

External Quality Assessment Scheme

***Clostridium difficile*, nucleic acid detection** **Round 1, 2023**

Specimens

Please find enclosed 2 lyophilized samples S001 and S002, and vials of rehydration fluid, each 0.5 mL.

Caution

Quality control samples must be handled with the same care as patient samples, i.e., as potential transmitters of serious diseases.

Examinations

C. difficile, nucleic acid (toxin gene) detection

Storage and use

After arrival, the samples should be stored at +2...8 °C. The laboratory should perform nucleic acid (toxin gene) detection according to the routine protocol followed for corresponding patient samples.

1. Let the sample (blue-capped vial inside the foil package) and the rehydration fluid (vial with white cap) warm up to room temperature.
2. Aseptically remove the pellet with sterile forceps from the blue-capped vial and place it in the rehydration fluid vial (white cap). Alternatively, you may add the rehydration fluid directly into the blue-capped vial.
3. Crush the pellet with a sterile loop until the suspension is homogenous.
4. Incubate the vial for 30 minutes in +35...37 °C.
5. Check that the pellet has dissolved properly.
6. Mix well the content of the vial and handle similar to a clinical sample.

Result reporting

Please enter the results via LabScala (www.labscala.com). If you cannot find your test in the dropdown menu, please contact the EQA Coordinator. Note, that merely the results reported in the "Report to the clinician" -part will be scored.

S001



S002



2023-01-24

INSTRUCTIONS

Product no. 5201
LQ760423011-012/US
UN3373

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 20, 2023

The expected results of the round are published in LabScala in the View reports section by February 22, 2023

Inquiries

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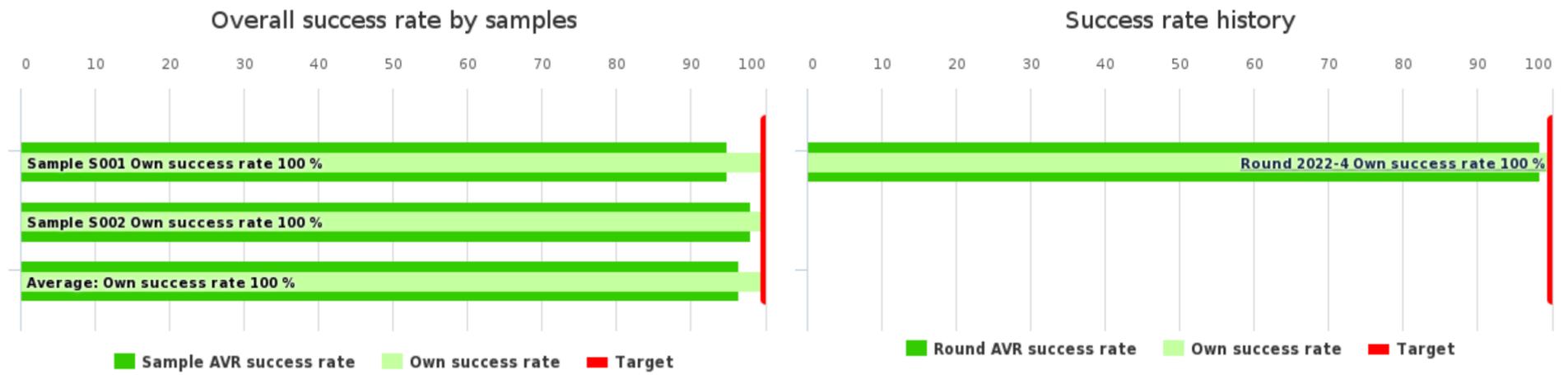
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Clostridioides difficile, culture and toxin detection, February, 1-2023	283	278	98.2 %
Clostridioides difficile, nucleic acid detection, February, 1-2023	46	45	97.8 %

Summary

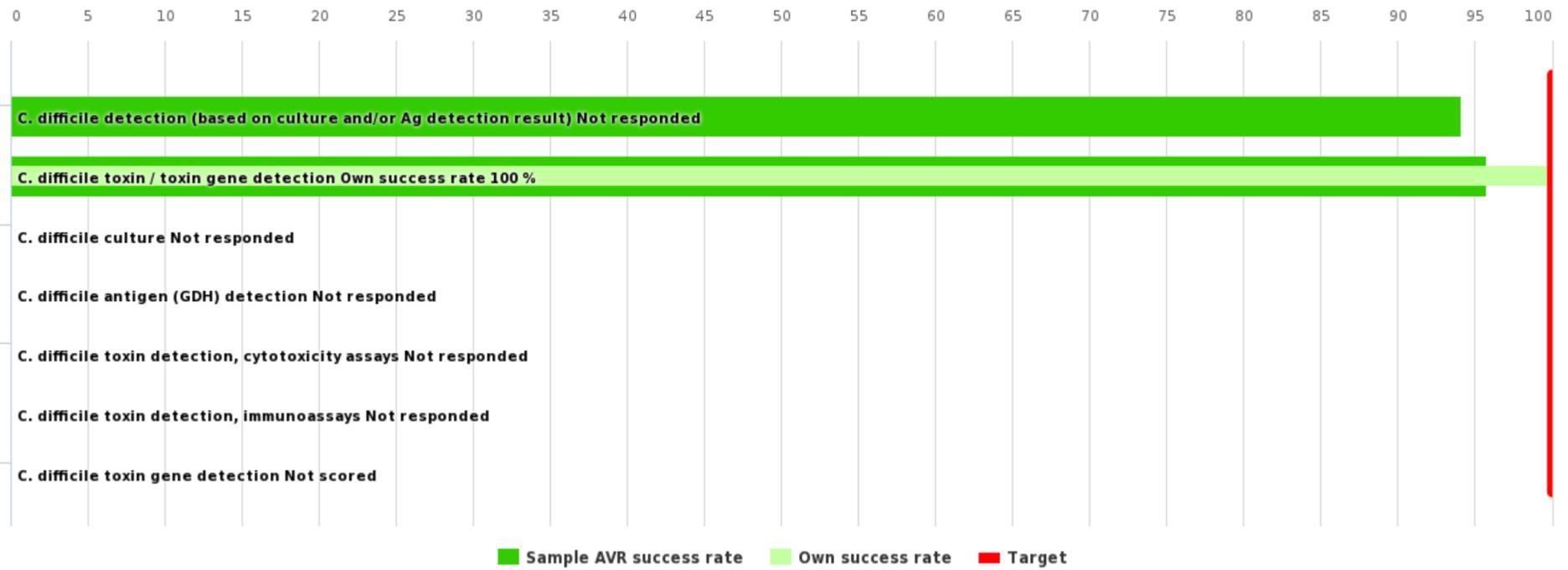


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	5 %	95 %
Sample S002	4	4	100 %	1.9 %	98.1 %
Average:			100 %	3.5 %	96.5 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	1.5 %	98.5 %

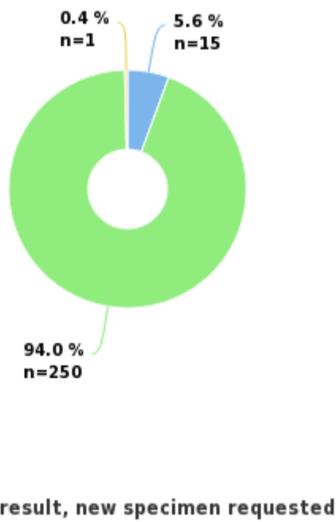
Sample S001 | Clostridioides difficile, toxin A/B negative

Sample S001 success rate

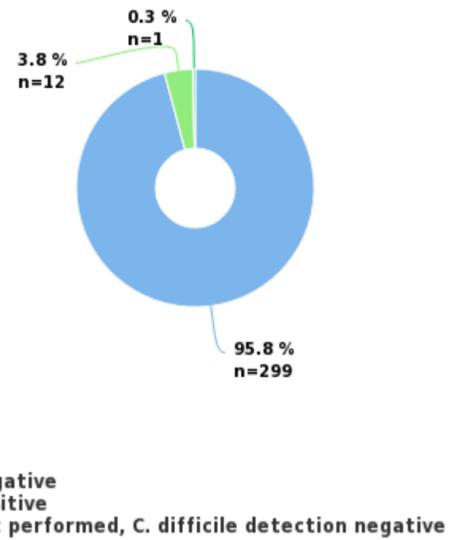


Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	C. difficile detection (based on culture and/or Ag detection result)	-	-	-	-	94.1 %	266
	C. difficile toxin / toxin gene detection	4	4	100 %	4.2 %	95.8 %	312
	C. difficile culture	-	-	-	-	-	82
	C. difficile antigen (GDH) detection	-	-	-	-	-	275
	C. difficile toxin detection, cytotoxicity assays	-	-	-	-	-	6
	C. difficile toxin detection, immunoassays	-	-	-	-	-	243
	C. difficile toxin gene detection	-	-	-	-	-	189
Total:		4	4	100 %	5 %	95 %	1373

Sample S001 C. difficile detection (based on culture and/or Ag detection result)



Sample S001 C. difficile toxin / toxin gene detection



C. difficile detection (based on culture and/or Ag detection result)	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate	Interpretation Score
	Negative	15	-	-	-	-	0 %	0
	Positive	250	-	-	-	-	100 %	4
	Equivocal result, new specimen requested	1	-	-	-	-	25 %	1
Total:		266	-	-	-	-	94.1 %	

C. difficile toxin / toxin gene detection	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate	Interpretation Score
	<input checked="" type="radio"/> Negative	299	4	4	100 %	0 %	100 %	4
	Positive	12	-	-	-	-	0 %	0

Not performed, C. difficile detection negative	1	-				0 %	0
Total:	312	4	4	100 %	4.2 %	95.8 %	

C. difficile culture	Result	Method	Result count	Method count
No growth (-)		Selective medium	2	2
Scarce growth (+)		Chromogenic medium	12	1
		Nonselective medium		3
		Selective medium		8
Moderate growth (++)		Chromogenic medium	40	10
		Nonselective medium		4
		Selective medium		26
Heavy growth (+++)		Chromogenic medium	28	12
		Selective medium		16
Total:			82	

C. difficile antigen (GDH) detection	Result	Method	Result count	Method count
Negative		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test	8	1
		Monlab C. difficile GDH and Toxins A+B Trio		1
		Servibio ParaSign GDH/Toxine A&B Color		1
		Techlab C. DIFF Quik Chek		1
		Techlab C. DIFF Quik Chek Complete		4
Positive		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test	267	4
		bioMerieux Vidas C. difficile GDH		5
		Biosynex Immunoquick C. difficile GDH		3
		Biotical Health biotical Clostridium difficile GDH Card		1
		CerTest Biotec CerTest CLIA GDH Ag		1
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		7
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		Coris BioConcept Clostridium K-SeT		2
		DiaSorin LIAISON C. difficile GDH		7
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Meridian Bioscience ImmunoCard C. difficile GDH Ag		16
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
		Monlab C. difficile Ag (GDH) Monlab Test		2
		nal von minden NADAL Clostridium difficile GDH		1
		Operon Simple GDH		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RidaQuick C. difficile GDH		14
		Savyon Diagnostics CoproELISA C. difficile GDH		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		6
		SD Biosensor Standard F C. difficile GDH FIA		9
		Servibio ParaSign GDH/Toxine A&B Color		3
		Servibio Parasign Sign GDH		6
		Techlab C. DIFF Quik Chek		18
Techlab C. DIFF Quik Chek Complete		145		
Vidia Rapid-VIDITEST C. difficile Ag		1		
Vitassay Clostridium difficile antigen GDH		1		
Total:			275	

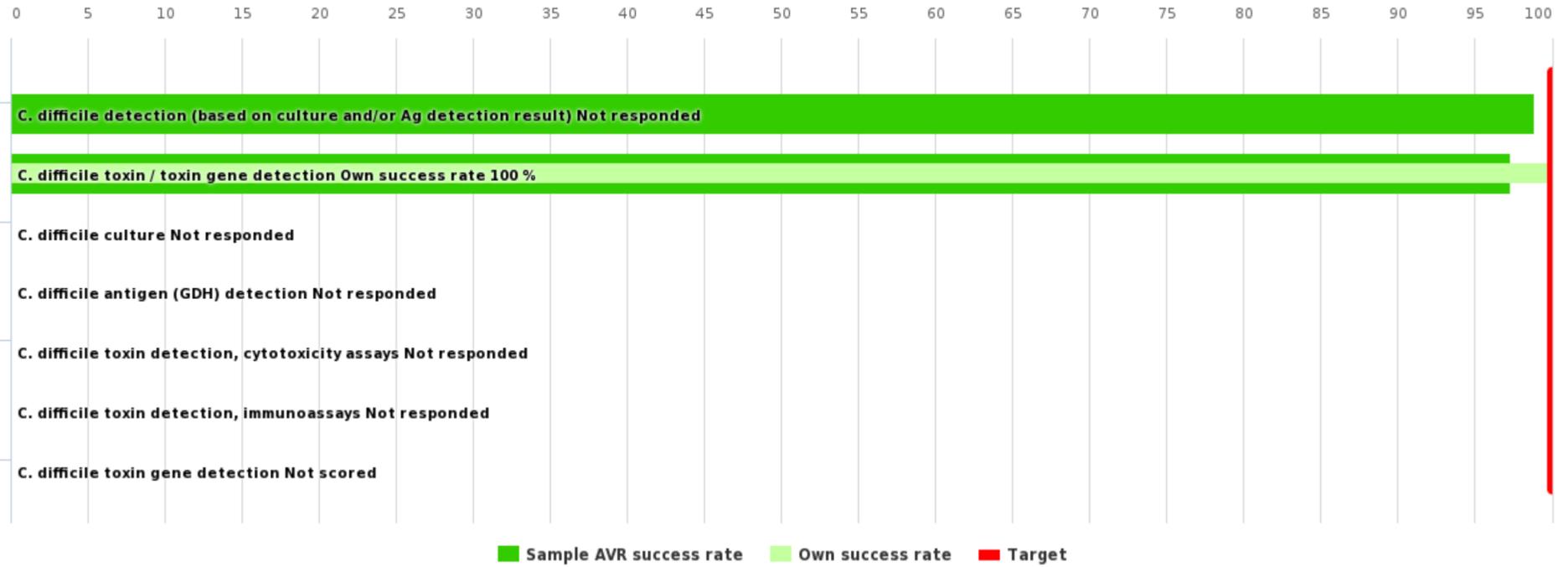
C. difficile toxin detection, cytotoxicity assays	Result	Method	Result count	Method count
Negative		Techlab C. difficile TOX-B Test	6	6
Total:			6	

C. difficile toxin detection, immunoassays	Result	Method	Result count	Method count
	Negative		237	
		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		2
		Acro Biotech Clostridium difficile Toxin A+Toxin B Combo Rapid Test		2
		bioMerieux VIDAS Clostridium difficile A&B		4
		Biosynex Immunoquick Tox A&B		2
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		CerTest Biotec CerTest Clostridium difficile Toxin A+B		5
		DiaSorin LIAISON C. difficile Toxins A&B		8
		Mascia Brunelli C. difficile Toxin A+B Card		1
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		8
		Meridian Bioscience ImmunoCard Toxins A&B		8
		Monlab C. difficile Toxins A+B Monlab Test		4
		Operon Simple 2A-Bdiff		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RIDA QUICK C. difficile Toxin A/B		12
		R-Biopharm Ridascreen C.difficile Toxin A/B Kit		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		7
		SD Biosensor Standard F C. difficile Toxin A/B FIA		8
		Servibio ParaSign GDH/Toxine A&B Color		4
		Servibio Parasign Toxine A&B Color		3
		Techlab C. DIFF Quik Chek Complete		135
		Techlab C.difficile TOX A/B II		3
		Techlab TOX A/B Quik Chek		12
		Veda Lab DuoToxin A+B		1
		Vitassay Clostridium difficile Toxin A+B		1
	Positive		6	
		bioMerieux VIDAS Clostridium difficile A&B		1
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		1
		Techlab C. DIFF Quik Chek Complete		2
		Techlab TOX A/B Quik Chek		1
	Total:		243	

C. difficile toxin gene detection	Result	Method	Result count	Method count
	<input checked="" type="radio"/> Negative		183	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		8
		Amplex Biosystems Genie II Eazyplex C. difficile Complete		2
		Becton Dickinson BD MAX Cdiff Assay		15
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		5
		Cepheid Xpert C. difficile		11
		<input checked="" type="radio"/> Cepheid Xpert C. difficile BT		87
		EliTechGroup C. difficile ELITe MGB Kit		1
		Meridian Bioscience Illumigene C. difficile test		14
		Mobidiag Amplidiag C. difficile+027		1
		Mobidiag Novodiag Bacterial GE+		1
		Mobidiag Novodiag C. difficile		9
		PCR, In house		2
		Qiagen QIAstat-Dx Gastrointestinal Panel		2
		R-Biopharm RidaGene C. difficile Toxin A/B		1
		Roche Diagnostics cobas Cdiff (LIAT System)		1
		Seegene Allplex Gastrointestinal Panel		22
		Serosep EntericBio C. difficile		1
	Positive		6	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		1
		Becton Dickinson BD MAX Cdiff Assay		1
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		1
		Cepheid Xpert C. difficile BT		2
		Meridian Bioscience Illumigene C. difficile test		1
	Total:		189	

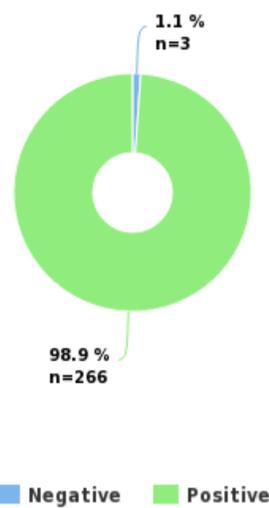
Sample S002 | Clostridioides difficile, toxin A/B positive

Sample S002 success rate

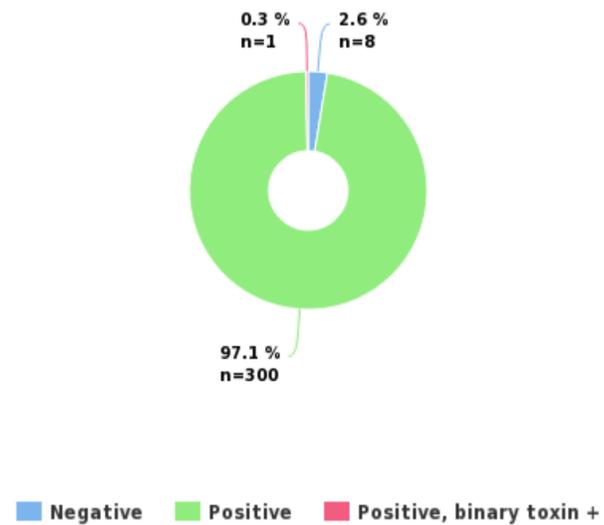


Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	C. difficile detection (based on culture and/or Ag detection result)	-	-	-	-	98.9 %	269
	C. difficile toxin / toxin gene detection	4	4	100 %	2.7 %	97.3 %	309
	C. difficile culture	-	-	-	-	-	77
	C. difficile antigen (GDH) detection	-	-	-	-	-	268
	C. difficile toxin detection, cytotoxicity assays	-	-	-	-	-	6
	C. difficile toxin detection, immunoassays	-	-	-	-	-	241
	C. difficile toxin gene detection	-	-	-	-	-	175
Total:		4	4	100 %	1.9 %	98.1 %	1345

Sample S002 C. difficile detection (based on culture and/or Ag detection result)



Sample S002 C. difficile toxin / toxin gene detection



C. difficile detection (based on culture and/or Ag detection result)	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate	Interpretation Score
	Negative	3	-	-	-	-	0 %	0
	Positive	266	-	-	-	-	100 %	4
Total:		269	-	-	-	-	98.9 %	

C. difficile toxin / toxin gene detection	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate	Interpretation Score
	Negative	8	-	-	-	-	0 %	0
	Positive	300	4	4	100 %	0 %	100 %	4
	Positive, binary toxin +	1	-	-	-	-	75 %	3
Total:		309	4	4	100 %	2.7 %	97.3 %	

C. difficile culture	Result	Method	Result count	Method count
	Scarce growth (+)		5	
		Chromogenic medium		2
		Nonselective medium		2
		Selective medium		1
	Moderate growth (++)		35	
		Chromogenic medium		6
		Nonselective medium		3
		Selective medium		26
	Heavy growth (+++)		37	
		Chromogenic medium		14
		Nonselective medium		2
		Selective medium		21
	Total:		77	

C. difficile antigen (GDH) detection	Result	Method	Result count	Method count
	Negative		1	
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		1
	Positive		267	
		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		4
		bioMerieux Vidas C. difficile GDH		6
		Biosynex Immunoquick C. difficile GDH		3
		Biotal Health biotal Clostridium difficile GDH Card		1
		CerTest Biotec CerTest CLIA GDH Ag		1
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		6
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		Coris BioConcept Clostridium K-SeT		2
		DiaSorin LIAISON C. difficile GDH		7
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Meridian Bioscience ImmunoCard C. difficile GDH Ag		16
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
		Monlab C. difficile Ag (GDH) Monlab Test		1
		Monlab C. difficile GDH and Toxins A+B Trio		1
		nal von minden NADAL Clostridium difficile GDH		1
		Operon Simple GDH		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RidaQuick C. difficile GDH		14
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		7
		SD Biosensor Standard F C. difficile GDH FIA		9
		Servibio ParaSign GDH/Toxine A&B Color		4
		Servibio Parasign Sign GDH		6
		Techlab C. DIFF Quik Chek		17
		Techlab C. DIFF Quik Chek Complete		145
		Vidia Rapid-VIDITEST C. difficile Ag		1
		Vitassay Clostridium difficile antigen GDH		1
	Total:		268	

C. difficile toxin detection, cytotoxicity assays	Result	Method	Result count	Method count
	Positive		6	
		Techlab C. difficile TOX-B Test		6
	Total:		6	

C. difficile toxin detection, immunoassays	Result	Method	Result count	Method count
	Negative		9	
		bioMerieux VIDAS Clostridium difficile A&B		2
		R-Biopharm RIDA QUICK C. difficile Toxin A/B		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		2
		Servibio ParaSign GDH/Toxine A&B Color		1
		Techlab C. DIFF Quik Chek Complete		2
		Techlab TOX A/B Quik Chek		1

Positive		232	
	Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		1
	Acro Biotech Clostridium difficile Toxin A+Toxin B Combo Rapid Test		2
	bioMerieux VIDAS Clostridium difficile A&B		5
	Biosynex Immunoquick Tox A&B		2
	CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
	CerTest Biotec CerTest Clostridium difficile Toxin A+B		5
	DiaSorin LIAISON C. difficile Toxins A&B		8
	Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
	Mascia Brunelli C. difficile Toxin A+B Card		3
	Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
	Meridian Bioscience ImmunoCard Toxins A&B		7
	Monlab C. difficile Toxins A+B Monlab Test		4
	Operon Simple 2A-Bdiff		1
	Quidel Sofia 2 C. difficile FIA		2
	R-Biopharm RIDA QUICK C. difficile Toxin A/B		13
	Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		6
	SD Biosensor Standard F C. difficile Toxin A/B FIA		8
	Servbio ParaSign GDH/Toxine A&B Color		3
	Servbio Parassign Toxine A&B Color		3
	Techlab C. DIFF Quik Chek Complete		131
	Techlab C.difficile TOX A/B II		2
	Techlab TOX A/B Quik Chek		13
	Veda Lab DuoToxin A+B		1
	Vitassay Clostridium difficile Toxin A+B		1
	Total:	241	

C. difficile toxin gene detection	Result	Method	Result count	Method count
	Negative		4	
		Cepheid Xpert C. difficile BT		4
	<input checked="" type="radio"/> Positive		167	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		8
		Amplex Biosystems Genie II Eazyplex C. difficile Complete		2
		Becton Dickinson BD MAX Cdiff Assay		15
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		3
		Cepheid Xpert C. difficile		5
		<input checked="" type="radio"/> Cepheid Xpert C. difficile BT		80
		EliTechGroup C. difficile ELITE MGB Kit		1
		Meridian Bioscience Illumigene C. difficile test		15
		Mobidiag Amplidiag C. difficile+027		1
		Mobidiag Novodiag Bacterial GE+		1
		Mobidiag Novodiag C. difficile		8
		PCR, In house		2
		Qiagen QIAstat-Dx Gastrointestinal Panel		2
		Roche Diagnostics cobas Cdiff (LIAT System)		1
		Seegene Allplex Gastrointestinal Panel		22
		Serosep EntericBio C. difficile		1
	Positive, binary toxin +		3	
		Becton Dickinson BD MAX Cdiff Assay		1
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		1
		Mobidiag Novodiag C. difficile		1
	Indeterminate result		1	
		Meridian Bioscience Illumigene C. difficile test		1
	Total:		175	

Report Info**PARTICIPANTS**

Altogether 329 laboratories from 21 countries participated in this EQA round.

REPORT INFO

On the front page you can see a summary of the overall average success rate and sample specific success rates which have been calculated from the scores. The reported results and the scores are presented in separate tables.

In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button . In the participant specific report, the participant's own success is shown both as scores and as success rates (%) generated from the score values.

If you have not reported 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 results in the "Report to the clinician" part can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results. Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

The following general rules are applied:

4 points is reached by reporting the expected correct result

1-3 points is given to results that are partly correct/insufficient regarding the expected finding

0 points is given for an incorrect/false result

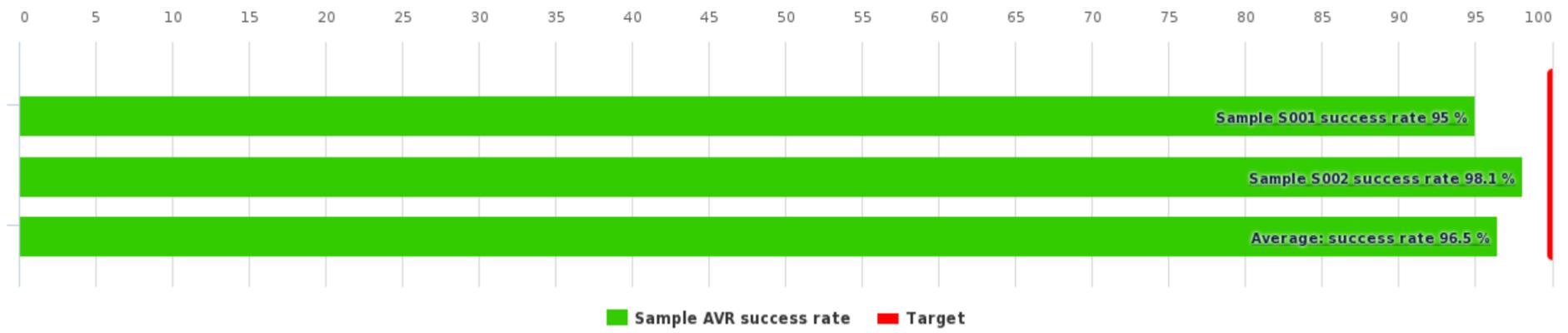
Regarding negative samples and the C. difficile toxin/toxin gene detection, the result "Not performed, C. difficile detection negative" will not be scored.

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Clostridioides difficile, culture and toxin detection, February, 1-2023	283	278	98.2 %
Clostridioides difficile, nucleic acid detection, February, 1-2023	46	45	97.8 %

Summary

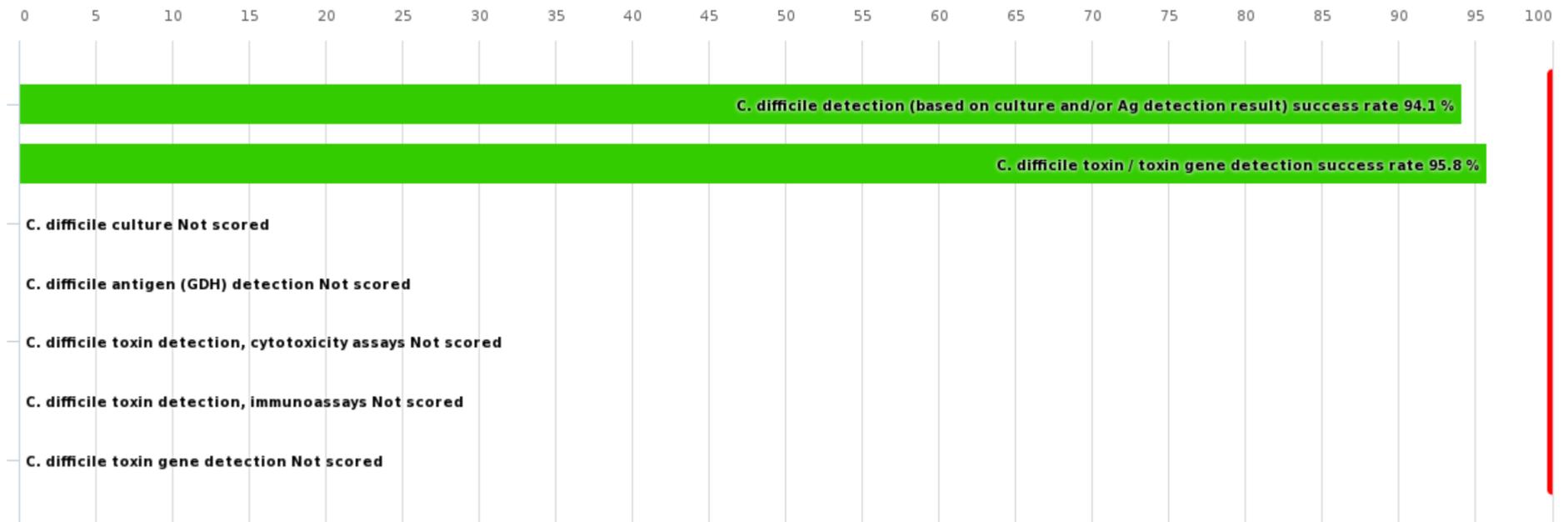
Overall success rate by samples



Summary	AVR success rate
Sample S001	95 %
Sample S002	98.1 %
Average:	96.5 %

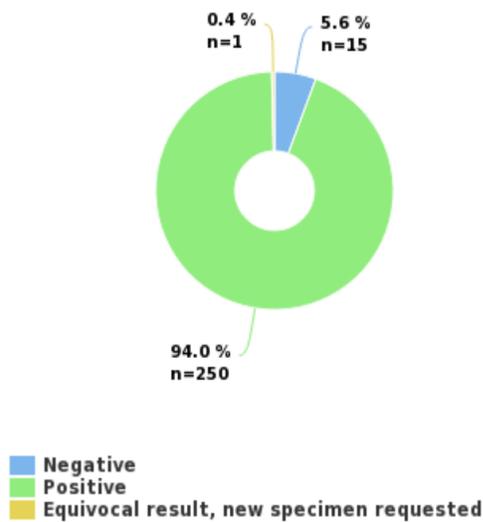
Sample S001 | Clostridioides difficile, toxin A/B negative

Sample S001 success rate

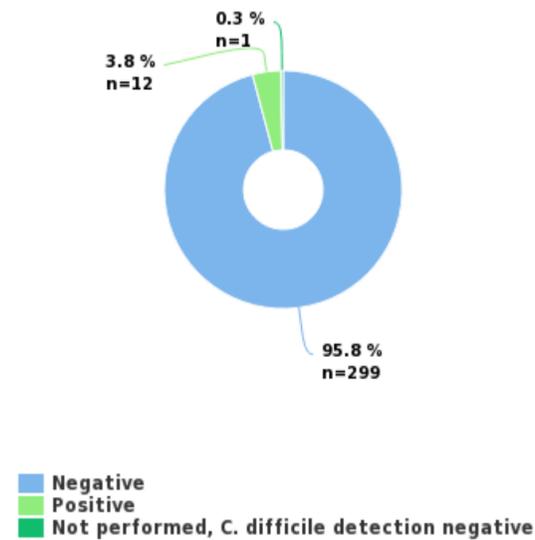


Sample S001 results	Responded	AVR success rate	Count
	C. difficile detection (based on culture and/or Ag detection result)	94.1 %	266
	C. difficile toxin / toxin gene detection	95.8 %	312
	C. difficile culture	-	82
	C. difficile antigen (GDH) detection	-	275
	C. difficile toxin detection, cytotoxicity assays	-	6
	C. difficile toxin detection, immunoassays	-	243
	C. difficile toxin gene detection	-	189
Total:		95 %	1373

Sample S001 C. difficile detection (based on culture and/or Ag detection result)



Sample S001 C. difficile toxin / toxin gene detection



C. difficile detection (based on culture and/or Ag detection result)	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Negative	15	0 %	0
	Positive	250	100 %	4
	Equivocal result, new specimen requested	1	25 %	1
	Total:	266	94.1 %	

C. difficile toxin / toxin gene detection	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Negative	299	100 %	4
	Positive	12	0 %	0
	Not performed, C. difficile detection negative	1	0 %	0
	Total:	312	95.8 %	

C. difficile culture	Result	Method	Result count	Method count
	No growth (-)		2	
		Selective medium		2
	Scarce growth (+)		12	
		Chromogenic medium		1
		Nonselective medium		3
		Selective medium		8
	Moderate growth (++)		40	
		Chromogenic medium		10
		Nonselective medium		4
		Selective medium		26
	Heavy growth (+++)		28	
		Chromogenic medium		12
		Selective medium		16
	Total:		82	

C. difficile antigen (GDH) detection	Result	Method	Result count	Method count
	Negative		8	
		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		1
		Monlab C. difficile GDH and Toxins A+B Trio		1
		Servibio ParaSign GDH/Toxine A&B Color		1
		Techlab C. DIFF Quik Chek		1
		Techlab C. DIFF Quik Chek Complete		4
	Positive		267	
		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		4
		bioMerieux Vidas C. difficile GDH		5
		Biosynex Immunoquick C. difficile GDH		3
		Biotal Health biotal Clostridium difficile GDH Card		1
		CerTest Biotec CerTest CLIA GDH Ag		1
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		7
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		Coris BioConcept Clostridium K-SeT		2
		DiaSorin LIAISON C. difficile GDH		7
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Meridian Bioscience ImmunoCard C. difficile GDH Ag		16
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
		Monlab C. difficile Ag (GDH) Monlab Test		2
		nal von minden NADAL Clostridium difficile GDH		1
		Operon Simple GDH		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RidaQuick C. difficile GDH		14
		Savyon Diagnostics CoproELISA C. difficile GDH		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		6
		SD Biosensor Standard F C. difficile GDH FIA		9
		Servibio ParaSign GDH/Toxine A&B Color		3
		Servibio Parasign Sign GDH		6
		Techlab C. DIFF Quik Chek		18
		Techlab C. DIFF Quik Chek Complete		145
		Vidia Rapid-VIDITEST C. difficile Ag		1
		Vitassay Clostridium difficile antigen GDH		1
	Total:		275	

C. difficile toxin detection, cytotoxicity assays	Result	Method	Result count	Method count
	Negative		6	
		Techlab C. difficile TOX-B Test		6
	Total:		6	

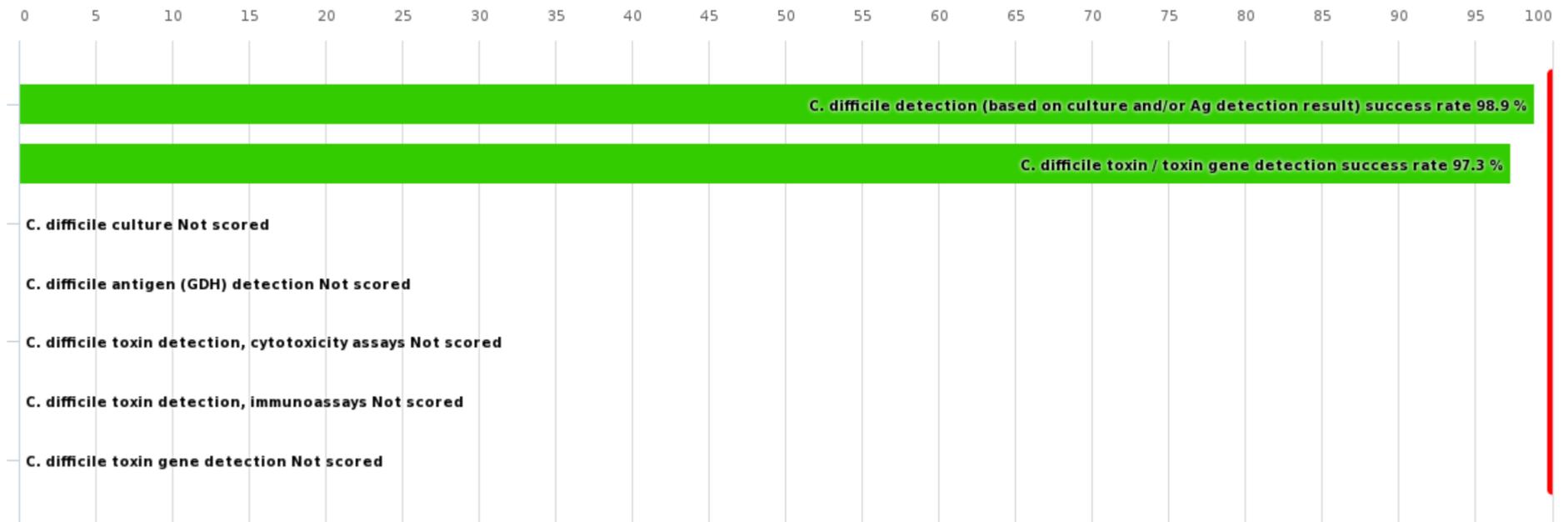
C. difficile toxin detection, immunoassays	Result	Method	Result count	Method count
	Negative		237	

		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		2
		Acro Biotech Clostridium difficile Toxin A+Toxin B Combo Rapid Test		2
		bioMerieux VIDAS Clostridium difficile A&B		4
		Biosynex Immunoquick Tox A&B		2
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		CerTest Biotec CerTest Clostridium difficile Toxin A+B		5
		DiaSorin LIAISON C. difficile Toxins A&B		8
		Mascia Brunelli C. difficile Toxin A+B Card		1
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		8
		Meridian Bioscience ImmunoCard Toxins A&B		8
		Monlab C. difficile Toxins A+B Monlab Test		4
		Operon Simple 2A-Bdiff		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RIDA QUICK C. difficile Toxin A/B		12
		R-Biopharm Ridascreen C.difficile Toxin A/B Kit		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		7
		SD Biosensor Standard F C. difficile Toxin A/B FIA		8
		Servibio ParaSign GDH/Toxine A&B Color		4
		Servibio Parassign Toxine A&B Color		3
		Techlab C. DIFF Quik Chek Complete		135
		Techlab C.difficile TOX A/B II		3
		Techlab TOX A/B Quik Chek		12
		Veda Lab DuoToxin A+B		1
		Vitassay Clostridium difficile Toxin A+B		1
	Positive		6	
		bioMerieux VIDAS Clostridium difficile A&B		1
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		1
		Techlab C. DIFF Quik Chek Complete		2
		Techlab TOX A/B Quik Chek		1
	Total:		243	

C. difficile toxin gene detection	Result	Method	Result count	Method count
	Negative		183	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		8
		Amplex Biosystems Genie II Eazyplex C. difficile Complete		2
		Becton Dickinson BD MAX Cdiff Assay		15
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		5
		Cepheid Xpert C. difficile		11
		Cepheid Xpert C. difficile BT		87
		EliTechGroup C. difficile ELITE MGB Kit		1
		Meridian Bioscience Illumigene C. difficile test		14
		Mobidiag Amplidiag C. difficile+027		1
		Mobidiag Novodiag Bacterial GE+		1
		Mobidiag Novodiag C. difficile		9
		PCR, In house		2
		Qiagen QIAstat-Dx Gastrointestinal Panel		2
		R-Biopharm RidaGene C. difficile Toxin A/B		1
		Roche Diagnostics cobas Cdiff (LIAT System)		1
		Seegene Allplex Gastrointestinal Panel		22
		Serosep EntericBio C. difficile		1
	Positive		6	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		1
		Becton Dickinson BD MAX Cdiff Assay		1
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		1
		Cepheid Xpert C. difficile BT		2
		Meridian Bioscience Illumigene C. difficile test		1
	Total:		189	

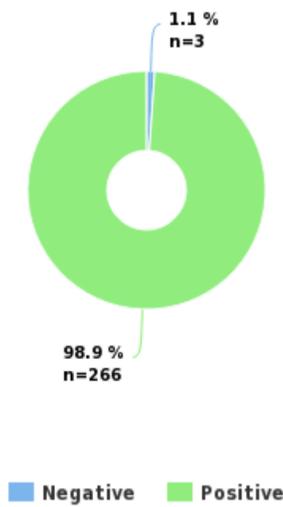
Sample S002 | Clostridioides difficile, toxin A/B positive

Sample S002 success rate

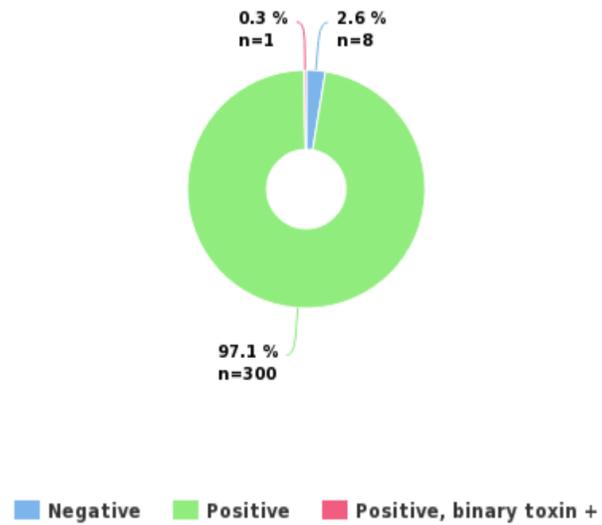


Sample S002 results	Responded	AVR success rate	Count
	C. difficile detection (based on culture and/or Ag detection result)	98.9 %	269
	C. difficile toxin / toxin gene detection	97.3 %	309
	C. difficile culture	-	77
	C. difficile antigen (GDH) detection	-	268
	C. difficile toxin detection, cytotoxicity assays	-	6
	C. difficile toxin detection, immunoassays	-	241
	C. difficile toxin gene detection	-	175
Total:		98.1 %	1345

Sample S002 C. difficile detection (based on culture and/or Ag detection result)



Sample S002 C. difficile toxin / toxin gene detection



C. difficile detection (based on culture and/or Ag detection result)	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Negative	3	0 %	0
	Positive	266	100 %	4
	Total:	269	98.9 %	

C. difficile toxin / toxin gene detection	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Negative	8	0 %	0
	Positive	300	100 %	4
	Positive, binary toxin +	1	75 %	3
	Total:	309	97.3 %	

C. difficile culture	Result	Method	Result count	Method count
	Scarce growth (+)		5	
		Chromogenic medium		2
		Nonselective medium		2
		Selective medium		1
	Moderate growth (++)		35	
		Chromogenic medium		6
		Nonselective medium		3
		Selective medium		26
	Heavy growth (+++)		37	
		Chromogenic medium		14
		Nonselective medium		2
		Selective medium		21
	Total:		77	

C. difficile antigen (GDH) detection	Result	Method	Result count	Method count
	Negative		1	
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		1
	Positive		267	
		Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		4
		bioMerieux Vidas C. difficile GDH		6
		Biosynex Immunoquick C. difficile GDH		3
		Biotical Health biotical Clostridium difficile GDH Card		1
		CerTest Biotec CerTest CLIA GDH Ag		1
		CerTest Biotec CerTest Clostridium difficile Antigen GDH		6
		CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
		Coris BioConcept Clostridium K-SeT		2
		DiaSorin LIAISON C. difficile GDH		7
		Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
		Meridian Bioscience ImmunoCard C. difficile GDH Ag		16
		Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
		Monlab C. difficile Ag (GDH) Monlab Test		1
		Monlab C. difficile GDH and Toxins A+B Trio		1
		nal von minden NADAL Clostridium difficile GDH		1
		Operon Simple GDH		1
		Quidel Sofia 2 C. difficile FIA		2
		R-Biopharm RidaQuick C. difficile GDH		14
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		7
		SD Biosensor Standard F C. difficile GDH FIA		9
		Servibio ParaSign GDH/Toxine A&B Color		4
		Servibio Parasign Sign GDH		6
		Techlab C. DIFF Quik Chek		17
		Techlab C. DIFF Quik Chek Complete		145
		Vidia Rapid-VIDITEST C. difficile Ag		1
		Vitassay Clostridium difficile antigen GDH		1
	Total:		268	

C. difficile toxin detection, cytotoxicity assays	Result	Method	Result count	Method count
	Positive		6	
		Techlab C. difficile TOX-B Test		6
	Total:		6	

C. difficile toxin detection, immunoassays	Result	Method	Result count	Method count
	Negative		9	
		bioMerieux VIDAS Clostridium difficile A&B		2
		R-Biopharm RIDA QUICK C. difficile Toxin A/B		1
		Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		2
		Servibio ParaSign GDH/Toxine A&B Color		1
		Techlab C. DIFF Quik Chek Complete		2
		Techlab TOX A/B Quik Chek		1
	Positive		232	

	Acro Biotech Clostridium difficile GDH+Toxin A+Toxin B Combo Rapid Test		1
	Acro Biotech Clostridium difficile Toxin A+Toxin B Combo Rapid Test		2
	bioMerieux VIDAS Clostridium difficile A&B		5
	Biosynex Immunoquick Tox A&B		2
	CerTest Biotec CerTest Clostridium difficile GDH + Toxin A + Toxin B		3
	CerTest Biotec CerTest Clostridium difficile Toxin A+B		5
	DiaSorin LIAISON C. difficile Toxins A&B		8
	Hangzhou Alltest Biotech Beright Clostridium difficile GDH+ToxinA+B Combo Rapid Test Feces		1
	Mascia Brunelli C. difficile Toxin A+B Card		3
	Meridian Bioscience Immunocard STAT! C. difficile GDH-AB		7
	Meridian Bioscience ImmunoCard Toxins A&B		7
	Monlab C. difficile Toxins A+B Monlab Test		4
	Operon Simple 2A-Bdiff		1
	Quidel Sofia 2 C. difficile FIA		2
	R-Biopharm RIDA QUICK C. difficile Toxin A/B		13
	Savyon Diagnostics CoproStrip C. difficile GDH+ToxA+ToxB		6
	SD Biosensor Standard F C. difficile Toxin A/B FIA		8
	Servibio ParaSign GDH/Toxine A&B Color		3
	Servibio Parasign Toxine A&B Color		3
	Techlab C. DIFF Quik Chek Complete		131
	Techlab C.difficile TOX A/B II		2
	Techlab TOX A/B Quik Chek		13
	Veda Lab DuoToxin A+B		1
	Vitassay Clostridium difficile Toxin A+B		1
	Total:		241

C. difficile toxin gene detection	Result	Method	Result count	Method count
	Negative		4	
		Cepheid Xpert C. difficile BT		4
	Positive		167	
		Abacus Diagnostica GenomEra C. difficile Assay Kit		8
		Amplex Biosystems Genie II Eazyplex C. difficile Complete		2
		Becton Dickinson BD MAX Cdiff Assay		15
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		3
		Cepheid Xpert C. difficile		5
		Cepheid Xpert C. difficile BT		80
		EliTechGroup C. difficile ELITe MGB Kit		1
		Meridian Bioscience Illumigene C. difficile test		15
		Mobidiag Amplidiag C. difficile+027		1
		Mobidiag Novodiag Bacterial GE+		1
		Mobidiag Novodiag C. difficile		8
		PCR, In house		2
		Qiagen QIAstat-Dx Gastrointestinal Panel		2
		Roche Diagnostics cobas Cdiff (LIAT System)		1
		Seegene Allplex Gastrointestinal Panel		22
		Serosep EntericBio C. difficile		1
	Positive, binary toxin +		3	
		Becton Dickinson BD MAX Cdiff Assay		1
		bioMerieux BioFire FilmArray Gastrointestinal (GI) Panel		1
		Mobidiag Novodiag C. difficile		1
	Indeterminate result		1	
		Meridian Bioscience Illumigene C. difficile test		1
	Total:		175	

Report Info**PARTICIPANTS**

Altogether 329 laboratories from 21 countries participated in this EQA round.

REPORT INFO

On the front page you can see a summary of the overall average success rate and sample specific success rates which have been calculated from the scores. The reported results and the scores are presented in separate tables.

In general, the expected results are marked with green color. Accepted results may also be indicated with yellow color. Laboratory's own results are indicated with a black radio button . In the participant specific report, the participant's own success is shown both as scores and as success rates (%) generated from the score values.

If you have not reported 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 results in the "Report to the clinician" part can be scored when at least 60% of the participants have reported the correct/expected result and when there are at least three reported results. Laboratory's scores have been converted to percentage (own success rate, % from maximum scores) with a target at 100%. Own success rate is compared with the success rate of all results.

The following general rules are applied:

4 points is reached by reporting the expected correct result

1-3 points is given to results that are partly correct/insufficient regarding the expected finding

0 points is given for an incorrect/false result

Regarding negative samples and the C. difficile toxin/toxin gene detection, the result "Not performed, C. difficile detection negative" will not be scored.

External Quality Assessment Scheme

***Clostridioides difficile*, culture and toxin detection (5200)**

***Clostridioides difficile*, nucleic acid detection (5201) Rounds 1, 2023**

Specimens

The round included two lyophilized specimens. 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, pre-testing 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 samples included the following microbes:

Sample S001 (LQ760423011)
Clostridioides difficile GL0592 (toxin A/B negative)
Escherichia coli GL0104

Expected result: *C. difficile* toxin A/B negative

Sample S002 (LQ760423012)
Clostridioides difficile GL0353 (toxin A/B positive)
Lactobacillus acidophilus GL0083

Expected result: *C. difficile* toxin A/B positive

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, as it contains important information of the samples and results in each round.

Comments – Expert

This round consisted of a toxin negative *C. difficile* together with *E. coli* in sample S001 and a toxin positive *C. difficile* together with *Lactobacillus acidophilus* in sample S002. There were altogether 323 participants, of which 329 reported results. Culture was performed by 83 participants, GDH antigen detection by 254, toxin detection by 221, toxin gene detection by 181 and cytotoxin testing by 7 participants.

Sample S001

The overall success rate for *C. difficile* detection (culture, GDH) was 94.1% and for toxin detection 95.8%.

There were 15 false negative *C. difficile* detection results with 7 false test results (GDH, 'no growth'), but for the rest there seems to be interpretation and/or reporting errors, e.g., GDH pos./Tox neg. results reported as *C. difficile* negative.

There were 12 false positive toxin reports, of which 7 were based on false tests results (4 toxin gene and 3 immunologic results), but again the rest

2023-03-06

FINAL REPORT

Product no. 5200, 5201

Subcontracting: Sample pretesting

Samples sent	2023-01-24
Round closed	2023-02-20
Expected results	2023-02-22
Final report	2023-03-06

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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seemed to be due to reporting/handling errors, e.g., cross wise mixed results with sample S002 or initial correct result but incorrect final report.

Sample S002

The overall success rate for *C. difficile* detection (culture, GDH) was 98.9% and for toxin detection 97.1%.

There were 3 false negative *C. difficile* results, of which 2 were most likely reporting errors with positive initial GDH test result.

There were 8 false negative toxin results, of which 4 were based on false test results (2 toxin gene and 2 immunologic results) and the rest reporting errors as seen for sample S001. In addition, there were 3 false positive binary toxin results but only 1 of them was reported as a final result to the clinician.

Conclusions

In general, the overall performance was very good. Noteworthy, only half of the false reports were clearly based on false test results. This highlights the importance of careful management of the sample processing protocol as a whole, including pre- and post-analytics, not just the testing step.

Exceptions in scoring

No exceptions.

End of report