LABQUALITY

External Quality Assessment Scheme

CMV and EBV, nucleic acid detection, quantitative
Round 1, 2023

Specimens
Please find enclosed 5 plasma simulating samples S001, S002, S003, S004 and S005, each 1.5 mL.

Caution
Specimens do not contain viable microorganisms or viruses. The specimens are HBsAg, HIVAb and HCVAb negative according to the supplier. However, no known test method offers complete assurance that hepatitis B virus, HIV or other infectious agents are absent, and the specimens should therefore be handled with the same care as corresponding patient specimens.

Examinations
CMV NAT, quantitative
EBV NAT, quantitative

Storage and use
After arrival, the samples should be stored at +2…8 °C and analyzed as soon as possible. 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 method from the registry, please contact the EQA Coordinator. Report only the results of examinations that are in use in your laboratory. Please report quantitative results in IU/mL. Only qualitative results will be scored.

S001


S002


S003


S004


S005


2023-03-07

INSTRUCTIONS

Product no. 5651
LQ776223011-015/US

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 31, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 5, 2023.

Inquiries
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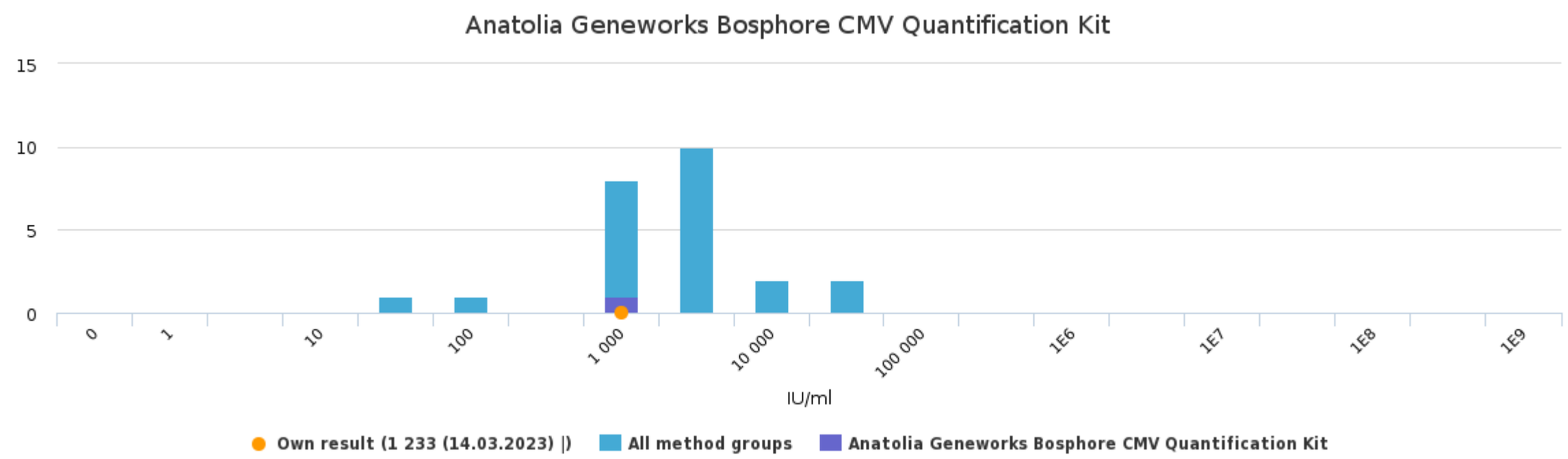
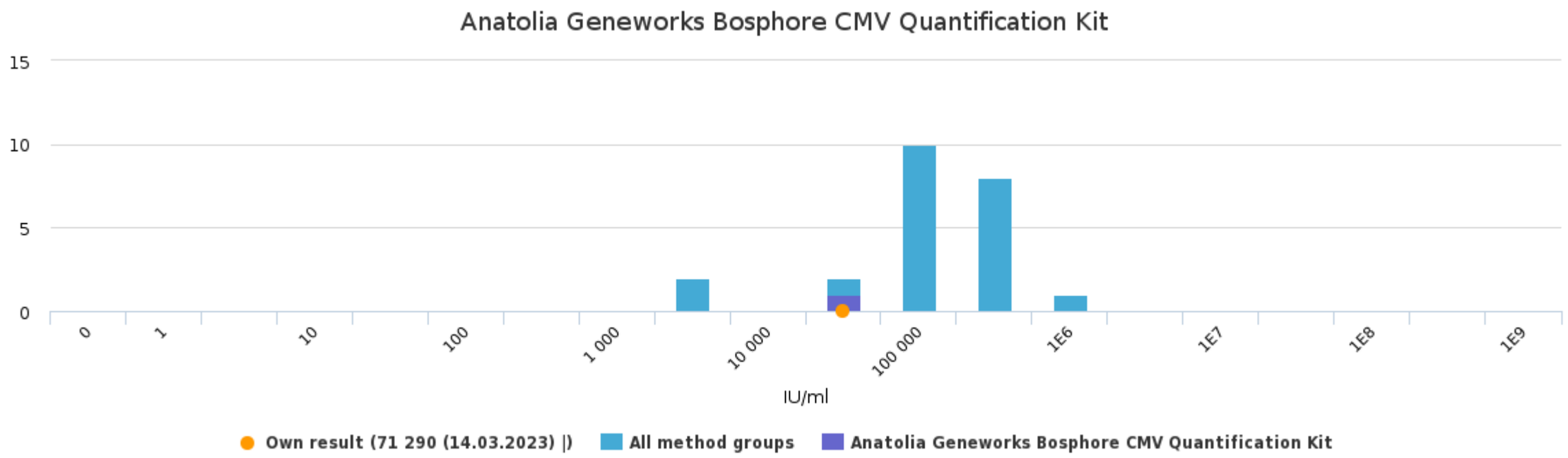
Sample S002 | CMV NAT, IU/ml



	Median	min	max	n
Anatolia Geneworks Bosphore CMV Quantification Kit	-	1 233	1 233	1
All methods	4 392	59	44 807	24

Sample S005 | CMV NAT, IU/ml



	Median	min	max	n
Anatolia Geneworks Bosphore CMV Quantification Kit	-	71 290	71 290	1
All methods	262 433	3 822	893 435	23

Report info

Participants

28 participants from 10 countries.

Report info

The quantitative results from the positive samples are presented as histograms as well as a numerical summary table. Your own result should be compared to others using the same method.

The median value of each method group is the median of the results where results deviating more than +/- 3*standard deviation from the median are removed. In case the client's result is the only one in the method group, no median value will be presented. In case there are only a few results in the client's own method group, the result can be compared to all method median or to a group that is similar to the own method. Results reported with < or > signs cannot be included in the statistics. The result distribution can also be viewed graphically from the histograms.

For information on report interpretation and performance evaluation, please see the " EQAS Interpretation guidelines" LabScala User instructions (top right corner ?Help link).

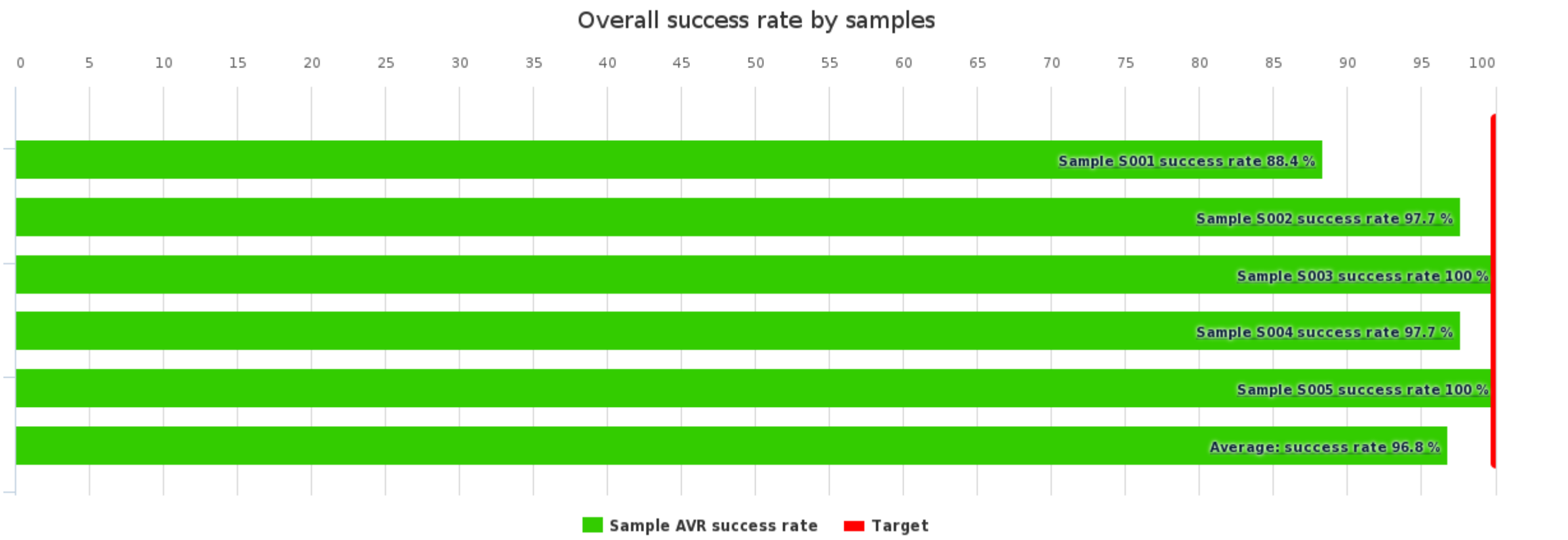
CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

Scoring report

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
CMV and EBV, nucleic acid detection, quantitative, March, 1-2023	28	25	89.3 %

Summary

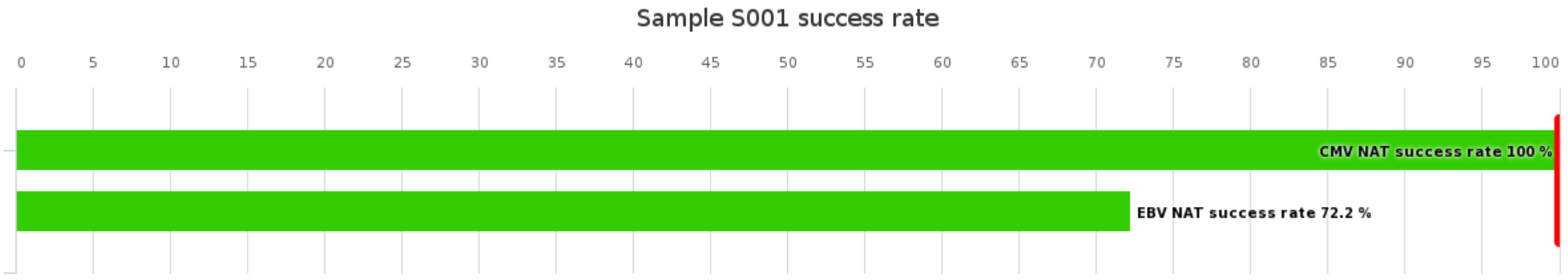


Summary	AVR success rate
Sample S001	88.4 %
Sample S002	97.7 %
Sample S003	100 %
Sample S004	97.7 %
Sample S005	100 %
Average:	96.8 %

LABQUALITY CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

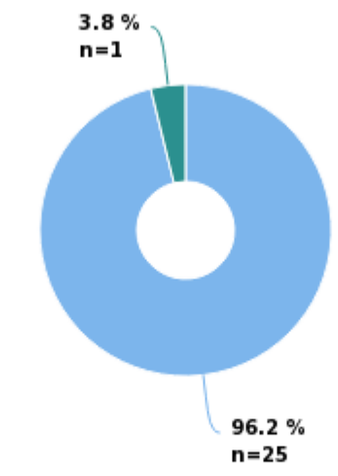
Scoring report

Sample S001

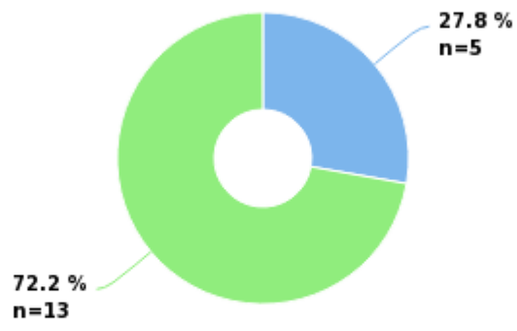


Sample S001 results	Responded	AVR success rate	Count
	CMV NAT	100 %	26
	EBV NAT	72.2 %	18
Total:		88.4 %	44

Sample S001 CMV NAT



Sample S001 EBV NAT



CMV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		25		100 %	2
		Abbott Alinity m CMV AMP Kit		2		
		Abbott RealTime CMV		1		
		Anatolia Geneworks Bosphore CMV Quantification Kit		1		
		Biocorp BC-CMV		1		
		bioMerieux CMV R-GENE		1		
		ELITechGroup CMV ELITe InGenius		8		
		GeneProof CMV PCR		4		
		NeuMoDx CMV Quant Test Strip		2		
		Qiagen Artus PCR CMV		1		
		Roche cobas CMV		3		
		Sansure Biotech Human Cytomegalovirus DNA Quantitative Fluorescence Diagnostic Kit		1		
	No result		1		-	-
		altona Diagnostics RealStar CMV PCR Kit 1.0		1		
	Total:		26		100 %	

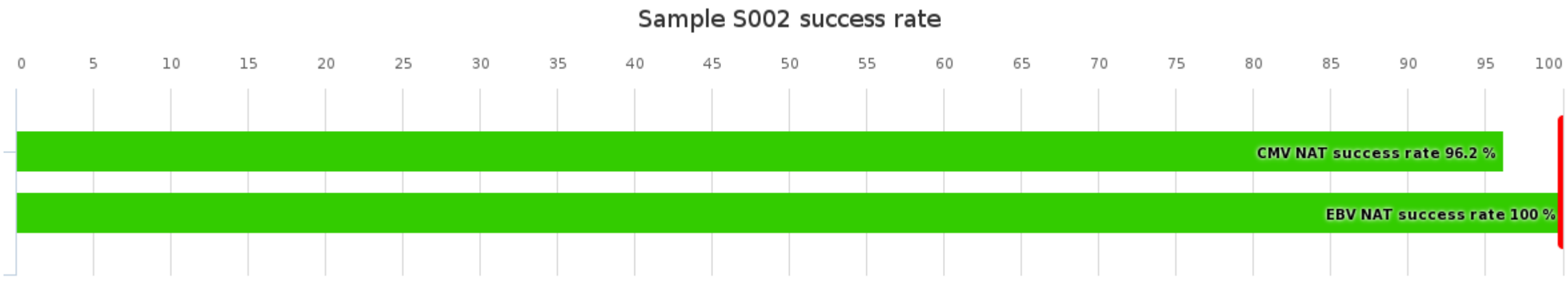
EBV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		5		0 %	0
		Abbott RealTime EBV		1		
		Biocorp BC-EBV		1		
		bioMerieux EBV R-GENE		1		
		ELITechGroup EBV ELITe InGenius		1		

		GeneProof EBV PCR		1		
	Positive		13		100 %	2
		Abbott RealTime EBV		1		
		DNA-Technology Epstein Barr virus (EBV) REAL-TIME PCR Detection Kit		1		
		ELITechGroup EBV ELITe InGenius		5		
		GeneProof EBV PCR		2		
		NeuMoDx EBV Quant Test Strip		2		
		Qiagen Artus PCR EBV		1		
		Roche cobas EBV		1		
	Total:		18		72.2 %	

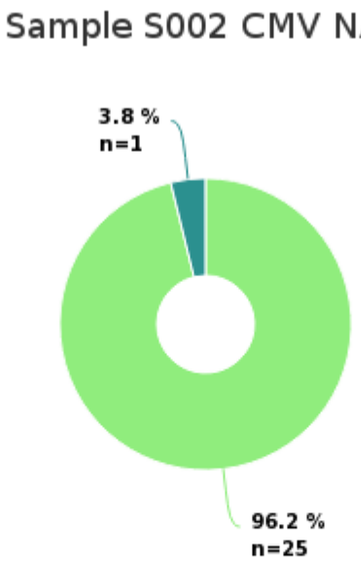
LABQUALITY CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

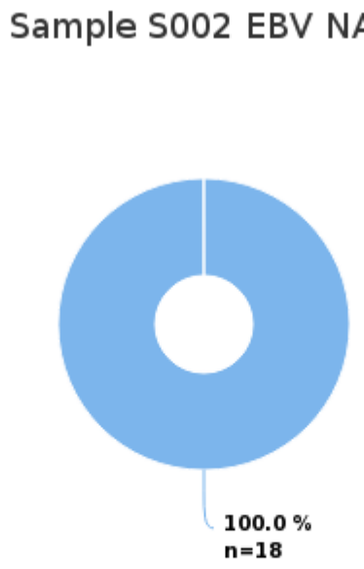
Scoring report

Sample S002



Sample S002 results	Responded	AVR success rate	Count
	CMV NAT	96.2 %	26
	EBV NAT	100 %	18
Total:		97.7 %	44





CMV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Positive		25		100 %	2
		Abbott Alinity m CMV AMP Kit		2		
		Abbott RealTime CMV		1		
		Anatolia Geneworks Bosphore CMV Quantification Kit		1		
		Biocorp BC-CMV		1		
		bioMerieux CMV R-GENE		1		
		ELITechGroup CMV ELITe InGenius		8		
		GeneProof CMV PCR		4		
		NeuMoDx CMV Quant Test Strip		2		
		Qiagen Artus PCR CMV		1		
		Roche cobas CMV		3		
		Sansure Biotech Human Cytomegalovirus DNA Quantitative Fluorescence Diagnostic Kit		1		
	No result		1		0 %	0
		altona Diagnostics RealStar CMV PCR Kit 1.0		1		
	Total:		26		96.2 %	

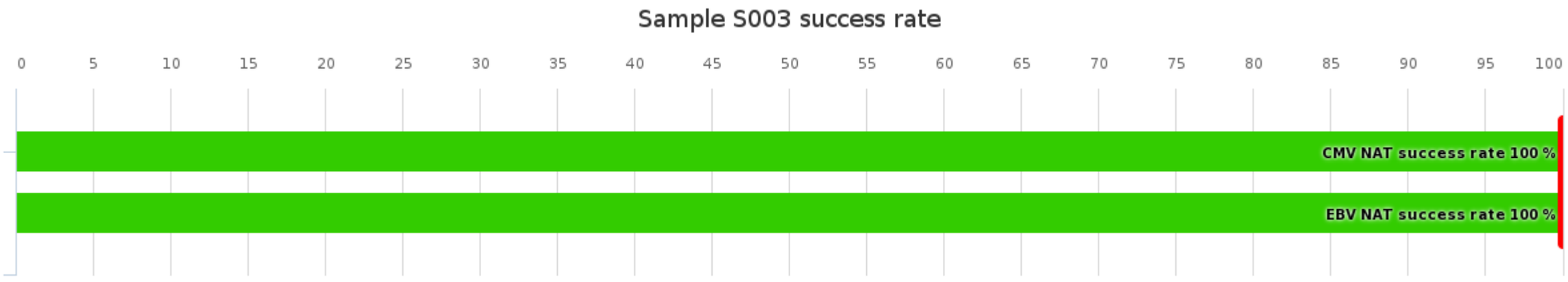
EBV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		18		100 %	2
		Abbott RealTime EBV		2		
		Biocorp BC-EBV		1		
		bioMerieux EBV R-GENE		1		

		DNA-Technology Epstein Barr virus (EBV) REAL-TIME PCR Detection Kit		1		
		ELITechGroup EBV ELITe InGenius		6		
		GeneProof EBV PCR		3		
		NeuMoDx EBV Quant Test Strip		2		
		Qiagen Artus PCR EBV		1		
		Roche cobas EBV		1		
	Total:		18		100 %	

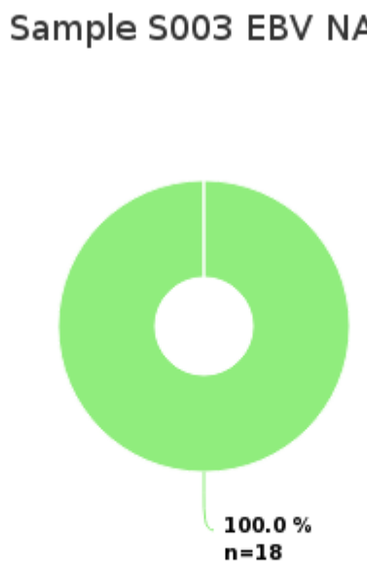
CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

Scoring report

Sample S003



Sample S003 results	Responded	AVR success rate	Count
	CMV NAT	100 %	26
	EBV NAT	100 %	18
Total:		100 %	44



CMV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		26		100 %	2
		Abbott Alinity m CMV AMP Kit		2		
		Abbott RealTime CMV		1		
		altona Diagnostics RealStar CMV PCR Kit 1.0		1		
		Anatolia Geneworks Bosphore CMV Quantification Kit		1		
		Biocorp BC-CMV		1		
		bioMerieux CMV R-GENE		1		
		ELITechGroup CMV ELITe InGenius		8		
		GeneProof CMV PCR		4		
		NeuMoDx CMV Quant Test Strip		2		
		Qiagen Artus PCR CMV		1		
		Roche cobas CMV		3		
		Sansure Biotech Human Cytomegalovirus DNA Quantitative Fluorescence Diagnostic Kit		1		
	Total:		26		100 %	

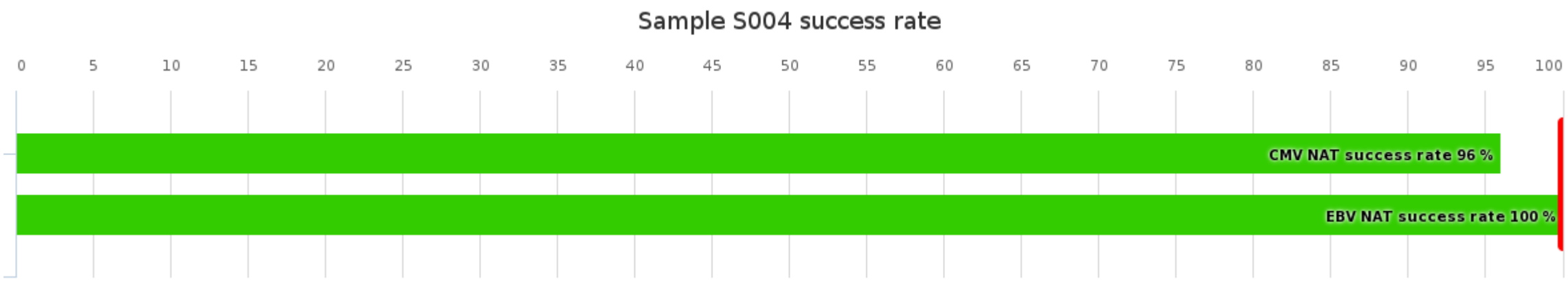
EBV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Positive		18		100 %	2
		Abbott RealTime EBV		2		
		Biocorp BC-EBV		1		
		bioMerieux EBV R-GENE		1		
		DNA-Technology Epstein Barr virus (EBV) REAL-TIME PCR Detection Kit		1		

		ELITechGroup EBV ELITe InGenius		6		
		GeneProof EBV PCR		3		
		NeuMoDx EBV Quant Test Strip		2		
		Qiagen Artus PCR EBV		1		
		Roche cobas EBV		1		
	Total:		18		100 %	

CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

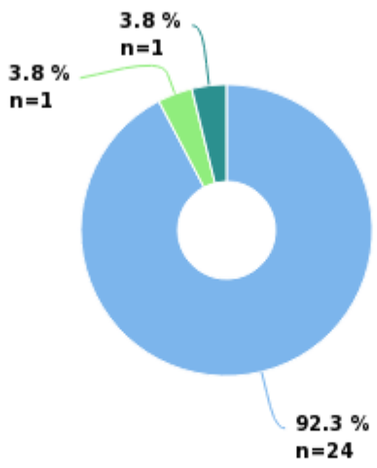
Scoring report

Sample S004

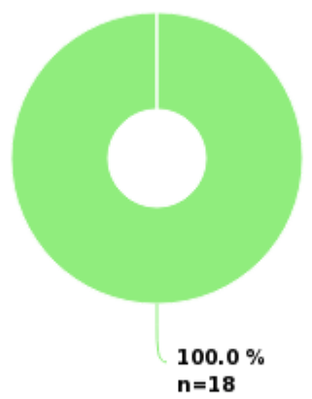


Sample S004 results	Responded	AVR success rate	Count
	CMV NAT	96 %	26
	EBV NAT	100 %	18
Total:		97.7 %	44

Sample S004 CMV NAT



Sample S004 EBV NAT



CMV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		24		100 %	2
		Abbott Alinity m CMV AMP Kit		2		
		Abbott RealTime CMV		1		
		Anatolia Geneworks Bosphore CMV Quantification Kit		1		
		Biocorp BC-CMV		1		
		bioMerieux CMV R-GENE		1		
		ELITechGroup CMV ELITe InGenius		7		
		GeneProof CMV PCR		4		
		NeuMoDx CMV Quant Test Strip		2		
		Qiagen Artus PCR CMV		1		
		Roche cobas CMV		3		
		Sansure Biotech Human Cytomegalovirus DNA Quantitative Fluorescence Diagnostic Kit		1		
	Positive		1		0 %	0
		ELITechGroup CMV ELITe InGenius		1		
	No result		1		-	-
		altona Diagnostics RealStar CMV PCR Kit 1.0		1		
	Total:		26		96 %	

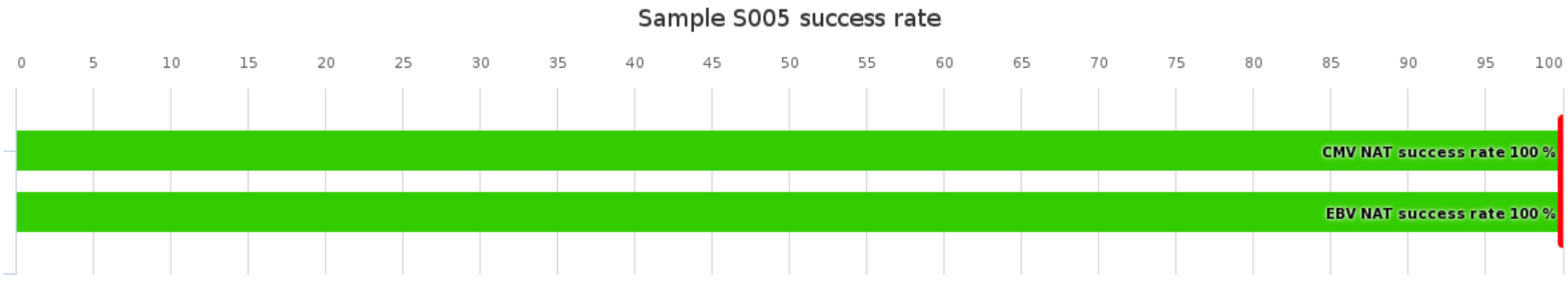
EBV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Positive		18		100 %	2
		Abbott RealTime EBV		2		
		Biocorp BC-EBV		1		

		bioMerieux EBV R-GENE		1		
		DNA-Technology Epstein Barr virus (EBV) REAL-TIME PCR Detection Kit		1		
		ELITechGroup EBV ELITe InGenius		6		
		GeneProof EBV PCR		3		
		NeuMoDx EBV Quant Test Strip		2		
		Qiagen Artus PCR EBV		1		
		Roche cobas EBV		1		
	Total:		18		100 %	

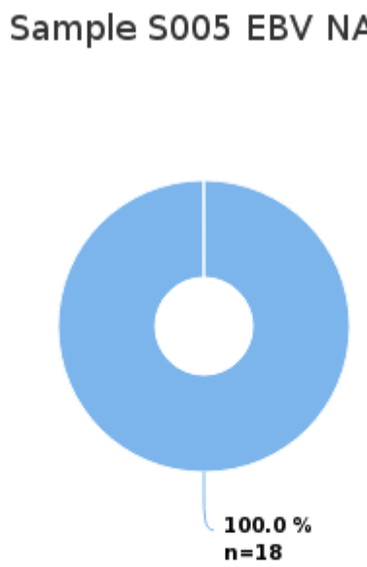
LABQUALITY CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

Scoring report

Sample S005



Sample S005 results	Responded	AVR success rate	Count
	CMV NAT	100 %	26
	EBV NAT	100 %	18
Total:		100 %	44



CMV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Positive		26		100 %	2
		Abbott Alinity m CMV AMP Kit		2		
		Abbott RealTime CMV		1		
		altona Diagnostics RealStar CMV PCR Kit 1.0		1		
		Anatolia Geneworks Bosphore CMV Quantification Kit		1		
		Biocorp BC-CMV		1		
		bioMerieux CMV R-GENE		1		
		ELITechGroup CMV ELITe InGenius		8		
		GeneProof CMV PCR		4		
		NeuMoDx CMV Quant Test Strip		2		
		Qiagen Artus PCR CMV		1		
		Roche cobas CMV		3		
		Sansure Biotech Human Cytomegalovirus DNA Quantitative Fluorescence Diagnostic Kit		1		
	Total:		26		100 %	

EBV NAT	Qualitative interpretation	Method	Qualitative interpretation count	Method count	AVR success rate	Qualitative interpretation Score
	Negative		18		100 %	2
		Abbott RealTime EBV		2		
		Biocorp BC-EBV		1		
		bioMerieux EBV R-GENE		1		
		DNA-Technology Epstein Barr virus (EBV) REAL-TIME PCR Detection Kit		1		

		ELITechGroup EBV ELITe InGenius		6		
		GeneProof EBV PCR		3		
		NeuMoDx EBV Quant Test Strip		2		
		Qiagen Artus PCR EBV		1		
		Roche cobas EBV		1		
	Total:		18		100 %	

LABQUALITY CMV and EBV, nucleic acid detection, quantitative, March, 1-2023

Scoring report

Report Info

PARTICIPANTS

Altogether 28 laboratories from 10 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.

LABQUALITY

External Quality Assessment Scheme

CMV and EBV, nucleic acid detection, quantitative
Round 1, 2023

Specimens
Samples of this EQA round were simulated 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 (LQ776223011)
CMV NAT Negative, <35 IU/mL
EBV NAT Positive, 110 IU/mL

Sample S002 (LQ776223012)
CMV NAT Positive, 3 800 IU/mL
EBV NAT Negative, <35 IU/mL

Sample S003 (LQ776223013)
CMV NAT Negative, <35 IU/mL
EBV NAT Positive, 5 000 IU/mL

Sample S004 (LQ776223014)
CMV NAT Negative, <35 IU/mL
EBV NAT Positive, 61 000 IU/mL

Sample S005 (LQ776223015)
CMV NAT Positive, 370 000 IU/mL
EBV NAT Negative, <35 IU/mL

Pre-test methods: Roche, cobas CMV and Roche, cobas EBV.

Report info
Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. The round is scored based on the qualitative results. The quantitative results from the CMV and/or EBV NAT positive samples, reported in unit IU/mL are presented in a separate laboratory-specific report as histograms as well as a numerical summary table. The quantitative results reported with < or > signs, or, if the CMV and/or EBV DNA level of the sample is >100 000 000 IU/mL, are not processed. The quantitative results cannot be compared statistically due to the low number of results. It is important to read the Final report first, because it contains important information of the samples and results in each round.

Comments – Expert
A total of 28 sets of samples were distributed for testing with 25 (89.3%) participants reporting results within the specified time-period. Some laboratories had reported results for multiple test methods.

The reported qualitative (pos./neg.) results were overall in excellent agreement with each other. The only slight variation was seen with the low positive EBV (~100 IU/mL) in sample S001, which was correctly reported by only 72.2% of the laboratories.

2023-04-14

FINAL REPORT

Product no. 5651

Subcontracting: Sample pretesting

Samples sent	2023-03-07
Round closed	2023-03-31
Expected results	2023-04-05
Final report	2023-04-14

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
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The median quantitative EBV results were as follows: sample S001: 104 IU/mL (log 2.02), S003: 9 400 IU/mL (log 3.97), and S004: 115 944 IU/mL (log 5.06). For all samples, the reported results were within 1 log of the result median.

The median quantitative CMV results were as follows: sample S002: 4 392 IU/mL (log 3.64) and S005: 262 433 IU/mL (log 5.42). Of the reported results, 85.4% were within 1 log of the result median. For sample S002, four reported results differed by more than 1 log from the result median. The discrepant results were from different methods. For sample S005, two results differed by more than 1 log from the result median, and one result differed by more than 3 logs.

Exceptions in scoring
No exceptions.

End of report