

PCR-/NAT *Clostridium difficile*
(RV 545) Mai 2024



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
545A 240521 01	∅	62	<i>Escherichia coli</i> K12
545A 240521 02	+++	61/ 71,72,73,75	<i>Clostridium difficile</i> Ribotyp O27 (~ 1x10 ⁶ CFU/mL)
545A 240521 03	++	61/ 71,72,73,75	<i>Clostridium difficile</i> Ribotyp O27 (~ 2x10 ⁴ CFU/mL)
545A 240521 04	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 199	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	0	198	197	1	n.d.	2	2	2	2
Negativ	199	1	2	198	nein <i>no</i>	197	197	197	197
Fraglich <i>Questionable</i>	0	0	0	0	ja <i>yes</i>	0	0	0	0

Tabelle 3: Häufigkeit richtig positiver und richtig negativer NAT-Befunde bei Anwendern verschiedener Methoden.

Absolute numbers and relative frequency of reported true positive and true negative results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	02		03		01		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Altona RealStar <i>C. difficile</i> (n = 7)	7	100	7	100	7	100	7	100
Amplex eazyplex <i>C. difficile</i> (n = 4)	4	100	4	100	4	100	4	100
AmpliGnost <i>C. difficile</i> Tox. A +B (n = 3)	3	100	3	100	3	100	3	100
BD MAX <i>C. difficile</i> (n = 22)	22	100	22	100	22	100	22	100
Bruker-HAIN FluoroType CDiff (n = 1)	1	100	1	100	1	100	1	100
Bruker-HAIN GenoType CDiff (n = 1)	1	100	1	100	1	100	1	100
Cepheid Xpert <i>C. difficile</i> (n = 72)	71	99	71	99	72	100	72	100

C. difficile ELITe MGB Kit (n = 2)	2	100	2	100	2	100	2	100
EasyScreen Pan-Enteric Pathogen (n = 1)	1	100	1	100	1	100	1	100
Meridian Alethia C. difficile (n = 10)	10	100	10	100	10	100	10	100
Quidel Solana C. difficile (n = 1)	1	100	1	100	1	100	1	100
Roche Cobas Liat Cdiff (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI Bacteria (n = 14)	14	100	14	100	14	100	14	100
Seegene Allplex GI-EB Screening (n = 16)	16	100	16	100	16	100	16	100
LightMix Kit (n= 1)	1	100	1	100	1	100	1	100
LightMix Cdiff Toxin Gene tcdA/tcdB (n= 2)	2	100	2	100	2	100	2	100
RIDAGENE C. difficile (n = 21)	21	100	20	95	21	100	21	100
RIDAGENE Hospital stool panel (n = 1)	1	100	1	100	1	100	1	100
In house PCR assay (n = 9)	9	100	9	100	9	100	9	100
Other commercial tests (n = 10)	10	100	10	100	10	100	9	90

Comments:

1. The following tests are listed under "Other commercial tests": BioMerieux BioFire FILMARRAY GI Panel (3x), AusDiagnostics Faecal Pathogen M 16-well (1x), Bioeksen Bio-Speedy C.difficile Toxin A-B qPCR Kit (1x), CerTest VIASURE multiplex C.difficile toxins A+B Real Time PCR Detection Kit (1x), IDT C.diff qPCR Assay (1x), QIAGEN QIAstat-Dx Gastrointestinal Panel (1x) and UC-TIB-EHEC_C.diff (1x).