

External Quality Assessment Scheme

## EBV mononucleosis, POCT Round 1, 2023

### Specimens

Please find enclosed 3 human plasma 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 are found to be HBsAg, HCVAb and HIVAgAb 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

MonAb, POCT

### 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. The participants of this EQA scheme are able to report three (3) results for each sample, provided that the material is sufficient for additional analysis. To open a new result form, press the "Add result +" button on the right side of the blue bar for each sample in LabScala. All reported examinations will be scored.

S001



S002



S003



2023-02-14

### INSTRUCTIONS

Product no. 5640  
LQ776123011-013/FI

Subcontracting: Sample preparation, sample pretesting

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi).

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The results should be reported no later than **March 9, 2023**.

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

### Inquiries

EQA Coordinator  
Kati Luiro  
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### Labquality Oy

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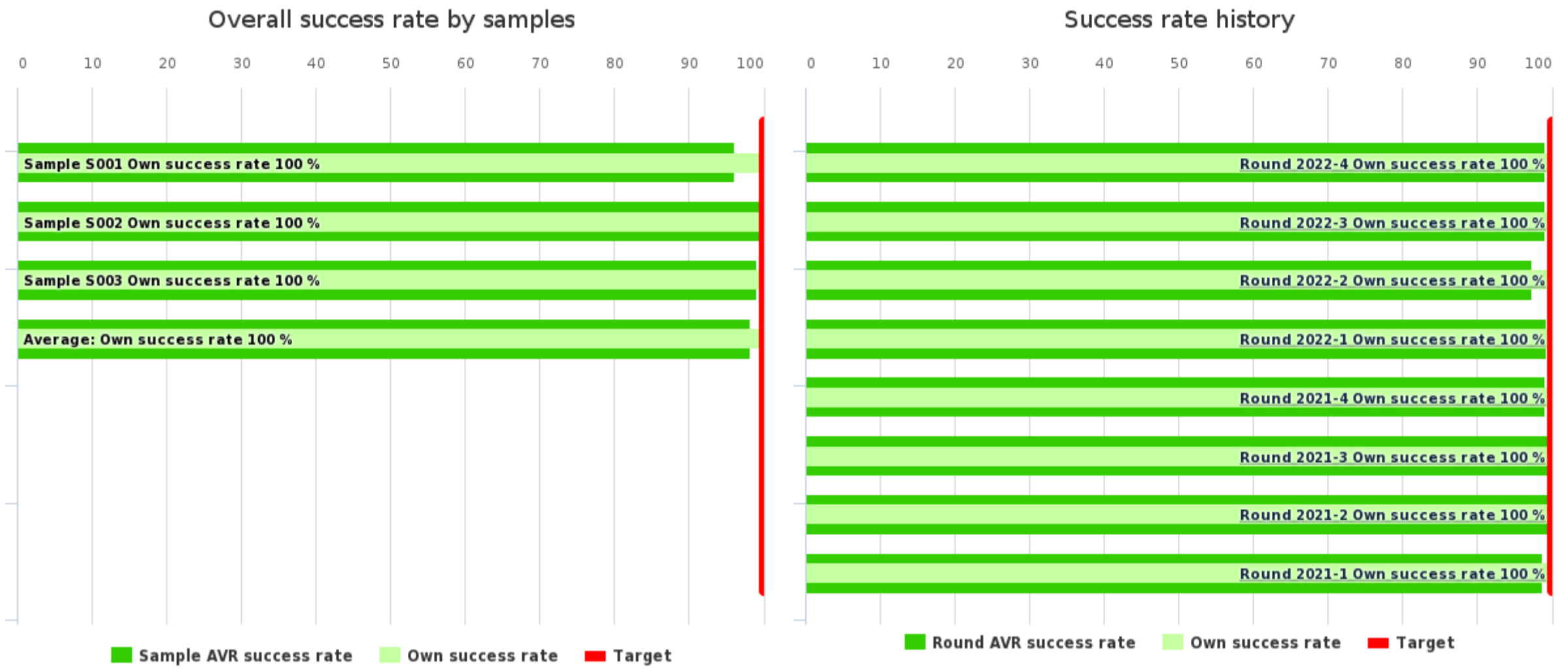
[info@labquality.fi](mailto:info@labquality.fi)  
[www.labquality.com](http://www.labquality.com)



Client report

	No of participants	No of responded participants	Response percentage
EBV mononucleosis, POCT, February, 1-2023	262	254	96.9 %

Summary

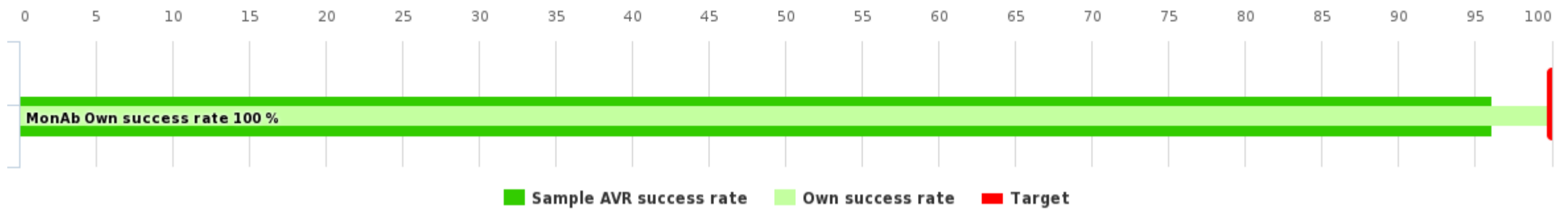


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	3.9 %	96.1 %
Sample S002	2	2	100 %	0.4 %	99.6 %
Sample S003	2	2	100 %	0.8 %	99.2 %
Average:			100 %	1.7 %	98.3 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	0.8 %	99.2 %
Round 2022-3	1-1	100 %	0.9 %	99.1 %
Round 2022-2	1-1	100 %	2.6 %	97.4 %
Round 2022-1	1-1	100 %	0.7 %	99.3 %
Round 2021-4	1-1	100 %	0.9 %	99.1 %
Round 2021-3	1-1	100 %	0.5 %	99.5 %
Round 2021-2	1-1	100 %	0.3 %	99.7 %
Round 2021-1	1-1	100 %	1.2 %	98.8 %

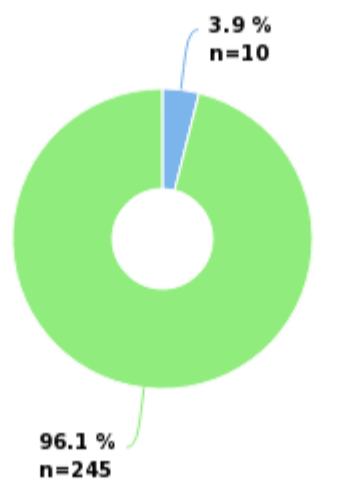
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	MonAb	2	2	100 %	3.9 %	96.1 %	255
	Total:	2	2	100 %	3.9 %	96.1 %	255

Sample S001 MonAb



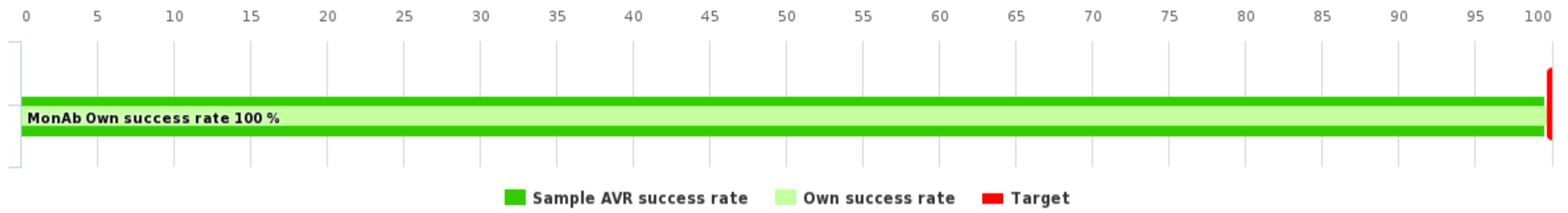
■ Negative ■ Positive

MonAb	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		10		-				0 %
		Acro Biotech MONO Rapid Test Cassette		1					
		Bio-Rad BioPlex 2200 EBV IgM		1					
		ELITechGroup ELITex Bicolor Mono		1					
		Fumouze Diagnostics M.N.I. Test Fumouze		2					
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		3					
		nal von minden Nadal Mononucleosis		2					
	<input checked="" type="radio"/> Positive		245		2	2	100 %	0 %	100 %
		Abbott Clearview IM		5					
		<input checked="" type="radio"/> Abbott Clearview IM II		122					
		All. Diag Mnitop		2					
		Biokit Monogen		8					
		Biosynex Mnitop optima IM		7					
		Biosynex MONO BSS		7					
		CITEST Mono Rapid Test Cassette		1					
		DIPROMed Rapid mononucleosis test cassette		1					
		Fumouze Diagnostics M.N.I. Test Fumouze		3					
		Giese Diagnostics Infectious Mononucleosis		1					
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		32					
		Hitado Mononukleose		2					
		Innovacon InstAlert		3					
		Launch Dianostics Accusay Mono		5					
		Meridian Monospot		2					

		nal von minden Nadal Mononucleosis		31					
		Oxoid Infectious Mononucleosis kit		1					
		Quidel QuickVue		1					
		Sekisui Diagnostics OSOM Mono Test		11					
	Total:		255		2	2	100 %	3.9 %	96.1 %

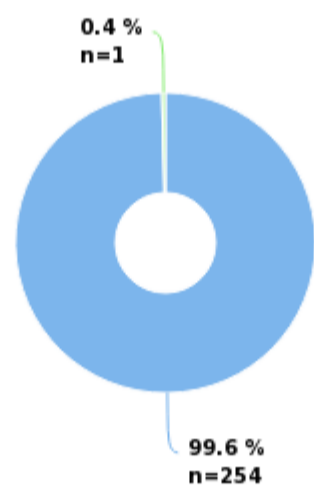
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	MonAb	2	2	100 %	0.4 %	99.6 %	255
Total:		2	2	100 %	0.4 %	99.6 %	255

Sample S002 MonAb



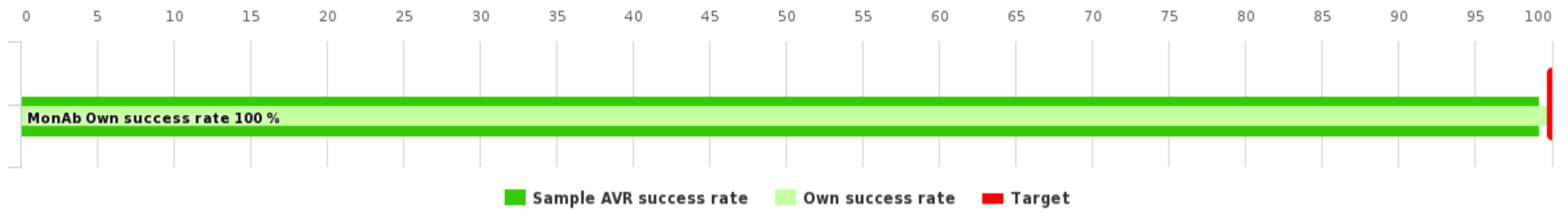
■ Negative ■ Positive

MonAb	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		254		2	2	100 %	0 %	100 %
		Abbott Clearview IM		5					
		<input checked="" type="radio"/> Abbott Clearview IM II		122					
		Acro Biotech MONO Rapid Test Cassette		1					
		All. Diag Mnitop		2					
		Bio-Rad BioPlex 2200 EBV IgM		1					
		Biokit Monogen		8					
		Biosynex Mnitop optima IM		7					
		Biosynex MONO BSS		7					
		CITEST Mono Rapid Test Cassette		1					
		DIPROMed Rapid mononucleosis test cassette		1					
		ELITechGroup ELITex Bicolor Mono		1					
		Fumouze Diagnostics M.N.I. Test Fumouze		5					
		Giese Diagnostics Infectious Mononucleosis		1					
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		35					
		Hitado Mononukleose		2					
		Innovacon InstAlert		3					
		Launch Dianostics Accusay Mono		5					
		Meridian Monospot		2					
		nal von minden Nadal Mononucleosis		32					
		Oxoid Infectious Mononucleosis kit		1					
		Quidel QuickVue		1					
		Sekisui Diagnostics OSOM Mono Test		11					
	<input type="radio"/> Positive		1		-				0 %
		nal von minden Nadal Mononucleosis		1					

Total:		255		2	2	100 %	0.4 %	99.6 %
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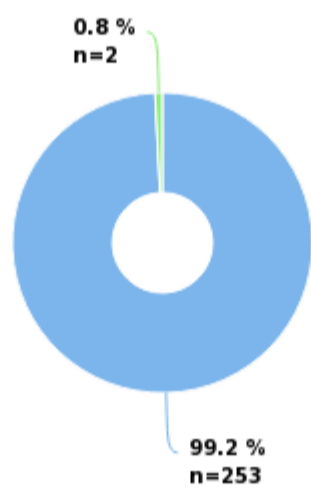
Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	MonAb	2	2	100 %	0.8 %	99.2 %	255
Total:		2	2	100 %	0.8 %	99.2 %	255

Sample S003 MonAb



■ Negative ■ Positive

MonAb	Result	Test kit	Result count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		253		2	2	100 %	0 %	100 %
		Abbott Clearview IM		4					
		<input checked="" type="radio"/> Abbott Clearview IM II		121					
		Acro Biotech MONO Rapid Test Cassette		1					
		All. Diag Mnitop		2					
		Bio-Rad BioPlex 2200 EBV IgM		1					
		Biokit Monogen		8					
		Biosynex Mnitop optima IM		7					
		Biosynex MONO BSS		7					
		CITEST Mono Rapid Test Cassette		1					
		DIPROMed Rapid mononucleosis test cassette		1					
		ELITechGroup ELITex Bicolor Mono		1					
		Fumouze Diagnostics M.N.I. Test Fumouze		5					
		Giese Diagnostics Infectious Mononucleosis		1					
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		35					
		Hitado Mononukleose		2					
		Innovacon InstAlert		3					
		Launch Dianostics Accusay Mono		5					
		Meridian Monospot		2					
		nal von minden Nadal Mononucleosis		33					
		Oxoid Infectious Mononucleosis kit		1					
		Quidel QuickVue		1					
		Sekisui Diagnostics OSOM Mono Test		11					
	<input type="radio"/> Positive		2		-				0 %
		Abbott Clearview IM		1					

		Abbott Clearview IM II		1					
	Total:		255		2	2	100 %	0.8 %	99.2 %



**Report Info****PARTICIPANTS**

Altogether 262 laboratories from 16 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
EBV mononucleosis, POCT, February, 1-2023	262	254	96.9 %

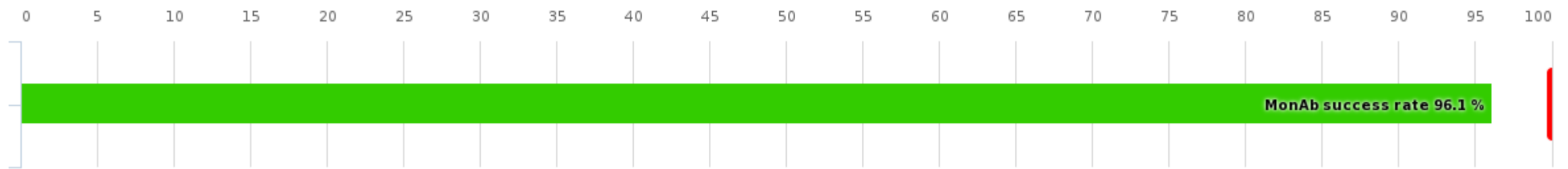
Summary



Summary	AVR success rate
Sample S001	96.1 %
Sample S002	99.6 %
Sample S003	99.2 %
Average:	98.3 %

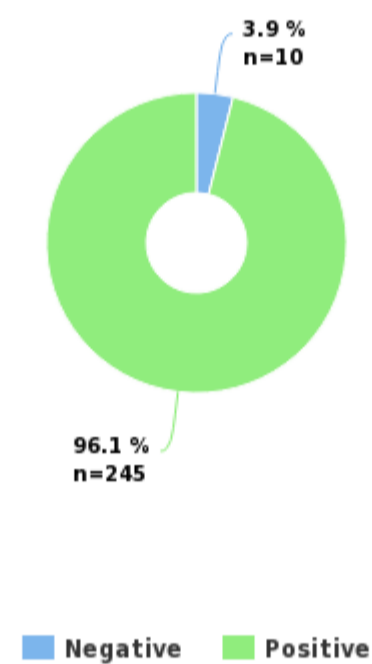
### Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	MonAb	96.1 %	255
	Total:	96.1 %	255

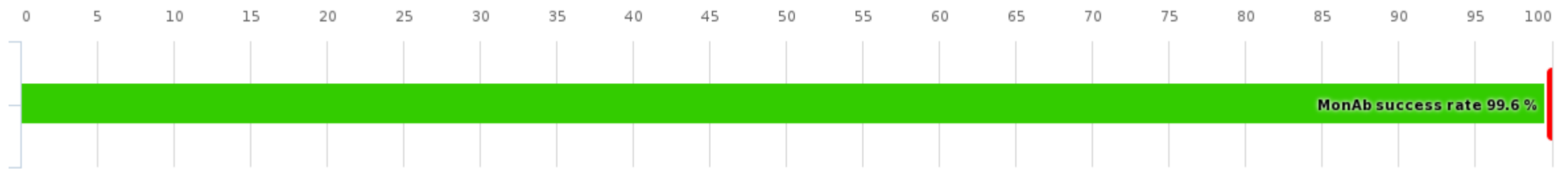
Sample S001 MonAb



MonAb	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		10		0 %	0
		Acro Biotech MONO Rapid Test Cassette		1		
		Bio-Rad BioPlex 2200 EBV IgM		1		
		ELITechGroup ELITex Bicolor Mono		1		
		Fumouze Diagnostics M.N.I. Test Fumouze		2		
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		3		
		nal von minden Nadal Mononucleosis		2		
	Positive		245		100 %	2
		Abbott Clearview IM		5		
		Abbott Clearview IM II		122		
		All. Diag Mnitop		2		
		Biokit Monogen		8		
		Biosynex Mnitop optima IM		7		
		Biosynex MONO BSS		7		
		CITEST Mono Rapid Test Cassette		1		
		DIPROMed Rapid mononucleosis test cassette		1		
		Fumouze Diagnostics M.N.I. Test Fumouze		3		
		Giese Diagnostics Infectious Mononucleosis		1		
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		32		
		Hitado Mononukleose		2		
		Innovacon InstAlert		3		
		Launch Dianostics Accusay Mono		5		
		Meridian Monospot		2		
		nal von minden Nadal Mononucleosis		31		
		Oxoid Infectious Mononucleosis kit		1		
		Quidel QuickVue		1		
		Sekisui Diagnostics OSOM Mono Test		11		
	Total:		255		96.1 %	

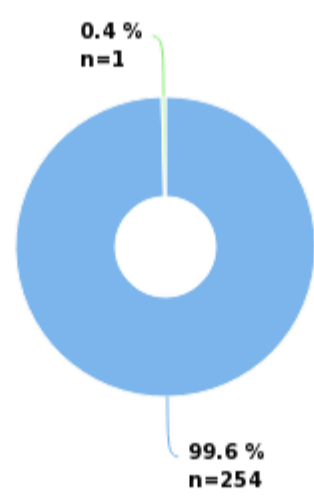
### Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	MonAb	99.6 %	255
	Total:	99.6 %	255

Sample S002 MonAb

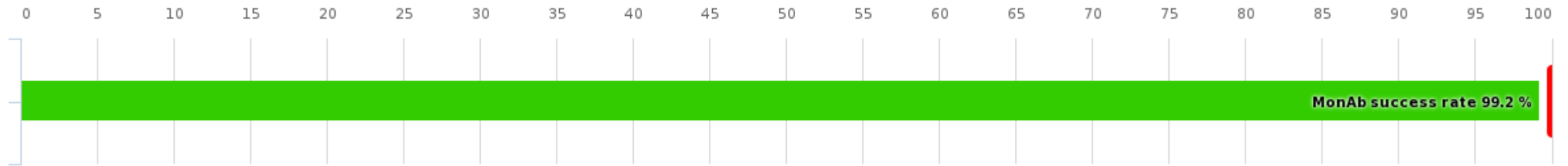


■ Negative ■ Positive

MonAb	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		254		100 %	2
		Abbott Clearview IM		5		
		Abbott Clearview IM II		122		
		Acro Biotech MONO Rapid Test Cassette		1		
		All. Diag Mnitop		2		
		Bio-Rad BioPlex 2200 EBV IgM		1		
		Biokit Monogen		8		
		Biosynex Mnitop optima IM		7		
		Biosynex MONO BSS		7		
		CITEST Mono Rapid Test Cassette		1		
		DIPROMed Rapid mononucleosis test cassette		1		
		ELITechGroup ELITex Bicolor Mono		1		
		Fumouze Diagnostics M.N.I. Test Fumouze		5		
		Giesse Diagnostics Infectious Mononucleosis		1		
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		35		
		Hitado Mononukleose		2		
		Innovacon InstAlert		3		
		Launch Dianostics Accusay Mono		5		
		Meridian Monospot		2		
		nal von minden Nadal Mononucleosis		32		
		Oxoid Infectious Mononucleosis kit		1		
		Quidel QuickVue		1		
		Sekisui Diagnostics OSOM Mono Test		11		
	Positive		1		0 %	0
		nal von minden Nadal Mononucleosis		1		
	Total:		255		99.6 %	

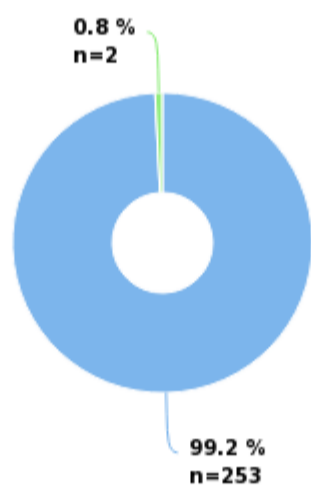
### Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	MonAb	99.2 %	255
	Total:	99.2 %	255

Sample S003 MonAb



■ Negative ■ Positive

MonAb	Result	Test kit	Result count	Test kit count	AVR success rate	Result Score
	Negative		253		100 %	2
		Abbott Clearview IM		4		
		Abbott Clearview IM II		121		
		Acro Biotech MONO Rapid Test Cassette		1		
		All. Diag Mnitop		2		
		Bio-Rad BioPlex 2200 EBV IgM		1		
		Biokit Monogen		8		
		Biosynex Mnitop optima IM		7		
		Biosynex MONO BSS		7		
		CITEST Mono Rapid Test Cassette		1		
		DIPROMed Rapid mononucleosis test cassette		1		
		ELITechGroup ELITex Bicolor Mono		1		
		Fumouze Diagnostics M.N.I. Test Fumouze		5		
		Giesse Diagnostics Infectious Mononucleosis		1		
		Hangzhou AllTest Biotech Mono Rapid Test Cassette		35		
		Hitado Mononukleose		2		
		Innovacon InstAlert		3		
		Launch Dianostics Accusay Mono		5		
		Meridian Monospot		2		
		nal von minden Nadal Mononucleosis		33		
		Oxoid Infectious Mononucleosis kit		1		
		Quidel QuickVue		1		
		Sekisui Diagnostics OSOM Mono Test		11		
	Positive		2		0 %	0
		Abbott Clearview IM		1		
		Abbott Clearview IM II		1		
	Total:		255		99.2 %	

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External Quality Assessment Scheme

## EBV mononucleosis, POCT Round 1, 2023

### Specimens

Samples of this EQA round were human plasma, 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 accepted results were as follows:

Sample S001 (LQ776123011)  
MonAb Positive

Sample S002 (LQ776123012)  
MonAb Negative

Sample S003 (LQ776123013)  
MonAb Negative

Pre-test method: Abbott Clearview IM 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

In the first round of the year, a total of 262 set of samples were distributed to the participants, of which 96.9% (n=254) reported their results within the specified period. The average success rate for the whole round was 98.3%, which was an excellent result overall.

### Exceptions in scoring

No exceptions.

### End of report

2023-03-14

### FINAL REPORT

Product no. 5640

Subcontracting: Sample preparation,  
sample pretesting

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

### 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  
Kati Luiro  
kati.luiro@labquality.fi

### Expert

PhD, Clinical Microbiologist  
Jari Martelin,  
Uniogen, Turku, Finland

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