

External Quality Assessment Scheme

HIV, antibodies and antigen detection Round 1, 2023

Specimens

Please find enclosed 3 human plasma or serum samples S001, S002 and S003, each 0.7 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 (1/2)
HIVAgAb (combo)
HIVAg (p24)
HIVAb confirmatory test
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 *HIVAb confirmatory test*, to which the result of the virus type is reported.

Previously created devices for the screening tests should work as usual. 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.labscale.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator. Report only the results of examinations that are in use in your laboratory. All reported examinations will be scored.

S001



S002



S003



2023-02-07

INSTRUCTIONS

Product no. 5091
LQ773623011-013/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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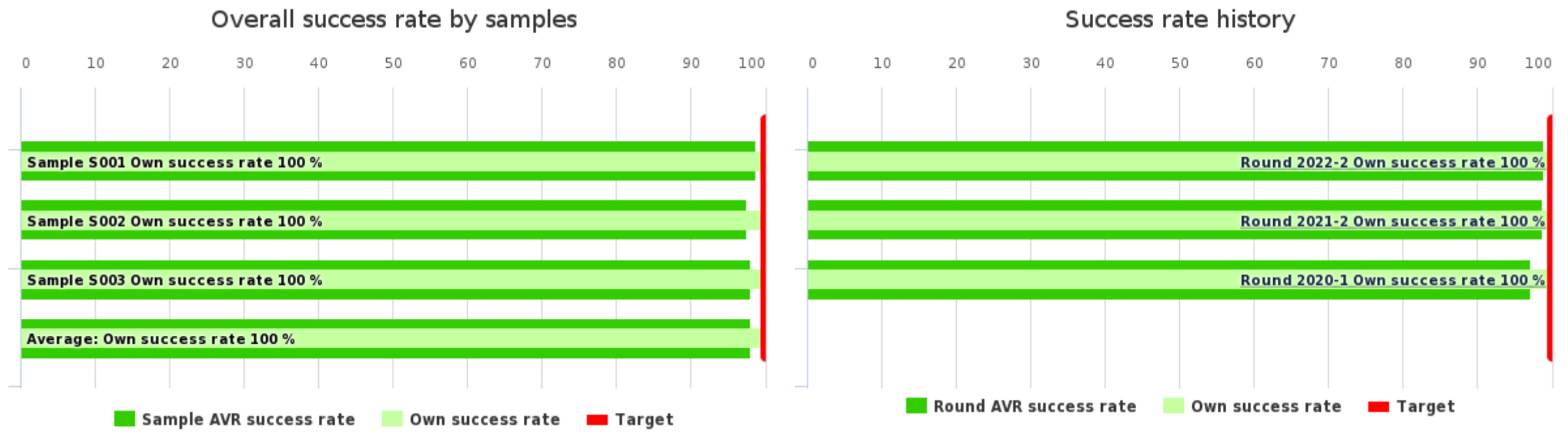
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
HIV, antibodies and antigen detection, February, 1-2023	177	176	99.4 %

Summary

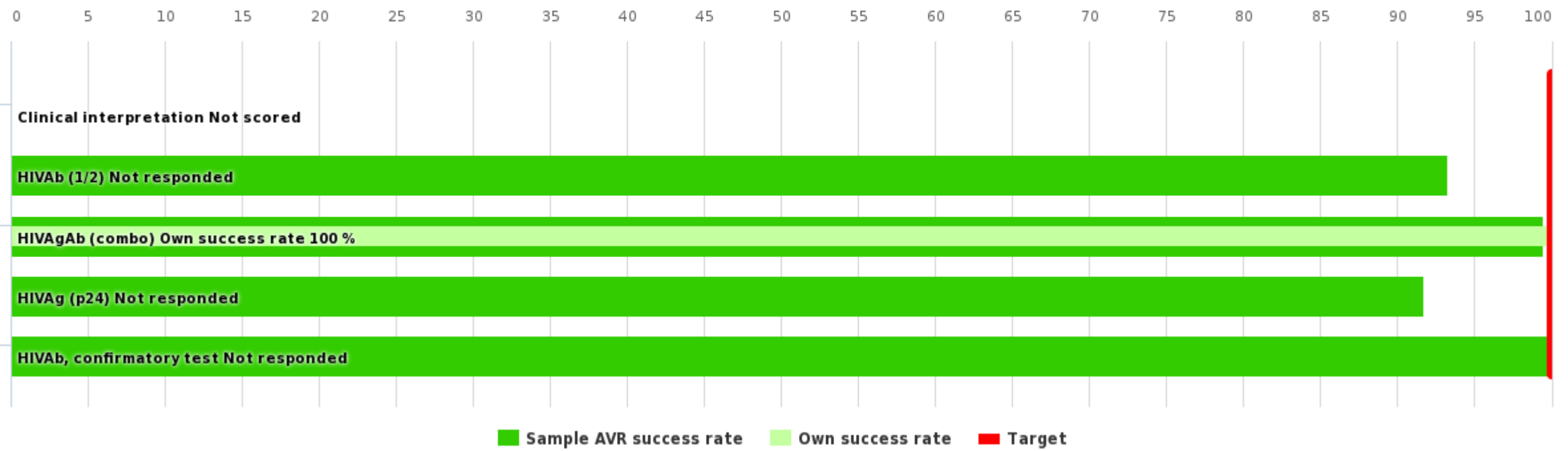


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	1.2 %	98.8 %
Sample S002	6	6	100 %	2.5 %	97.5 %
Sample S003	2	2	100 %	2 %	98 %
Average:			100 %	1.9 %	98.1 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-2	1-1	100 %	1.1 %	98.9 %
Round 2021-2	1-1	100 %	1.3 %	98.7 %
Round 2020-1	1-1	100 %	2.8 %	97.2 %

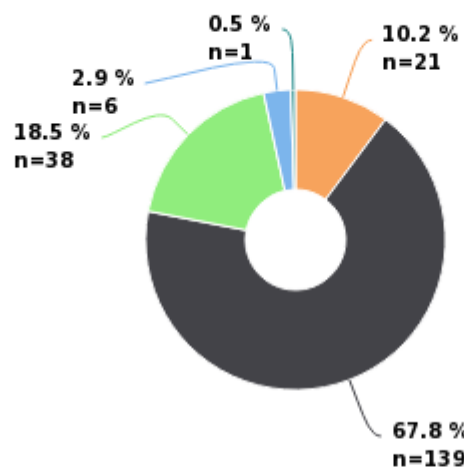
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	-	205
	HIVAb (1/2)	-	-	-	-	93.3 %	15
	HIVAgAb (combo)	2	2	100 %	0.5 %	99.5 %	195
	HIVAg (p24)	-	-	-	-	91.7 %	12
	HIVAb, confirmatory test	-	-	-	-	100 %	22
	Total:	2	2	100 %	1.2 %	98.8 %	449

Sample S001 Clinical interpretation



- HIV-1 positive, confirmed
- HIV screening test positive, laboratory does not give clinical interpretation
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV-1 and 2 positive, confirmed
- HIV negative

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIV-1 positive, confirmed		21		-	-			-
		New sample requested		2	-	-			
	HIV screening test positive, laboratory does not give clinical interpretation		139		-	-			-
		Would be referred to another laboratory for further examination		101	-	-			
		New sample requested		18	-	-			
	<input checked="" type="radio"/> HIV antigen positive, infection will be confirmed with a confirmatory test		38		-	-			-
		<input checked="" type="radio"/> Would be referred to another laboratory for further examination		29	-	-			
		New sample requested		12	-	-			
	HIV-1 and 2 positive, confirmed		6		-	-			-

		Would be referred to another laboratory for further examination		5	-	-			
		New sample requested		2	-	-			
	HIV negative			1	-	-			-
	Total:			205	-	-	-	-	-

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		14		-				100 %
		Abbott Determine HIV 1/2		2					
		Abbott Determine HIV Early Detect		1					
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Biosynex Exacto Pro HIV		1					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1					
		Roche Elecsys HIV Duo		5					
	Test does not give a clear result		1		-				0 %
		bioMerieux VIDAS HIV Duo Ultra		1					
	Total:		15		-	-	-	-	93.3 %

OWN DEVICE: COBAS 411

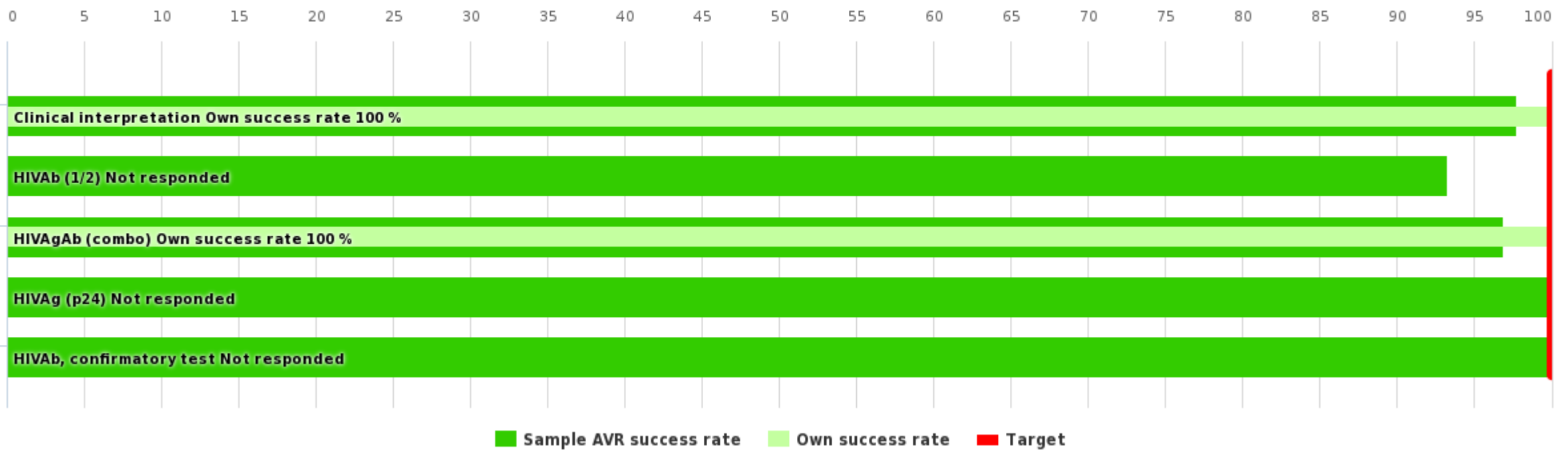
HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Roche Elecsys HIV combi PT		1					
	<input checked="" type="radio"/> Positive		194		2	2	100 %	0 %	100 %
		Abbott Alinity i HIV Ag/Ab Combo		33					
		Abbott ARCHITECT HIV Ag/Ab Combo		43					
		Abbott Determine HIV 1/2 Ag/Ab Combo		1					
		Access HIV-1/2, Beckman Coulter		1					
		Bio-Rad Access HIV Combo		1					
		Bio-Rad Genscreen ULTRA HIVAgAb		5					
		bioMerieux VIDAS HIV Duo Quick		2					
		bioMerieux VIDAS HIV Duo Ultra		6					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5					
		Diasorin Murex HIV Ag/Ab Combination		1					
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1					
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1					
		<input checked="" type="radio"/> Roche Elecsys HIV combi PT		51					
		Roche Elecsys HIV Duo		25					
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4					
		Siemens Atellica HIV Ag/Ab Combo		11					
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1					
	Total:		195		2	2	100 %	0.5 %	99.5 %

HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		11		-				100 %
		Abbott Determine HIV Early Detect		1					
		bioMerieux VIDAS P24 II		2					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Roche Elecsys HIV Duo		5					
	Positive		1		-				0 %
		Roche Elecsys HIV Duo		1					

Total:			12		-	-	-	-	91.7 %
HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIV-1 Positive		20		-				100 %
		Bio-Rad Geenius HIV 1/2 confirmatory assay		7					
		Bio-Rad New LAV Blot I/II		4					
		Fujirebio INNO-LIA HIV I/II Score		8					
		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1					
	Positive		2		-				100 %
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2					
Total:			22		-	-	-	-	100 %

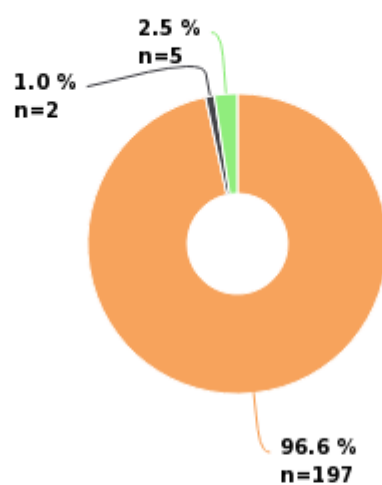
Sample S002

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 %	2.2 %	97.8 %	204
	HIVAb (1/2)	-	-	-	-	93.3 %	15
	HIVAgAb (combo)	2	2	100 %	3.1 %	96.9 %	194
	HIVAg (p24)	-	-	-	-	100 %	11
	HIVAb, confirmatory test	-	-	-	-	100 %	8
	Total:	6	6	100 %	2.5 %	97.5 %	432

Sample S002 Clinical interpretation



- HIV negative
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV screening test positive, laboratory does not give clinical interpretation

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> HIV negative		197		4	4	100 %	0 %	100 %
		<input checked="" type="radio"/> New sample requested		7	-	-			
		Would be referred to another laboratory for further examination		2	-	-			
	HIV antigen positive, infection will be confirmed with a confirmatory test		2		-				0 %
		Would be referred to another laboratory for further examination		2	-	-			
	HIV screening test positive, laboratory does not give clinical interpretation		5		-				0 %
		New sample requested		1	-	-			
	Total:		204		4	4	100 %	2.2 %	97.8 %

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		14		-				100 %
		Abbott Determine HIV 1/2		2					
		Abbott Determine HIV Early Detect		1					
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Biosynex Exacto Pro HIV		1					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1					
		Roche Elecsys HIV Duo		5					
	Borderline		1		-				0 %
		bioMerieux VIDAS HIV Duo Ultra		1					
	Total:		15		-	-	-	-	93.3 %

OWN DEVICE: COBAS 411

HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		188		2	2	100 %	0 %	100 %
		Abbott Alinity i HIV Ag/Ab Combo		34					
		Abbott ARCHITECT HIV Ag/Ab Combo		43					
		Abbott Determine HIV 1/2 Ag/Ab Combo		1					
		Access HIV-1/2, Beckman Coulter		1					
		Bio-Rad Access HIV Combo		1					
		Bio-Rad Genscreen ULTRA HIVAgAb		5					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5					
		Diasorin Murex HIV Ag/Ab Combination		1					
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1					
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1					
		<input checked="" type="radio"/> Roche Elecsys HIV combi PT		52					
		Roche Elecsys HIV Duo		25					
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4					
		Siemens Atellica HIV Ag/Ab Combo		11					
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1					
	Positive		6		-				0 %
		bioMerieux VIDAS HIV Duo Quick		2					
		bioMerieux VIDAS HIV Duo Ultra		4					
	Total:		194		2	2	100 %	3.1 %	96.9 %

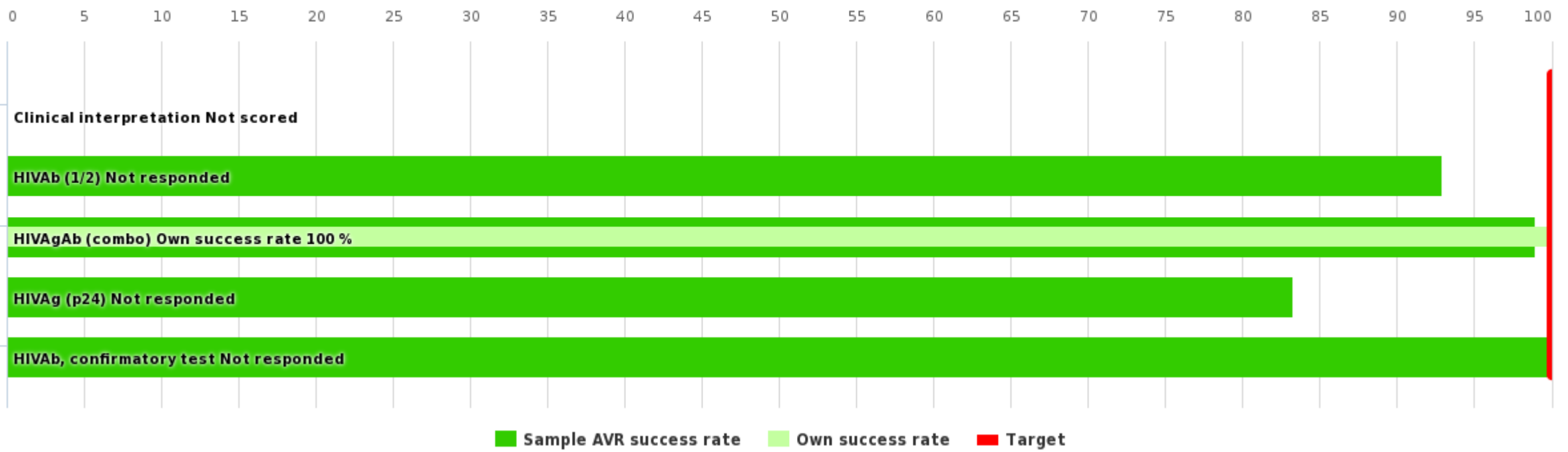
HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		11		-				100 %
		Abbott Determine HIV Early Detect		1					
		bioMerieux VIDAS P24 II		1					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Roche Elecsys HIV Duo		6					
	Total:		11		-	-	-	-	100 %

HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		8		-				100 %
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2					
		Bio-Rad New LAV Blot I/II		1					
		Fujirebio INNO-LIA HIV I/II Score		4					
		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1					

Total:		8		-	-	-	-	100 %
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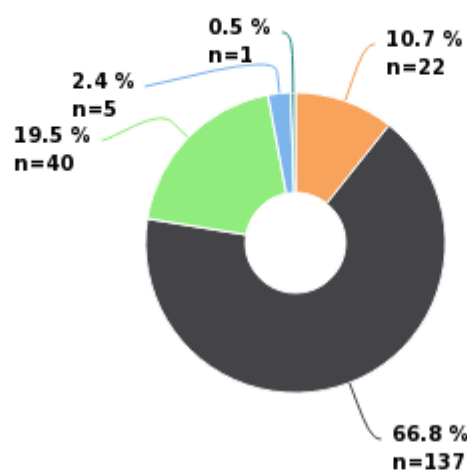
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	-	205
	HIVAb (1/2)	-	-	-	-	92.9 %	14
	HIVAgAb (combo)	2	2	100 %	1 %	99 %	196
	HIVAg (p24)	-	-	-	-	83.3 %	12
	HIVAb, confirmatory test	-	-	-	-	100 %	22
	Total:	2	2	100 %	2 %	98 %	449

Sample S003 Clinical interpretation



- HIV-1 positive, confirmed
- HIV screening test positive, laboratory does not give clinical interpretation
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV-1 and 2 positive, confirmed
- HIV negative

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIV-1 positive, confirmed		22		-	-			-
		New sample requested		3	-	-			
		Would be referred to another laboratory for further examination		1	-	-			
	HIV screening test positive, laboratory does not give clinical interpretation		137		-	-			-
		Would be referred to another laboratory for further examination		98	-	-			
		New sample requested		16	-	-			
	<input checked="" type="radio"/> HIV antigen positive, infection will be confirmed with a confirmatory test		40		-	-			-
		<input checked="" type="radio"/> Would be referred to another laboratory for further examination		31	-	-			

		New sample requested	5	14	-	-			
	HIV-1 and 2 positive, confirmed		5		-	-			-
		Would be referred to another laboratory for further examination		4	-	-			
		New sample requested		2	-	-			
	HIV negative		1		-	-			-
	Total:		205		-	-	-	-	

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		13		-				100 %
		Abbott Determine HIV 1/2		2					
		Abbott Determine HIV Early Detect		1					
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1					
		Biosynex Exacto Pro HIV		1					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Roche Elecsys HIV Duo		5					
	Test does not give a clear result		1		-				0 %
		bioMerieux VIDAS HIV Duo Ultra		1					
	Total:		14		-	-	-	-	92.9 %

OWN DEVICE: COBAS 411

HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Roche Elecsys HIV combi PT		1					
		Roche Elecsys HIV Duo		1					
	<input checked="" type="radio"/> Positive		194		2	2	100 %	0 %	100 %
		Abbott Alinity i HIV Ag/Ab Combo		33					
		Abbott ARCHITECT HIV Ag/Ab Combo		43					
		Abbott Determine HIV 1/2 Ag/Ab Combo		1					
		Access HIV-1/2, Beckman Coulter		1					
		Bio-Rad Access HIV Combo		1					
		Bio-Rad Genscreen ULTRA HIVAgAb		5					
		bioMerieux VIDAS HIV Duo Quick		2					
		bioMerieux VIDAS HIV Duo Ultra		6					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2					
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5					
		Diasorin Murex HIV Ag/Ab Combination		1					
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1					
		Ortho Clinical Diagnostics VITROS HIV Combo Test		2					
		<input checked="" type="radio"/> Roche Elecsys HIV combi PT		51					
		Roche Elecsys HIV Duo		24					
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4					
		Siemens Atellica HIV Ag/Ab Combo		11					
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1					
	Total:		196		2	2	100 %	1 %	99 %

HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		10		-				100 %
		Abbott Determine HIV Early Detect		1					
		bioMerieux VIDAS P24 II		2					
		DiaSorin LIAISON XL HIV Ab / Ag		3					
		Roche Elecsys HIV Duo		4					
	Positive		2		-				0 %

		Roche Elecsys HIV Duo		2					
	Total:		12		-	-	-	-	83.3 %

HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	HIV-1 Positive		18		-				100 %
		Bio-Rad Geenius HIV 1/2 confirmatory assay		7					
		Bio-Rad New LAV Blot I/II		3					
		Fujirebio INNO-LIA HIV I/II Score		7					
		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1					
	Positive		4		-				100 %
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2					
		Bio-Rad New LAV Blot I/II		1					
		Fujirebio INNO-LIA HIV I/II Score		1					
	Total:		22		-	-	-	-	100 %

Report Info

PARTICIPANTS

Altogether 177 laboratories from 18 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
Further actions for positive samples 1/1 points

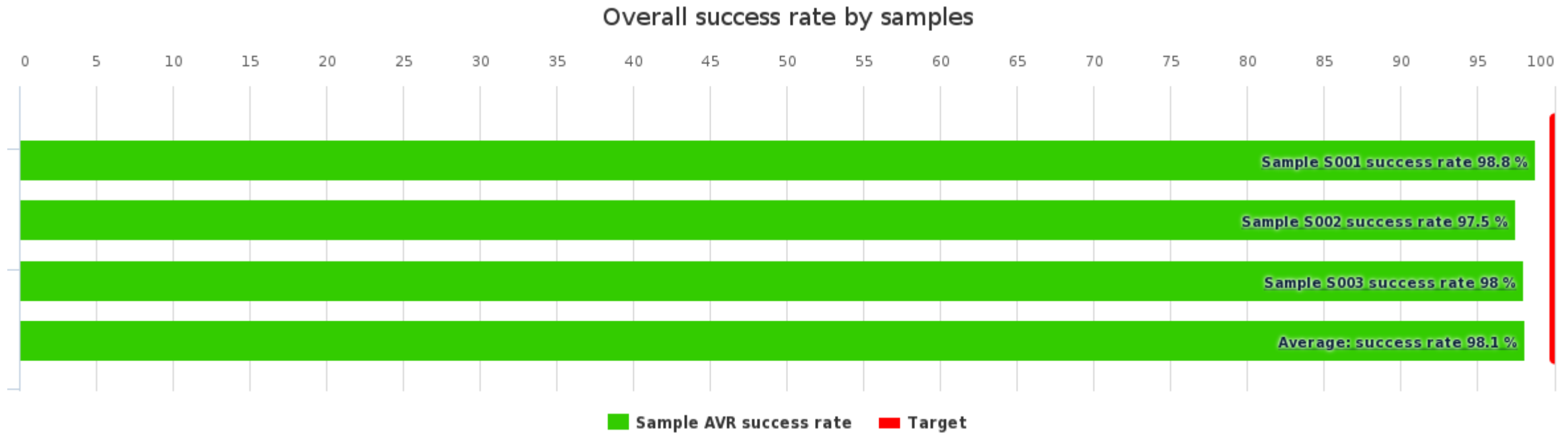
The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores*100). The Laboratory's Own success rate is the average of the sample 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, February, 1-2023	177	176	99.4 %

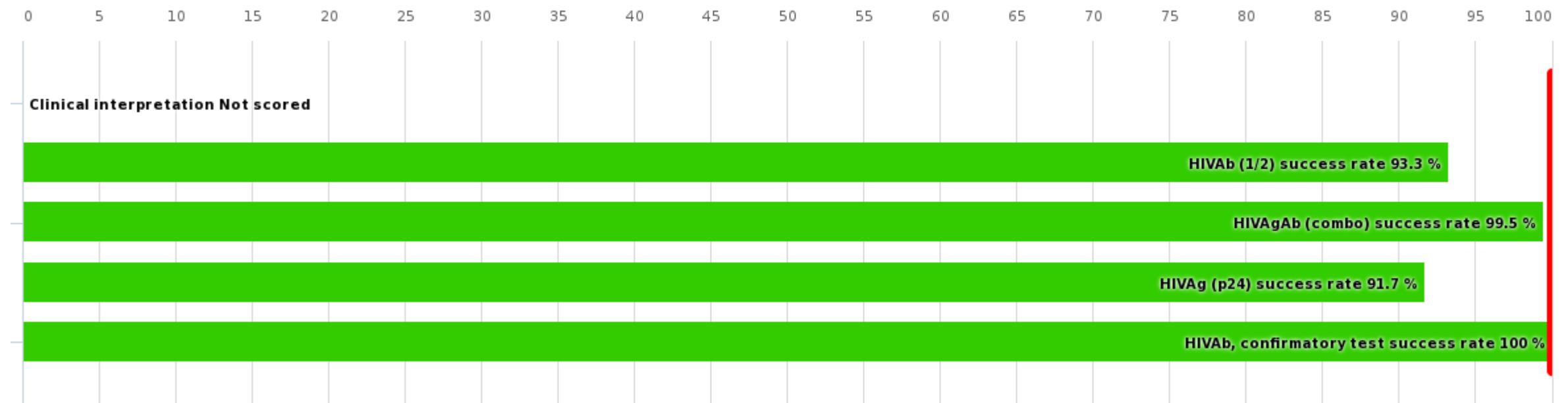
Summary



Summary	AVR success rate
Sample S001	98.8 %
Sample S002	97.5 %
Sample S003	98 %
Average:	98.1 %

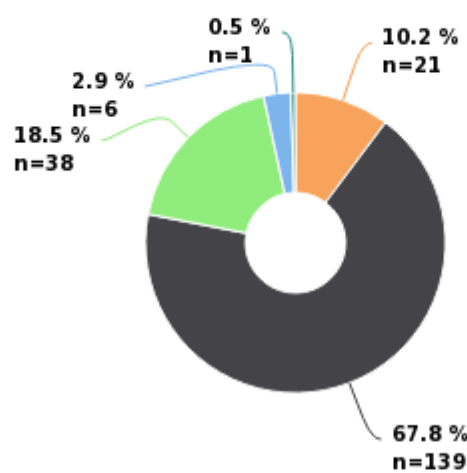
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	-	205
	HIVAb (1/2)	93.3 %	15
	HIVAgAb (combo)	99.5 %	195
	HIVAg (p24)	91.7 %	12
	HIVAb, confirmatory test	100 %	22
	Total:	98.8 %	449

Sample S001 Clinical interpretation



- HIV-1 positive, confirmed
- HIV screening test positive, laboratory does not give clinical interpretation
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV-1 and 2 positive, confirmed
- HIV negative

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	HIV-1 positive, confirmed		21		-	-	
		New sample requested		2	-		-
	HIV screening test positive, laboratory does not give clinical interpretation		139		-	-	
		Would be referred to another laboratory for further examination		101	-		-
		New sample requested		18	-		-
	HIV antigen positive, infection will be confirmed with a confirmatory test		38		-	-	
		Would be referred to another laboratory for further examination		29	-		-
		New sample requested		12	-		-
	HIV-1 and 2 positive, confirmed		6		-	-	
		Would be referred to another laboratory for further examination		5	-		-

		New sample requested		2	-	-
	HIV negative		1		-	-
	Total:		205			

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Positive		14		100 %	2
		Abbott Determine HIV 1/2		2		
		Abbott Determine HIV Early Detect		1		
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Biosynex Exacto Pro HIV		1		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1		
		Roche Elecsys HIV Duo		5		
	Test does not give a clear result		1		0 %	0
		bioMerieux VIDAS HIV Duo Ultra		1		
	Total:		15		93.3 %	

HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		1		0 %	0
		Roche Elecsys HIV combi PT		1		
	Positive		194		100 %	2
		Abbott Alinity i HIV Ag/Ab Combo		33		
		Abbott ARCHITECT HIV Ag/Ab Combo		43		
		Abbott Determine HIV 1/2 Ag/Ab Combo		1		
		Access HIV-1/2, Beckman Coulter		1		
		Bio-Rad Access HIV Combo		1		
		Bio-Rad Genscreen ULTRA HIVAgAb		5		
		bioMerieux VIDAS HIV Duo Quick		2		
		bioMerieux VIDAS HIV Duo Ultra		6		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5		
		Diasorin Murex HIV Ag/Ab Combination		1		
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1		
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1		
		Roche Elecsys HIV combi PT		51		
		Roche Elecsys HIV Duo		25		
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4		
		Siemens Atellica HIV Ag/Ab Combo		11		
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1		
	Total:		195		99.5 %	

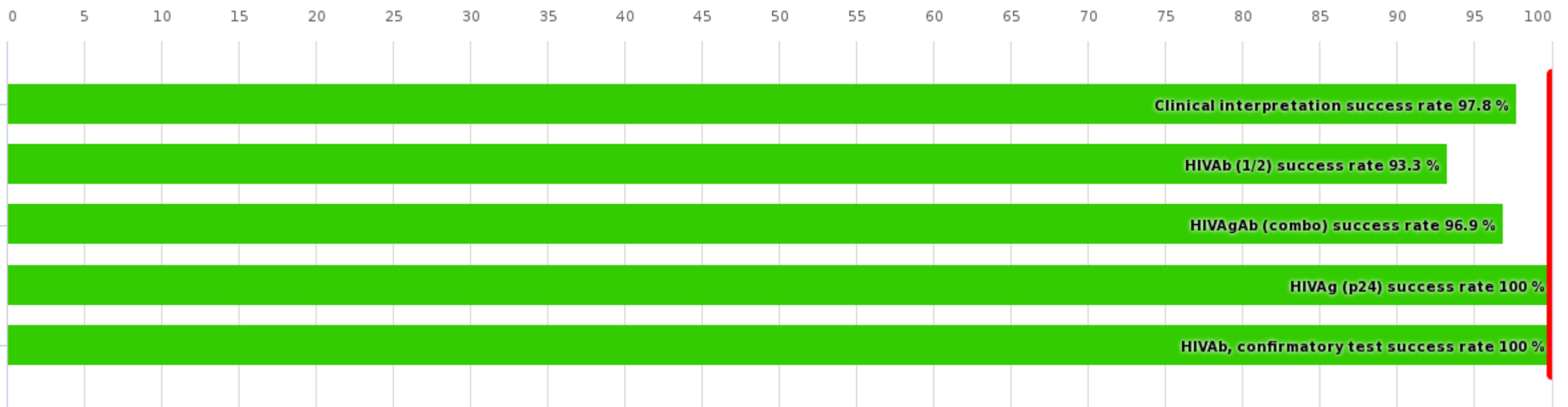
HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		11		100 %	2
		Abbott Determine HIV Early Detect		1		
		bioMerieux VIDAS P24 II		2		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Roche Elecsys HIV Duo		5		
	Positive		1		0 %	0
		Roche Elecsys HIV Duo		1		
	Total:		12		91.7 %	

HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	HIV-1 Positive		20		100 %	2
		Bio-Rad Geenius HIV 1/2 confirmatory assay		7		
		Bio-Rad New LAV Blot I/II		4		
		Fujirebio INNO-LIA HIV I/II Score		8		
		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1		

	Positive		2		100 %	2
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2		
	Total:		22		100 %	

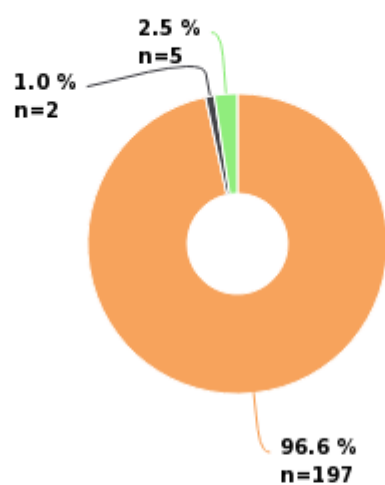
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	97.8 %	204
	HIVAb (1/2)	93.3 %	15
	HIVAgAb (combo)	96.9 %	194
	HIVAg (p24)	100 %	11
	HIVAb, confirmatory test	100 %	8
	Total:	97.5 %	432

Sample S002 Clinical interpretation



- HIV negative
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV screening test positive, laboratory does not give clinical interpretation

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	HIV negative		197		100 %	4	
		New sample requested		7	-		-
		Would be referred to another laboratory for further examination		2	-		-
	HIV antigen positive, infection will be confirmed with a confirmatory test		2		0 %	0	
		Would be referred to another laboratory for further examination		2	-		-
	HIV screening test positive, laboratory does not give clinical interpretation		5		0 %	0	
		New sample requested		1	-		-
	Total:		204		97.8 %		

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		14		100 %	2
		Abbott Determine HIV 1/2		2		
		Abbott Determine HIV Early Detect		1		
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Biosynex Exacto Pro HIV		1		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1		
		Roche Elecsys HIV Duo		5		
	Borderline		1		0 %	0
		bioMerieux VIDAS HIV Duo Ultra		1		
	Total:		15		93.3 %	

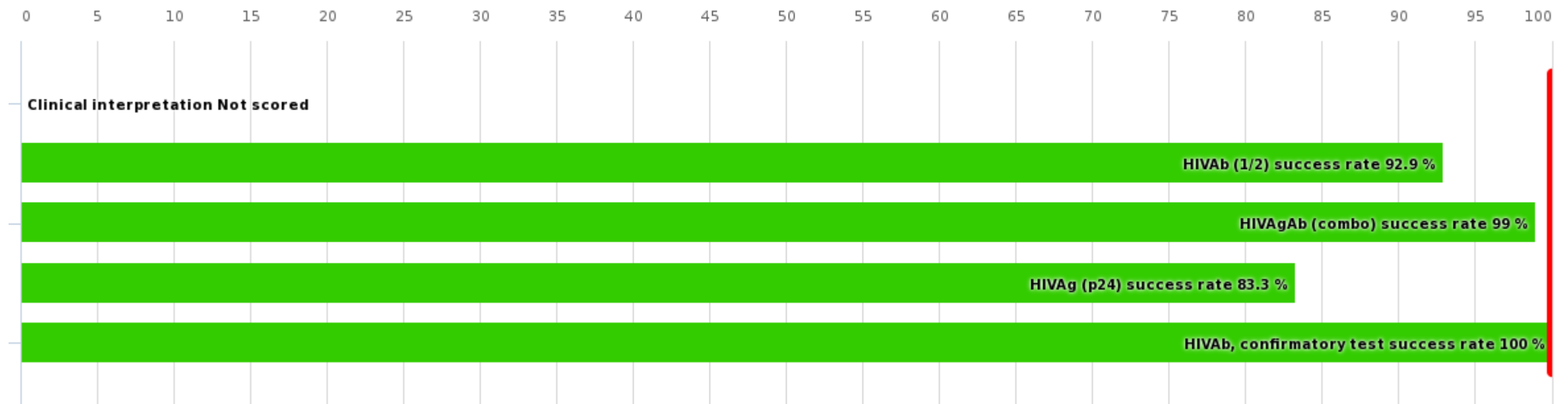
HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		188		100 %	2
		Abbott Alinity i HIV Ag/Ab Combo		34		
		Abbott ARCHITECT HIV Ag/Ab Combo		43		
		Abbott Determine HIV 1/2 Ag/Ab Combo		1		
		Access HIV-1/2, Beckman Coulter		1		
		Bio-Rad Access HIV Combo		1		
		Bio-Rad Genscreen ULTRA HIVAgAb		5		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5		
		Diasorin Murex HIV Ag/Ab Combination		1		
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1		
		Ortho Clinical Diagnostics VITROS HIV Combo Test		1		
		Roche Elecsys HIV combi PT		52		
		Roche Elecsys HIV Duo		25		
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4		
		Siemens Atellica HIV Ag/Ab Combo		11		
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1		
	Positive		6		0 %	0
		bioMerieux VIDAS HIV Duo Quick		2		
		bioMerieux VIDAS HIV Duo Ultra		4		
	Total:		194		96.9 %	

HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		11		100 %	2
		Abbott Determine HIV Early Detect		1		
		bioMerieux VIDAS P24 II		1		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Roche Elecsys HIV Duo		6		
	Total:		11		100 %	

HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		8		100 %	2
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2		
		Bio-Rad New LAV Blot I/II		1		
		Fujirebio INNO-LIA HIV I/II Score		4		
		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1		
	Total:		8		100 %	

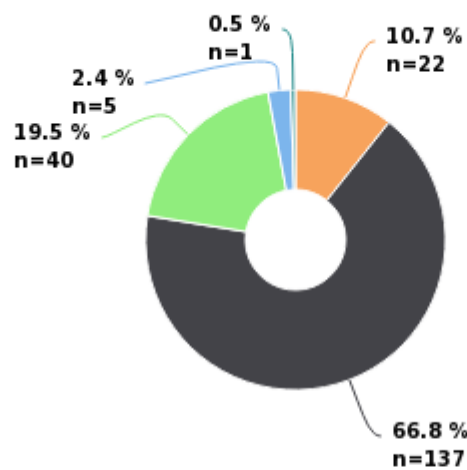
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Clinical interpretation	-	205
	HIVAb (1/2)	92.9 %	14
	HIVAgAb (combo)	99 %	196
	HIVAg (p24)	83.3 %	12
	HIVAb, confirmatory test	100 %	22
	Total:	98 %	449

Sample S003 Clinical interpretation



- HIV-1 positive, confirmed
- HIV screening test positive, laboratory does not give clinical interpretation
- HIV antigen positive, infection will be confirmed with a confirmatory test
- HIV-1 and 2 positive, confirmed
- HIV negative

Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	HIV-1 positive, confirmed		22		-	-	
		New sample requested		3	-		-
		Would be referred to another laboratory for further examination		1	-		-
	HIV screening test positive, laboratory does not give clinical interpretation		137		-	-	
		Would be referred to another laboratory for further examination		98	-		-
		New sample requested		16	-		-
	HIV antigen positive, infection will be confirmed with a confirmatory test		40		-	-	
		Would be referred to another laboratory for further examination		31	-		-
		New sample requested		14	-		-
	HIV-1 and 2 positive, confirmed		5		-	-	

		Would be referred to another laboratory for further examination		4	-	-
		New sample requested		2	-	-
	HIV negative		1		-	-
	Total:		205			

HIVAb (1/2)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Positive		13		100 %	2
		Abbott Determine HIV 1/2		2		
		Abbott Determine HIV Early Detect		1		
		Artron Human Immunodeficiency Virus 1/2 (HIV1/2) Antibody Test		1		
		Biosynex Exacto Pro HIV		1		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Roche Elecsys HIV Duo		5		
	Test does not give a clear result		1		0 %	0
		bioMerieux VIDAS HIV Duo Ultra		1		
	Total:		14		92.9 %	

HIVAgAb (combo)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		2		0 %	0
		Roche Elecsys HIV combi PT		1		
		Roche Elecsys HIV Duo		1		
	Positive		194		100 %	2
		Abbott Alinity i HIV Ag/Ab Combo		33		
		Abbott ARCHITECT HIV Ag/Ab Combo		43		
		Abbott Determine HIV 1/2 Ag/Ab Combo		1		
		Access HIV-1/2, Beckman Coulter		1		
		Bio-Rad Access HIV Combo		1		
		Bio-Rad Genscreen ULTRA HIVAgAb		5		
		bioMerieux VIDAS HIV Duo Quick		2		
		bioMerieux VIDAS HIV Duo Ultra		6		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag		2		
		DiaSorin LIAISON XL MUREX HIV Ab / Ag HT		5		
		Diasorin Murex HIV Ag/Ab Combination		1		
		DiaSorin Murex HIV Ag/Ab Combination ELISA		1		
		Ortho Clinical Diagnostics VITROS HIV Combo Test		2		
		Roche Elecsys HIV combi PT		51		
		Roche Elecsys HIV Duo		24		
		Siemens Advia Centaur HIV Ag/Ab Combo (CHIV)		4		
		Siemens Atellica HIV Ag/Ab Combo		11		
		Snibe Maglumi HIV Ab/Ag Combi (CLIA)		1		
	Total:		196		99 %	

HIVAg (p24)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		10		100 %	2
		Abbott Determine HIV Early Detect		1		
		bioMerieux VIDAS P24 II		2		
		DiaSorin LIAISON XL HIV Ab / Ag		3		
		Roche Elecsys HIV Duo		4		
	Positive		2		0 %	0
		Roche Elecsys HIV Duo		2		
	Total:		12		83.3 %	

HIVAb, confirmatory test	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	HIV-1 Positive		18		100 %	2
		Bio-Rad Geenius HIV 1/2 confirmatory assay		7		
		Bio-Rad New LAV Blot I/II		3		
		Fujirebio INNO-LIA HIV I/II Score		7		

		Mikrogen Diagnostik recomLine HIV-1& HIV-2 IgG		1		
	Positive		4		100 %	2
		Bio-Rad Geenius HIV 1/2 confirmatory assay		2		
		Bio-Rad New LAV Blot I/II		1		
		Fujirebio INNO-LIA HIV I/II Score		1		
	Total:		22		100 %	

Report Info

PARTICIPANTS

Altogether 177 laboratories from 18 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
Further actions for positive samples 1/1 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 ($\text{scores}/\text{maximum scores} \times 100$). 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 ($\text{all scores}/\text{maximum scores} \times 100$). 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 Round 1, 2023

Specimens

Samples of this EQA round were human plasma. The anti-HIV positive samples S001 and S003 consisted of one single anti-HIV positive donation diluted in 1:5 with one single anti-HIV negative donation plasma. The anti-HIV negative sample S002 consisted of one single donor human plasma. 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 (LQ773623011)

HIVAb (1/2)	Positive
HIVAgAb (combo)	Positive
HIVAg (p24)	Negative
HIVAb confirmatory	HIV-1 positive

Sample S002 (LQ773623012)

HIVAb (1/2)	Negative
HIVAgAb (combo)	Negative
HIVAg (p24)	Negative
HIVAb confirmatory	Negative

Sample S003 (LQ773623013)

HIVAb (1/2)	Positive
HIVAgAb (combo)	Positive
HIVAg (p24)	Negative
HIVAb confirmatory	HIV-1 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 and 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 – Expert and EQA Coordinator

The round included two HIV antibody positive samples S001 and S003 and one HIV negative sample S002. All three samples were negative for HIV antigen. Participants performed well in this EQA round. The reported test results were mainly correct/as expected, but some incorrect test results were also reported.

One participant reported all three samples as negative, and one participant reported results only for the HIVAg (p24) analyte, even though the reported test was a HIVAgAb combination test. Sample S001 was negative for HIV antigen in preliminary testing. Very similar test results were reported for the sample S003, which was HIV antibody positive and antigen negative in preliminary testing.

For the negative sample S002, all other test results were reported correctly/as expected, except for results reported by one commercial test manufacturer's tests. One borderline and six positive results were reported from the sample.

2023-03-23

FINAL REPORT

Product no. 5091

Subcontracting: Sample preparation, sample pretesting

Samples sent	2023-02-07
Round closed	2023-03-02
Expected results	2023-03-07
Final report	2023-03-23

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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However, the reported numerical values of the test results were low. These deviating results were possibly due to a non-specific reaction. The deviating test results also led to false clinical interpretations for five of these participants. Two other incorrect clinical interpretations were also reported, even though the test results were correct.

The update of the clinical interpretations clearly confused the participants. The clinical interpretation of HIV antigen positive sample "HIV antigen positive, infection will be confirmed with a confirmatory test" was reported by several laboratories, even though the combination test had been used for most of these participants. If the test does not distinguish between antibodies and antigen, the expected interpretation would have been "HIV screening test positive, the laboratory does not give a clinical interpretation", which was chosen by most of the screening laboratories. In addition, a few participants reported "HIV-1 and 2 positive, confirmed" as a clinical interpretation, although most of them had not examined the sample with a confirmation test. Some participants had possibly interpreted this as a situation where virus typing has not been done.

We apologize for the ambiguity of the clinical interpretations, and we are still working to clarify these for the next round. In this round, the clinical interpretations have been excluded from scoring for positive samples (S001 and S003).

Exceptions in scoring

The clinical interpretations have been excluded from scoring for positive samples S001 and S003.

End of report

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