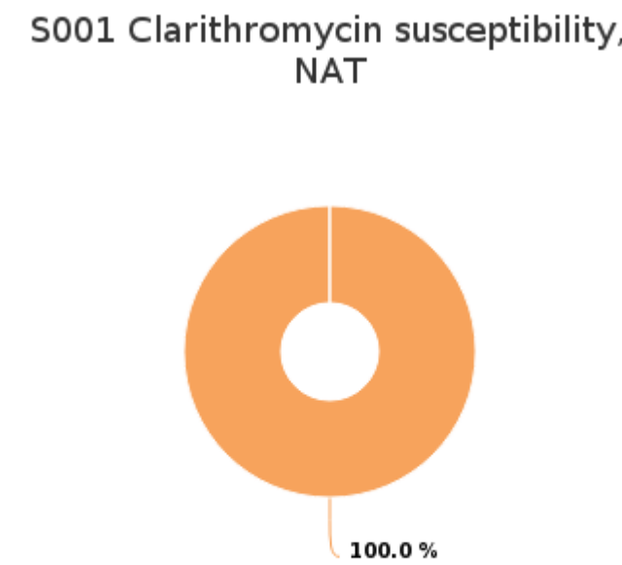
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S001



S001 results	Responded	AVR success rate	Count
	Helicobacter pylori, NAT	100 %	13
	Clarithromycin susceptibility, NAT	100 %	9
Total:		100 %	34



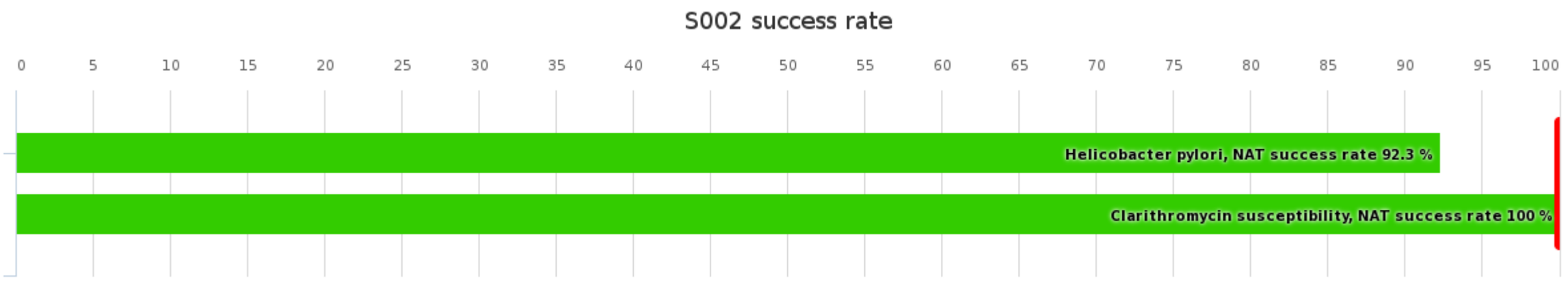


Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	H. pylori detected		13		100 %	2
		BioCorp BC-H. pylori		2		
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1		
		In house		2		
		LightGene H. pylori		1		
		Mobidiag Amplidiag® H. pylori+ClariR		3		
		R-Biopharm RIDAGENE Helicobacter pylori		3		
		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Total:		13		100 %	

Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to clarithromycin not detected		9		100 %	2
		In house		2		
		Mobidiag Amplidiag® H. pylori+ClariR		3		
		R-Biopharm RIDAGENE Helicobacter pylori		3		
		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Total:		9		100 %	

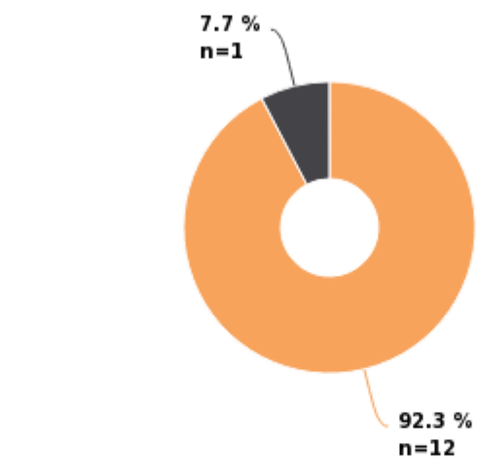
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S002

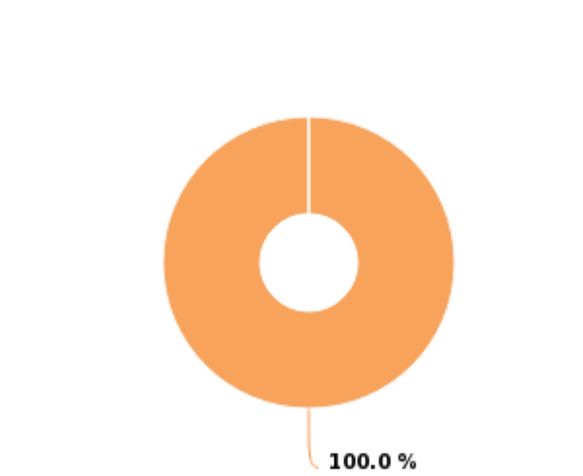


S002 results	Responded	AVR success rate	Count
	Helicobacter pylori, NAT	92.3 %	13
	Clarithromycin susceptibility, NAT	100 %	7
Total:		95 %	31

S002 Helicobacter pylori, NAT



S002 Clarithromycin susceptibility, NAT

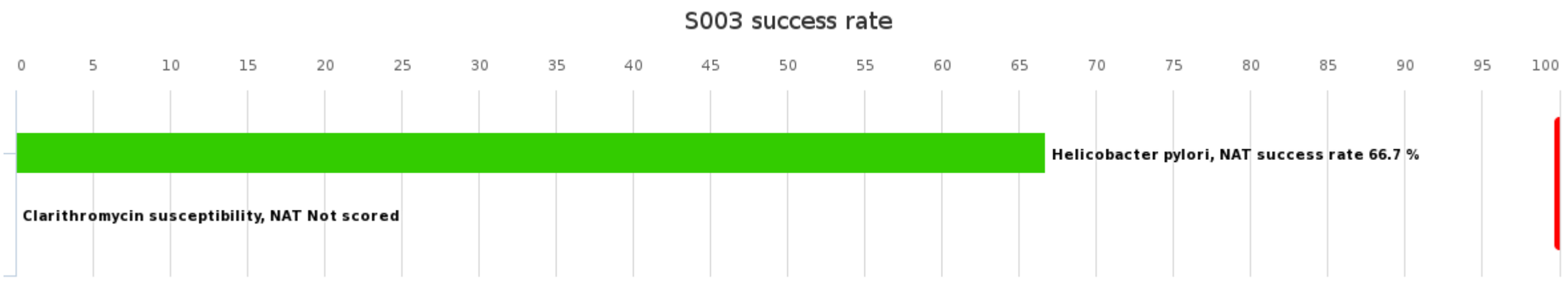


Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	H. pylori not detected		12		100 %	2
		BioCorp BC-H. pylori		1		
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1		
		In house		2		
		LightGene H. pylori		1		
		Mobidiag Amplidiag® H. pylori+ClariR		3		
		R-Biopharm RIDAGENE Helicobacter pylori		3		
		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Invalid/unclear test result		1		0 %	0
		BioCorp BC-H. pylori		1		
	Total:		13		92.3 %	

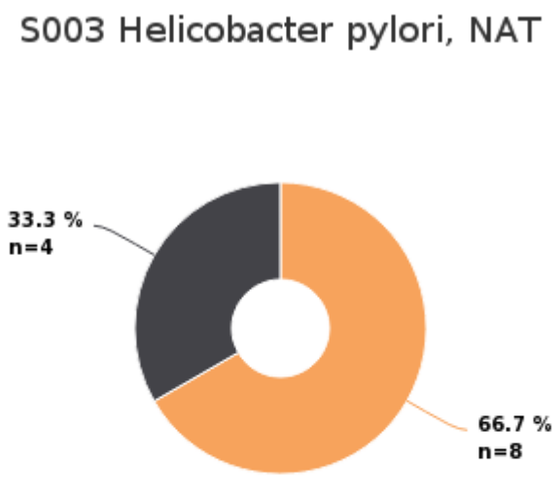
Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to clarithromycin not detected		7		100 %	2
		In house		1		
		Mobidiag Amplidiag® H. pylori+ClariR		3		
		R-Biopharm RIDAGENE Helicobacter pylori		2		
		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Total:		7		100 %	

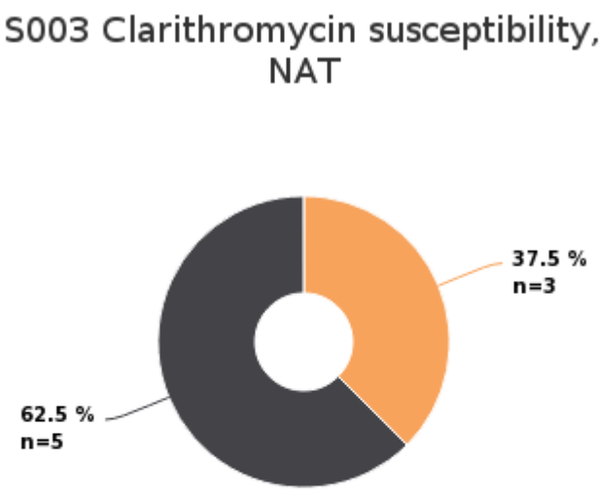
Helicobacter pylori, nucleic acid detection - Pilot, October, 1-2023

S003



S003 results	Responded	AVR success rate	Count
	Helicobacter pylori, NAT	66.7 %	12
	Clarithromycin susceptibility, NAT	-	8
Total:		66.7 %	20





Helicobacter pylori, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	H. pylori detected		8		100 %	2
		BioCorp BC-H. pylori		1		
		In house		2		
		LightGene H. pylori		1		
		Mobidiag Amplidiag® H. pylori+ClariR		3		
		R-Biopharm RIDAGENE Helicobacter pylori		1		
	H. pylori not detected		4		0 %	0
		BioCorp BC-H. pylori		1		
		DNA-Technology Helicobacter pylori REAL-TIME PCR Detection Kit		1		
		R-Biopharm RIDAGENE Helicobacter pylori		1		
		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Total:		12		66.7 %	

Clarithromycin susceptibility, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Resistance to clarithromycin detected		3		-	-
		Mobidiag Amplidiag® H. pylori+ClariR		2		
		R-Biopharm RIDAGENE Helicobacter pylori		1		
	Resistance to clarithromycin not detected		5		-	-
		In house		2		
		Mobidiag Amplidiag® H. pylori+ClariR		1		
		R-Biopharm RIDAGENE Helicobacter pylori		1		

		Seegene Allplex™ H. pylori & ClariR Assay		1		
	Total:		8			

LABQUALITY

External Quality Assessment Scheme

Helicobacter pylori, nucleic acid detection Round 1, 2023 (pilot)

Specimens
Samples S001 and S002 of this EQA round were artificial swab samples and sample S003 was a lyophilized faecal sample. 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 (LQ763323011)	
Helicobacter pylori	*H. pylori* detected
Clarithromycin susceptibility	Resistance to clarithromycin not detected
Sample S002 (LQ763323012)	
Helicobacter pylori	*H. pylori* not detected
Clarithromycin susceptibility	Resistance to clarithromycin not detected
Sample S003 (LQ763323013)	
Helicobacter pylori	*H. pylori* detected
Clarithromycin susceptibility	Resistance to clarithromycin not analysed

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
In this pilot round 13/17 participants (12 participants in sample S003) had reported the results on time.

Eight different methods had been used and with five methods it was possible to determine clarithromycin resistance. The success rate for this round was 87.2%.

Sample S001 was *Helicobacter pylori* positive, and no clarithromycin resistance was detected. The analysis of this sample went very well, and all the laboratories reported expected results.

Sample S002 was negative. 95% of the laboratories reported expected negative results for *H. pylori.* One laboratory reported “Unclear test result”. No clear reason for this was found. All the laboratories reported expected negative results for clarithromycin.

Sample S003 was *H. pylori* positive. The sample was challenging and only 8/12 (66.7%) of the laboratories reported the expected result. Two methods yielded both positive and negative results. Clarithromycin resistance test was not scored although over 60% of laboratories reported ”Resistance to clarithromycin not detected”. Two methods out of five yielded both “Resistance to clarithromycin not detected” and “Resistance to clarithromycin detected” results.

Sample S003 was a low positive sample which might have affected the variation of the results of different laboratories. Unlike samples S001 and S002, sample S003 was a lyophilized faecal sample.

2023-11-30

REPORT

Product no. 5253

Samples sent	2023-10-17
Round closed	2023-11-16
Final report	2023-11-30

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
Kati Luiro
kati.luiro@labquality.fi

Expert
Clinical microbiologist
Santra Karumaa,
SYNLAB Suomi Oy

Labquality Oy
Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200

info@labquality.fi
www.labquality.com

Both the pre-treatment of this sample and the deviant sample type may have also affected the results. This type of sample matrix is not routinely validated in many laboratories or for many nucleic acid detection tests (in-house or commercial).

Exceptions in scoring
For sample S003, the clarithromycin resistance results were not scored due to low *H. pylori* concentration in the sample, and also the deviant sample type and success of the pre-treatment could have affected the variation of the results.

End of report