LABQUALITY

External Quality Assessment Scheme

Hepatitis B, s-antigen antibodies, quantitative
Round 2, 2023

Specimens
Please find enclosed 2 human plasma or serum samples S001 and S002, each 0.5 mL.

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 HIVAb 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.

Examinations
HBsAb (anti-HBs), quantitative

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 ready for 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.

The positivity limits/cut off values of the tests can be reported in the comments field. Report the test results (quantitative result) and the semi-quantitative results (interpretation). Please report your anti-HBs quantitative results in mIU/mL unit. Note that quantitative results reported “< or > digits” cannot be processed. Semi-quantitative results will be scored.

S001

S002

2023-04-04

INSTRUCTIONS

Product no. 5093
LQ773423021-022/FI

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 **May 2, 2023**.

The expected results of the round are published in LabScala in the View Reports section by May 5, 2023.

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FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023

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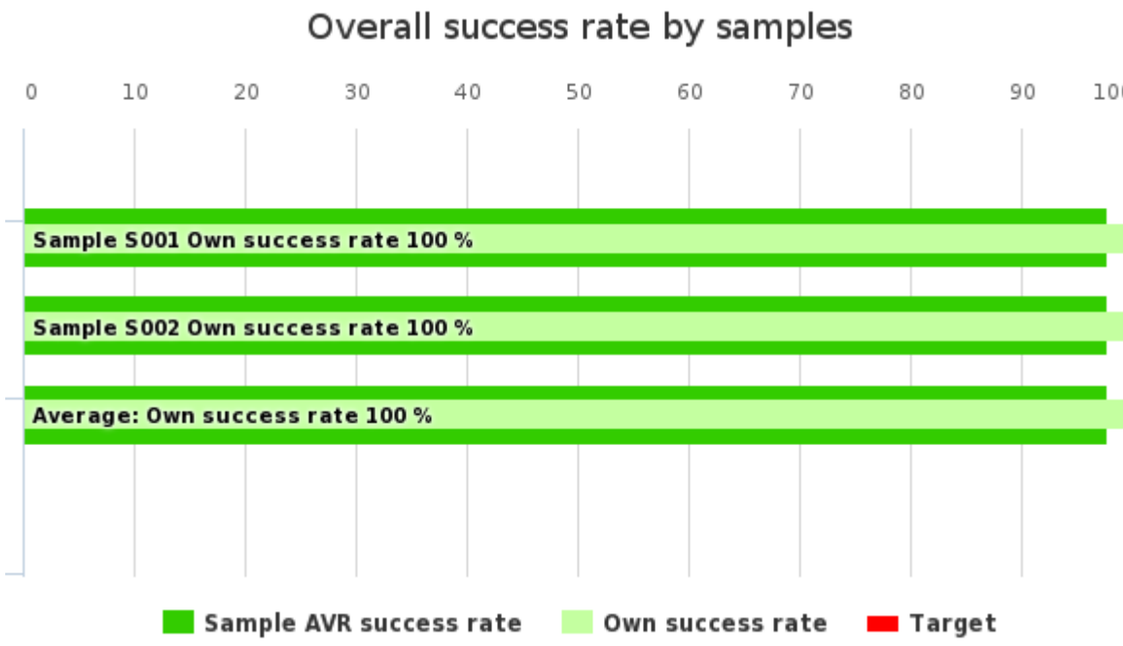
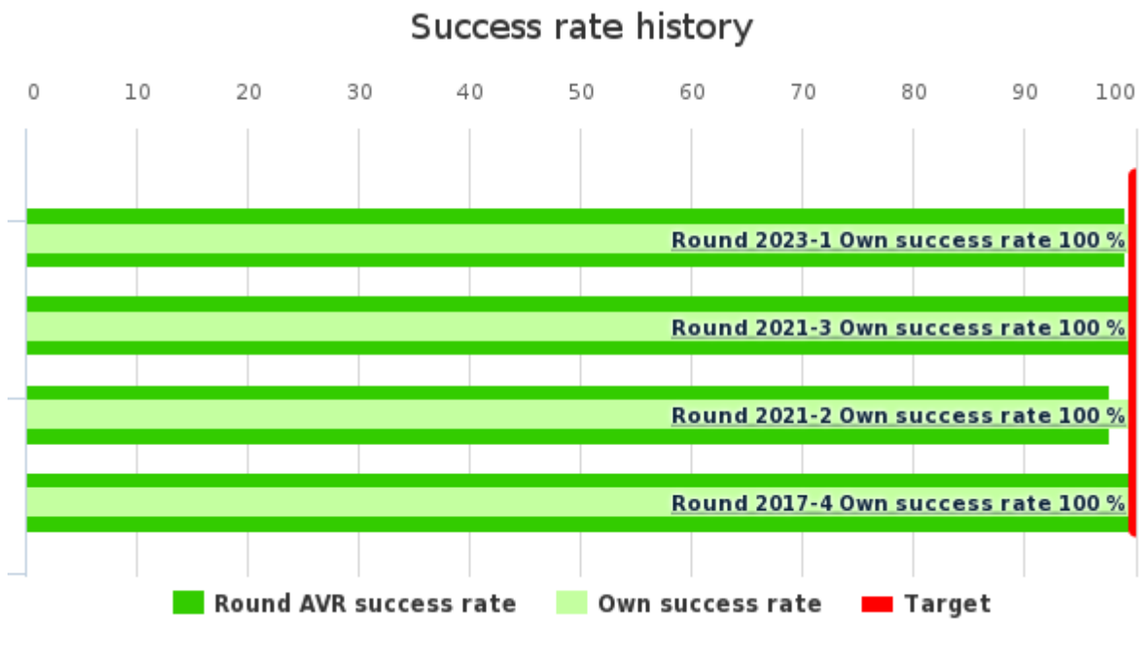
Semi-quantitative scoring report

Client report

	No of participants	No of responded participants	Response percentage
Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023	94	90	95.7 %

Summary

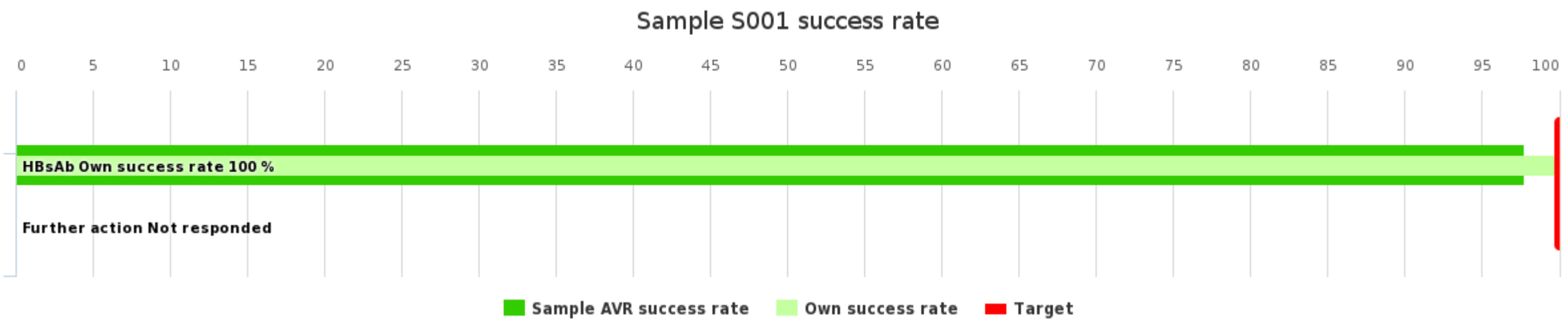




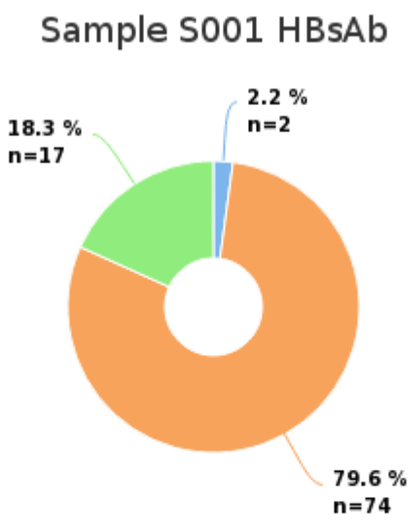
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	2.2 %	97.8 %
Sample S002	2	2	100 %	2.2 %	97.8 %
Average:			100 %	2.2 %	97.8 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2023-1	1-1	100 %	0.9 %	99.1 %
Round 2021-3	1-1	100 %	0 %	100 %
Round 2021-2	1-1	100 %	2.3 %	97.7 %
Round 2017-4	1-1	100 %	0.5 %	99.5 %

Sample S001



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HBsAb	2	2	100 %	2.2 %	97.8 %	93
	Further action	-	-	-	-	-	12
Total:		2	2	100 %	2.2 %	97.8 %	105



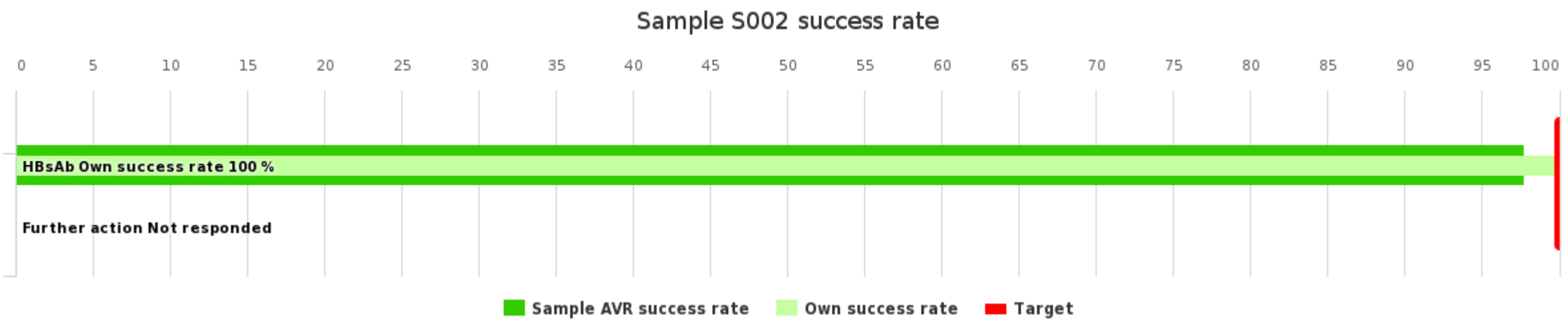
OWN DEVICE: E402

HBsAb	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative, <10 mIU/ml		2		-				0 %
		Roche Elecsys		2					
	◉ Low positive, 10-100 mIU/ml		74		2	2	100 %	0 %	100 %
		Abbott Alinity		20					
		Abbott Architect		6					
		Beckman Coulter Access/Unicel		1					
		bioMerieux Vidas		2					
		Ortho Vitros		2					
		◉ Roche Elecsys		39					
		Siemens Advia Centaur		1					
		Siemens Atellica		3					
	Positive, >100 mIU/ml		17		-				100 %
		Abbott Alinity		2					
		Abbott Architect		4					
		Diasorin Liaison		5					
		Roche Elecsys		3					
		Siemens Atellica		3					
	Total:		93		2	2	100 %	2.2 %	97.8 %

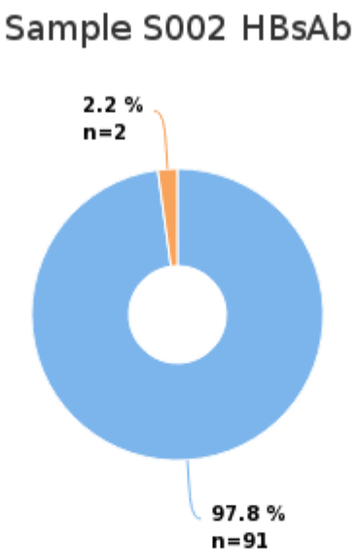
Further action	Response	Response count	Own score	Max score	Own success rate	Difference	AVR success rate
	A second specimen is requested	4	-				-

	Referred to confirmation	3	-				-
	A second specimen is requested and referred to confirmation	5	-				-
	Total:	12	-	-	-	-	

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HBsAb	2	2	100 %	2.2 %	97.8 %	93
	Further action	-	-	-	-	-	11
Total:		2	2	100 %	2.2 %	97.8 %	104



OWN DEVICE: E402

HBsAb	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative, <10 mIU/ml		91		2	2	100 %	0 %	100 %
		Abbott Alinity		21					
		Abbott Architect		11					
		Beckman Coulter Access/Unicel		1					
		bioMerieux Vidas		2					
		Diasorin Liaison		5					
		Ortho Vitros		2					
		◉ Roche Elecsys		42					
		Siemens Advia Centaur		1					
		Siemens Atellica		6					
	Low positive, 10-100 mIU/ml		2		-				0 %
		Roche Elecsys		2					
	Total:		93		2	2	100 %	2.2 %	97.8 %

Further action	Response	Response count	Own score	Max score	Own success rate	Difference	AVR success rate
	A second specimen is requested	9	-				-
	Referred to confirmation	1	-				-
	A second specimen is requested and referred to confirmation	1	-				-
	Total:	11	-	-	-	-	

Report Info

PARTICIPANTS

Altogether 94 laboratories from 15 countries participated in this EQA round.

REPORT INFO

The semi-quantitative results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. The categories are presented as follows: negative (<10 mIU/mL), low positive (10-100 mIU/mL) and positive (>100 mIU/mL). 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 semi-quantitative results when 60% or more of the participants report the expected result.
The following general rules are applied:

Correct/expected result 2/2 points
Correct positive/negative result, but deviating category 1/2 points
Deviating positive/negative 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.

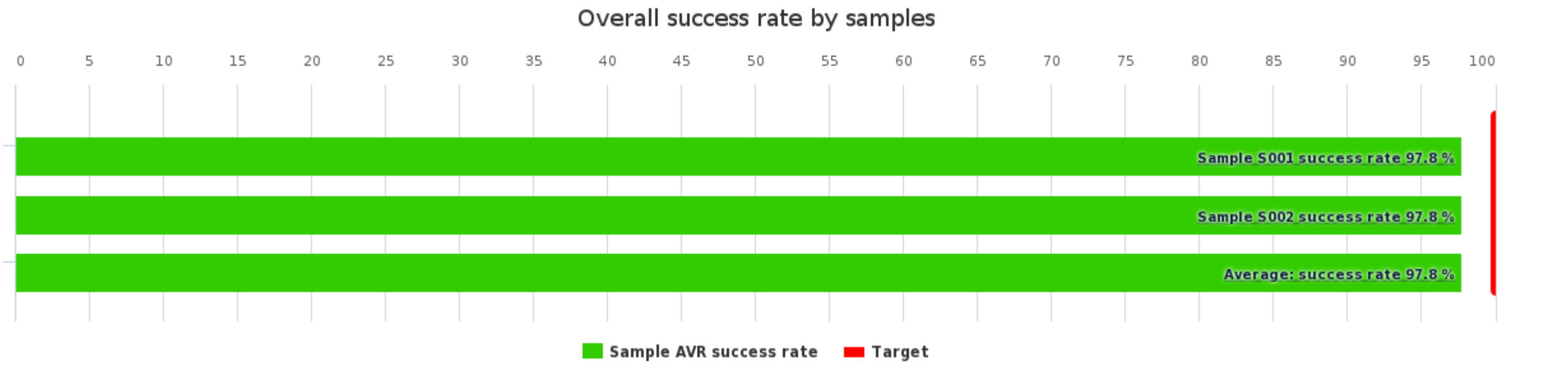
Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023

Semi-quantitative scoring report

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023	94	90	95.7 %

Summary

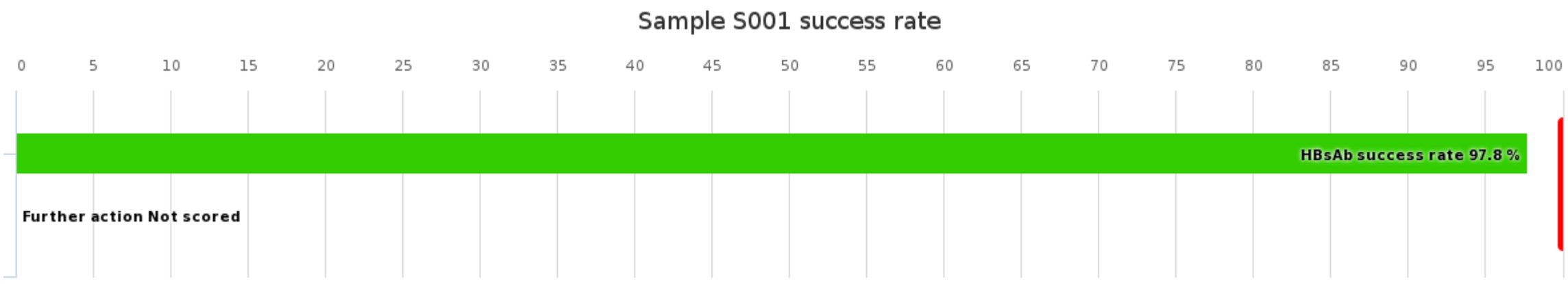


Summary	AVR success rate
Sample S001	97.8 %
Sample S002	97.8 %
Average:	97.8 %

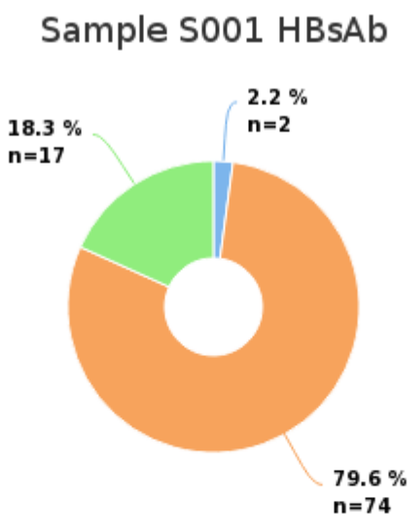
Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023

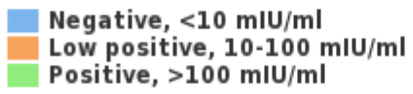
Semi-quantitative scoring report

Sample S001



Sample S001 results	Responded	AVR success rate	Count
	HBsAb	97.8 %	93
	Further action	-	12
Total:		97.8 %	105





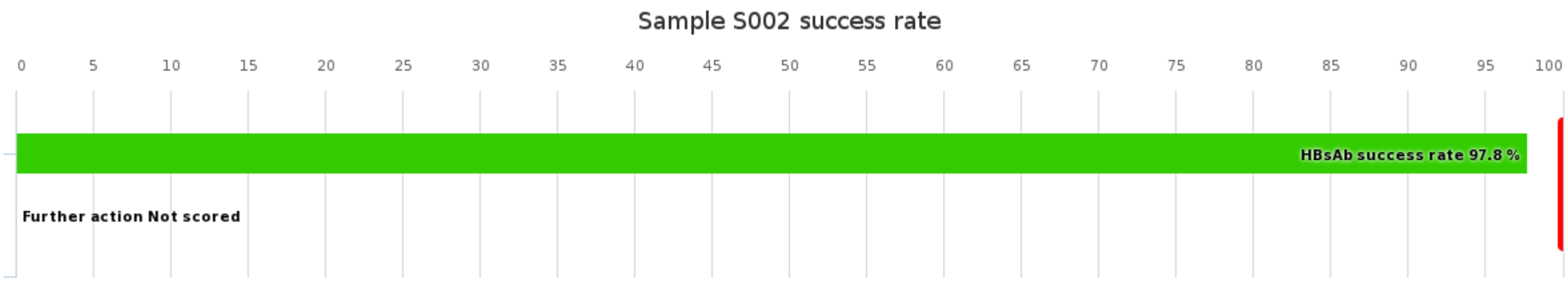
HBsAb	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative, <10 mIU/ml		2		0 %	0
		Roche Elecsys		2		
	Low positive, 10-100 mIU/ml		74		100 %	2
		Abbott Alinity		20		
		Abbott Architect		6		
		Beckman Coulter Access/Unicel		1		
		bioMerieux Vidas		2		
		Ortho Vitros		2		
		Roche Elecsys		39		
		Siemens Advia Centaur		1		
		Siemens Atellica		3		
	Positive, >100 mIU/ml		17		100 %	2
		Abbott Alinity		2		
		Abbott Architect		4		
		Diasorin Liaison		5		
		Roche Elecsys		3		
		Siemens Atellica		3		
	Total:		93		97.8 %	

Further action	Response	Response count	AVR success rate	Response Score
	A second specimen is requested	4	-	-
	Referred to confirmation	3	-	-
	A second specimen is requested and referred to confirmation	5	-	-
	Total:	12		

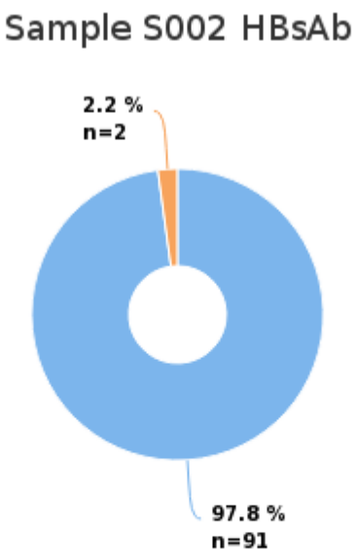
Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023

Semi-quantitative scoring report

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	HBsAb	97.8 %	93
	Further action	-	11
Total:		97.8 %	104



HBsAb	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative, <10 mIU/ml		91		100 %	2
		Abbott Alinity		21		
		Abbott Architect		11		
		Beckman Coulter Access/Unicel		1		
		bioMerieux Vidas		2		
		Diasorin Liaison		5		
		Ortho Vitros		2		
		Roche Elecsys		42		
		Siemens Advia Centaur		1		
		Siemens Atellica		6		
	Low positive, 10-100 mIU/ml		2		0 %	0
		Roche Elecsys		2		
	Total:		93		97.8 %	

Further action	Response	Response count	AVR success rate	Response Score
	A second specimen is requested	9	-	-
	Referred to confirmation	1	-	-
	A second specimen is requested and referred to confirmation	1	-	-
	Total:	11		

Hepatitis B, s-antigen antibodies, quantitative, April, 2-2023

Semi-quantitative scoring report

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LABQUALITY

External Quality Assessment Scheme

Hepatitis B, s-antigen antibodies, quantitative
Round 2, 2023

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

The expected results were as follows:

Sample S001 (LQ773423021)
HBsAb: Low Positive or Positive
Quantitative result according to the pre-testing ~27-97 mIU/mL

Sample S002 (LQ773423022)
HBsAb: Negative
Quantitative result according to the pre-testing <10 mIU/mL

Pre-test methods: Abbott Architect or Abbott Alinity and bioMérieux Vidas or Diasorin Liaison.

Report info
Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. The quantitative results from the HBsAb positive samples are presented as histograms as well as a numerical summary table. The quantitative results reported with < or > signs, or, if the antibody level of the sample is >1000 mIU/mL, are not processed. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – EQA Coordinator
According to the pretesting, sample S001 was expected to be low positive for HBsAb (10-100 mIU/mL), whereas S002 was expected to be HBsAb negative (<10 mIU/mL). For S001, as expected, the results were distributed into both categories (10-100 mIU/mL and >100 mIU/mL) as the antibody level was rather close to 100 mIU/mL with most of the test methods in use. Most of the reported results were below 100 mIU/ml. For S002, a clear consensus of negative anti HBs status (<10 mIU/mL) was achieved. Two false positive results were reported, which were probably due to a sample mix-up.

When quantitative results are compared, each laboratory should compare their test results only to the mean of their own method group as antibody level variation between the different test methods is observed.

Exceptions in scoring
No exceptions.

End of report

2023-05-05

FINAL REPORT

Product no. 5093

Subcontracting: Sample pretesting

Samples sent	2023-04-04
Round closed	2023-05-02
Expected results	2023-05-04
Final report	2023-05-05

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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