

External Quality Assessment Scheme

***Helicobacter pylori*, antibodies**

Round 1, 2023

Specimens

Please find enclosed 2 human serum or plasma samples S001 and S002, each 0.4mL.

Caution

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Background information

The specimens are human single donor serum or plasma samples from patients who have not been treated for *Helicobacter pylori*.

Examinations

Antibodies, qualitative methods:

HepyAb

Clinical interpretation

Antibodies, quantitative methods:

HepyAbA

HepyAbG

Clinical interpretation

Storage and use

The specimens should be stored at 2 ... 8 °C and analysed as soon as possible, preferably within a week from sample arrival. Samples are ready to use. Analyse as patient samples.

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 reported examinations will be scored.

S001:



S002:



2023-03-07

INSTRUCTIONS

Product no. 5860

LQ757623011-012/F1

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**

The expected results of the round are published in LabScala in the View Reports section by April 03, 2023.

Inquiries

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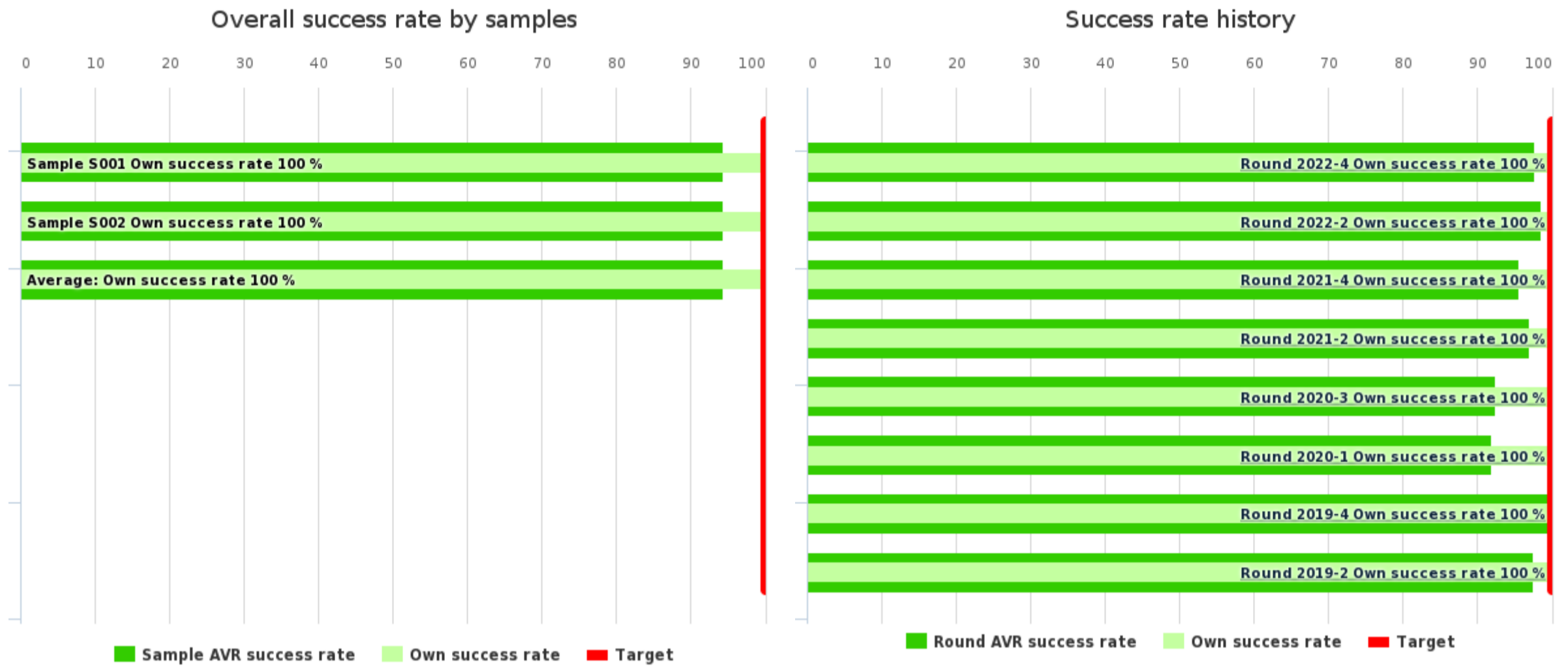
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Helicobacter pylori, antibodies, March, 1-2023	136	128	94.1 %

Summary

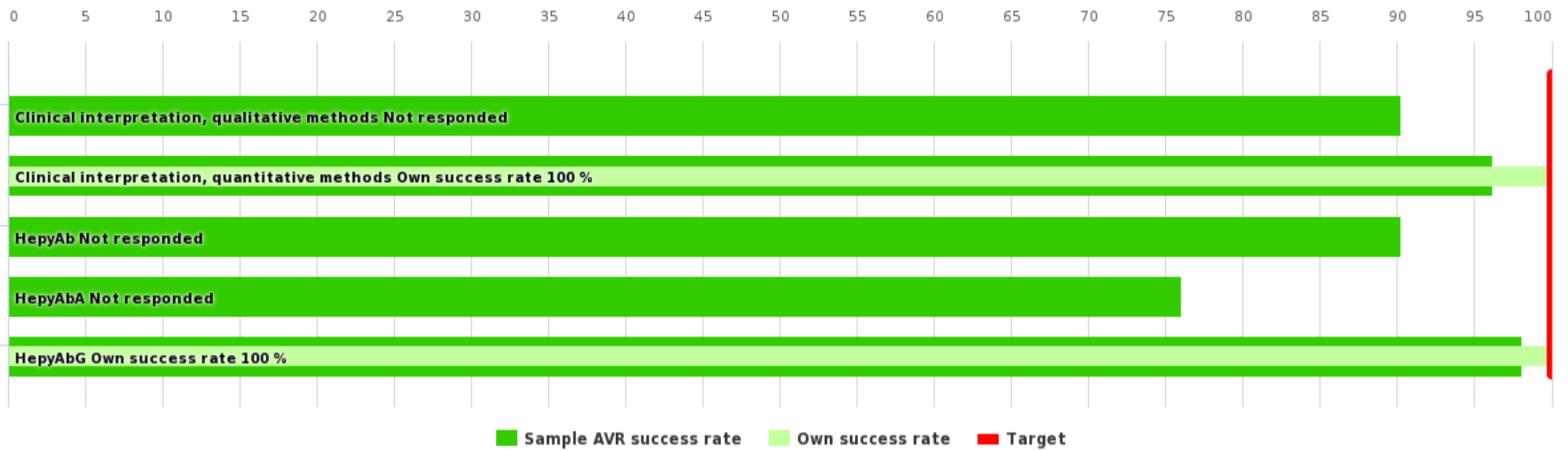


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	6	6	100 %	5.7 %	94.3 %
Sample S002	6	6	100 %	5.7 %	94.3 %
Average:			100 %	5.7 %	94.3 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	2.3 %	97.7 %
Round 2022-2	1-1	100 %	1.4 %	98.6 %
Round 2021-4	1-1	100 %	4.4 %	95.6 %
Round 2021-2	1-1	100 %	2.9 %	97.1 %
Round 2020-3	1-1	100 %	7.6 %	92.4 %
Round 2020-1	1-1	100 %	8.1 %	91.9 %
Round 2019-4	1-1	100 %	0.2 %	99.8 %
Round 2019-2	1-1	100 %	2.4 %	97.6 %

Sample S001

Sample S001 success rate



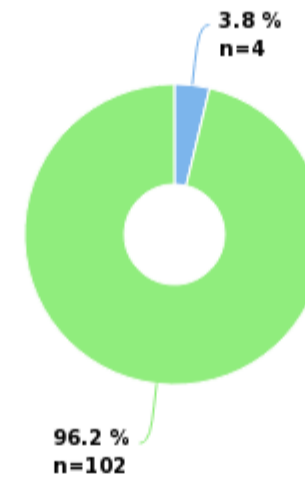
Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation, qualitative methods	-	-	-	-	90.3 %	31
	Clinical interpretation, quantitative methods	4	4	100 %	3.8 %	96.2 %	106
	HepyAb	-	-	-	-	90.3 %	31
	HepyAbA	-	-	-	-	76 %	25
	HepyAbG	2	2	100 %	1.9 %	98.1 %	106
	Total:	6	6	100 %	5.7 %	94.3 %	299

Sample S001 Clinical interpretation, qualitative methods



■ No indication of infection
■ Active or past infection

Sample S001 Clinical interpretation, quantitative methods

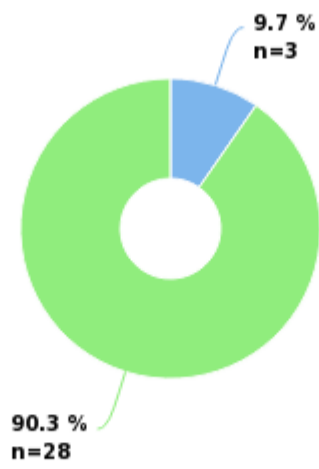


■ No indication of infection
■ Active or past infection

Clinical interpretation, qualitative methods	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	No indication of infection	3	-	-	-	-	0 %
	Active or past infection	28	-	-	-	-	100 %
	Total:	31	-	-	-	-	90.3 %

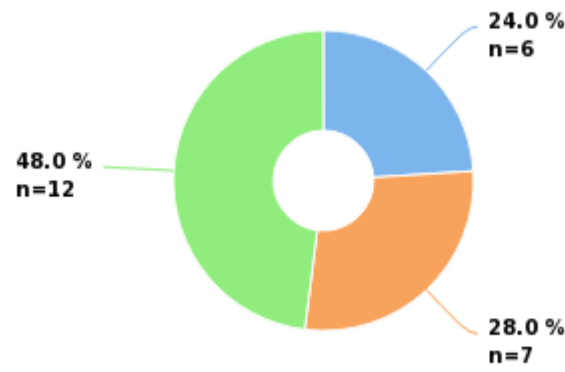
Clinical interpretation, quantitative methods	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	No indication of infection	4	-	-	-	-	0 %
	<input checked="" type="radio"/> Active or past infection	102	4	4	100 %	0 %	100 %
	Total:	106	4	4	100 %	3.8 %	96.2 %

Sample S001 HepyAb



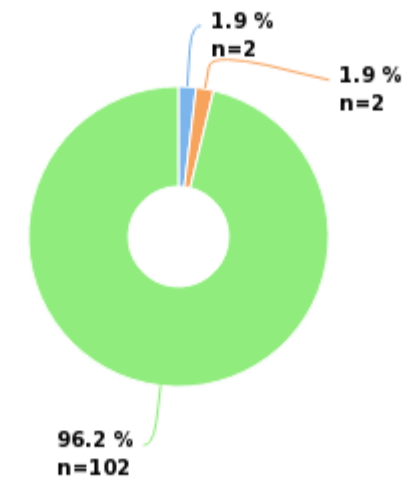
■ Negative ■ Positive

Sample S001 HepyAbA



■ Negative ■ Borderline ■ Positive

Sample S001 HepyAbG



■ Negative ■ Borderline ■ Positive

HepyAb	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		3		-				0 %
		Koroglu Medical Laboquick H. pylori Ab		3					
	Positive		28		-				100 %
		ABON H. Pylori Rapid diagnostics kit		1					
		AccuBiotech ACCU-TELL Rapid H. pylori Antibody Test		1					
		Acro Biotech H. pylori Antibody Rapid Test Cassette		3					
		AllDiag Pyloritop Ab+		1					
		DDS Diagnostic H. Pylori antibodies Rapid Test		1					
		Hydrex Diagnostics Helicobacter pylori Ab		3					
		Koroglu Medical Laboquick H. pylori Ab		1					
		Liaison H. pylori Ab (Diasorin)		9					
		Meridian Bioscience Immunocard H. pylori Ab		1					
		Meridian Bioscience Premier H. pylori Ab		3					
		nal von minden NADAL H. pylori Ab Test		1					
		Standard Diagnostics SD Bioline H. pylori Ab		1					
		Türklab H. pylori Ab		1					
		Ultimed Test Anticorps H.pylori Ab		1					
	Total:		31		-	-	-	-	90.3 %

HepyAbA	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		6		-				0 %
		DiaPro Diagnostics HP CagA IgA ELISA		1					
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		1					
		MAGLUMI CLIA H.pylori IgA		1					
		NovaTec Immunodiagnostica H. pylori IgA ELISA		2					
		TestLine BLOT-LINE Helicobacter IgA		1					
	Borderline		7		-				100 %
		Diese Chorus H. pylori IgA ELISA		1					
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		1					
		Euroimmun Helicobacter pylori IgA EIA/ELISA		2					
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgA		1					
		Testline Helicobacter MONO IgA EIA		1					
		Virotech Helicobacter pylori ELISA IgA		1					

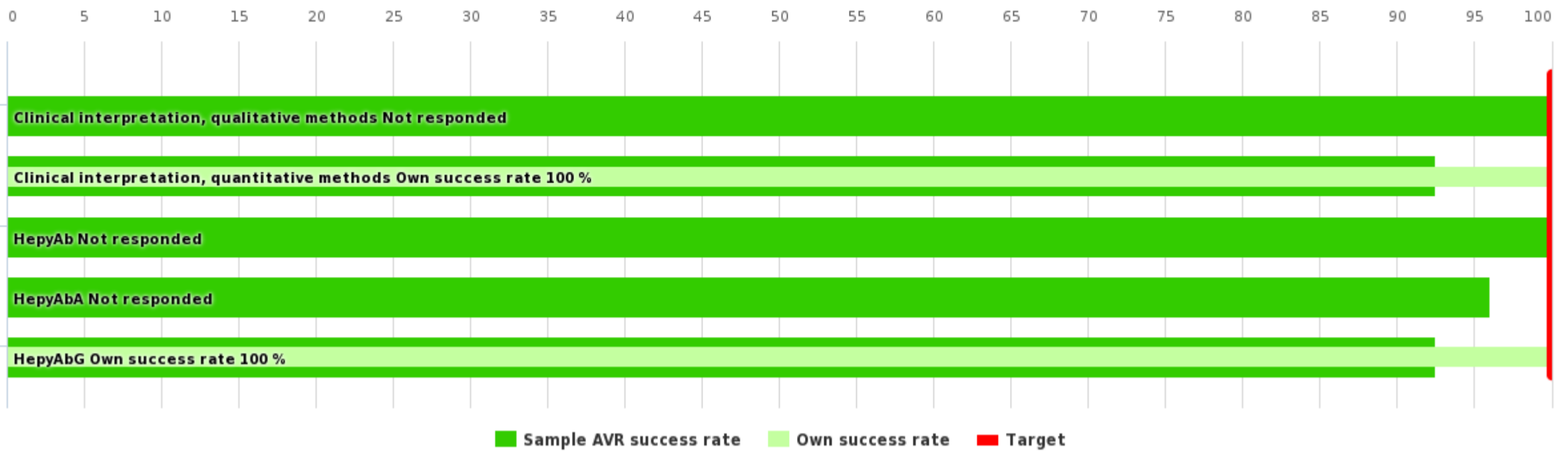
	Positive		12		-				100 %
		Euroimmun Helicobacter pylori IgA EIA/ELISA		3					
		Orgentec Alegria Anti-Helicobacter pylori IgA ELISA		6					
		Testline Helicobacter MONO IgA EIA		3					
	Total:		25		-	-	-	-	76 %

OWN DEVICE: HELICOBACTER PYLORI

HepyAbG	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		DiaPro Diagnostics HP CagA IgG ELISA		1					
		Virotech Helicobacter pylori ELISA IgG		1					
	Borderline		2		-				100 %
		Euroimmun Helicobacter pylori IgG EIA/ELISA		1					
		Siemens Immulite H. pylori IgG		1					
	<input checked="" type="radio"/> Positive		102		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> bioMerieux Vidas H. pylori IgG		27					
		Diasorin Liaison H. pylori IgG		31					
		Diesse Chorus H. pylori IgG ELISA		2					
		Euroimmun Helicobacter pylori IgG EIA/ELISA		10					
		NovaTec Immunodiagnostica H. pylori IgG ELISA		2					
		Orgentec Alegria Anti-Helicobacter pylori IgG ELISA		7					
		SERION classic Helicobacter pylori IgG ELISA		2					
		Siemens Immulite H. pylori IgG		12					
		TestLine BLOT-LINE Helicobacter IgG		1					
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgG		1					
		Testline Helicobacter MONO IgG EIA		3					
		Vircell Helicobacter pylori VirCla IgG		3					
		ZEUS H. pylori IgG ELISA		1					
	Total:		106		2	2	100 %	1.9 %	98.1 %

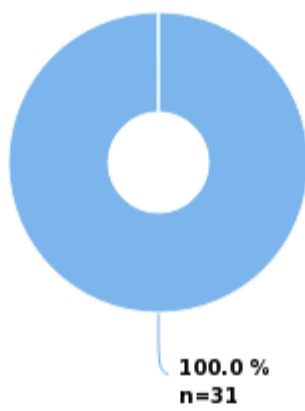
Sample S002

Sample S002 success rate



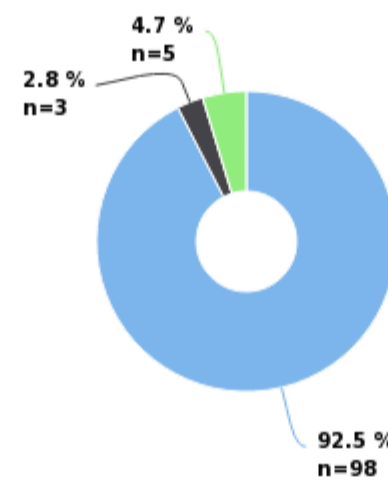
Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation, qualitative methods	-	-	-	-	100 %	31
	Clinical interpretation, quantitative methods	4	4	100 %	7.5 %	92.5 %	106
	HepyAb	-	-	-	-	100 %	31
	HepyAbA	-	-	-	-	96 %	25
	HepyAbG	2	2	100 %	7.5 %	92.5 %	106
	Total:	6	6	100 %	5.7 %	94.3 %	299

Sample S002 Clinical interpretation, qualitative methods



No indication of infection

Sample S002 Clinical interpretation, quantitative methods

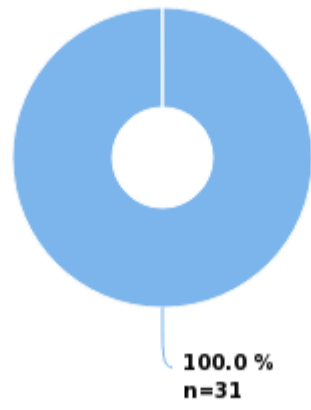


No indication of infection
Borderline interpretation
Active or past infection

Clinical interpretation, qualitative methods	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	No indication of infection	31	-	-	-	-	100 %
	Total:	31	-	-	-	-	100 %

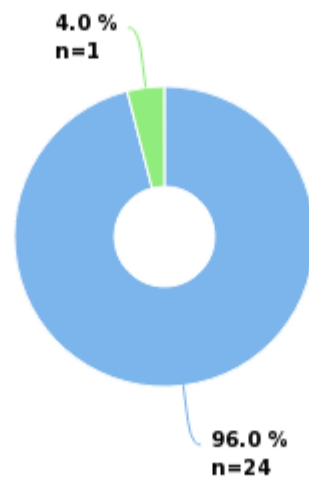
Clinical interpretation, quantitative methods	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> No indication of infection	98	4	4	100 %	0 %	100 %
	Borderline interpretation	3	-	-	-	-	0 %
	Active or past infection	5	-	-	-	-	0 %
	Total:	106	4	4	100 %	7.5 %	92.5 %

Sample S002 HepyAb



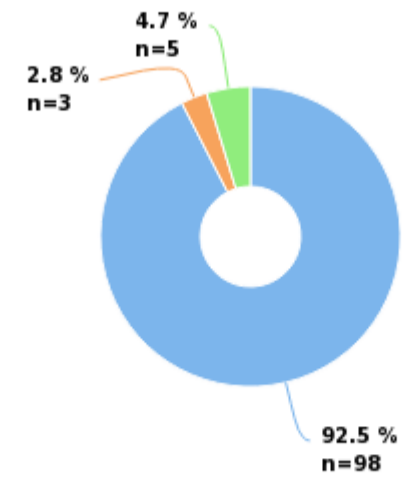
■ Negative

Sample S002 HepyAbA



■ Negative ■ Positive

Sample S002 HepyAbG



■ Negative ■ Borderline ■ Positive

HepyAb	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		31		-				100 %
		ABON H. Pylori Rapid diagnostics kit		1					
		Acro Biotech H. pylori Antibody Rapid Test Cassette		4					
		AllDiag Pyloritop Ab+		1					
		DDS Diagnostic H. Pylori antibodies Rapid Test		1					
		Hydrex Diagnostics Helicobacter pylori Ab		3					
		Koroglu Medical Laboquick H. pylori Ab		4					
		Liaison H. pylori Ab (Diasorin)		9					
		Meridian Bioscience Immunocard H. pylori Ab		1					
		Meridian Bioscience Premier H. pylori Ab		3					
		nal von minden NADAL H. pylori Ab Test		1					
		Standard Diagnostics SD Bioline H. pylori Ab		1					
		Türklab H. pylori Ab		1					
		Ultimed Test Anticorps H.pylori Ab		1					
	Total:		31		-	-	-	-	100 %

HepyAbA	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		24		-				100 %
		DiaPro Diagnostics HP CagA IgA ELISA		1					
		Diesse Chorus H. pylori IgA ELISA		1					
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		2					
		Euroimmun Helicobacter pylori IgA EIA/ELISA		5					
		MAGLUMI CLIA H.pylori IgA		1					
		NovaTec Immunodiagnostica H. pylori IgA ELISA		1					
		Orgentec Alegria Anti-Helicobacter pylori IgA ELISA		6					
		TestLine BLOT-LINE Helicobacter IgA		1					
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgA		1					
		Testline Helicobacter MONO IgA EIA		4					
		Virotech Helicobacter pylori ELISA IgA		1					
	Positive		1		-				0 %
		NovaTec Immunodiagnostica H. pylori IgA ELISA		1					
	Total:		25		-	-	-	-	96 %

OWN DEVICE: HELICOBACTER PYLORI

HepyAbG	Interpretation	Test	Interpretation count	Test count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		98		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> bioMerieux Vidas H. pylori IgG		25					
		DiaPro Diagnostics HP CagA IgG ELISA		1					
		Diasorin Liaison H. pylori IgG		31					
		Diesse Chorus H. pylori IgG ELISA		2					
		Euroimmun Helicobacter pylori IgG EIA/ELISA		11					
		Orgentec Alegria Anti-Helicobacter pylori IgG ELISA		7					
		SERION classic Helicobacter pylori IgG ELISA		2					
		Siemens Immulite H. pylori IgG		13					
		TestLine BLOT-LINE Helicobacter IgG		1					
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgG		1					
		Testline Helicobacter MONO IgG EIA		3					
		ZEUS H. pylori IgG ELISA		1					
	Borderline		3		-				0 %
		bioMerieux Vidas H. pylori IgG		2					
		Vircell Helicobacter pylori VirCla IgG		1					
	Positive		5		-				0 %
		NovaTec Immunodiagnostica H. pylori IgG ELISA		2					
		Vircell Helicobacter pylori VirCla IgG		2					
		Virotech Helicobacter pylori ELISA IgG		1					
	Total:		106		2	2	100 %	7.5 %	92.5 %

Report Info

PARTICIPANTS

Altogether 136 laboratories from 25 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 and clinical interpretations 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
Correct/expected clinical interpretation 4/4 points
False/deviating clinical interpretation 0/4 points

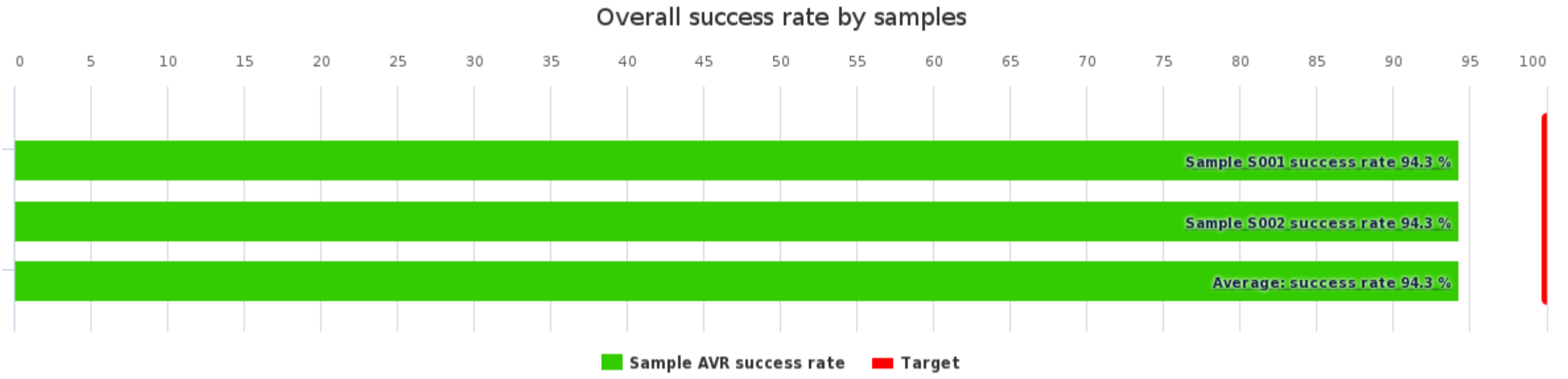
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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, antibodies, March, 1-2023	136	128	94.1 %

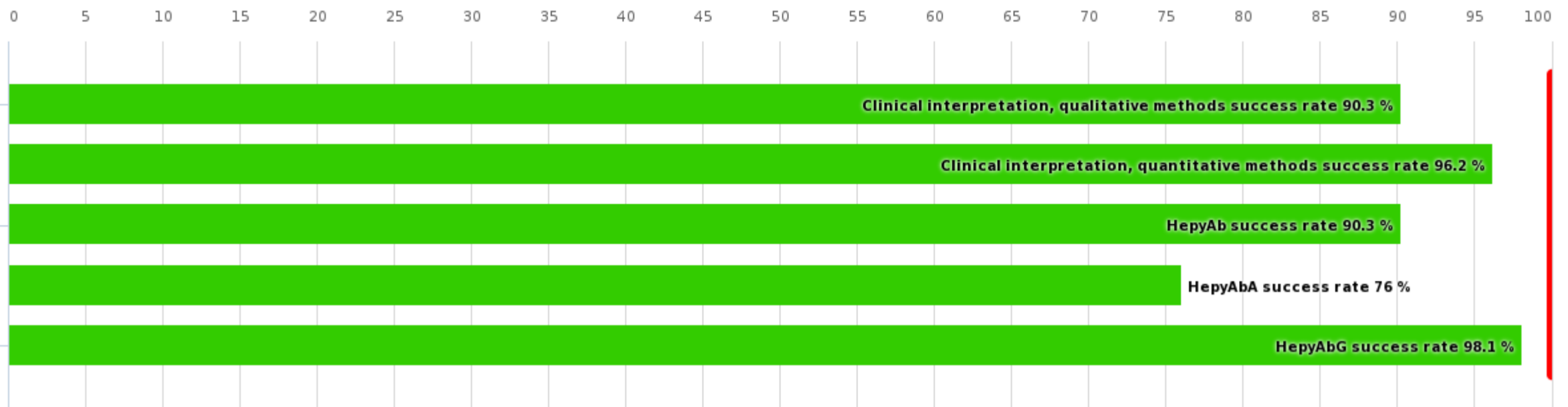
Summary



Summary	AVR success rate
Sample S001	94.3 %
Sample S002	94.3 %
Average:	94.3 %

Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation, qualitative methods	90.3 %	31
	Clinical interpretation, quantitative methods	96.2 %	106
	HepyAb	90.3 %	31
	HepyAbA	76 %	25
	HepyAbG	98.1 %	106
	Total:	94.3 %	299

Sample S001 Clinical interpretation, qualitative methods



No indication of infection
Active or past infection

Sample S001 Clinical interpretation, quantitative methods

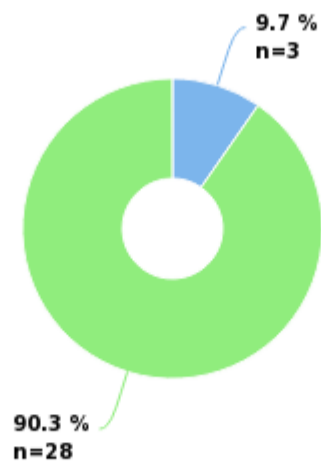


No indication of infection
Active or past infection

Clinical interpretation, qualitative methods	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	No indication of infection	3	0 %	0
	Active or past infection	28	100 %	4
	Total:	31	90.3 %	

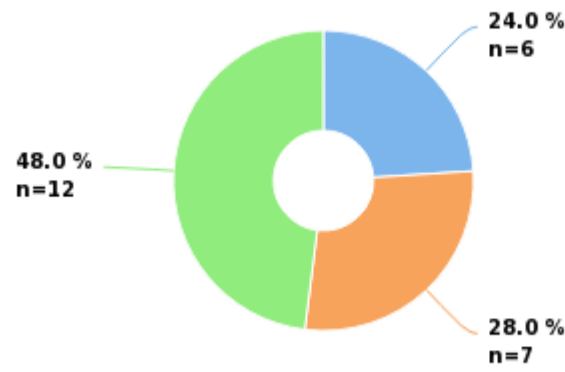
Clinical interpretation, quantitative methods	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	No indication of infection	4	0 %	0
	Active or past infection	102	100 %	4
	Total:	106	96.2 %	

Sample S001 HepyAb



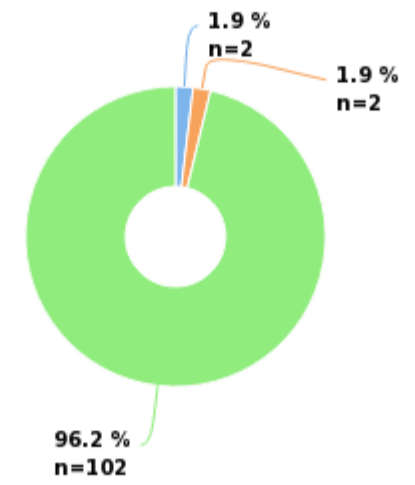
■ Negative ■ Positive

Sample S001 HepyAbA



■ Negative ■ Borderline ■ Positive

Sample S001 HepyAbG



■ Negative ■ Borderline ■ Positive

HepyAb	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
	Negative		3		0 %	0
		Koroglu Medical Laboquick H. pylori Ab		3		
	Positive		28		100 %	2
		ABON H. Pylori Rapid diagnostics kit		1		
		AccuBiotech ACCU-TELL Rapid H. pylori Antibody Test		1		
		Acro Biotech H. pylori Antibody Rapid Test Cassette		3		
		AllDiag Pyloritop Ab+		1		
		DDS Diagnostic H. Pylori antibodies Rapid Test		1		
		Hydrex Diagnostics Helicobacter pylori Ab		3		
		Koroglu Medical Laboquick H. pylori Ab		1		
		Liaison H. pylori Ab (Diasorin)		9		
		Meridian Bioscience Immunocard H. pylori Ab		1		
		Meridian Bioscience Premier H. pylori Ab		3		
		nal von minden NADAL H. pylori Ab Test		1		
		Standard Diagnostics SD Bioline H. pylori Ab		1		
		Türklab H. pylori Ab		1		
		Ultimed Test Anticorps H.pylori Ab		1		
	Total:		31		90.3 %	

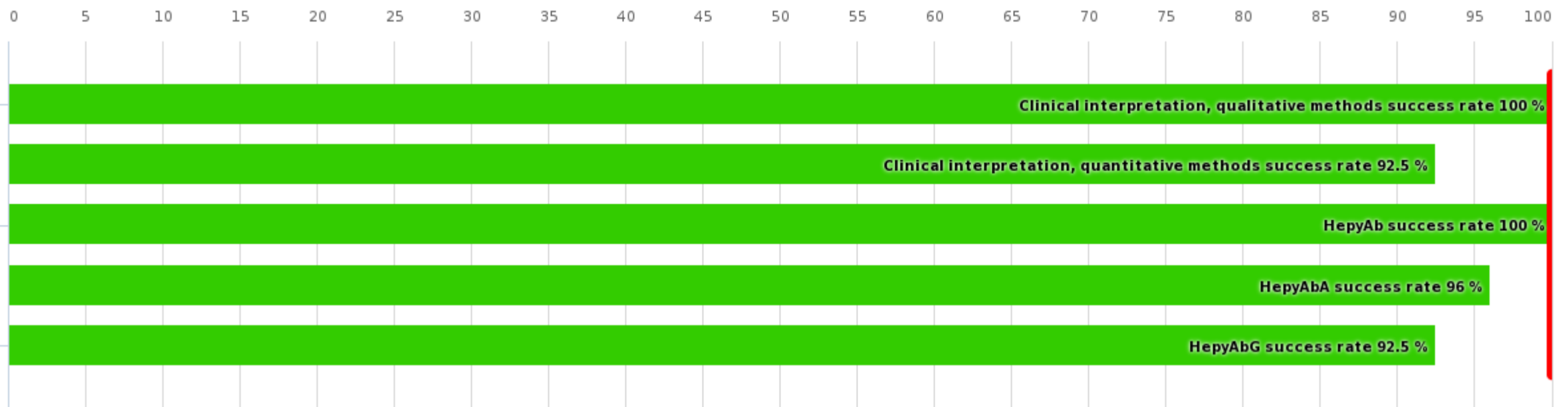
HepyAbA	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
	Negative		6		0 %	0
		DiaPro Diagnostics HP CagA IgA ELISA		1		
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		1		
		MAGLUMI CLIA H.pylori IgA		1		
		NovaTec Immunodiagnostica H. pylori IgA ELISA		2		
		TestLine BLOT-LINE Helicobacter IgA		1		
	Borderline		7		100 %	2
		Diesse Chorus H. pylori IgA ELISA		1		
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		1		
		Euroimmun Helicobacter pylori IgA EIA/ELISA		2		
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgA		1		
		Testline Helicobacter MONO IgA EIA		1		
		Virotech Helicobacter pylori ELISA IgA		1		
	Positive		12		100 %	2
		Euroimmun Helicobacter pylori IgA EIA/ELISA		3		
		Orgentec Alegria Anti-Helicobacter pylori IgA ELISA		6		
		Testline Helicobacter MONO IgA EIA		3		
	Total:		25		76 %	

HepyAbG	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
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Negative		2		0 %	0
	DiaPro Diagnostics HP CagA IgG ELISA		1		
	Virotech Helicobacter pylori ELISA IgG		1		
Borderline		2		100 %	2
	Euroimmun Helicobacter pylori IgG EIA/ELISA		1		
	Siemens Immulite H. pylori IgG		1		
Positive		102		100 %	2
	bioMerieux Vidas H. pylori IgG		27		
	Diasorin Liaison H. pylori IgG		31		
	Diesse Chorus H. pylori IgG ELISA		2		
	Euroimmun Helicobacter pylori IgG EIA/ELISA		10		
	NovaTec Immunodiagnostica H. pylori IgG ELISA		2		
	Orgentec Alegria Anti-Helicobacter pylori IgG ELISA		7		
	SERION classic Helicobacter pylori IgG ELISA		2		
	Siemens Immulite H. pylori IgG		12		
	TestLine BLOT-LINE Helicobacter IgG		1		
	TestLine Clinical Diagnostics CLIA Helicobacter MONO IgG		1		
	Testline Helicobacter MONO IgG EIA		3		
	VirCell Helicobacter pylori VirClia IgG		3		
	ZEUS H. pylori IgG ELISA		1		
Total:		106		98.1 %	

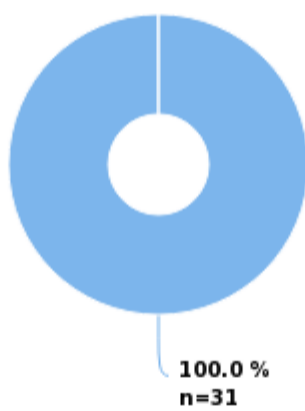
Sample S002

Sample S002 success rate



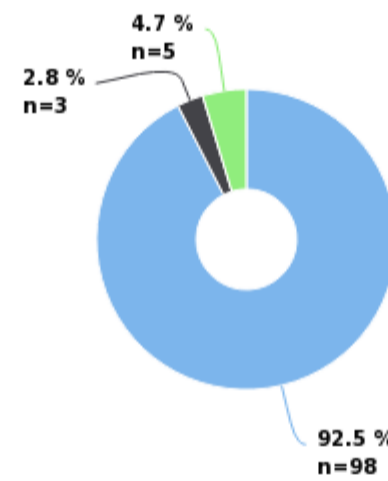
Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation, qualitative methods	100 %	31
	Clinical interpretation, quantitative methods	92.5 %	106
	HepyAb	100 %	31
	HepyAbA	96 %	25
	HepyAbG	92.5 %	106
	Total:	94.3 %	299

Sample S002 Clinical interpretation, qualitative methods



No indication of infection

Sample S002 Clinical interpretation, quantitative methods

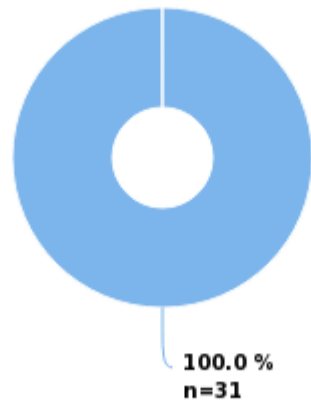


No indication of infection
Borderline interpretation
Active or past infection

Clinical interpretation, qualitative methods	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	No indication of infection	31	100 %	4
	Total:	31	100 %	

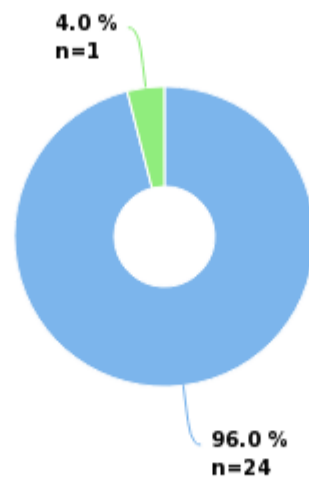
Clinical interpretation, quantitative methods	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	No indication of infection	98	100 %	4
	Borderline interpretation	3	0 %	0
	Active or past infection	5	0 %	0
	Total:	106	92.5 %	

Sample S002 HepyAb



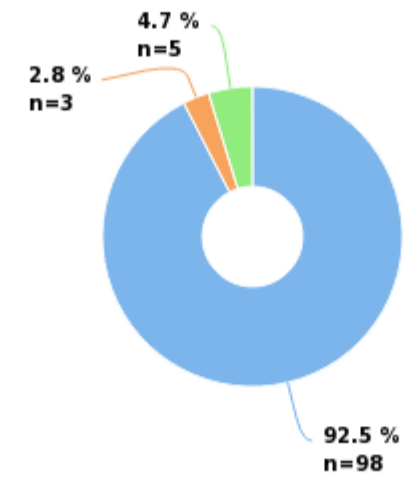
■ Negative

Sample S002 HepyAbA



■ Negative ■ Positive

Sample S002 HepyAbG



■ Negative ■ Borderline ■ Positive

HepyAb	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
	Negative		31		100 %	2
		ABON H. Pylori Rapid diagnostics kit		1		
		Acro Biotech H. pylori Antibody Rapid Test Cassette		4		
		AllDiag Pyloritop Ab+		1		
		DDS Diagnostic H. Pylori antibodies Rapid Test		1		
		Hydrex Diagnostics Helicobacter pylori Ab		3		
		Koroglu Medical Laboquick H. pylori Ab		4		
		Liaison H. pylori Ab (Diasorin)		9		
		Meridian Bioscience Immunocard H. pylori Ab		1		
		Meridian Bioscience Premier H. pylori Ab		3		
		nal von minden NADAL H. pylori Ab Test		1		
		Standard Diagnostics SD Bioline H. pylori Ab		1		
		Türklab H. pylori Ab		1		
		Ultimed Test Anticorps H.pylori Ab		1		
	Total:		31		100 %	

HepyAbA	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
	Negative		24		100 %	2
		DiaPro Diagnostics HP CagA IgA ELISA		1		
		Diesse Chorus H. pylori IgA ELISA		1		
		Euroimmun Anti-Helicobacter pylori CagA IgA ELISA		2		
		Euroimmun Helicobacter pylori IgA EIA/ELISA		5		
		MAGLUMI CLIA H.pylori IgA		1		
		NovaTec Immunodiagnostica H. pylori IgA ELISA		1		
		Orgentec Alegria Anti-Helicobacter pylori IgA ELISA		6		
		TestLine BLOT-LINE Helicobacter IgA		1		
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgA		1		
		Testline Helicobacter MONO IgA EIA		4		
		Virotech Helicobacter pylori ELISA IgA		1		
	Positive		1		0 %	0
		NovaTec Immunodiagnostica H. pylori IgA ELISA		1		
	Total:		25		96 %	

HepyAbG	Interpretation	Test	Interpretation count	Test count	AVR success rate	Interpretation Score
	Negative		98		100 %	2
		bioMerieux Vidas H. pylori IgG		25		
		DiaPro Diagnostics HP CagA IgG ELISA		1		
		Diasorin Liaison H. pylori IgG		31		
		Diesse Chorus H. pylori IgG ELISA		2		
		Euroimmun Helicobacter pylori IgG EIA/ELISA		11		

		Orgentec Alegria Anti-Helicobacter pylori IgG ELISA		7		
		SERION classic Helicobacter pylori IgG ELISA		2		
		Siemens Immulite H. pylori IgG		13		
		TestLine BLOT-LINE Helicobacter IgG		1		
		TestLine Clinical Diagnostics CLIA Helicobacter MONO IgG		1		
		Testline Helicobacter MONO IgG EIA		3		
		ZEUS H. pylori IgG ELISA		1		
	Borderline		3		0 %	0
		bioMerieux Vidas H. pylori IgG		2		
		Vircell Helicobacter pylori VirClia IgG		1		
	Positive		5		0 %	0
		NovaTec Immunodiagnostica H. pylori IgG ELISA		2		
		Vircell Helicobacter pylori VirClia IgG		2		
		Virotech Helicobacter pylori ELISA IgG		1		
	Total:		106		92.5 %	

Report Info**PARTICIPANTS**

Altogether 136 laboratories from 25 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 and clinical interpretations 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
Correct/expected clinical interpretation 4/4 points
False/deviating clinical interpretation 0/4 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, antibodies Round 1, 2023

Specimens

Samples of this EQA round were human plasma or serum, each of which originated from a single separate donor. 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 any temperature control packaging.

The accepted results were as follows:

Sample S001 (LQ757623011)

IgG	positive
IgA	positive
Clinical interpretation	Active or past infection

Sample S002 (LQ757623012)

IgG	negative
IgA	negative
Clinical interpretation	No indication of infection

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 results of the first round of the year were mainly correct.

Most laboratories reported positive results of sample S001, which contained *Helicobacter pylori* antibodies. 28 out of 31 laboratories using a qualitative method correctly reported positive results of the sample. In IgG antibodies, 104 of the 106 participating laboratories reported correct results. Also, in IgA antibodies, a consensus was reached with 19/25 laboratories reporting positive or borderline IgA results. The correct clinical interpretation of sample S001 was “Active or past infection”.

The majority of the participating laboratories obtained negative results of the negative sample S002. There were eight false borderline/positive IgG results, and one false positive IgA results. All laboratories using qualitative methods correctly reported negative results of the sample. Clinical interpretation of sample S002 was “No indication of infection”.

Exceptions in scoring

No exceptions

End of report

2023-04-03

FINAL REPORT

Product no. 5860

Subcontracting: Sample pretesting

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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