

PCR-/NAT *Clostridium difficile*
(RV 545) Mai / Juni 2019



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1915451	++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁴ CFU/mL)
1915452	+++	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ⁵ CFU/mL)
1915453	Ø	62	<i>Escherichia coli</i> K12
1915454	+	61 / 71,72	<i>Clostridium difficile</i> (~ 1x10 ³ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 168	Probennummer (Sample no.)				Inhibition				
Befund <i>Result</i>	1915451	1915452	1915453	1915454	1915451	1915452	1915453	1915454	
Positiv	168	167	1	145	n.d.	0	0	0	0
Negativ	0	1	167	21	nein <i>no</i>	168	168	168	168
Fraglich <i>Questionable</i>	0	0	0	2	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Cepheid Xpert <i>C.difficile</i> [20] (n=60)	170	170 / 179 §	95	59	59 / 60	98
BD MAX <i>C.difficile</i> [21] (n =20)	60	60 / 60	100	20	20 / 20	100
r-Biopharm RIDAGENE Cdif [22] (n =27)	76	76 / 81	94	27	27 / 27	100
Commercial assay / kit [27] (n =46)	133	133 / 138	96	46	46 / 46	100
<i>In house</i> PCR assay [28] (n = 16)	44	44 / 48	92	16	16 / 16	100
Andere / k.A. / other [29] (n = 6)	17	17 / 17 §	100	6	6 / 6	100

§ Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 4) von der Anzahl der Teilnehmer abweichen.
Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants.

Comments: ¹⁾ As sample #1915454 contained a low number of *Clostridium difficile* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.