

LABQUALITY

External Quality Assessment Scheme

Helicobacter pylori, antigen detection in faeces

Round 1, 2023

Specimens

Please find enclosed one swab sample S001 and 2 lyophilized human faecal specimens S002 and S003 each 0.5g.

Caution

Be aware, that the specimens simulate clinical specimens and should therefore be handled with the same care as normal patient samples, capable of transmitting infectious disease. Not for patient use.

Examinations

F -HepyAg

Sample S001 storage and use (swab)

The specimen should be stored at refrigerated or room temperature (2-30°C) and analysed as soon as possible, preferably within a week. Do not freeze.

1. Allow the swab to reach room temperature (15- 30°C) prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the swab from its sealed pouch. Add the test's own buffer into the testing tube or vial, put the swab in, mix and incubate at least 1 minute and extract as much liquid possible from the swab.
3. Prepare and analyse the specimens as patient samples according to the instructions of the kit manufacturer.

Sample S002 and S003 storage and use (vials)

The specimens should be stored at 2 ... 8 °C and analysed as soon as possible, preferably within a week.

1. Add 500 µL distilled or deionized water into the vial. Let the vial rest for 10 minutes at room temperature and vortex for about 30 seconds until complete homogenisation has been achieved.
2. Prepare and analyse the specimens as patient samples according to the instructions of the kit manufacturer.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator. All the reported test results are scored.

S001: LQ760723011



S003: LQ760723013



S002: LQ760723012



2023-03-07

INSTRUCTIONS

Product no. 5596
LQ760723011-013/DE, PL
UN3373

Subcontracting: Sample pretesting

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

The results should be reported no later than **March 28, 2023.**

Expected results of the round are published in LabScala in the View reports section by April 03,2023.

Inquiries

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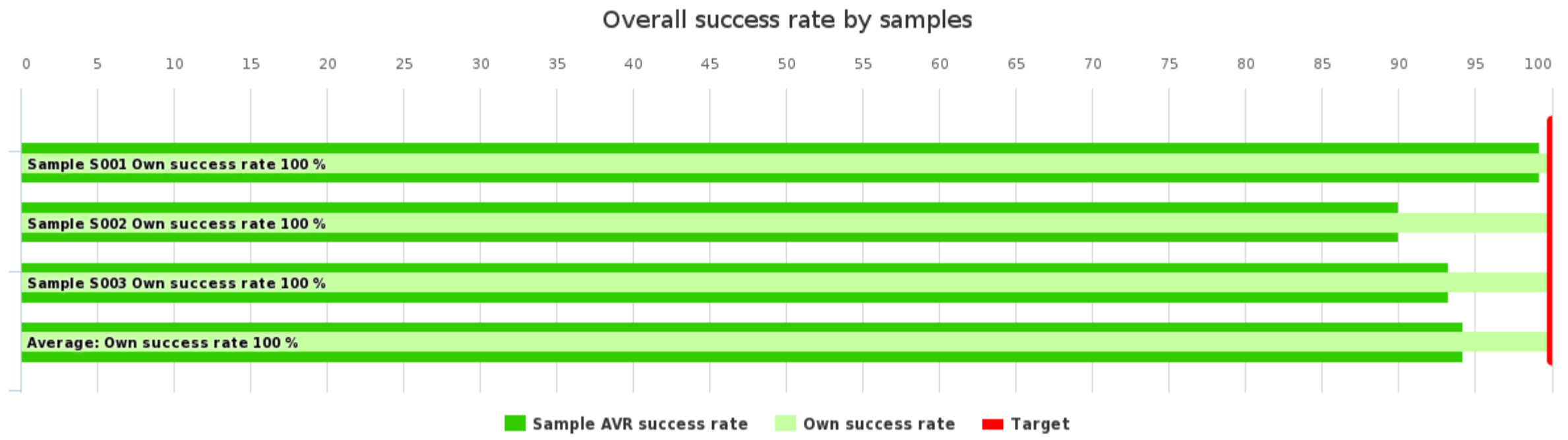
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Helicobacter pylori, antigen detection in faeces, March, 1-2023	269	264	98.1 %

Summary

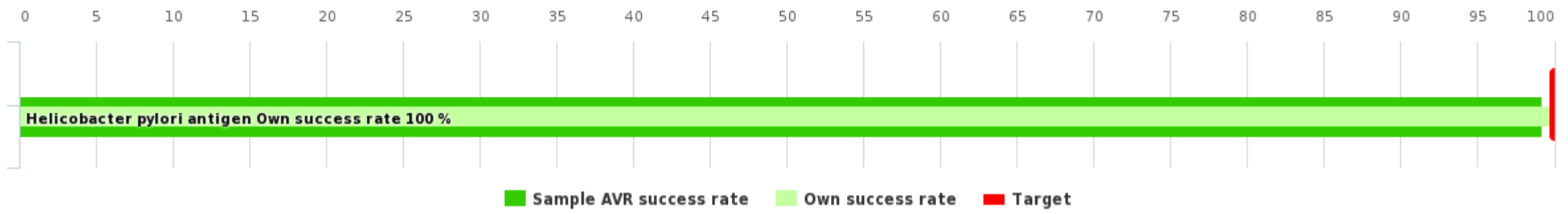


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0.8 %	99.2 %
Sample S002	2	2	100 %	10 %	90 %
Sample S003	2	2	100 %	6.7 %	93.3 %
Average:			100 %	5.8 %	94.2 %

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

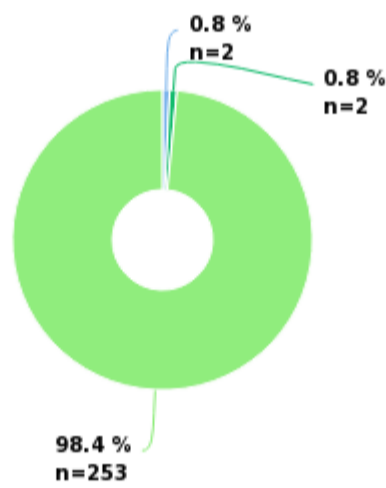
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori antigen	2	2	100 %	0.8 %	99.2 %	257
Total:		2	2	100 %	0.8 %	99.2 %	257

Sample S001 Helicobacter pylori antigen



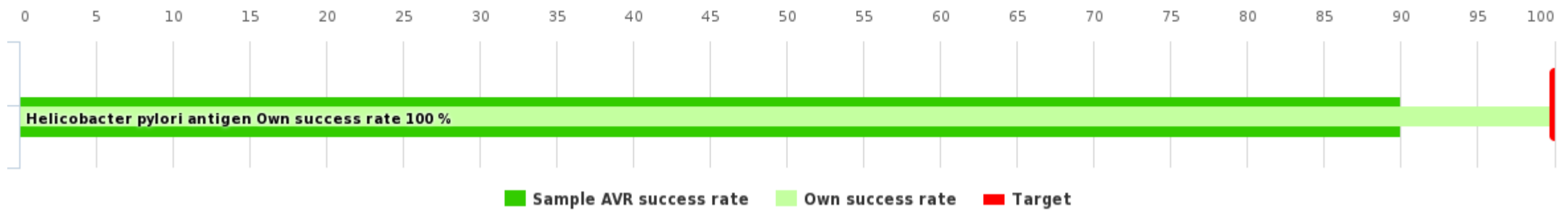
■ Negative ■ Weak positive ■ Positive

Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Koroglu Medical Laboquick H. pylori Ag Rapid		1					
		nal von minden NADAL H. pylori Ag		1					
	Weak positive		2		-				100 %
		Coris BioConcept Pylori Ag K-Set		1					
		R-Biopharm RIDA QUICK Helicobacter		1					
	<input checked="" type="radio"/> Positive		253		2	2	100 %	0 %	100 %
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		9					
		Alere/Standard Diagnostics SD Biline H. pylori Ag		5					
		Apacor Rapydtest H. pylori Ag		1					
		BioMaxima HELICO H. pylori Ag		3					
		Certest Biotec H. pylori Ag Blister Test		5					
		<input checked="" type="radio"/> Certest Biotec H. pylori Ag Card Test		11					
		CerTest CLIA H. Pylori Ag		1					
		Coris BioConcept Pylori-Strip Ag		1					
		DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1					
		Dialab DIAQUICK H. pylori Ag Stool Casette		1					
		DiaSorin Liaison H. pylori Stool Antigen SA		12					
		Diasorin LIAISON Meridian H. pylori SA		46					
		Dima/BioSynex H. pylori Ag		3					
		H. pylori Ag MonlabTest		1					
		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		4					
		Humasis H.pylori Ag Test		2					

	Hydrex Helicobacter Antygen Test		1						
	IDK HepyAg ELISA		1						
	Intermedical Helicobacter pylori Ag		2						
	Mascia Brunelli Hepy Stool Ag Card Plus		4						
	Meridian Curian HpSA		1						
	Meridian ImmunoCard STAT! HpSA Ag Test		5						
	Meridian ImmunoCard STAT! HpSA HD Ag Test		14						
	Meridian Premier Platinum HpSA PLUS		33						
	nal von minden NADAL H. pylori Ag		22						
	Oxoid Amplified IDEIA Hp StAR Ag Test		26						
	Oxoid RAPID Hp StAR Ag Test		3						
	Prolab Diagnostics Proflow H. pylori Ag		10						
	R-Biopharm RIDA QUICK Helicobacter		3						
	R-Biopharm Ridascreen Helicobacter		3						
	Savyon Diagnostics CoproStrip H. pylori Ag		2						
	SD Biosensor STANDARD F H.pylori Ag FIA		11						
	Sentinel Diagnostics Easy-Card H. pylori Ag		3						
	Vitassay H. Pylori Single Card		2						
	Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1						
	Total:		257		2	2	100 %	0.8 %	99.2 %

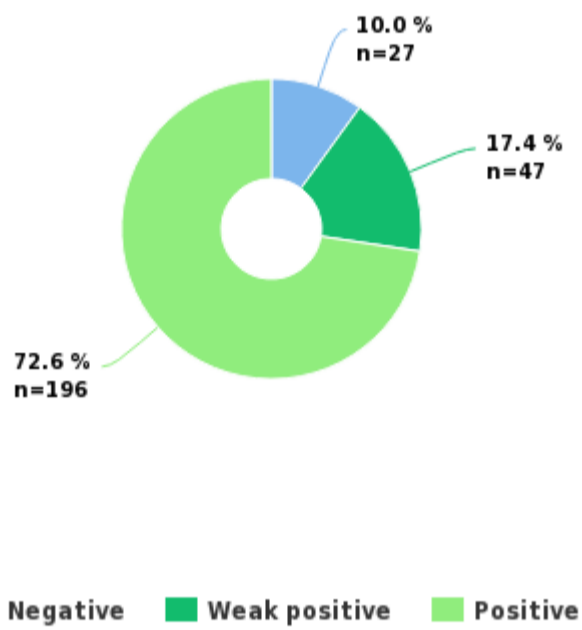
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori antigen	2	2	100 %	10 %	90 %	270
Total:		2	2	100 %	10 %	90 %	270

Sample S002 Helicobacter pylori antigen

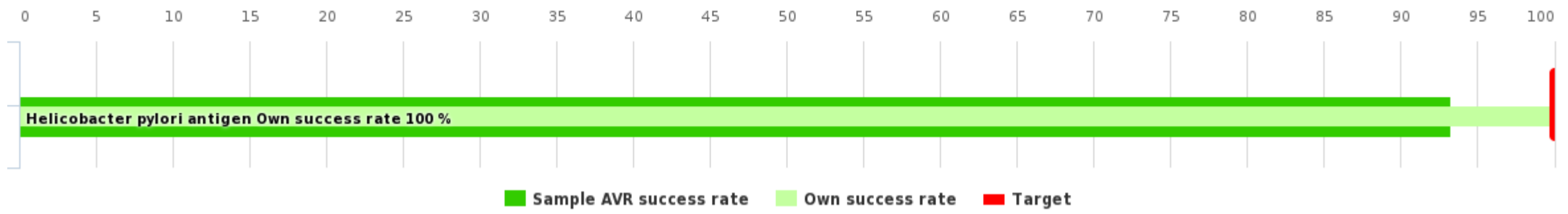


Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		27		-				0 %
		Certest Biotec H. pylori Ag Blister Test		1					
		Certest Biotec H. pylori Ag Card Test		3					
		Coris BioConcept Pylori Ag K-Set		1					
		Dialab DIAQUICK H. pylori Ag Stool Casette		1					
		DiaSorin Liaison H. pylori Stool Antigen SA		1					
		H. pylori Ag MonlabTest		1					
		Hydrex Helicobacter Antygen Test		1					
		Koroglu Medical Laboquick H. pylori Ag Rapid		1					
		Mascia Brunelli Hepy Stool Ag Card Plus		1					
		Meridian ImmunoCard STAT! HpSA Ag Test		2					
		Meridian Premier Platinum HpSA PLUS		1					
		nal von minden NADAL H. pylori Ag		7					
		Prolab Diagnostics Proflow H. pylori Ag		4					
		R-Biopharm RIDA QUICK Helicobacter		1					
		Vitassay H. Pylori Single Card		1					
	Weak positive		47		-				100 %
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		1					
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		3					
		Apacor Rapydtest H. pylori Ag		1					
		BioMaxima HELICO H. pylori Ag		1					
		Certest Biotec H. pylori Ag Blister Test		4					
		Certest Biotec H. pylori Ag Card Test		6					

	Coris BioConcept Pylori-Strip Ag		1					
	DiaSorin Liaison H. pylori Stool Antigen SA		4					
	Diasorin LIAISON Meridian H. pylori SA		1					
	Dima/BioSynex H. pylori Ag		2					
	Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		2					
	Humasis H.pylori Ag Test		2					
	Hydrex Helicobacter Antygen Test		1					
	IDK HepyAg ELISA		1					
	Intermedical Helicobacter pylori Ag		1					
	Mascia Brunelli Hepy Stool Ag Card Plus		1					
	Meridian ImmunoCard STAT! HpSA Ag Test		1					
	Meridian ImmunoCard STAT! HpSA HD Ag Test		1					
	nal von minden NADAL H. pylori Ag		6					
	Oxoid Amplified IDEIA Hp StAR Ag Test		1					
	Prolab Diagnostics Proflow H. pylori Ag		3					
	R-Biopharm RIDA QUICK Helicobacter		2					
	Vitassay H. Pylori Single Card		1					
<input checked="" type="radio"/>	Positive		196	2	2	100 %	0 %	100 %
	Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		8					
	Alere/Standard Diagnostics SD Biline H. pylori Ag		2					
	BioMaxima HELICO H. pylori Ag		2					
	<input checked="" type="radio"/> Certest Biotec H. pylori Ag Card Test		2					
	CerTest CLIA H. Pylori Ag		1					
	DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1					
	DiaSorin Liaison H. pylori Stool Antigen SA		9					
	Diasorin LIAISON Meridian H. pylori SA		47					
	Dima/BioSynex H. pylori Ag		1					
	Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		2					
	Intermedical Helicobacter pylori Ag		1					
	Mascia Brunelli Hepy Stool Ag Card Plus		2					
	Meridian Curian HpSA		2					
	Meridian ImmunoCard STAT! HpSA Ag Test		2					
	Meridian ImmunoCard STAT! HpSA HD Ag Test		14					
	Meridian Premier Platinum HpSA PLUS		33					
	nal von minden NADAL H. pylori Ag		13					
	Oxoid Amplified IDEIA Hp StAR Ag Test		24					
	Oxoid RAPID Hp StAR Ag Test		5					
	Prolab Diagnostics Proflow H. pylori Ag		4					
	R-Biopharm RIDA QUICK Helicobacter		1					
	R-Biopharm Ridascreen Helicobacter		3					
	Savyon Diagnostics CoproStrip H. pylori Ag		2					
	SD Biosensor STANDARD F H.pylori Ag FIA		11					
	Sentinel Diagnostics Easy-Card H. pylori Ag		3					
	Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1					
	Total:		270	2	2	100 %	10 %	90 %

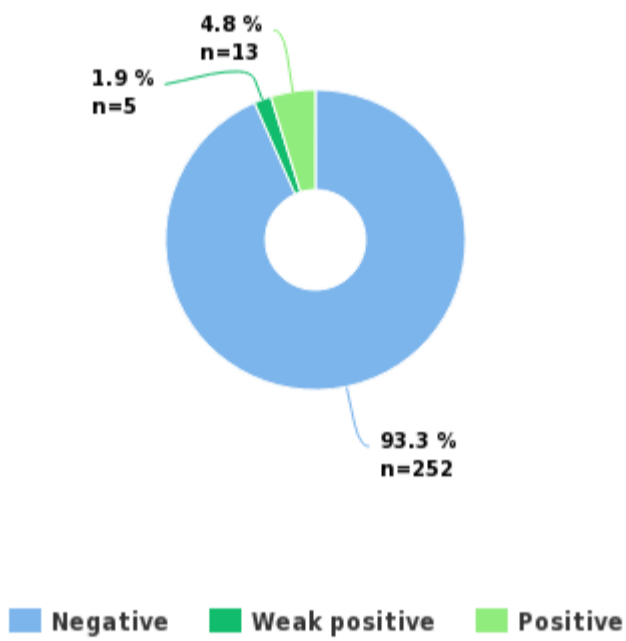
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Helicobacter pylori antigen	2	2	100 %	6.7 %	93.3 %	270
Total:		2	2	100 %	6.7 %	93.3 %	270

Sample S003 Helicobacter pylori antigen



Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		252		2	2	100 %	0 %	100 %
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		9					
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		4					
		Apacor Rapydtest H. pylori Ag		1					
		BioMaxima HELICO H. pylori Ag		1					
		Certest Biotec H. pylori Ag Blister Test		5					
		<input checked="" type="radio"/> Certest Biotec H. pylori Ag Card Test		11					
		CerTest CLIA H. Pylori Ag		1					
		Coris BioConcept Pylori Ag K-Set		1					
		Coris BioConcept Pylori-Strip Ag		1					
		DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1					
		Dialab DIAQUICK H. pylori Ag Stool Cassette		1					
		DiaSorin Liaison H. pylori Stool Antigen SA		12					
		Diasorin LIAISON Meridian H. pylori SA		41					
		Dima/BioSynex H. pylori Ag		3					
		H. pylori Ag MonlabTest		1					
		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		4					
		Humasis H.pylori Ag Test		2					
		Hydrex Helicobacter Antygen Test		2					
		IDK HepyAg ELISA		1					
		Intermedical Helicobacter pylori Ag		2					
		Koroglu Medical Laboquick H. pylori Ag Rapid		1					
		Mascia Brunelli Hepy Stool Ag Card Plus		4					

		Meridian Curian HpSA		2					
		Meridian ImmunoCard STAT! HpSA Ag Test		5					
		Meridian ImmunoCard STAT! HpSA HD Ag Test		15					
		Meridian Premier Platinum HpSA PLUS		30					
		nal von minden NADAL H. pylori Ag		25					
		Oxoid Amplified IDEIA Hp StAR Ag Test		25					
		Oxoid RAPID Hp StAR Ag Test		5					
		Prolab Diagnostics Proflow H. pylori Ag		11					
		R-Biopharm RIDA QUICK Helicobacter		4					
		R-Biopharm Ridascreen Helicobacter		3					
		Savyon Diagnostics CoproStrip H. pylori Ag		2					
		SD Biosensor STANDARD F H.pylori Ag FIA		11					
		Sentinel Diagnostics Easy-Card H. pylori Ag		3					
		Vitassay H. Pylori Single Card		2					
	Weak positive		5		-				0 %
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		1					
		DiaSorin Liaison H. pylori Stool Antigen SA		1					
		Diasorin LIAISON Meridian H. pylori SA		1					
		Meridian Premier Platinum HpSA PLUS		1					
		Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1					
	Positive		13		-				0 %
		BioMaxima HELICO H. pylori Ag		2					
		DiaSorin Liaison H. pylori Stool Antigen SA		1					
		Diasorin LIAISON Meridian H. pylori SA		6					
		Meridian Premier Platinum HpSA PLUS		3					
		nal von minden NADAL H. pylori Ag		1					
	Total:		270		2	2	100 %	6.7 %	93.3 %

Report Info

PARTICIPANTS

Altogether 269 laboratories from 29 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. Accepted results are marked with green color and laboratory's own result 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 result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

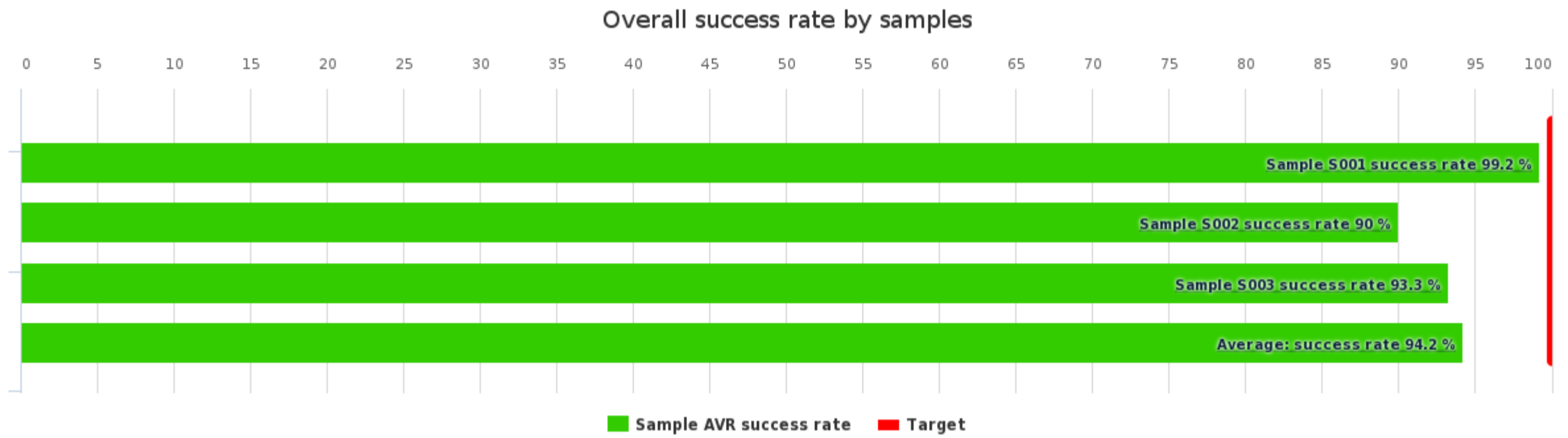
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample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

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Helicobacter pylori, antigen detection in faeces, March, 1-2023	269	264	98.1 %

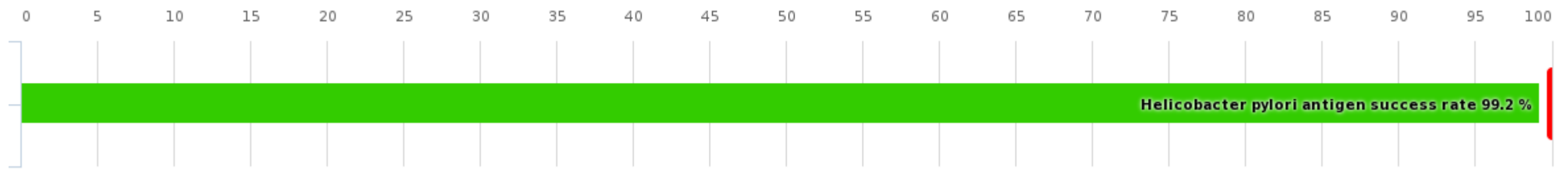
Summary



Summary	AVR success rate
Sample S001	99.2 %
Sample S002	90 %
Sample S003	93.3 %
Average:	94.2 %

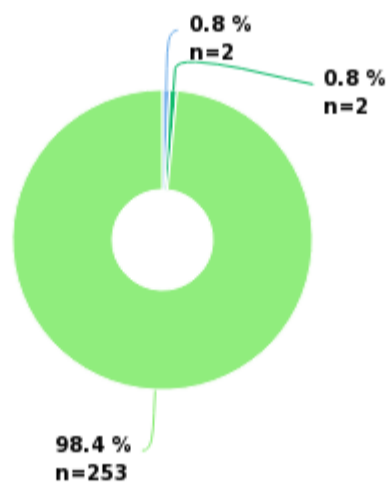
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Helicobacter pylori antigen	99.2 %	257
Total:		99.2 %	257

Sample S001 Helicobacter pylori antigen



■ Negative
 ■ Weak positive
 ■ Positive

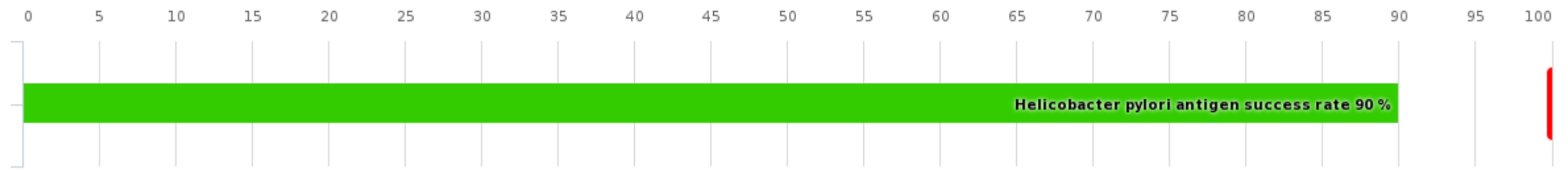
Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		2		0 %	0
		Koroglu Medical Laboquick H. pylori Ag Rapid		1		
		nal von minden NADAL H. pylori Ag		1		
	Weak positive		2		100 %	2
		Coris BioConcept Pylori Ag K-Set		1		
		R-Biopharm RIDA QUICK Helicobacter		1		
	Positive		253		100 %	2
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		9		
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		5		
		Apacor Rapydtest H. pylori Ag		1		
		BioMaxima HELICO H. pylori Ag		3		
		Certest Biotec H. pylori Ag Blister Test		5		
		Certest Biotec H. pylori Ag Card Test		11		
		CerTest CLIA H. Pylori Ag		1		
		Coris BioConcept Pylori-Strip Ag		1		
		DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1		
		Dialab DIAQUICK H. pylori Ag Stool Casette		1		
		DiaSorin Liaison H. pylori Stool Antigen SA		12		
		Diasorin LIAISON Meridian H. pylori SA		46		
		Dima/BioSynex H. pylori Ag		3		
		H. pylori Ag MonlabTest		1		
		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		4		
		Humasis H.pylori Ag Test		2		
		Hydrex Helicobacter Antygen Test		1		
		IDK HepyAg ELISA		1		
		Intermedical Helicobacter pylori Ag		2		
		Mascia Brunelli Hepy Stool Ag Card Plus		4		

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	Meridian Curian HpSA		1		
	Meridian ImmunoCard STAT! HpSA Ag Test		5		
	Meridian ImmunoCard STAT! HpSA HD Ag Test		14		
	Meridian Premier Platinum HpSA PLUS		33		
	nal von minden NADAL H. pylori Ag		22		
	Oxoid Amplified IDEIA Hp StAR Ag Test		26		
	Oxoid RAPID Hp StAR Ag Test		3		
	Prolab Diagnostics Proflow H. pylori Ag		10		
	R-Biopharm RIDA QUICK Helicobacter		3		
	R-Biopharm Ridascreen Helicobacter		3		
	Savyon Diagnostics CoproStrip H. pylori Ag		2		
	SD Biosensor STANDARD F H.pylori Ag FIA		11		
	Sentinel Diagnostics Easy-Card H. pylori Ag		3		
	Vitassay H. Pylori Single Card		2		
	Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1		
	Total:		257		99.2 %

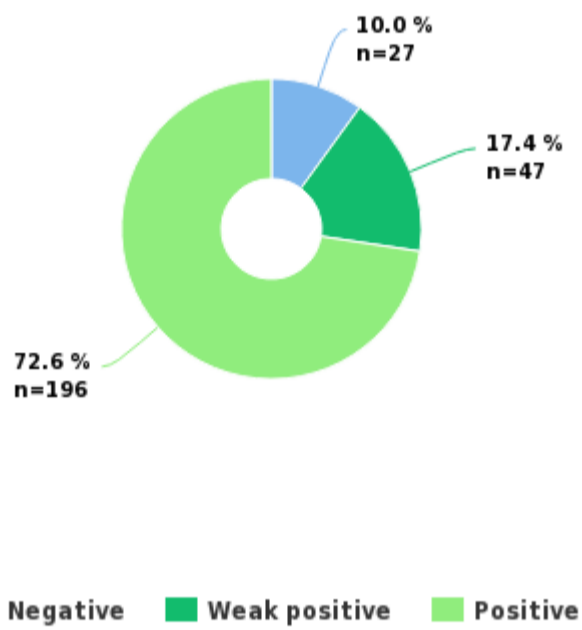
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Helicobacter pylori antigen	90 %	270
Total:		90 %	270

Sample S002 Helicobacter pylori antigen



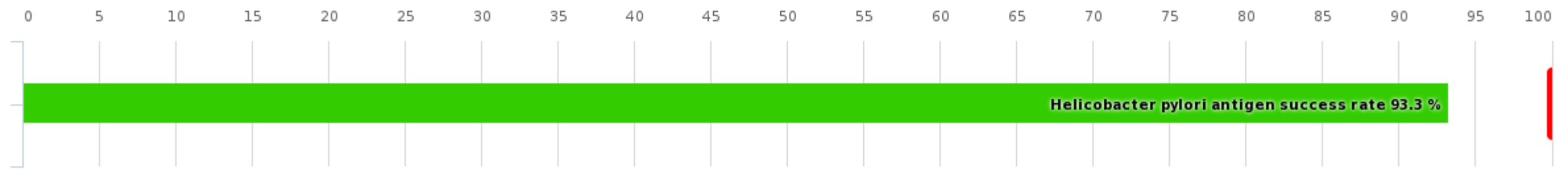
Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
Negative	Negative		27		0 %	0
		Certest Biotec H. pylori Ag Blister Test		1		
		Certest Biotec H. pylori Ag Card Test		3		
		Coris BioConcept Pylori Ag K-Set		1		
		Dialab DIAQUICK H. pylori Ag Stool Cassette		1		
		DiaSorin Liaison H. pylori Stool Antigen SA		1		
		H. pylori Ag MonlabTest		1		
		Hydrex Helicobacter Antygen Test		1		
		Koroglu Medical Laboquick H. pylori Ag Rapid		1		
		Mascia Brunelli Hepy Stool Ag Card Plus		1		
		Meridian ImmunoCard STAT! HpSA Ag Test		2		
		Meridian Premier Platinum HpSA PLUS		1		
		nal von minden NADAL H. pylori Ag		7		
		Prolab Diagnostics Proflow H. pylori Ag		4		
		R-Biopharm RIDA QUICK Helicobacter		1		
		Vitassay H. Pylori Single Card		1		
		Weak positive	Weak positive		47	
Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)				1		
Alere/Standard Diagnostics SD Bioline H. pylori Ag				3		
Apacor Rapydtest H. pylori Ag				1		
BioMaxima HELICO H. pylori Ag				1		
Certest Biotec H. pylori Ag Blister Test				4		
Certest Biotec H. pylori Ag Card Test				6		
Coris BioConcept Pylori-Strip Ag				1		
DiaSorin Liaison H. pylori Stool Antigen SA				4		
Diasorin LIAISON Meridian H. pylori SA				1		
Dima/BioSynex H. pylori Ag				2		

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		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		2		
		Humasis H.pylori Ag Test		2		
		Hydrex Helicobacter Antygen Test		1		
		IDK HepyAg ELISA		1		
		Intermedical Helicobacter pylori Ag		1		
		Mascia Brunelli Hepy Stool Ag Card Plus		1		
		Meridian ImmunoCard STAT! HpSA Ag Test		1		
		Meridian ImmunoCard STAT! HpSA HD Ag Test		1		
		nal von minden NADAL H. pylori Ag		6		
		Oxoid Amplified IDEIA Hp StAR Ag Test		1		
		Prolab Diagnostics Proflow H. pylori Ag		3		
		R-Biopharm RIDA QUICK Helicobacter		2		
		Vitassay H. Pylori Single Card		1		
	Positive		196		100 %	2
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		8		
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		2		
		BioMaxima HELICO H. pylori Ag		2		
		Certest Biotec H. pylori Ag Card Test		2		
		CerTest CLIA H. Pylori Ag		1		
		DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1		
		DiaSorin Liaison H. pylori Stool Antigen SA		9		
		Diasorin LIAISON Meridian H. pylori SA		47		
		Dima/BioSynex H. pylori Ag		1		
		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		2		
		Intermedical Helicobacter pylori Ag		1		
		Mascia Brunelli Hepy Stool Ag Card Plus		2		
		Meridian Curian HpSA		2		
		Meridian ImmunoCard STAT! HpSA Ag Test		2		
		Meridian ImmunoCard STAT! HpSA HD Ag Test		14		
		Meridian Premier Platinum HpSA PLUS		33		
		nal von minden NADAL H. pylori Ag		13		
		Oxoid Amplified IDEIA Hp StAR Ag Test		24		
		Oxoid RAPID Hp StAR Ag Test		5		
		Prolab Diagnostics Proflow H. pylori Ag		4		
		R-Biopharm RIDA QUICK Helicobacter		1		
		R-Biopharm Ridascreen Helicobacter		3		
		Savyon Diagnostics CoproStrip H. pylori Ag		2		
		SD Biosensor STANDARD F H.pylori Ag FIA		11		
		Sentinel Diagnostics Easy-Card H. pylori Ag		3		
		Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1		
	Total:		270		90 %	

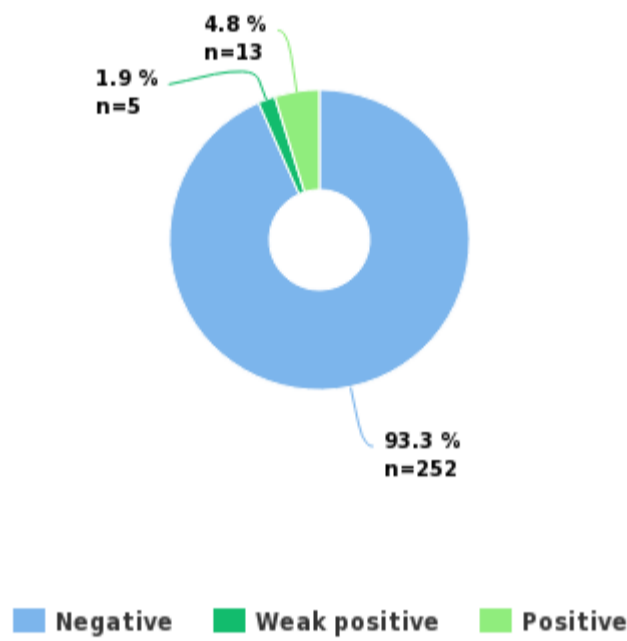
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Helicobacter pylori antigen	93.3 %	270
Total:		93.3 %	270

Sample S003 Helicobacter pylori antigen



Helicobacter pylori antigen	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		252		100 %	2
		Acro Biotech H. pylori Antigen Rapid Test Dipstick (Feces)		9		
		Alere/Standard Diagnostics SD Bioline H. pylori Ag		4		
		Apacor Rapydtest H. pylori Ag		1		
		BioMaxima HELICO H. pylori Ag		1		
		Certest Biotec H. pylori Ag Blister Test		5		
		Certest Biotec H. pylori Ag Card Test		11		
		CerTest CLIA H. Pylori Ag		1		
		Coris BioConcept Pylori Ag K-Set		1		
		Coris BioConcept Pylori-Strip Ag		1		
		DDS Diagnostic H. Pylori Antigen Feces Rapid Test		1		
		Dialab DIAQUICK H. pylori Ag Stool Casette		1		
		DiaSorin Liaison H. pylori Stool Antigen SA		12		
		Diasorin LIAISON Meridian H. pylori SA		41		
		Dima/BioSynex H. pylori Ag		3		
		H. pylori Ag MonlabTest		1		
		Hangzhou Alltest Biotech H. pylori Antigen Rapid Test		4		
		Humasis H.pylori Ag Test		2		
		Hydrex Helicobacter Antyege Test		2		
		IDK HepyAg ELISA		1		
		Intermedical Helicobacter pylori Ag		2		
		Koroglu Medical Laboquick H. pylori Ag Rapid		1		
		Mascia Brunelli Hepy Stool Ag Card Plus		4		
		Meridian Curian HpSA		2		
		Meridian ImmunoCard STAT! HpSA Ag Test		5		
		Meridian ImmunoCard STAT! HpSA HD Ag Test		15		
		Meridian Premier Platinum HpSA PLUS		30		

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		nal von minden NADAL H. pylori Ag		25		
		Oxoid Amplified IDEIA Hp StAR Ag Test		25		
		Oxoid RAPID Hp StAR Ag Test		5		
		Prolab Diagnostics Proflow H. pylori Ag		11		
		R-Biopharm RIDA QUICK Helicobacter		4		
		R-Biopharm Ridascreen Helicobacter		3		
		Savyon Diagnostics CoproStrip H. pylori Ag		2		
		SD Biosensor STANDARD F H.pylori Ag FIA		11		
		Sentinel Diagnostics Easy-Card H. pylori Ag		3		
		Vitassay H. Pylori Single Card		2		
	Weak positive		5		0 %	0
		Alere/Standard Diagnostics SD Biline H. pylori Ag		1		
		DiaSorin Liaison H. pylori Stool Antigen SA		1		
		Diasorin LIAISON Meridian H. pylori SA		1		
		Meridian Premier Platinum HpSA PLUS		1		
		Zhejiang Orient Gene/Healgen H. pylori Ag Rapid Test		1		
	Positive		13		0 %	0
		BioMaxima HELICO H. pylori Ag		2		
		DiaSorin Liaison H. pylori Stool Antigen SA		1		
		Diasorin LIAISON Meridian H. pylori SA		6		
		Meridian Premier Platinum HpSA PLUS		3		
		nal von minden NADAL H. pylori Ag		1		
	Total:		270		93.3 %	

Report Info

PARTICIPANTS

Altogether 269 laboratories from 29 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. Accepted results are marked with green color and laboratory's own result 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 result and when at least three results are reported. The following general rules are applied:

Correct/expected test result 2/2 points
False/deviating test result 0/2 points

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.

External Quality Assessment Scheme

***Helicobacter pylori*, antigen detection in faeces**

Round 1, 2023

Specimens

Sample S001 was a swab sample and samples S002 and S003 of this EQA round were lyophilized faecal specimens. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ760723011) *Helicobacter pylori* Ag positive
Sample S002 (LQ760723012) *Helicobacter pylori* Ag positive
Sample S003 (LQ760723013) *Helicobacter pylori* Ag negative

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

The first round of the year included three samples, two of which were *Helicobacter pylori* antigen positive while one was antigen negative. The results reported by the participants were mainly correct, although sample S002 appeared to be somewhat tricky.

Antigen positive sample S001 was easy. All but two of the 257 reported results were positive or weakly positive.

Sample S002 was also antigen positive. Nevertheless, 27 laboratories reported negative results. Positive was, however, the consensus in the case of this sample also, since 243 laboratories reported positive or weakly positive results. Methods that had obtained negative results also reported positive and weakly positive results, so the false negative results do not seem to be due to the lower sensitivity of the individual test.

Of the negative sample S003, 18 participating laboratories reported false positive or weakly positive results. Thus, a clear consensus of the sample was negative.

Exceptions in scoring

No exceptions.

End of report

2023-04-03

FINAL REPORT

Product no. 5596

Samples sent	2023-03-07
Round closed	2023-03-28
Expected results	2023-04-03
Final report	2023-04-03

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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