

External Quality Assessment Scheme

Human T-cell lymphotropic virus, antibodies 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

HTLVAb, screening tests
HTLVAb, confirmatory tests
Clinical interpretation

Note! The result form in LabScala has been updated. We have simplified the reporting of results by separating the screening and confirmatory tests into their own sections. In the confirmatory test section, there will be only one analyte *HTLVAb confirmatory test*, to which the result of the virus type is reported. Please contact the EQA Coordinator if you have any problems entering the results.

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. All reported examinations will be scored.

S001



S002



S003



2023-02-14

INSTRUCTIONS

Product no. 5089
LQ773723011-013/FI
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 9, 2023.

The expected results of the round are published in LabScala in the View Reports section by March 14, 2023.

Inquiries

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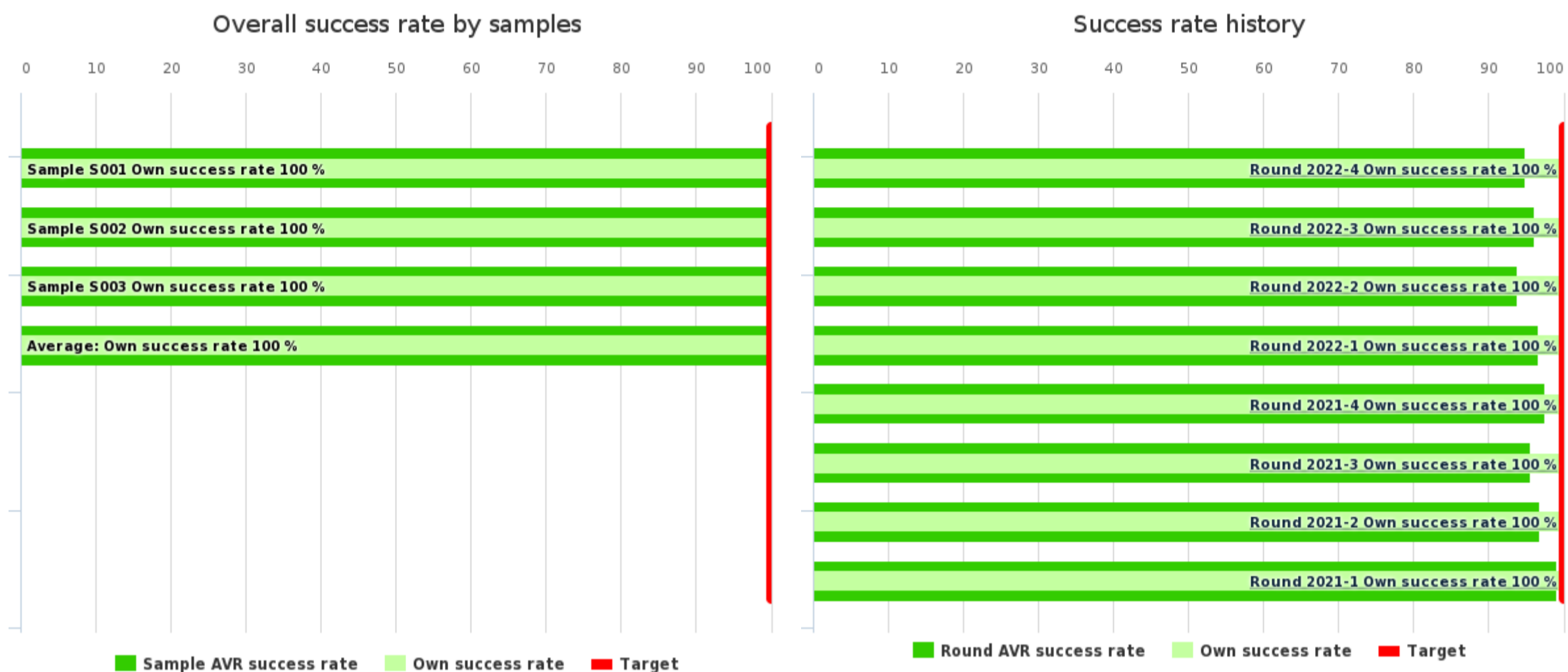
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Human T-cell lymphotropic virus, antibodies, February, 1-2023	37	37	100 %

Summary

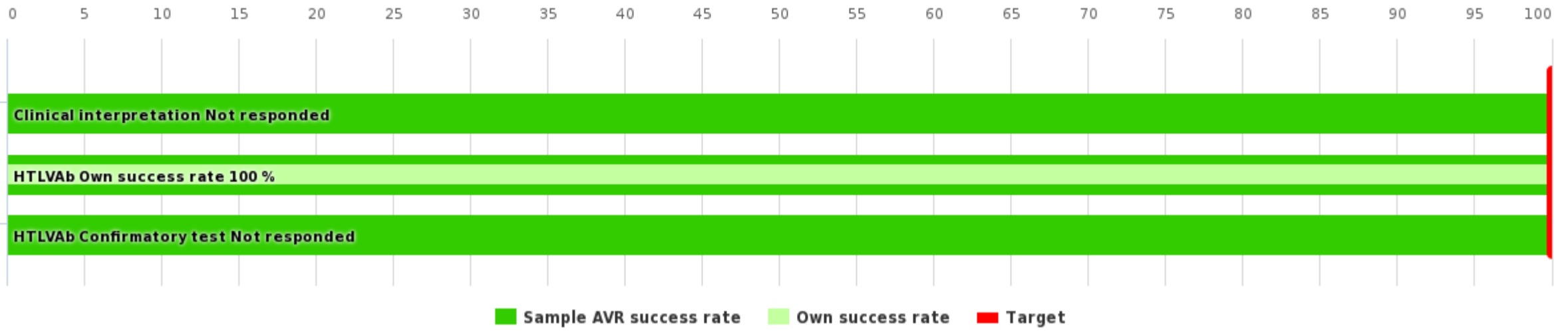


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	6	6	100 %	0 %	100 %
Sample S003	2	2	100 %	0 %	100 %
Average:			100 %	0 %	100 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	5.1 %	94.9 %
Round 2022-3	1-1	100 %	3.9 %	96.1 %
Round 2022-2	1-1	100 %	6.2 %	93.8 %
Round 2022-1	1-1	100 %	3.4 %	96.6 %
Round 2021-4	1-1	100 %	2.5 %	97.5 %
Round 2021-3	1-1	100 %	4.4 %	95.6 %
Round 2021-2	1-1	100 %	3.2 %	96.8 %
Round 2021-1	1-1	100 %	0.8 %	99.2 %

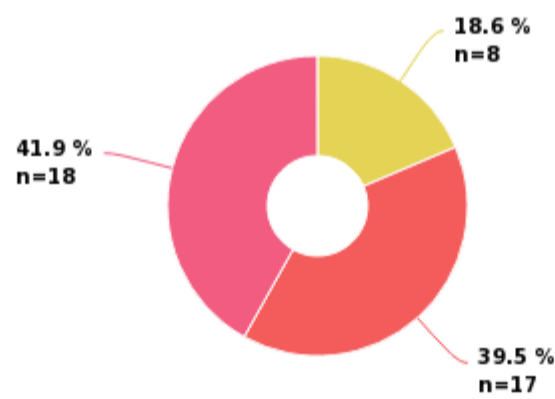
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	100 %	43
	HTLVAb	2	2	100 %	0 %	100 %	42
	HTLVAb Confirmatory test	-	-	-	-	100 %	9
	Total:	2	2	100 %	0 %	100 %	94

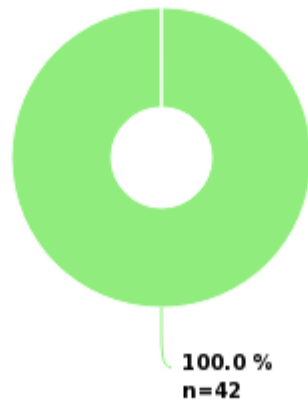
Sample S001 Clinical interpretation



■ HTLV-2 positive, confirmed
 ■ HTLV screening test positive
 ■ Laboratory does not give clinical interpretation

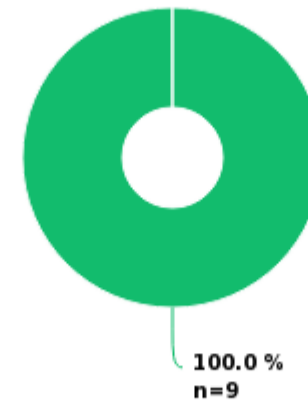
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	HTLV-2 positive, confirmed		8		-				100 %
	HTLV screening test positive		17		-				100 %
		New sample requested		4	-	-			
		Would be referred to another laboratory for further examination		11	-	-			
	<input checked="" type="radio"/> Laboratory does not give clinical interpretation		18		-				-
		<input checked="" type="radio"/> Would be referred to another laboratory for further examination		11	-	-			
		<input checked="" type="radio"/> New sample requested		3	-	-			
	Total:		43		-	-	-	-	100 %

Sample S001 HTLVAb



Positive

Sample S001 HTLVAb Confirmatory test



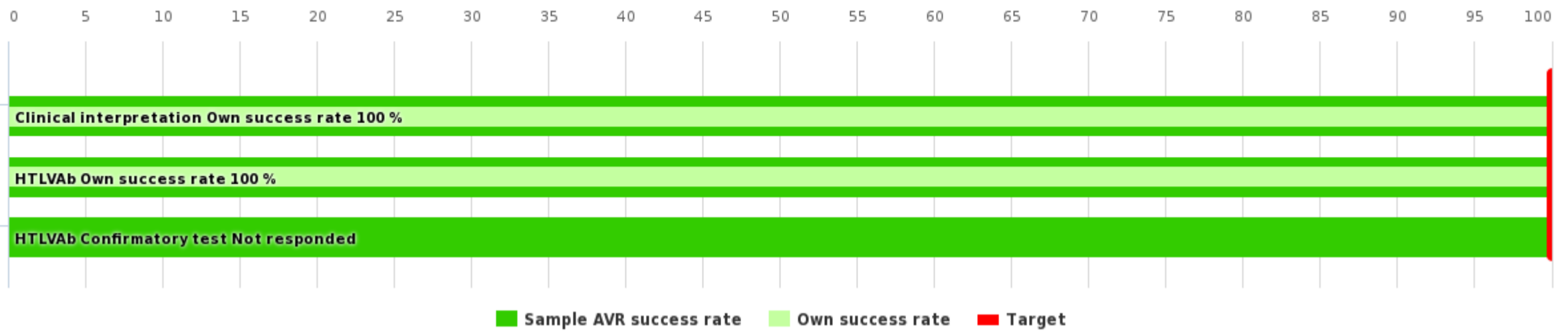
HTLV-2 Positive

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		42		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Alinity rHTLV-I/II		12					
		Abbott ARCHITECT rHTLV-I/II		8					
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2					
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8					
		DiaSorin Murex HTLV I+II		6					
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1					
		Roche Elecsys HTLV-I/II		5					
	Total:		42		2	2	100 %	0 %	100 %

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	HTLV-2 Positive		9		-				100 %
		Fujirebio INNO-LIA HTLV I/II Score		5					
		MP Biomedicals HTLV Blot 2.4		4					
	Total:		9		-	-	-	-	100 %

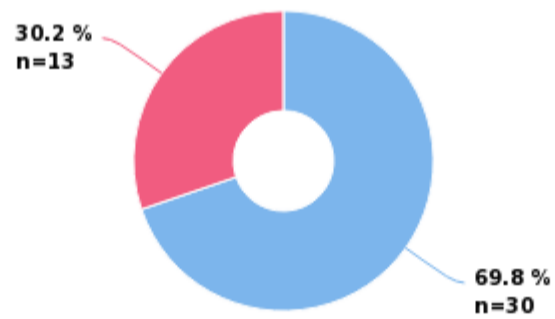
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	43
	HTLVAb	2	2	100 %	0 %	100 %	42
	HTLVAb Confirmatory test	-	-	-	-	100 %	3
	Total:	6	6	100 %	0 %	100 %	88

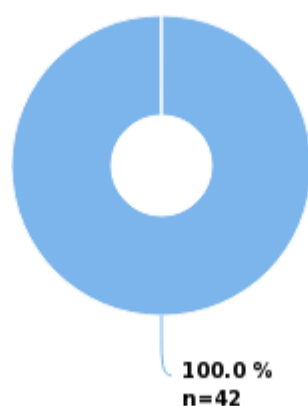
Sample S002 Clinical interpretation



HTLV negative Laboratory does not give clinical interpretation

Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> HTLV negative		30		4	4	100 %	0 %	100 %
	Laboratory does not give clinical interpretation		13		-				-
	Total:		43		4	4	100 %	0 %	100 %

Sample S002 HTLVAb



■ Negative

Sample S002 HTLVAb Confirmatory test



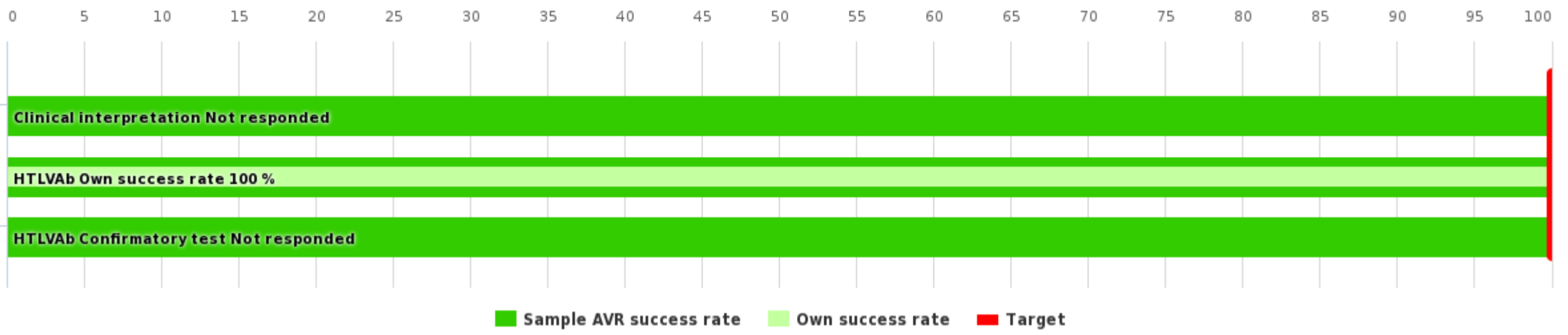
■ Negative

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		42		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Alinity rHTLV-I/II		12					
		Abbott ARCHITECT rHTLV-I/II		8					
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2					
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8					
		DiaSorin Murex HTLV I+II		6					
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1					
		Roche Elecsys HTLV-I/II		5					
	Total:		42		2	2	100 %	0 %	100 %

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		3		-				100 %
		Fujirebio INNO-LIA HTLV I/II Score		3					
	Total:		3		-	-	-	-	100 %

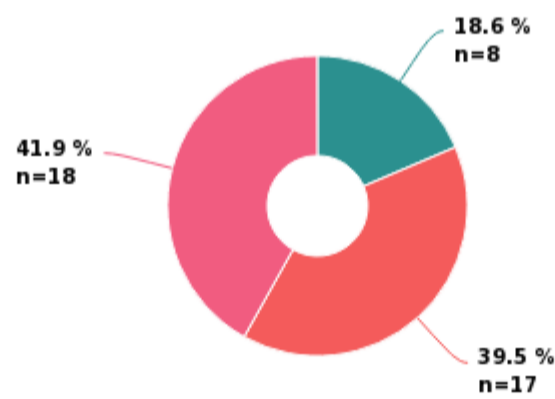
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	100 %	43
	HTLVAb	2	2	100 %	0 %	100 %	42
	HTLVAb Confirmatory test	-	-	-	-	100 %	9
	Total:	2	2	100 %	0 %	100 %	94

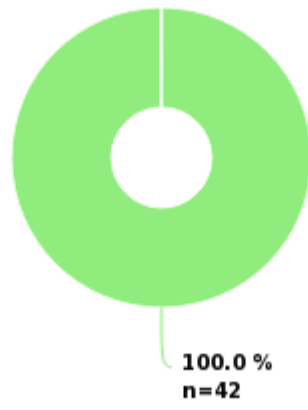
Sample S003 Clinical interpretation



■ HTLV-1 positive, confirmed
 ■ HTLV screening test positive
■ Laboratory does not give clinical interpretation

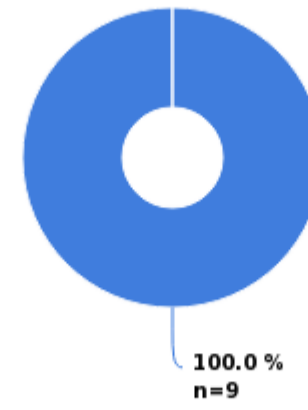
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	HTLV-1 positive, confirmed		8		-				100 %
	HTLV screening test positive		17		-				100 %
		Would be referred to another laboratory for further examination		11	-	-			
		New sample requested		4	-	-			
	<input checked="" type="radio"/> Laboratory does not give clinical interpretation		18		-				-
		<input checked="" type="radio"/> New sample requested		3	-	-			
		<input checked="" type="radio"/> Would be referred to another laboratory for further examination		11	-	-			
	Total:		43		-	-	-	-	100 %

Sample S003 HTLVAb



Positive

Sample S003 HTLVAb Confirmatory test



HTLV-1 Positive

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		42		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Alinity rHTLV-I/II		12					
		Abbott ARCHITECT rHTLV-I/II		8					
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2					
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8					
		DiaSorin Murex HTLV I+II		6					
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1					
		Roche Elecsys HTLV-I/II		5					
	Total:		42		2	2	100 %	0 %	100 %

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	HTLV-1 Positive		9		-				100 %
		Fujirebio INNO-LIA HTLV I/II Score		5					
		MP Biomedicals HTLV Blot 2.4		4					
	Total:		9		-	-	-	-	100 %

Report Info

PARTICIPANTS

Altogether 37 laboratories from 12 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

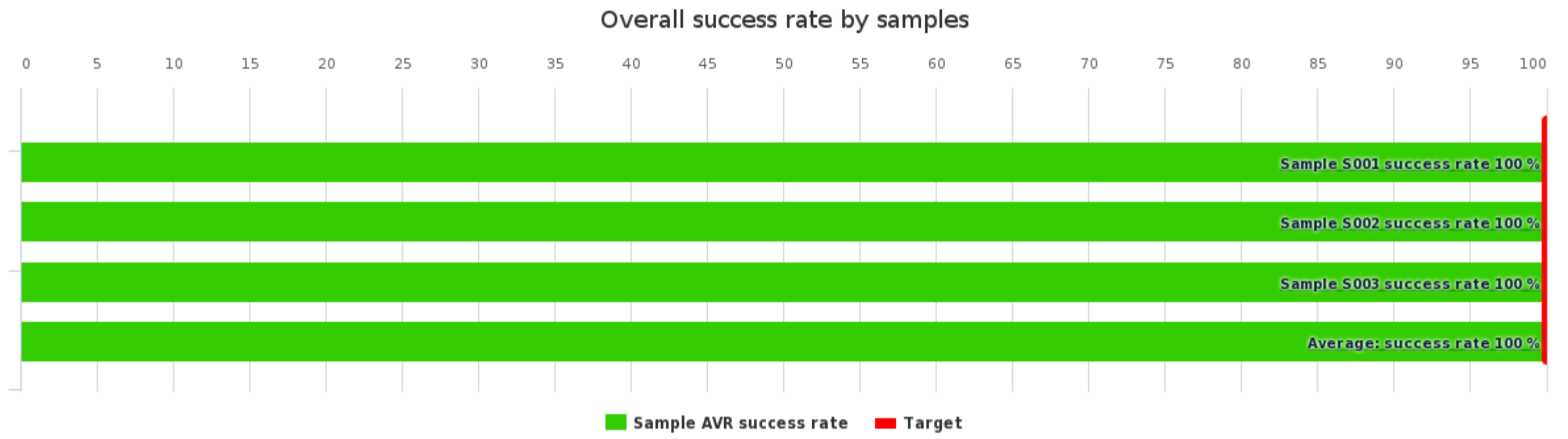
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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
Human T-cell lymphotropic virus, antibodies, February, 1-2023	37	37	100 %

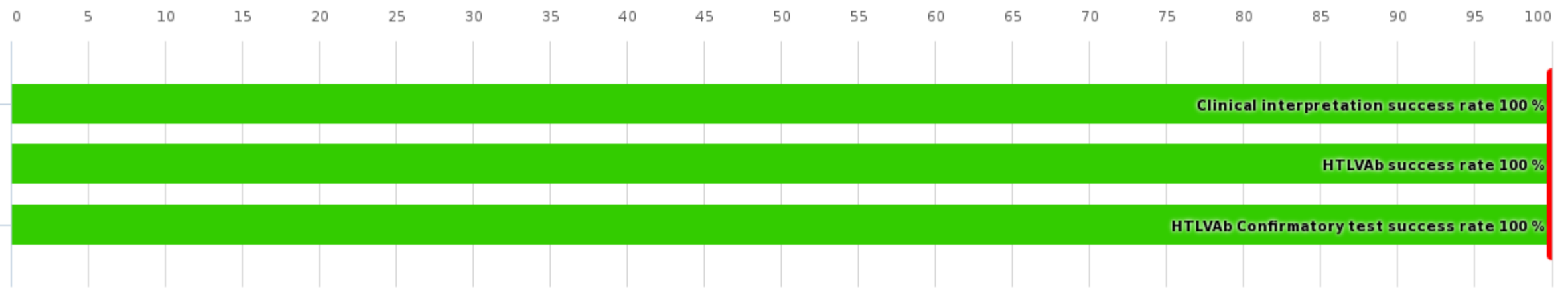
Summary



Summary	AVR success rate
Sample S001	100 %
Sample S002	100 %
Sample S003	100 %
Average:	100 %

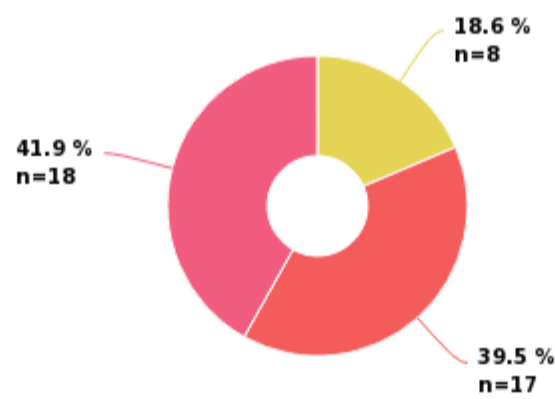
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	43
	HTLVAb	100 %	42
	HTLVAb Confirmatory test	100 %	9
	Total:	100 %	94

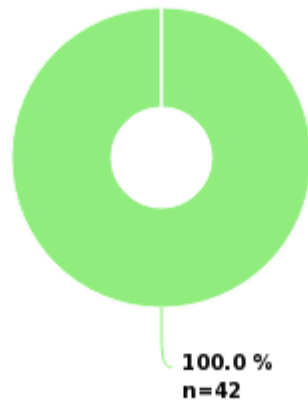
Sample S001 Clinical interpretation



■ HTLV-2 positive, confirmed
 ■ HTLV screening test positive
■ Laboratory does not give clinical interpretation

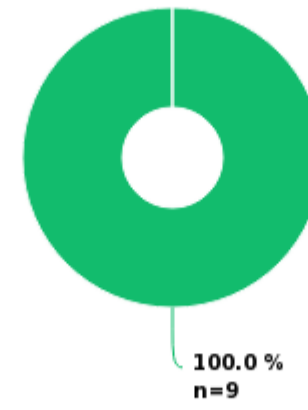
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score	Further action Score
	HTLV-2 positive, confirmed		8		100 %	4	
	HTLV screening test positive		17		100 %	4	
		New sample requested		4	-		-
		Would be referred to another laboratory for further examination		11	-		-
	Laboratory does not give clinical interpretation		18		-	-	
		Would be referred to another laboratory for further examination		11	-		-
		New sample requested		3	-		-
	Total:		43		100 %		

Sample S001 HTLVAb



■ Positive

Sample S001 HTLVAb Confirmatory test



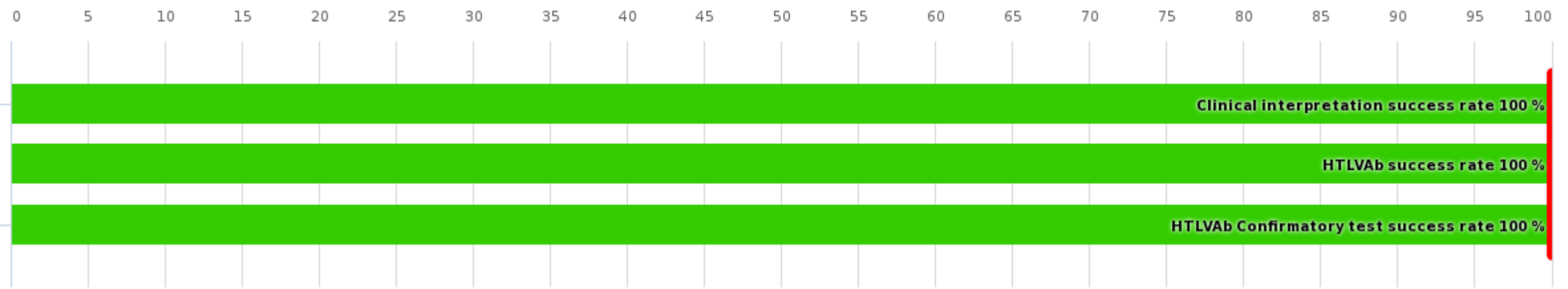
■ HTLV-2 Positive

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Positive		42		100 %	2
		Abbott Alinity rHTLV-I/II		12		
		Abbott ARCHITECT rHTLV-I/II		8		
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2		
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8		
		DiaSorin Murex HTLV I+II		6		
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1		
		Roche Elecsys HTLV-I/II		5		
	Total:		42		100 %	

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	HTLV-2 Positive		9		100 %	2
		Fujirebio INNO-LIA HTLV I/II Score		5		
		MP Biomedicals HTLV Blot 2.4		4		
	Total:		9		100 %	

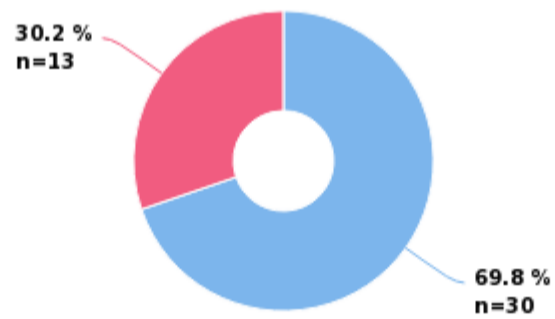
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	43
	HTLVAb	100 %	42
	HTLVAb Confirmatory test	100 %	3
	Total:	100 %	88

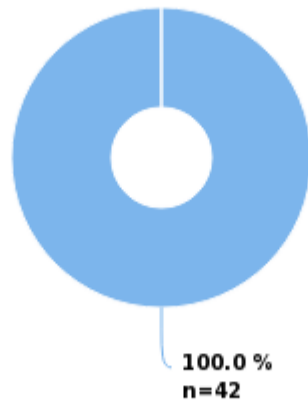
Sample S002 Clinical interpretation



■ HTLV negative ■ Laboratory does not give clinical interpretation

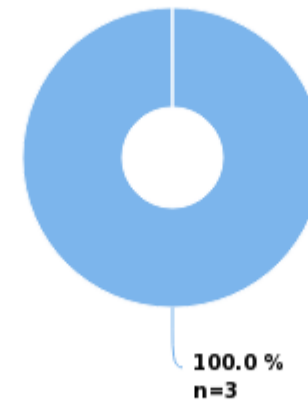
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score	Further action Score
	HTLV negative		30		100 %	4	
	Laboratory does not give clinical interpretation		13		-	-	
	Total:		43		100 %		

Sample S002 HTLVAb



■ Negative

Sample S002 HTLVAb Confirmatory test



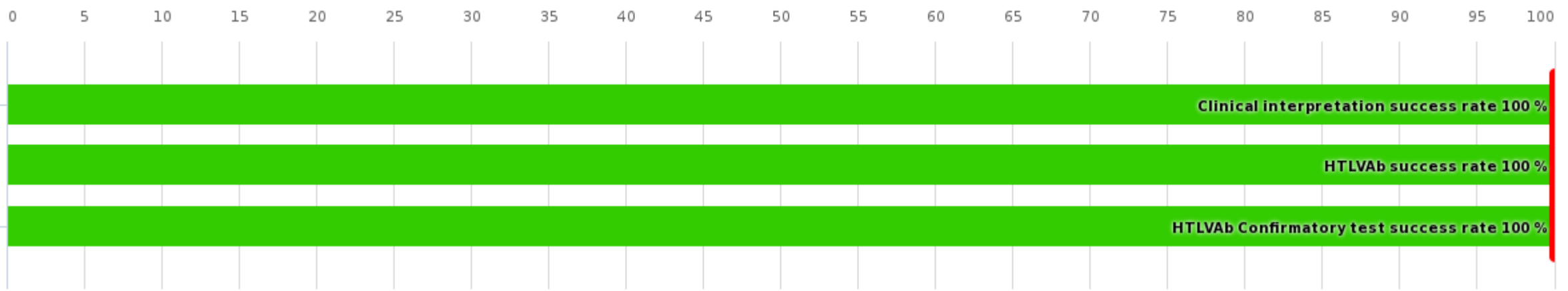
■ Negative

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		42		100 %	2
		Abbott Alinity rHTLV-I/II		12		
		Abbott ARCHITECT rHTLV-I/II		8		
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2		
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8		
		DiaSorin Murex HTLV I+II		6		
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1		
		Roche Elecsys HTLV-I/II		5		
	Total:		42		100 %	

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		3		100 %	2
		Fujirebio INNO-LIA HTLV I/II Score		3		
	Total:		3		100 %	

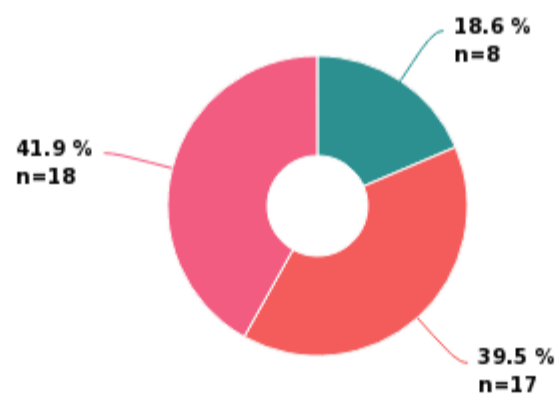
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	43
	HTLVAb	100 %	42
	HTLVAb Confirmatory test	100 %	9
	Total:	100 %	94

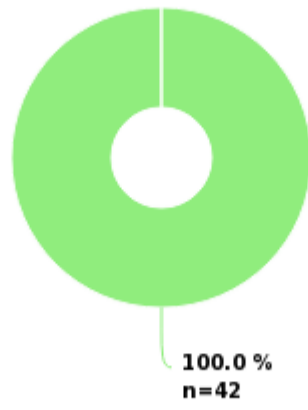
Sample S003 Clinical interpretation



■ HTLV-1 positive, confirmed
 ■ HTLV screening test positive
■ Laboratory does not give clinical interpretation

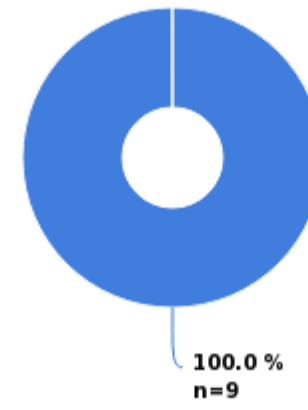
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score	Further action Score
	HTLV-1 positive, confirmed		8		100 %	4	
	HTLV screening test positive		17		100 %	4	
		Would be referred to another laboratory for further examination		11	-		-
		New sample requested		4	-		-
	Laboratory does not give clinical interpretation		18		-	-	
		New sample requested		3	-		-
		Would be referred to another laboratory for further examination		11	-		-
	Total:		43		100 %		

Sample S003 HTLVAb



■ Positive

Sample S003 HTLVAb Confirmatory test



■ HTLV-1 Positive

HTLVAb	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Positive		42		100 %	2
		Abbott Alinity rHTLV-I/II		12		
		Abbott ARCHITECT rHTLV-I/II		8		
		Dia.Pro Diagnostic HTLV I&II Ab (Version ULTRA)		2		
		DiaSorin LIAISON XL MUREX recHTLV-I/II		8		
		DiaSorin Murex HTLV I+II		6		
		Ortho Clinical Diagnostics VITROS Anti-HTLV I/II assay		1		
		Roche Elecsys HTLV-I/II		5		
	Total:		42		100 %	

HTLVAb Confirmatory test	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	HTLV-1 Positive		9		100 %	2
		Fujirebio INNO-LIA HTLV I/II Score		5		
		MP Biomedicals HTLV Blot 2.4		4		
	Total:		9		100 %	

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External Quality Assessment Scheme

Human T-cell lymphotropic virus, antibodies Round 1, 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 (LQ773723011)
HTLVAb HTLV-2 Positive

Sample S002 (LQ773723012)
HTLVAb Negative

Sample S003 (LQ773723013)
HTLVAb HTLV-1 Positive

Pre-test methods: Abbott Alinity/Architect rHTLV-I/II and Fujirebio Inno-Lia HTLV I/II.

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 – EQA Coordinator

The round included one HTLV-2 positive sample (S001), one HTLV negative sample (S002) and one HTLV-1 positive sample (S003). Participants performed very well in this EQA round. The renewal of the result form clarified the reporting of the results. All reported test results as well as clinical interpretations were correct.

Exceptions in scoring

No exceptions.

End of report

2023-03-15

FINAL REPORT

Product no. 5089

Subcontracting: Sample pretesting

Samples sent	2023-02-14
Round closed	2023-03-09
Expected results	2023-03-10
Final report	2023-03-15

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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