LABQUALITY

External Quality Assessment Scheme

Gastrointestinal viral multiplex, nucleic acid detection Round 1, 2023

Specimens

Please find enclosed 3 simulated faecal samples S001, S002 and S003, each 1 $\,\mathrm{mL}$.

Caution

Quality control specimens must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. According to the sample manufacturer the specimens do not contain viable microbes and the specimens are found to be HBsAg, HCVAb and HIVAb negative when tested with licensed reagents. However, no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Examinations

Please see page 2.

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. Perform the analysis according to the manufacturer's instructions for a liquid specimen.

Result reporting

Please enter the results and methods via LabScala (www.labscala.com).

Report the measurement date, test selection (tick the box) and method in the "Test selection" tab on the Pre-analytics page. If a listed pathogen is not included in your test selection, please choose "not in test selection" for the analyte in question. This information is transferred automatically to each sample and to the next round. You can change the information sample-wise or return to this page in order to change the information for all samples. If your test method is missing from the list, please contact the EQA Coordinator.

First, report the number of pathogenic findings that were identified from the sample. This question concerns only the pathogens that are included in the panel of this EQA round and are in your test selection. Next, report the pos/neg interpretation of each pathogen separately and the test result (e.g. Ct value). If you wish, you may copy e.g. interpretation "negative" to all analytes and then change the deviating results. Please note that results which are in the "draft" mode are not accepted in the result processing.

The participants are scored according to their test selection. In general, only the positive findings are scored for each sample. Interpretations "No test result" and "Invalid/unclear test result" are excluded from scoring. It is expected that the pathogens indicated in the sample content are to be identified, whereas other deviating findings will reduce the overall success rate. For those samples that are negative regarding all pathogens included in the panel of this scheme, the scoring is based on the answer given to the question "number of pathogenic findings" and the expected result would be "Negative sample, no pathogens detected".

2023-05-02

INSTRUCTIONS

Product no. 5304 LQ782823011-013/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 **May 25, 2023**.

The expected results of the round are published in LabScala in the View Reports section by May 30, 2023.

Inquiries

EQA Coordinator Kati Luiro kati.luiro@labquality.fi

Labquality Oy

Kumpulantie 15 FI-00520 HELSINKI Finland

Tel. + 358 9 8566 8200 Fax + 358 9 8566 8280

info@labquality.fi www.labquality.com





Gastrointestinal viral multiplex

Examinations

The laboratory should examine the samples according to their routine protocol.

Adenovirus Astrovirus Norovirus G1/G2 Rotavirus Sapovirus

S001



S002



S003





Client report

	No of participants	No of responded participants	Response percentage
Gastrointestinal viral multiplex, nucleic acid detection, May, 1-2023	72	69	95.8 %

Summary

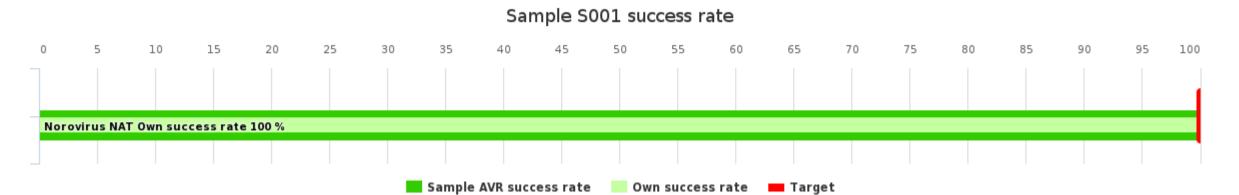


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	2	2	100 %	0 %	100 %
Sample S002	2	2	100 %	10.6 %	89.4 %
Sample S003	2	2	100 %	4.4 %	95.6 %
Average:			100 %	5 %	95 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-2	1-1	100 %	8.7 %	91.3 %
Round 2022-2	2-1	100 %	8.7 %	91.3 %
Round 2022-1	1-1	100 %	1.3 %	98.7 %
Round 2022-1	2-1	100 %	1.3 %	98.7 %

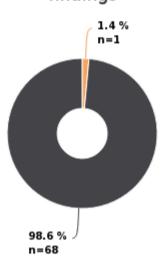
15.06.2023 1/11

Sample S001



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate
	Number of pathogenic findings	-	-	-	-	-
	Adenovirus NAT	-	-	-	-	-
	Astrovirus NAT	-	-	-	-	-
	Norovirus NAT	2	2	100 %	0 %	100 %
	Rotavirus NAT	-	-	-	-	-
	Sapovirus NAT	-	-	-	-	-
Total:		2	2	100 %	0 %	100 %

Sample S001 Number of pathogenic findings



Negative sample, no pathogens detected
Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative sample, no pathogens detected	1	-				-
Positive sample, 1 pathogen detected	68	-				-
Total:	69	_	_	_	_	

ADENOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	68	-				-
Not in test selection	1	-				-
Total:	69	-	-	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	o 20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	19	-	19
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ASTROVIRUS NAT

Copyright © Labquality Oy

15.06.2023 2/11





Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	67	-				-
Not in test selection	2	-				-
Total:	69	-	_	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	● 20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	67	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
G1 positive	26	-				100 %
Norovirus positive, no genotyping	42	2	2	100 %	0 %	100 %
Not in test selection	1	-				-
Total:	69	2	2	100 %	0 %	100 %

Method	G1 positive	Norovirus positive, no genotyping	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	-	1
BD MAX Enteric Viral Panel	-		-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	2	16	-	18
Genetic Signatures Enteric Viral ASRs	-	1	-	1
In house	1	-	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	2	4	-	6
Seegene Allplex GI-Virus Assay	18	-	-	18
SEROSEP EntericBio Viral Panel 3	2	-	-	2
Total:	26	42	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	69	-				-
Total:	69	-	-	-	-	

Method	Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1
BD MAX Enteric Viral Panel	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18
Genetic Signatures Enteric Viral ASRs	1
In house	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6
Seegene Allplex GI-Virus Assay	19
SEROSEP EntericBio Viral Panel 3	2
Total:	69

SAPOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	66	-				-
Not in test selection	3	-				-
Total:	69	-	_	-	-	

Method	Negative	Not in test selection	Total:
BD MAX Enteric Viral Panel	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6

Copyright © Labquality Oy

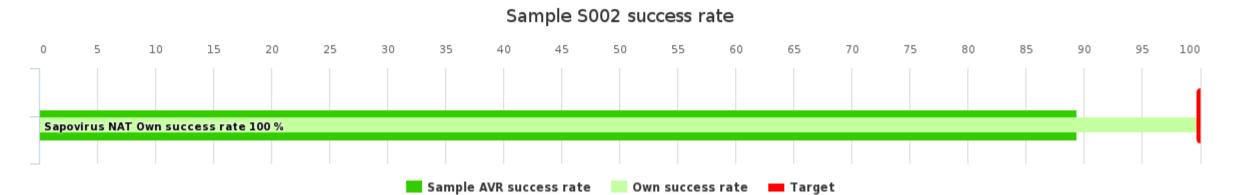
15.06.2023 3/11

XXXXX

Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	66	3	69

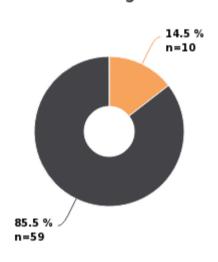
15.06.2023 4/11

Sample S002



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate
	Number of pathogenic findings	-	-	-	-	-
	Adenovirus NAT	-	-	-	-	-
	Astrovirus NAT	-	-	-	-	-
	Norovirus NAT	-	-	-	-	-
	Rotavirus NAT	-	-	-	-	-
	Sapovirus NAT	2	2	100 %	10.6 %	89.4 %
Total:		2	2	100 %	10.6 %	89.4 %

Sample S002 Number of pathogenic findings



Negative sample, no pathogens detected
Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative sample, no pathogens detected	10	-				-
Positive sample, 1 pathogen detected	59	-				-
Total:	69	_	_	_	_	

ADENOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	68	-				-
Not in test selection	1	-				-
Total:	69	-	-	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	o 20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	19	-	19
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ASTROVIRUS NAT

Copyright © Labquality Oy

15.06.2023 5/11





Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	67	-				-
Not in test selection	2	-				-
Total:	69	-	_	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	● 20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	67	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	68	-				-
Not in test selection	1	-				-
Total:	69	-	-	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	21	-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	<u> </u>	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	69	-				-
Total:	69	_	_	_	_	

Method		Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2		1
BD MAX Enteric Viral Panel	•	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel		18
Genetic Signatures Enteric Viral ASRs		1
In house		1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2		6
Seegene Allplex GI-Virus Assay		19
SEROSEP EntericBio Viral Panel 3		2
Total:		69

SAPOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	7	-				0 %
Weak positive	2	-				100 %
Positive	57	2	2	100 %	0 %	100 %
Not in test selection	3	-				-
Total:	69	2	2	100 %	10.6 %	89.4 %

Method	Negative	Weak positive	Positive	Not in test selection	Total:
BD MAX Enteric Viral Panel	1	1	18	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	1	-	17	-	18
Genetic Signatures Enteric Viral ASRs	-	-	1	-	1
In house	1	-	-	-	1

Copyright © Labquality Oy

6/11 15.06.2023

XXXXX

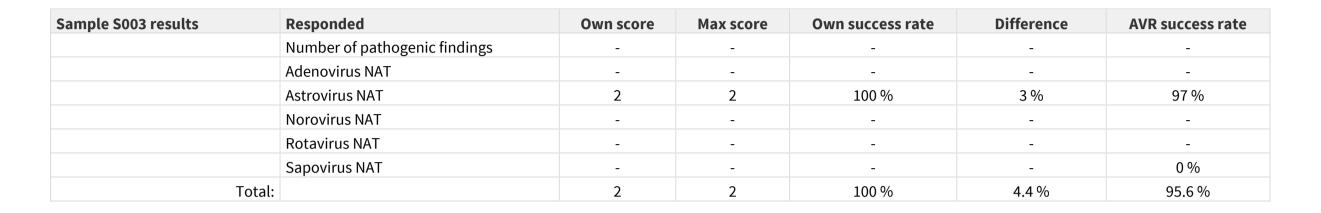
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	2	-	4	-	6
Seegene Allplex GI-Virus Assay	2	1	15	-	18
SEROSEP EntericBio Viral Panel 3	-	-	2	-	2
Total:	7	2	57	3	69

15.06.2023 7/11

Sample S003



Sample AVR success rate Own success rate Target



Sample S003 Number of pathogenic findings



Negative sample, no pathogens detected Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative sample, no pathogens detected	3	-				-
Positive sample, 1 pathogen detected	66	-				-
Total:	69	-	-	-	-	

ADENOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	68	-				-
Not in test selection	1	-				-
Total:	69	-	-	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	o 20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	<u>-</u>	18
Genetic Signatures Enteric Viral ASRs	1	<u>-</u>	1
In house	1	<u>-</u>	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	<u>-</u>	6
Seegene Allplex GI-Virus Assay	19	<u>-</u>	19
SEROSEP EntericBio Viral Panel 3	2	<u>-</u>	2
Total:	68	1	69

Copyright © Labquality Oy

15.06.2023 8/11



ASTROVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	2	-				0 %
Positive	65	2	2	100 %	0 %	100 %
Not in test selection	2	-				-
Total:	69	2	2	100 %	3 %	97 %

Method	Negative	Positive	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	-	1	<u>-</u>	1
BD MAX Enteric Viral Panel	-	● 20	<u>-</u>	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	-	18	-	18
Genetic Signatures Enteric Viral ASRs	-	1	-	1
In house	-	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	1	5	-	6
Seegene Allplex GI-Virus Assay	1	17	-	18
SEROSEP EntericBio Viral Panel 3	-	2	<u>-</u>	2
Total:	2	65	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	68	-				-
Not in test selection	1	-				-
Total:	69	-	-	-	-	

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	21	-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	<u>-</u>	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	69	-				-
Total:	69	_	_	-	-	

Method		Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2		1
BD MAX Enteric Viral Panel	•	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel		18
Genetic Signatures Enteric Viral ASRs		1
In house		1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2		6
Seegene Allplex GI-Virus Assay		19
SEROSEP EntericBio Viral Panel 3		2
Total:		69

SAPOVIRUS NAT

Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
Negative	65	-				-
Positive	1	-				0 %
Not in test selection	3	-				-
Total:	69	-	-	_	-	0 %

Method		Negative	Positive	Not in test selection	Total:
BD MAX Enteric Viral Panel	•	20	-	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel		18	-	-	18
Genetic Signatures Enteric Viral ASRs		1	-	-	1
In house		1	-	_	1

Copyright © Labquality Oy

9/11 15.06.2023

XXXXX

Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	-	6
Seegene Allplex GI-Virus Assay	17	1	-	18
SEROSEP EntericBio Viral Panel 3	2	-	-	2
Total:	65	1	3	69

15.06.2023 10/11



XXXXX

Report Info

PARTICIPANTS

Altogether 72 laboratories from 18 countries participated in this EQA round.

REPORT INFO

The reported results and the scores are presented in the same summary. Sample specific results are shown in the tables as counts. The expected results are indicated in the tables with green colour. The laboratory's own result is shown by a black radio button .

You can view the result distribution of each specimen and pathogen on screen one by one. The tables can be opened and closed by clicking the screen button at the right end of the row. The result tables of pathogens with a negative result expectation and for which no deviating results have been reported are by default closed for clarification of the report.

The participant's own success is shown both as scores and as success rates (%) generated from the score values. They are presented both in the summary and in the sample specific parts of the report. If you have no 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 participants are scored according to their test selection. 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.

In general, only the positive findings are scored for each specimen. It is expected that the pathogens indicated in the sample content are to be identified, whereas other deviating findings will reduce the overall success rate. For those specimens that are negative regarding all pathogens included in the panel of this scheme, the scoring is based on the answer given to the question "number of pathogenic findings" and the expected result would be "Negative sample, no pathogens detected". Answer "No test result" and "Invalid/unclear test result" will be excluded from the

The scoring range is 0-2 points and the following general rules are followed:

- 2/2 points is given to results that are correct/accepted regarding the expected result
- 1/2 point can be given to results that are partly correct/insufficient regarding the expected result
- 0/2 point is given to results that are incorrect/false regarding the expected result

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.

Copyright © Labquality Oy

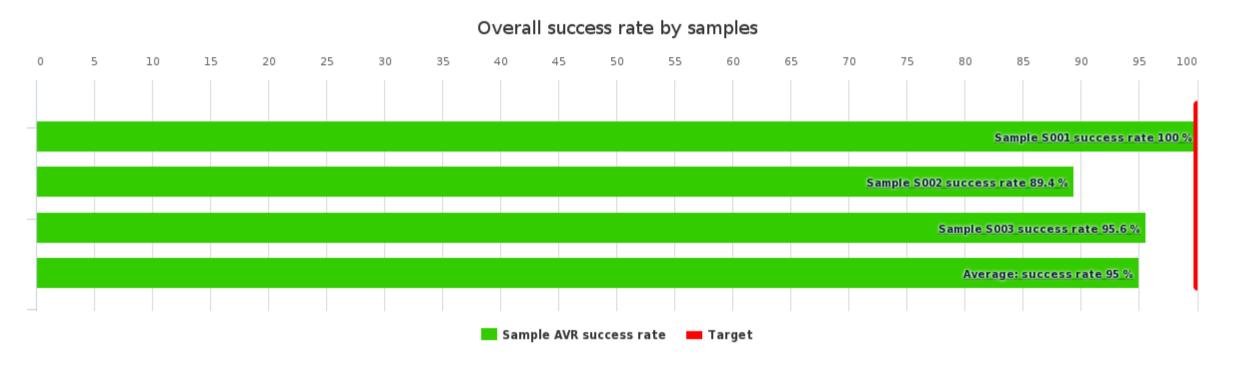
15.06.2023 11/11



GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Gastrointestinal viral multiplex, nucleic acid detection, May, 1-2023	72	69	95.8 %

Summary



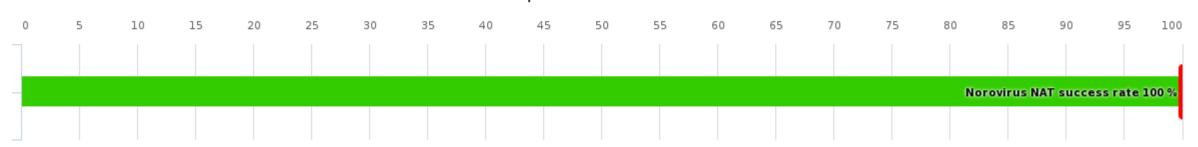
Summary	AVR success rate
Sample S001	100 %
Sample S002	89.4 %
Sample S003	95.6 %
Average:	95 %

1/11 14.06.2023



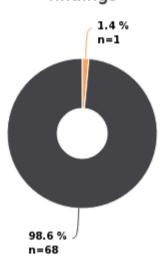
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate
	Number of pathogenic findings	-
	Adenovirus NAT	-
	Astrovirus NAT	-
	Norovirus NAT	100 %
	Rotavirus NAT	-
	Sapovirus NAT	-
	Total:	100 %

Sample S001 Number of pathogenic findings



Negative sample, no pathogens detected
Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative sample, no pathogens detected	1	-	-
Positive sample, 1 pathogen detected	68	-	-
Total:	69		

ADENOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
interpretation	interpretation count	AVK Success rate	interpretation score
Negative	68	-	-
Not in test selection	1	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	19	-	19
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ASTROVIRUS NAT

Copyright © Labquality Oy

14.06.2023 2/11



Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	67	<u>-</u>	-
Not in test selection	2	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	67	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
G1 positive	26	100 %	2
Norovirus positive, no genotyping	42	100 %	2
Not in test selection	1	-	-
Total:	69	100 %	

Method	G1 positive	Norovirus positive, no genotyping	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	-	1
BD MAX Enteric Viral Panel	-	21	-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	2	16	-	18
Genetic Signatures Enteric Viral ASRs	-	1	-	1
In house	1	-	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	2	4	-	6
Seegene Allplex GI-Virus Assay	18	_	-	18
SEROSEP EntericBio Viral Panel 3	2	<u>-</u>	-	2
Total:	26	42	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	69	-	-
Total:	69		

Method	Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1
BD MAX Enteric Viral Panel	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18
Genetic Signatures Enteric Viral ASRs	1
In house	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6
Seegene Allplex GI-Virus Assay	19
SEROSEP EntericBio Viral Panel 3	2
Total:	69

SAPOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	66	<u>-</u>	-
Not in test selection	3	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
BD MAX Enteric Viral Panel	20	<u>-</u>	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	<u>-</u>	18
Genetic Signatures Enteric Viral ASRs	1	<u>-</u>	1
In house	1	<u>-</u>	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	<u>-</u>	6
Seegene Allplex GI-Virus Assay	18	-	18

Copyright © Labquality Oy

14.06.2023 3/11



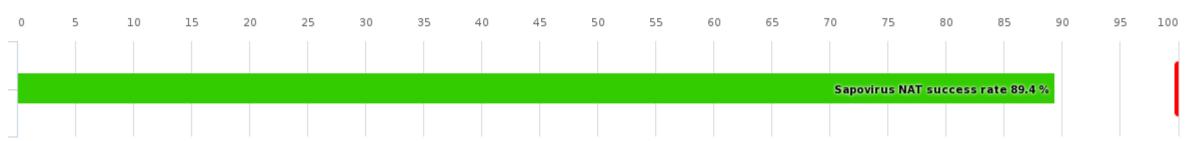
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	66	3	69

Copyright © Labquality Oy 14.06.2023



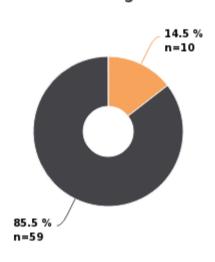
Sample S002





Sample S002 results	Responded	AVR success rate
	Number of pathogenic findings	-
	Adenovirus NAT	-
	Astrovirus NAT	_
	Norovirus NAT	_
	Rotavirus NAT	-
	Sapovirus NAT	89.4 %
Total:		89.4 %

Sample S002 Number of pathogenic findings



Negative sample, no pathogens detected
Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative sample, no pathogens detected	10	-	-
Positive sample, 1 pathogen detected	59	-	-
Total:	69		

ADENOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	68	-	-
Not in test selection	1	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	19	-	19
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ASTROVIRUS NAT

Copyright © Labquality Oy

14.06.2023 5/11



Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	67	_	<u>-</u>
Not in test selection	2	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	67	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	68	-	-
Not in test selection	1	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	21	-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	69	-	_
Total:	69		

Method	Negative
Methou	Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1
BD MAX Enteric Viral Panel	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18
Genetic Signatures Enteric Viral ASRs	1
In house	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6
Seegene Allplex GI-Virus Assay	19
SEROSEP EntericBio Viral Panel 3	2
Total:	69

SAPOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	7	0 %	0
Weak positive	2	100 %	2
Positive	57	100 %	2
Not in test selection	3	-	-
Total:	69	89.4 %	

Method	Negative	Weak positive	Positive	Not in test selection	Total:
BD MAX Enteric Viral Panel	1	1	18	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	1	-	17	-	18
Genetic Signatures Enteric Viral ASRs	-	-	1	-	1
In house	1	-	-	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	2	-	4	-	6

Copyright © Labquality Oy

6/11 14.06.2023



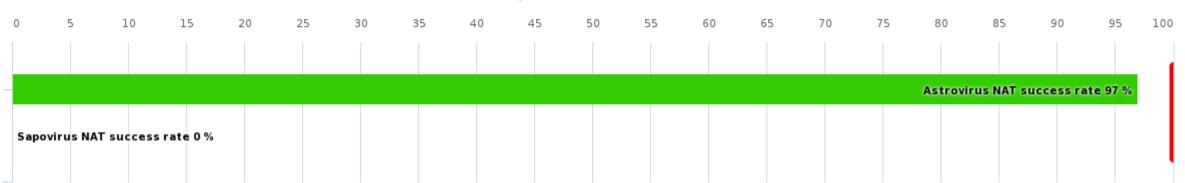
Seegene Allplex GI-Virus Assay	2	1	15	-	18
SEROSEP EntericBio Viral Panel 3	-	-	2	-	2
Total:	7	2	57	3	69

14.06.2023 7/11



Sample S003





Sample S003 results	Responded	AVR success rate
	Number of pathogenic findings	-
	Adenovirus NAT	-
	Astrovirus NAT	97 %
	Norovirus NAT	_
	Rotavirus NAT	_
	Sapovirus NAT	0 %
Total:		95.6 %

Sample S003 Number of pathogenic findings



Negative sample, no pathogens detected
 Positive sample, 1 pathogen detected

NUMBER OF PATHOGENIC FINDINGS

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative sample, no pathogens detected	3	-	-
Positive sample, 1 pathogen detected	66	-	<u>-</u>
Total:	69		

ADENOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	68	-	-
Not in test selection	1	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	<u>-</u>	1
BD MAX Enteric Viral Panel	20	<u>-</u>	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	<u>-</u>	18
Genetic Signatures Enteric Viral ASRs	1	<u>-</u>	1
In house	1	<u>-</u>	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	<u>-</u>	6
Seegene Allplex GI-Virus Assay	19	<u>-</u>	19
SEROSEP EntericBio Viral Panel 3	2	<u>-</u>	2
Total:	68	1	69

Copyright © Labquality Oy

14.06.2023 8/11



ASTROVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score	
Negative	2	0 %	0	
Positive	65	100 %	2	
Not in test selection	2	-	-	
Total:	69	97 %		

Method	Negative	Positive	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	-	1	-	1
BD MAX Enteric Viral Panel	-	20	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	-	18	-	18
Genetic Signatures Enteric Viral ASRs	-	1	-	1
In house	-	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	1	5	-	6
Seegene Allplex GI-Virus Assay	1	17	-	18
SEROSEP EntericBio Viral Panel 3	-	2	-	2
Total:	2	65	2	69

NOROVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	68	-	-
Not in test selection	1	-	-
Total:	69		

Method	Negative	Not in test selection	Total:
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1	-	1
BD MAX Enteric Viral Panel	21	-	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	18
Genetic Signatures Enteric Viral ASRs	1	-	1
In house	1	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	6
Seegene Allplex GI-Virus Assay	18	-	18
SEROSEP EntericBio Viral Panel 3	2	-	2
Total:	68	1	69

ROTAVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	69	-	-
Total:	69		

Method	Negative
Anatolia Geneworks Bosphore Gastroenteritis Panel Kit v2	1
BD MAX Enteric Viral Panel	21
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18
Genetic Signatures Enteric Viral ASRs	1
In house	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6
Seegene Allplex GI-Virus Assay	19
SEROSEP EntericBio Viral Panel 3	2
Total:	69

SAPOVIRUS NAT

Interpretation	Interpretation count	AVR success rate	Interpretation Score
Negative	65	-	-
Positive	1	0 %	0
Not in test selection	3	-	-
Total:	69	0 %	

Method	Negative	Positive	Not in test selection	Total:
BD MAX Enteric Viral Panel	20	-	-	20
bioMerieux BIOFIRE FilmArray Gastrointestinal (GI) Panel	18	-	-	18
Genetic Signatures Enteric Viral ASRs	1	-	-	1
In house	1	-	-	1
Qiagen STAT-Dx DiagCORE Gastrointestinal Panel V2	6	-	-	6

Copyright © Labquality Oy

14.06.2023 9/11



Seegene Allplex GI-Virus Assay	17	1	-	18
SEROSEP EntericBio Viral Panel 3	2	-	<u>-</u>	2
Total:	65	1	3	69



Report Info

PARTICIPANTS

Altogether 72 laboratories from 18 countries participated in this EQA round.

REPORT INFO

The reported results and the scores are presented in the same summary. Sample specific results are shown in the tables as counts. The expected results are indicated in the tables with green colour. The laboratory's own result is shown by a black radio button .

You can view the result distribution of each specimen and pathogen on screen one by one. The tables can be opened and closed by clicking the screen button at the right end of the row. The result tables of pathogens with a negative result expectation and for which no deviating results have been reported are by default closed for clarification of the report.

The participant's own success is shown both as scores and as success rates (%) generated from the score values. They are presented both in the summary and in the sample specific parts of the report. If you have no 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 participants are scored according to their test selection. 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.

In general, only the positive findings are scored for each specimen. It is expected that the pathogens indicated in the sample content are to be identified, whereas other deviating findings will reduce the overall success rate. For those specimens that are negative regarding all pathogens included in the panel of this scheme, the scoring is based on the answer given to the question "number of pathogenic findings" and the expected result would be "Negative sample, no pathogens detected". Answer "No test result" and "Invalid/unclear test result" will be excluded from the

The scoring range is 0-2 points and the following general rules are followed:

- 2/2 points is given to results that are correct/accepted regarding the expected result
- 1/2 point can be given to results that are partly correct/insufficient regarding the expected result
- 0/2 point is given to results that are incorrect/false regarding the expected result

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.

Copyright © Labquality Oy

14.06.2023 11/11

LABQUALITY

External Quality Assessment Scheme

Gastrointestinal viral multiplex, nucleic acid detection Round 1, 2023

Specimens

Samples of this EQA round were artificial faecal samples. The sample lots were tested in an accredited Finnish reference laboratory and the results were consistent with the certificates provided by the sample manufacturer. Based on the quality controls conducted by the sample material manufacturer, pretesting and the results obtained in the round, the sample lots are to be considered as homogeneous, stable and suitable for external quality assessment. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ782823011) Norovirus (GI) positive, Ct 23.25 ¹⁾

Sample S002 (LQ782823012)
Sapovirus (W303-Sapo V, recombinant) positive, Ct 36.06 1)

Sample S003 (LQ782823013)
Astrovirus (Type 8, ERE IID 2371) positive, Ct 32.8 1)

Pretest methods: Seegene Allplex GI-Virus Assay¹, BioFire FilmArray GI Panel and a laboratory developed test.

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

All participants reported the expected norovirus finding for the sample S001. 26 of the laboratories reported genogroup G1 for the finding. Ct value median of 19.0 with Seegene Allplex GI-Virus Assay (n=12) was observed.

For the sapovirus positive sample S002, Ct value median of 32.3 with Seegene Allplex GI-Virus Assay (n=12) was observed reflecting the relatively low viral load of the sample. Indeed, seven laboratories, using altogether five different test methods, interpreted the sample as negative.

Nearly all laboratories reported the sample S003 positive for astrovirus. Ct value median with Seegene Allplex GI-Virus Assay was 26.3 (n=12). Two participants interpreted the sample as negative, and one laboratory reported the sample positive for sapovirus.

Exceptions in scoring

No exceptions.

End of report

Copyright © Labquality Oy.

Labquality does not permit any reproduction for commercial purposes of any portion of the material subject to this copyright. Labquality prohibits any use of its name, or reference to Labquality EQA program, or material in this report in any advertising, brochures or other commercial publications. Labquality EQA data do not necessarily indicate the superiority of instruments, reagents, testing equipment or materials used by participating laboratories. Use of Labquality EQA data to suggest superiority or inferiority of equipment or materials may be deceptive and misleading. Proficiency test results are handled confidentially. Labquality will not issue any statements to third parties of the performance of laboratories in external quality assessment schemes unless otherwise agreed.

2023-06-16

FINAL REPORT

Product no. 5304

Subcontracting: Sample pretesting

 Samples sent
 2023-05-02

 Round closed
 2023-05-25

 Expected results
 2023-05-30

 Final report
 2023-06-16

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, Hospital Microbiologist Pia Jokela, HUS Diagnostic Center, Helsinki, Finland

Labquality Oy

Kumpulantie 15 FI-00520 HELSINKI Finland

Tel. + 358 9 8566 8200

info@labquality.fi www.labquality.com



