

External Quality Assessment Scheme

HIV, antibodies and antigen detection, POCT Round 1, 2023

Specimens

Please find enclosed 3 human plasma or serum samples S001, S002 and S003, 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 may contain infectious viruses. The specimens have not been inactivated.

Examinations

HIVAb, POCT

HIVAgAb (combo), POCT

Note! This scheme is only for the point of care tests. Laboratories performing both primary and confirmatory tests should order scheme 5091 HIV, antibodies and antigen detection.

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 test from the registry, please contact the EQA Coordinator. All reported examinations will be scored.

S001



S002



S003



2023-02-07

INSTRUCTIONS

Product no. 5090
LQ775923011-013/FI
UN3373

Subcontracting: Sample
preparation, 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 2, 2023.

The expected results of the round
are published in LabScala
in the View Reports section by
March 7, 2023.

Inquiries

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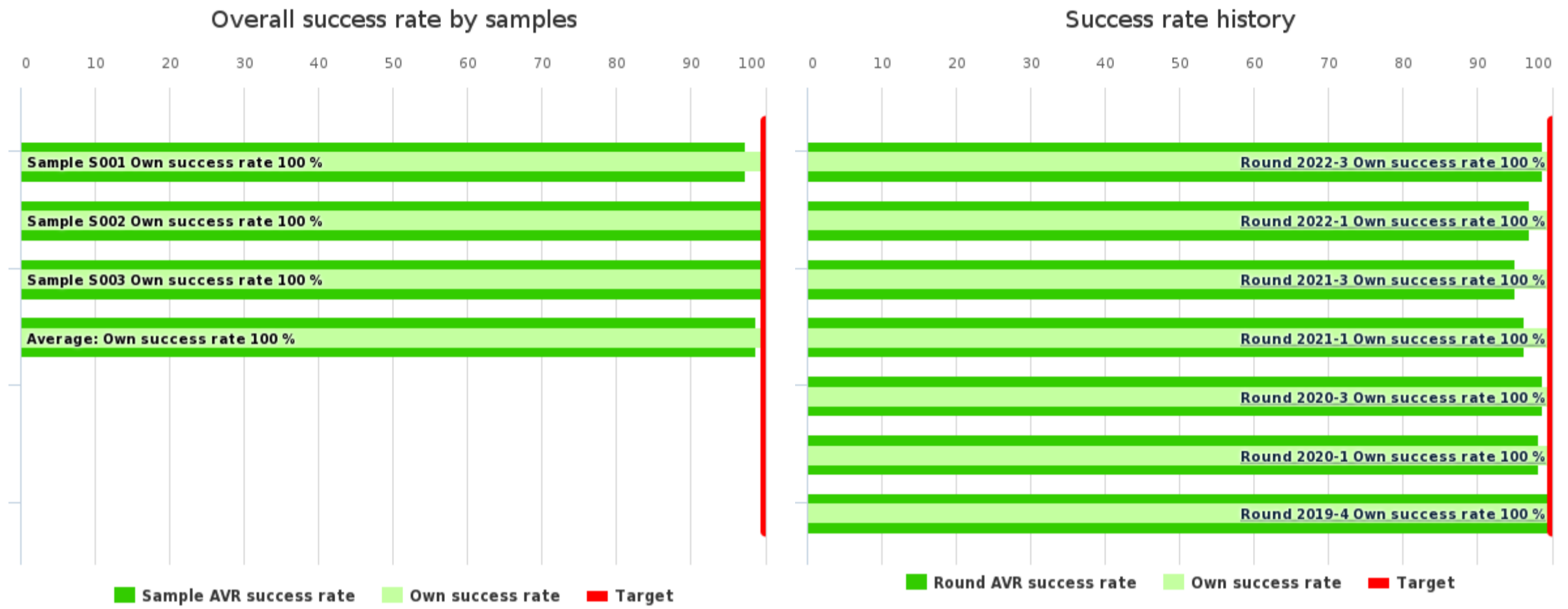
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
HIV, antibodies and antigen detection, POCT, February, 1-2023	80	73	91.3 %

Summary

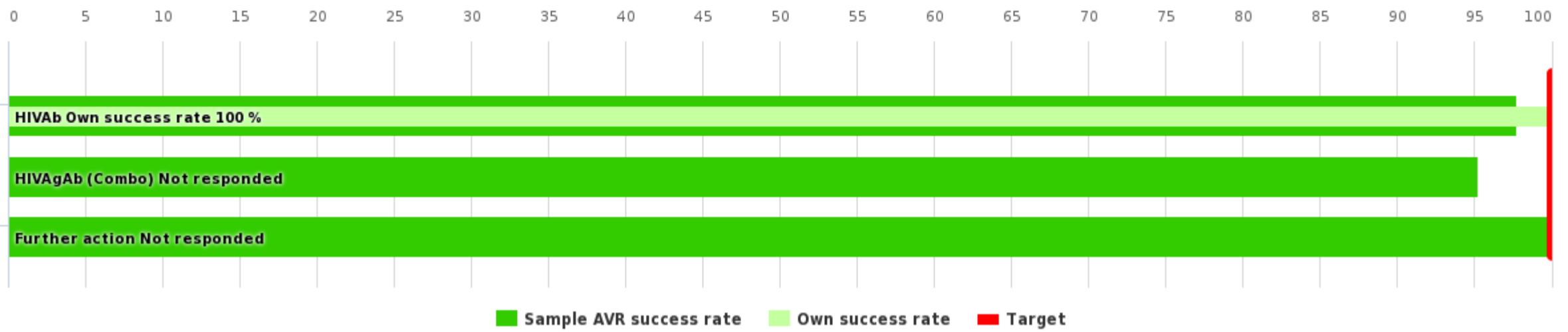


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	2.6 %	97.4 %
Sample S002	2	2	100 %	0.6 %	99.4 %
Sample S003	2	2	100 %	0.5 %	99.5 %
Average:			100 %	1.2 %	98.8 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-3	1-1	100 %	1.2 %	98.8 %
Round 2022-1	1-1	100 %	2.9 %	97.1 %
Round 2021-3	1-1	100 %	4.9 %	95.1 %
Round 2021-1	1-1	100 %	3.7 %	96.3 %
Round 2020-3	1-1	100 %	1.3 %	98.7 %
Round 2020-1	1-1	100 %	1.8 %	98.2 %
Round 2019-4	1-1	100 %	0.5 %	99.5 %

Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HIVAb	2	2	100 %	2.2 %	97.8 %	45
	HIVAgAb (Combo)	-	-	-	-	95.3 %	32
	Further action	-	-	-	-	100 %	41
	Total:	2	2	100 %	2.6 %	97.4 %	118

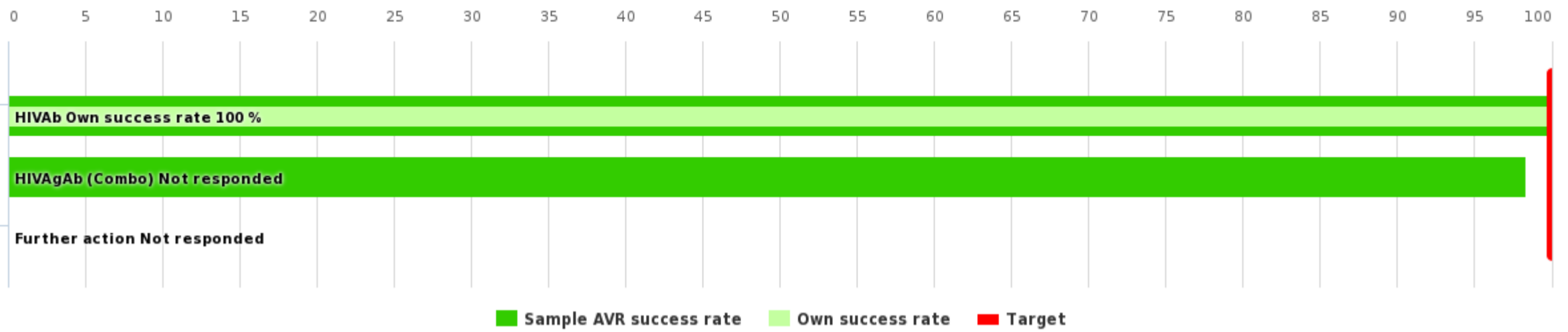
HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		44		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Determine HIV-1/2		21					
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1					
		Bio-Rad Genie Fast HIV 1/2		1					
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13					
		Biosynex Exacto Pro HIV		1					
		Hangzhou Biotest HIV 1/2 Rapid Test		1					
		Türklab Anti-HIV 1/2 Rapid Test		5					
	Test does not give a clear result		1		-				0 %
		Bio-Rad Genie Fast HIV 1/2		1					
	Total:		45		2	2	100 %	2.2 %	97.8 %

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIVAb Positive, HIVAg Negative		30		-				100 %
		Abbott Determine HIV Early Detect		22					
		Abbott Determine HIV Ultra		1					
		Abbott Determine HIV-1/2 Ag/Ab Combo		7					
	HIVAb Positive, HIVAg Positive		1		-				50 %
		Abbott Determine HIV-1/2 Ag/Ab Combo		1					
	HIVAb Negative, HIVAg Positive		1		-				0 %
		Abbott Determine HIV-1/2 Ag/Ab Combo		1					
	Total:		32		-	-	-	-	95.3 %

Further action	Further action	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	New sample requested	19	-				100 %
	Would be referred to another laboratory for further examination	22	-				100 %
	Total:	41	-	-	-	-	100 %

Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HIVAb	2	2	100 %	0 %	100 %	45
	HIVAgAb (Combo)	-	-	-	-	98.4 %	32
	Further action	-	-	-	-	-	10
	Total:	2	2	100 %	0.6 %	99.4 %	87

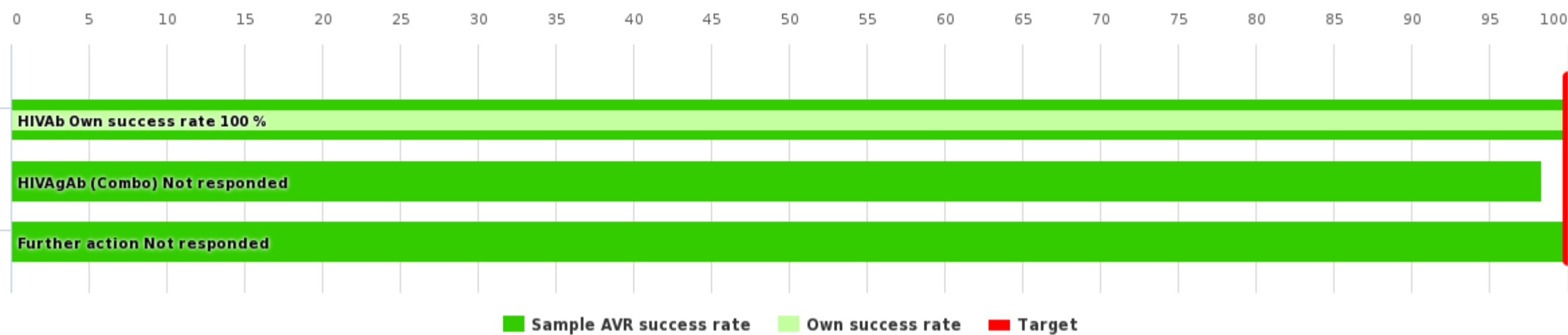
HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		45		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Determine HIV-1/2		21					
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1					
		Bio-Rad Genie Fast HIV 1/2		2					
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13					
		Biosynex Exacto Pro HIV		1					
		Hangzhou Biotest HIV 1/2 Rapid Test		1					
		Türklab Anti-HIV 1/2 Rapid Test		5					
	Total:		45		2	2	100 %	0 %	100 %

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIVAb Negative, HIVAg Negative		31		-				100 %
		Abbott Determine HIV Early Detect		22					
		Abbott Determine HIV Ultra		1					
		Abbott Determine HIV-1/2 Ag/Ab Combo		8					
	HIVAb Negative, HIVAg Positive		1		-				50 %
		Abbott Determine HIV-1/2 Ag/Ab Combo		1					
	Total:		32		-	-	-	-	98.4 %

Further action	Further action	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	New sample requested	4	-				-
	Would be referred to another laboratory for further examination	6	-				-
	Total:	10	-	-	-	-	

Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	HIVAb	2	2	100 %	0 %	100 %	44
	HIVAgAb (Combo)	-	-	-	-	98.4 %	32
	Further action	-	-	-	-	100 %	39
	Total:	2	2	100 %	0.5 %	99.5 %	115

HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		44		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Determine HIV-1/2		20					
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1					
		Bio-Rad Genie Fast HIV 1/2		2					
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13					
		Biosynex Exacto Pro HIV		1					
		Hangzhou Biotest HIV 1/2 Rapid Test		1					
		Türklab Anti-HIV 1/2 Rapid Test		5					
	Total:		44		2	2	100 %	0 %	100 %

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIVAb Positive, HIVAg Negative		30		-				100 %
		Abbott Determine HIV Early Detect		21					
		Abbott Determine HIV Ultra		2					
		Abbott Determine HIV-1/2 Ag/Ab Combo		7					
	HIVAb Positive, HIVAg Positive		1		-				100 %
		Abbott Determine HIV-1/2 Ag/Ab Combo		1					
	HIVAb Negative, HIVAg Positive		1		-				50 %
		Abbott Determine HIV-1/2 Ag/Ab Combo		1					
	Total:		32		-	-	-	-	98.4 %

Further action	Further action	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	New sample requested	19	-				100 %
	Would be referred to another laboratory for further examination	20	-				100 %
	Total:	39	-	-	-	-	100 %

Report Info**PARTICIPANTS**

Altogether 80 laboratories from 6 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

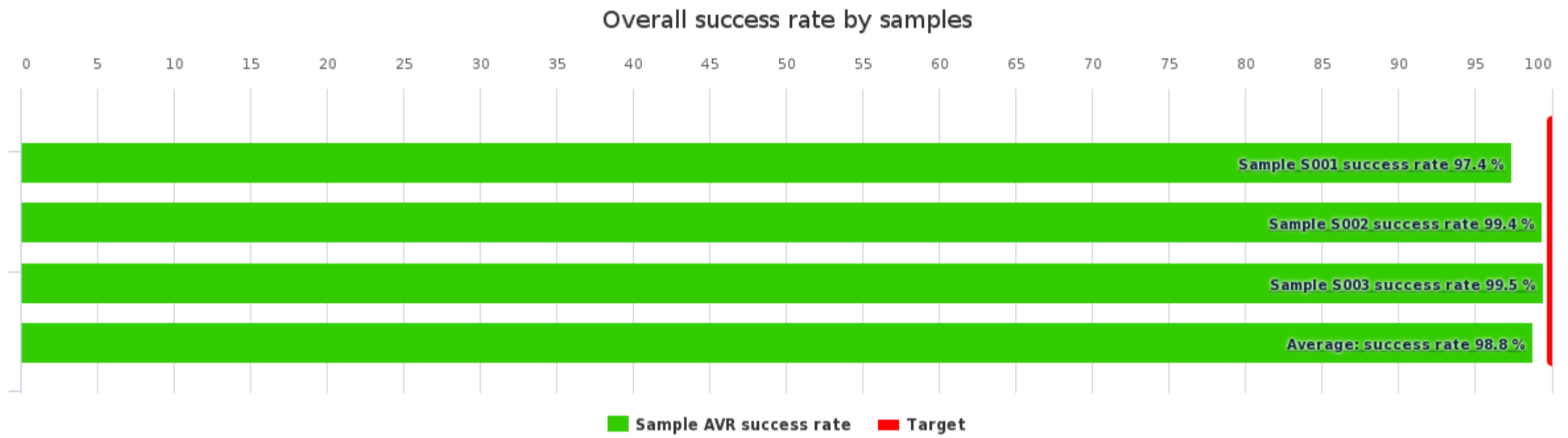
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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
HIV, antibodies and antigen detection, POCT, February, 1-2023	80	73	91.3 %

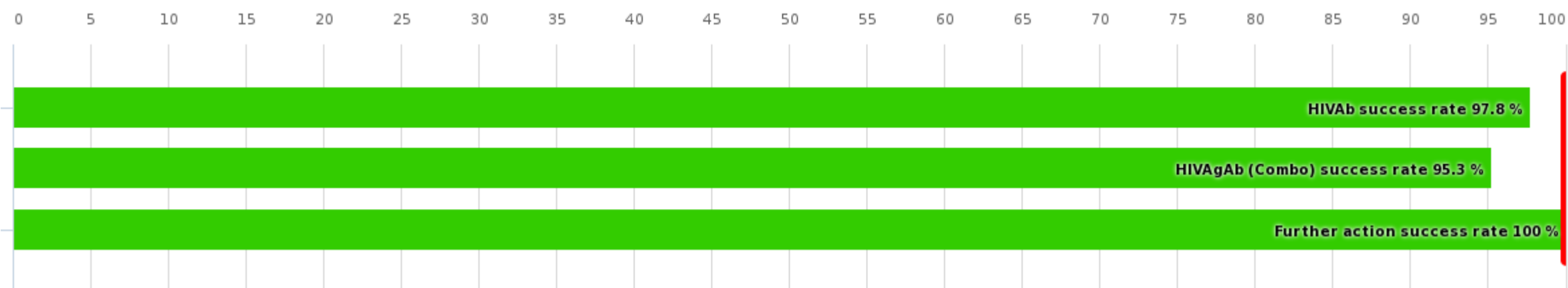
Summary



Summary	AVR success rate
Sample S001	97.4 %
Sample S002	99.4 %
Sample S003	99.5 %
Average:	98.8 %

Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	HIVAb	97.8 %	45
	HIVAgAb (Combo)	95.3 %	32
	Further action	100 %	41
	Total:	97.4 %	118

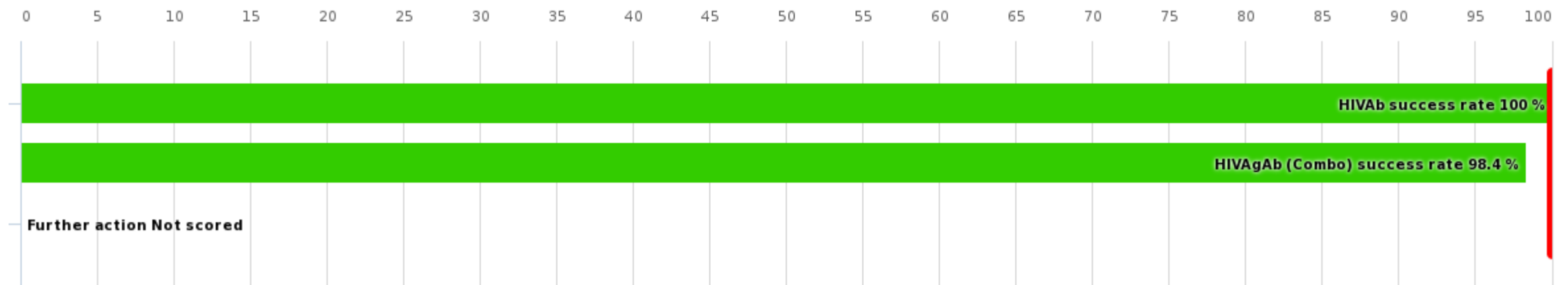
HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	Positive		44		100 %	2
		Abbott Determine HIV-1/2		21		
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1		
		Bio-Rad Genie Fast HIV 1/2		1		
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13		
		Biosynex Exacto Pro HIV		1		
		Hangzhou Biotest HIV 1/2 Rapid Test		1		
		Türklab Anti-HIV 1/2 Rapid Test		5		
	Test does not give a clear result		1		0 %	0
		Bio-Rad Genie Fast HIV 1/2		1		
	Total:		45		97.8 %	

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	HIVAb Positive, HIVAg Negative		30		100 %	2
		Abbott Determine HIV Early Detect		22		
		Abbott Determine HIV Ultra		1		
		Abbott Determine HIV-1/2 Ag/Ab Combo		7		
	HIVAb Positive, HIVAg Positive		1		50 %	1
		Abbott Determine HIV-1/2 Ag/Ab Combo		1		
	HIVAb Negative, HIVAg Positive		1		0 %	0
		Abbott Determine HIV-1/2 Ag/Ab Combo		1		
	Total:		32		95.3 %	

Further action	Further action	Further action count	AVR success rate	Further action Score
	New sample requested	19	100 %	1
	Would be referred to another laboratory for further examination	22	100 %	1
	Total:	41	100 %	

Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	HIVAb	100 %	45
	HIVAgAb (Combo)	98.4 %	32
	Further action	-	10
	Total:	99.4 %	87

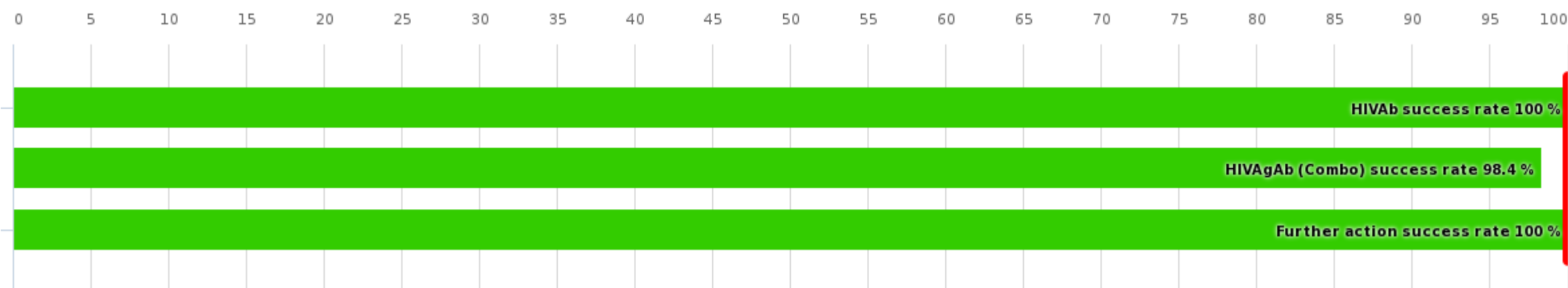
HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	Negative		45		100 %	2
		Abbott Determine HIV-1/2		21		
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1		
		Bio-Rad Genie Fast HIV 1/2		2		
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13		
		Biosynex Exacto Pro HIV		1		
		Hangzhou Biotest HIV 1/2 Rapid Test		1		
		Türklab Anti-HIV 1/2 Rapid Test		5		
	Total:		45		100 %	

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	HIVAb Negative, HIVAg Negative		31		100 %	2
		Abbott Determine HIV Early Detect		22		
		Abbott Determine HIV Ultra		1		
		Abbott Determine HIV-1/2 Ag/Ab Combo		8		
	HIVAb Negative, HIVAg Positive		1		50 %	1
		Abbott Determine HIV-1/2 Ag/Ab Combo		1		
	Total:		32		98.4 %	

Further action	Further action	Further action count	AVR success rate	Further action Score
	New sample requested	4	-	-
	Would be referred to another laboratory for further examination	6	-	-
	Total:	10		

Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	HIVAb	100 %	44
	HIVAgAb (Combo)	98.4 %	32
	Further action	100 %	39
	Total:	99.5 %	115

HIVAb	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	Positive		44		100 %	2
		Abbott Determine HIV-1/2		20		
		Artron One Step Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Bio-Rad Geenius HIV 1/2 Confirmatory Assay		1		
		Bio-Rad Genie Fast HIV 1/2		2		
		bioLytical Laboratories INSTI HIV-1/HIV-2 Antibody Test		13		
		Biosynex Exacto Pro HIV		1		
		Hangzhou Biotest HIV 1/2 Rapid Test		1		
		Türklab Anti-HIV 1/2 Rapid Test		5		
	Total:		44		100 %	

HIVAgAb (Combo)	Interpretation	Cassette/strip	Interpretation count	Cassette/strip count	AVR success rate	Interpretation Score
	HIVAb Positive, HIVAg Negative		30		100 %	2
		Abbott Determine HIV Early Detect		21		
		Abbott Determine HIV Ultra		2		
		Abbott Determine HIV-1/2 Ag/Ab Combo		7		
	HIVAb Positive, HIVAg Positive		1		100 %	2
		Abbott Determine HIV-1/2 Ag/Ab Combo		1		
	HIVAb Negative, HIVAg Positive		1		50 %	1
		Abbott Determine HIV-1/2 Ag/Ab Combo		1		
	Total:		32		98.4 %	

Further action	Further action	Further action count	AVR success rate	Further action Score
	New sample requested	19	100 %	1
	Would be referred to another laboratory for further examination	20	100 %	1
	Total:	39	100 %	

Report Info

PARTICIPANTS

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REPORT INFO

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False/deviating test result 0/2 points

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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

HIV, antibodies and antigen detection, POCT Round 1, 2023

Specimens

Samples of this EQA round were undiluted 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 (LQ775923011)

HIVAb Positive, HIV-2
HIVAgAb (combo) HIVAb Positive, HIVAg Negative

Sample S002 (LQ775923012)

HIVAb Negative
HIVAgAb (combo) HIVAb Negative, HIVAg Negative

Sample S003 (LQ775923013)

HIVAb Positive, HIV-1
HIVAgAb (combo) HIVAb Positive, HIVAg Negative/Positive

Pre-test methods: Abbott Determine HIV-1/2, Biolytical laboratories INSTI HIV-1 / HIV-2, DiaSorin Murex HIV Ag/Ab Combination, Fujirebio INNOTEST HIV Antigen mAb, Fujirebio INNOTEST HIV Antigen mAb Neutralization Reagents, Bio-Rad New LAV Blot I, Bio-Rad New LAV Blot II.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global report. 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

Participants performed well in this EQA round. Samples S001 and S003 were HIV antibody positive and sample S002 was negative. In pretesting, the sample S003 was also HIV antigen positive, but the antigen level was so low that it was not expected to be detected by antigen tests.

The results were mostly reported correctly/as expected. One "Test does not give a clear result" with HIVAb test was reported from the sample S001. With the HIVAgAb (combo) tests, one false positive HIV antigen result was reported, as well as one deviating "HIVAb Negative, HIVAg Positive" interpretation.

One deviating positive HIV antigen test result with the HIVAgAb (combo) test was reported from the negative sample S002. All reported HIV antibody results were correct.

Both negative and positive antigen results were accepted from sample S003. However, one false negative antibody result with the HIVAgAb (combo) test was also reported. The same participant had reported both antibody positive samples S001 and S003 as "HIVAb Negative, HIVAg Positive", so it is possible that there have been challenges in either interpreting the test strip or entering the results.

2023-03-08

FINAL REPORT

Product no. 5090

Subcontracting: Sample preparation, sample pretesting

Samples sent	2023-02-07
Round closed	2023-03-02
Expected results	2023-03-03
Final report	2023-03-08

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
Marsa Järvenpää
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Expert

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Note! Laboratories and point-of-care testing sites performing HIV POC tests should send a separately drawn venous blood sample from all HIVAb/HIVAg reactive or unclear patient samples to a reference laboratory for confirmation before giving final test results.

Exceptions in scoring

The deviating results of HIVAgAb (combo) tests were scored 1/2 points if one of the reported results was correct/as expected in the combination test. Both negative and positive antigen test results were accepted in the sample S003.

End of report

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