

External Quality Assessment Scheme

RF and CCPAb Round 1, 2023

Specimens

Please find enclosed 2 liquid human-derived samples S001 and S002, 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 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

RF
CCPAb

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. Report only the results of examinations that are in use in your laboratory. Only the Interpretation part will be scored.

S001



S002



2023-01-24

INSTRUCTIONS

Product no. 5820
LQ717623011-012/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 **February 16, 2023.**

Inquiries

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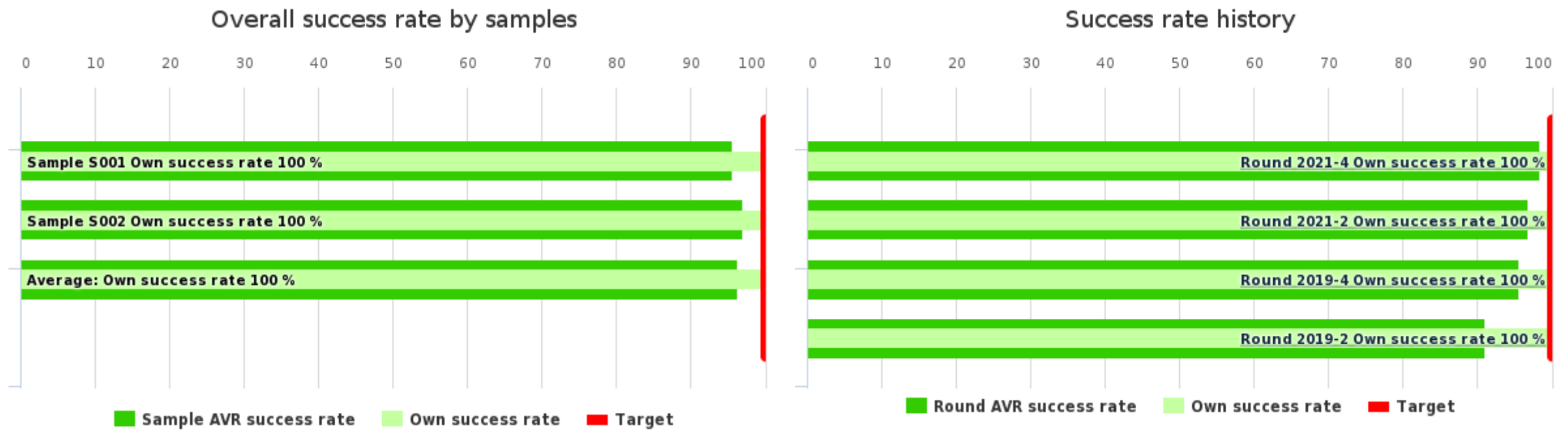
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Rheumatoid factor and citrullic peptide antibodies, January, 1-2023	88	83	94.3 %

Summary

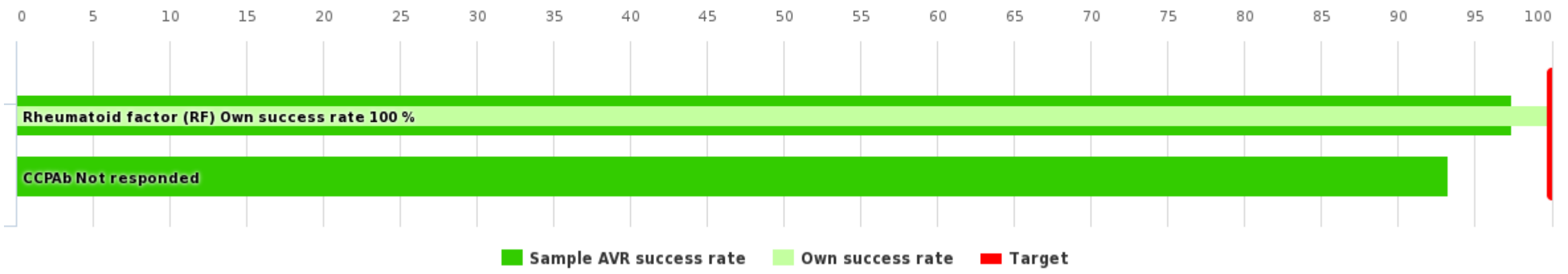


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	4.4 %	95.6 %
Sample S002	2	2	100 %	2.9 %	97.1 %
Average:			100 %	3.7 %	96.3 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2021-4	1-1	100 %	1.6 %	98.4 %
Round 2021-2	1-1	100 %	3.1 %	96.9 %
Round 2019-4	1-1	100 %	4.3 %	95.7 %
Round 2019-2	1-1	100 %	9 %	91 %

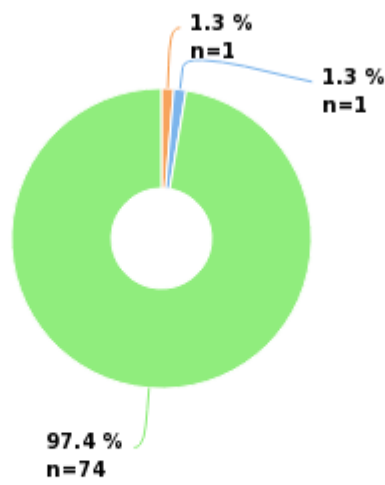
Sample S001

Sample S001 success rate



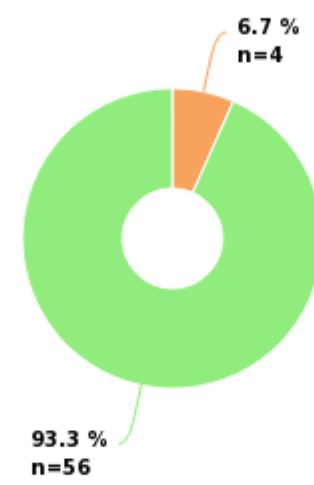
Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Rheumatoid factor (RF)	2	2	100 %	2.6 %	97.4 %	76
	CCPAb	-	-	-	-	93.3 %	60
Total:		2	2	100 %	4.4 %	95.6 %	136

Sample S001 Rheumatoid factor (RF)



Legend: Negative (orange), Borderline (blue), Positive (green)

Sample S001 CCPAb



Legend: Negative (orange), Positive (green)

OWN DEVICE: ARCH 8200

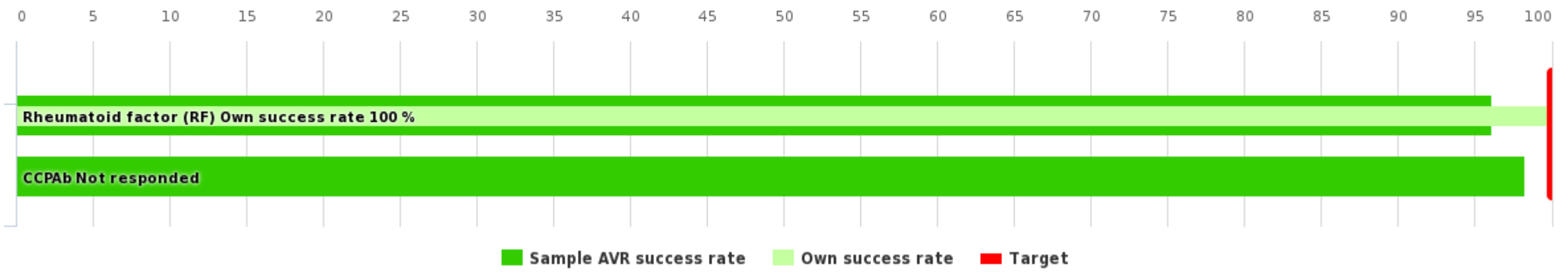
Rheumatoid factor (RF)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Roche Rheumatoid Factors II (RF-II)		1					
	Borderline		1		-				0 %
		Roche Rheumatoid Factors II (RF-II)		1					
	<input checked="" type="radio"/> Positive		74		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Rheumatoid Factor (RF)		13					
		Aidian (Orion Diagnostica) RF-PAIA		1					
		Beckman Coulter RF Latex		4					
		Beckman nephelometry		1					
		BioSystems RHEUMATOID FACTORS (RF) - SLIDE		1					
		Cormay RF		1					
		Diesse Chorus RF-M		1					
		Hydrex RF Latex		2					
		Orgentec Reumatoid Factor Alegria		1					
		Roche Rheumatoid Factors II (RF-II)		28					
		Siemens Advia RF assay		1					
		Siemens Atellica RF		6					
		Siemens Dimension Vista RF assay		1					
		Siemens Nephelometry		5					
		The Binding Site Optilite		1					
		Thermo Scientific Phadia EliA RF IgM		4					

		Thermo Scientific Rheumatoid factors 2		3					
	Total:		76		2	2	100 %	2.6 %	97.4 %

CCPAb	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		4		-				0 %
		Abbott Anti-CCP		1					
		Diesse Chorus line Anti-CCP		1					
		Orgentec Anti-CCP hs Alegria		2					
	Positive		56		-				100 %
		Abbott Anti-CCP		12					
		Aesku Diagnostics CCP Aeskulisa		1					
		Euroimmun ELISA		1					
		Inova Quanta Flash CCP3		1					
		MEDIPAN Medizym anti-CCP Ref		1					
		Roche Anti-CCP assay		15					
		Siemens Atellica Anti-CCP		5					
		Thermo Scientific Phadia ELIA CCP		20					
	Total:		60		-	-	-	-	93.3 %

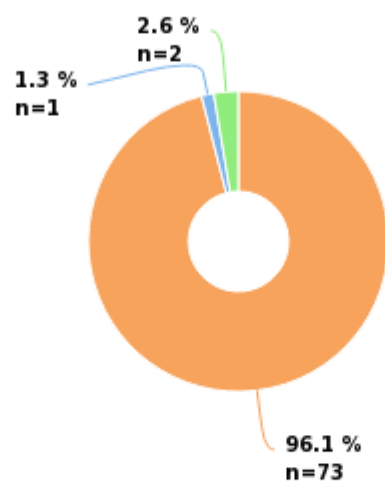
Sample S002

Sample S002 success rate



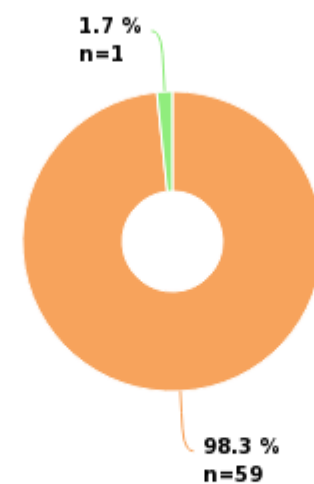
Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Rheumatoid factor (RF)	2	2	100 %	3.9 %	96.1 %	76
	CCPAb	-	-	-	-	98.3 %	60
Total:		2	2	100 %	2.9 %	97.1 %	136

Sample S002 Rheumatoid factor (RF)



Legend: Negative (Orange), Borderline (Blue), Positive (Green)

Sample S002 CCPAb



Legend: Negative (Orange), Positive (Green)

OWN DEVICE: ARCH 8200

Rheumatoid factor (RF)	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		73		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Abbott Rheumatoid Factor (RF)		13					
		Aidian (Orion Diagnostica) RF-PAIA		1					
		Beckman Coulter RF Latex		4					
		Beckman nephelometry		1					
		BioSystems RHEUMATOID FACTORS (RF) - SLIDE		1					
		Cormay RF		1					
		Diesse Chorus RF-M		1					
		Hydrex RF Latex		2					
		Orgentec Reumatoid Factor Alegria		1					
		Roche Rheumatoid Factors II (RF-II)		28					
		Siemens Advia RF assay		1					
		Siemens Atellica RF		6					
		Siemens Dimension Vista RF assay		1					
		Siemens Nephelometry		5					
		Thermo Scientific Phadia EliA RF IgM		4					
		Thermo Scientific Rheumatoid factors 2		3					
	<input type="radio"/> Borderline		1		-				0 %
		Roche Rheumatoid Factors II (RF-II)		1					
	<input type="radio"/> Positive		2		-				0 %
		Roche Rheumatoid Factors II (RF-II)		1					

	The Binding Site Optilite		1						
Total:		76		2	2	100 %	3.9 %	96.1 %	

CCPAb	Interpretation	Methodics	Interpretation count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		59		-				100 %
		Abbott Anti-CCP		12					
		Aesku Diagnostics CCP Aeskulisa		1					
		Diesse Chorus line Anti-CCP		1					
		Euroimmun ELISA		1					
		Inova Quanta Flash CCP3		1					
		MEDIPAN Medizym anti-CCP Ref		1					
		Orgentec Anti-CCP hs Alegria		2					
		Roche Anti-CCP assay		15					
		Siemens Atellica Anti-CCP		5					
		Thermo Scientific Phadia ELIA CCP		20					
	Positive		1		-				0 %
		Abbott Anti-CCP		1					
Total:			60		-	-	-	-	98.3 %

Report Info**PARTICIPANTS**

Altogether 88 laboratories from 17 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.

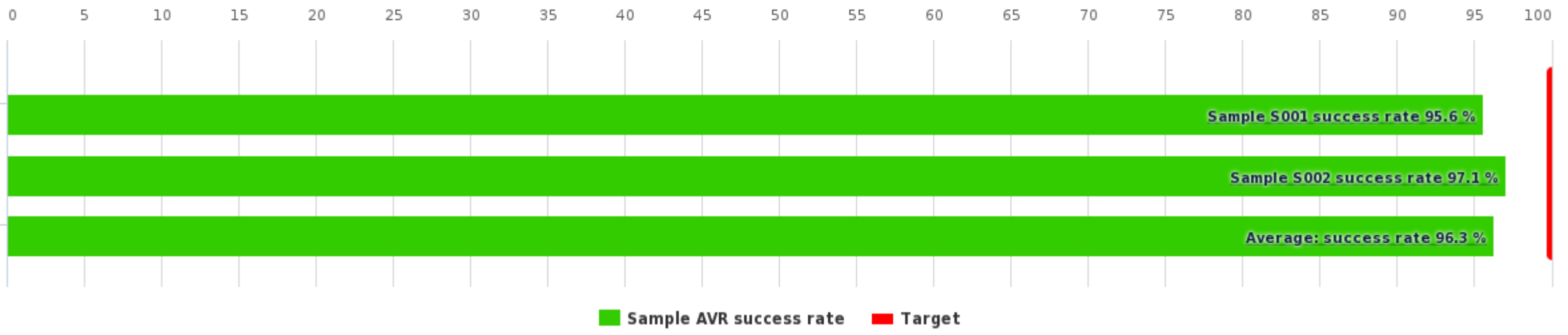
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Rheumatoid factor and citrullic peptide antibodies, January, 1-2023	88	83	94.3 %

Summary

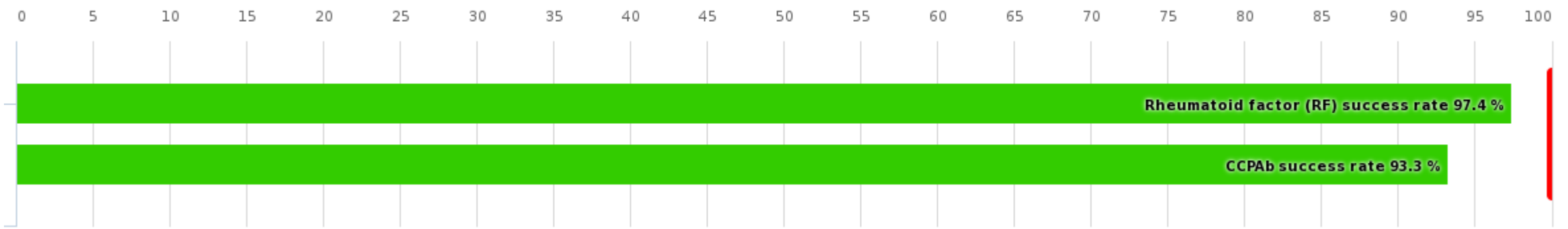
Overall success rate by samples



Summary	AVR success rate
Sample S001	95.6 %
Sample S002	97.1 %
Average:	96.3 %

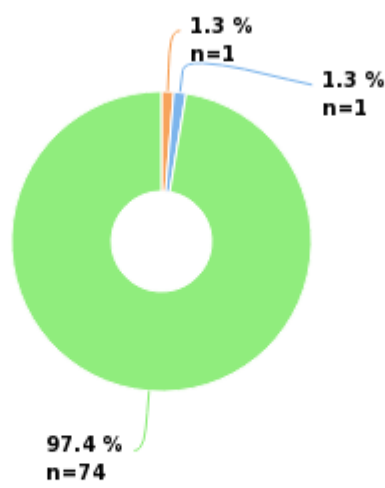
Sample S001

Sample S001 success rate



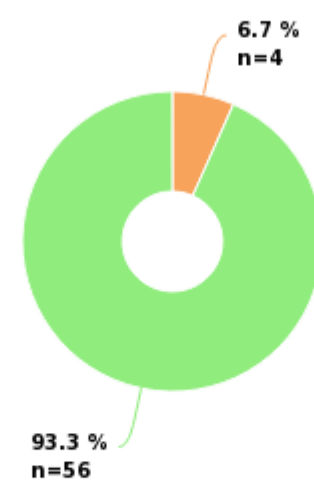
Sample S001 results	Responded	AVR success rate	Count
	Rheumatoid factor (RF)	97.4 %	76
	CCPAb	93.3 %	60
	Total:	95.6 %	136

Sample S001 Rheumatoid factor (RF)



Legend: Negative (orange), Borderline (blue), Positive (green)

Sample S001 CCPAb



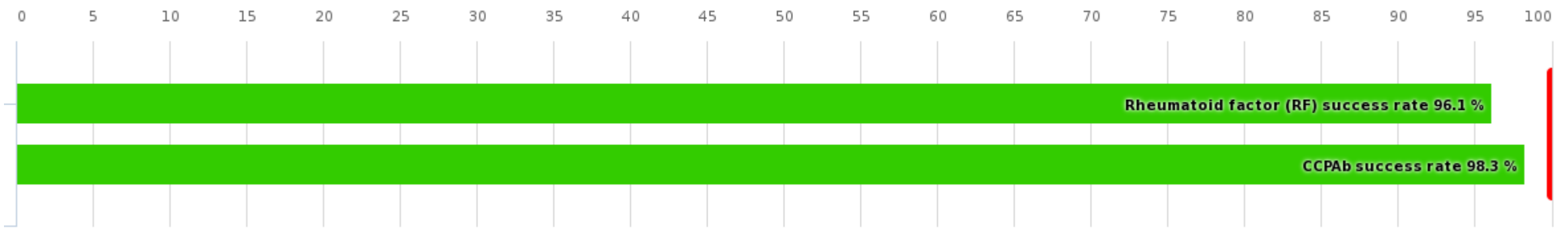
Legend: Negative (orange), Positive (green)

Rheumatoid factor (RF)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		1		0 %	0
		Roche Rheumatoid Factors II (RF-II)		1		
	Borderline		1		0 %	0
		Roche Rheumatoid Factors II (RF-II)		1		
	Positive		74		100 %	2
		Abbott Rheumatoid Factor (RF)		13		
		Aidian (Orion Diagnostica) RF-PAIA		1		
		Beckman Coulter RF Latex		4		
		Beckman nephelometry		1		
		BioSystems RHEUMATOID FACTORS (RF) - SLIDE		1		
		Cormay RF		1		
		Diesse Chorus RF-M		1		
		Hydrex RF Latex		2		
		Orgentec Reumatoid Factor Alegria		1		
		Roche Rheumatoid Factors II (RF-II)		28		
		Siemens Advia RF assay		1		
		Siemens Atellica RF		6		
		Siemens Dimension Vista RF assay		1		
		Siemens Nephelometry		5		
		The Binding Site Optilite		1		
		Thermo Scientific Phadia EliA RF IgM		4		
		Thermo Scientific Rheumatoid factors 2		3		
	Total:		76		97.4 %	

CCPAb	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		4		0 %	0
		Abbott Anti-CCP		1		
		Diesse Chorus line Anti-CCP		1		
		Orgentec Anti-CCP hs Alegria		2		
	Positive		56		100 %	2
		Abbott Anti-CCP		12		
		Aesku Diagnostics CCP Aeskulisa		1		
		Euroimmun ELISA		1		
		Inova Quanta Flash CCP3		1		
		MEDIPAN Medizym anti-CCP Ref		1		
		Roche Anti-CCP assay		15		
		Siemens Atellica Anti-CCP		5		
		Thermo Scientific Phadia ELIA CCP		20		
	Total:		60		93.3 %	

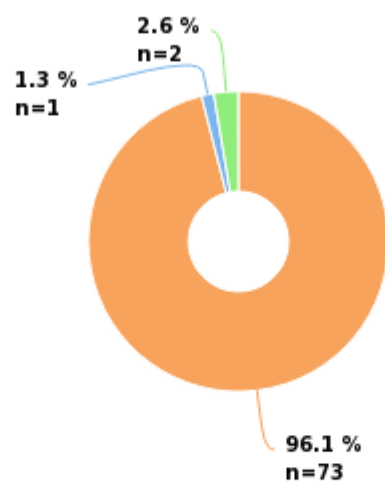
Sample S002

Sample S002 success rate



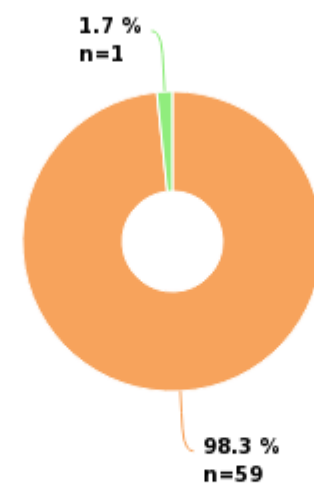
Sample S002 results	Responded	AVR success rate	Count
	Rheumatoid factor (RF)	96.1 %	76
	CCPAb	98.3 %	60
	Total:	97.1 %	136

Sample S002 Rheumatoid factor (RF)



Legend: Negative (Orange), Borderline (Blue), Positive (Green)

Sample S002 CCPAb



Legend: Negative (Orange), Positive (Green)

Rheumatoid factor (RF)	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		73		100 %	2
		Abbott Rheumatoid Factor (RF)		13		
		Aidian (Orion Diagnostica) RF-PAIA		1		
		Beckman Coulter RF Latex		4		
		Beckman nephelometry		1		
		BioSystems RHEUMATOID FACTORS (RF) - SLIDE		1		
		Cormay RF		1		
		Diesse Chorus RF-M		1		
		Hydrex RF Latex		2		
		Orgentec Reumatoid Factor Alegria		1		
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		Siemens Atellica RF		6		
		Siemens Dimension Vista RF assay		1		
		Siemens Nephelometry		5		
		Thermo Scientific Phadia EliA RF IgM		4		
		Thermo Scientific Rheumatoid factors 2		3		
	Borderline		1		0 %	0
		Roche Rheumatoid Factors II (RF-II)		1		
	Positive		2		0 %	0
		Roche Rheumatoid Factors II (RF-II)		1		
		The Binding Site Optilite		1		
	Total:		76		96.1 %	

CCPAb	Interpretation	Methodics	Interpretation count	Methodics count	AVR success rate	Interpretation Score
	Negative		59		100 %	2
		Abbott Anti-CCP		12		
		Aesku Diagnostics CCP Aeskulisa		1		
		Diesse Chorus line Anti-CCP		1		
		Euroimmun ELISA		1		
		Inova Quanta Flash CCP3		1		
		MEDIPAN Medizym anti-CCP Ref		1		
		Orgentec Anti-CCP hs Alegria		2		
		Roche Anti-CCP assay		15		
		Siemens Atellica Anti-CCP		5		
		Thermo Scientific Phadia ELIA CCP		20		
	Positive		1		0 %	0
		Abbott Anti-CCP		1		
	Total:		60		98.3 %	

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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

Rheumatoid Factor and Citrullinic Peptide Antibodies Round 1, 2023

Specimens

Samples of this EQA round were liquid human-derived preparations. 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 (LQ717623011)

RF Positive, concentration 183 IU/mL
CCPAb Positive, concentration 22 kU/L

Sample S002 (LQ717623012)

RF Negative, concentration <15 IU/mL
CCPAb Negative, concentration <7 kU/L

Pretest methods: Roche cobas RF-II and Thermo Scientific Phadia EliA CCP.

Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – Expert

The first RF and CCPAb quality assessment round of the year comprised one sample interpreted as clearly positive (S001), and one sample interpreted as negative (S002) regarding both analytes. The round went excellently, and the mean success rate from the samples was 96.3%. Although some deviations were detected, they were mainly due to sample confusions and typo errors.

Of the negative sample S002, all Roche anti-CCP assay users also had obtained the expected negative result. This sample was prepared in a serum matrix. Thus, false positive CCPAb results reported by the Roche method from negative samples in previous rounds were probably due to the previously used sample matrix. We will try to take this into account in future rounds.

RF and CCPAb EQA samples with high concentrations do not need to be diluted, it is sufficient that the result is reported > the upper limit of the method. Of the results reported in this way, we report numbers by analytes and methods in the Final report.

For sample S001, one RF result was reported >500 IU/mL with the Orgentec Reumatoid Factor Alegria test. Also, one CCPAb result was reported below (<) the measurement range or reference value of the method with the DIESSE Chorus line Anti-CCP test.

For sample S002, a total of 21/73 RF and 23/60 CCPAb results were reported below (<) the measurement range or reference value of the method. Only the quantitative results of the positive samples are presented as histograms as well as a numerical summary table.

Exceptions in scoring

No exceptions.

2023-03-03

FINAL REPORT

Product no. 5820

Subcontracting: Sample pretesting

Samples sent 2023-01-24
Round closed 2023-02-16
Final report 2023-03-03

Request for correction

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

Authorized by

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Expert

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End of report

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