

PCR-/NAT *Clostridium difficile*
(RV 545) Mai 2023



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
545 230523 01	∅	62	<i>Escherichia coli</i> K12
545 230523 02	+++	61/ 71,72,73,75	<i>Clostridium difficile</i> Ribotyp O27 (~ 5x10 ⁵ CFU/mL)
545 230523 03	∅	62	<i>Aeromonas hydrophila</i> (~1x10 ⁵ CFU/mL)
545 230523 04	++	61/ 71,72,73,75	<i>Clostridium difficile</i> Ribotyp O27 (~ 5x10 ⁴ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 191	Proben Nr. (Sample no.)					Inhibition			
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	2	188	3	190	n.d.	0	0	0	0
Negativ	189	3	188	1	nein <i>no</i>	191	191	191	191
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		04		01		03	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Altona RealStar <i>C. difficile</i> (n = 6)	6	100	6	100	6	100	6	100
Amplex eazyplex <i>C. difficile</i> (n = 3)	3	100	3	100	3	100	3	100
AmpliGnost <i>C. difficile</i> Tox. A +B (n = 2)	2	100	2	100	2	100	2	100
Aries Luminex <i>C. difficile</i> (n = 1)	1	100	1	100	1	100	1	100
BD MAX <i>C. difficile</i> (n = 23)	23	100	23	100	23	100	23	100
Bruker-HAIN GenoType CDiff (n = 1)	1	100	1	100	1	100	1	100
Cepheid Xpert <i>C. difficile</i> (n = 76)	75	99	75	99	76	100	73	96

Meridian Alethia C. difficile (n = 8)	8	100	8	100	8	100	8	100
Quidel Solana C. difficile (n = 2)	2	100	2	100	2	100	2	100
Roche COBAS Liat Cdiff (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex GI Bacteria (n = 9)	8	89	9	100	8	89	9	100
Seegene Allplex GI-EB Screening (n = 9)	9	100	9	100	9	100	9	100
LightMix Cdiff Toxin Gene tcdA/tcdB (n= 2)	2	100	2	100	2	100	2	100
RIDAGENE C. difficile (n = 21)	21	100	21	100	21	100	21	100
RIDAGENE Hospital stool panel (n = 3)	3	100	3	100	3	100	3	100
In house PCR assay (n = 9)	9	100	9	100	9	100	9	100
Other commercial tests (n = 15)	14	93	15	100	14	93	15	100

Comments:

1. The following tests are listed under "Other commercial tests": Vitassay qPCR Clostridium difficile und toxins A+B (1x), ELITechGroup C.difficile ELITe MGB Kit (2x), Genetic Signatures EasyScreen Pan Enteric Pathogen Detection Kits (2x), AusDiagnostics Faecal Pathogen M 16-well (1x), DiaSorin MDX C. difficile Direct (1x), BioFire FILMARRAY Gastrointestinal (GI) Panel (1x), Abacus Diagnostica GenomEra C. difficile (1x), Qiagen QiaStat-Dx Gastrointestinal Panel 2 (1x), Abacus Diagnostica GenomEra C. difficile (1x) and Biomerieux Biofire pneumo panel plus (1x).