

**PCR-/NAT *Clostridium difficile*
 (RV 545) November 2017**



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1725451	++	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 1x10 ⁴ CFU/mL)
1725452	+	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 5x10 ³ CFU/mL)
1725453	+++	61 / 71,72	<i>Clostridium difficile</i> O27 deletion (~ 1x10 ⁵ CFU/mL)
1725454	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 102</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	1725451	1725452	1725453	1725454		1725451	1725452	1725453	1725454
Befund <i>Result</i>									
Positiv	102	93	101	1	n.d.	0	0	0	0
Negativ	0	8 ¹⁾	1	101	nein <i>no</i>	102	102	102	102
Fraglich <i>Questionable</i>	0	1	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>		
	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%	Absolut <i>Absolute</i>	Relativ <i>Relative</i>	%
Cepheid Xpert <i>C.difficile</i> [20] (n=30)	84	84 / 89 §	94	30	30 / 30	100
BD MAX <i>C.difficile</i> [21] (n=14)	42	42 / 42	100	14	14 / 14	100
r-Biopharm RIDAGENE Cdif [22] (n=16)	47	47 / 48	98	15	15 / 16	94
Commercial assay / kit [27] (n=30)	89	89 / 90	99	30	30 / 30	100
<i>In house</i> PCR assay [28] (n=11)	31	31 / 33	94	11	11 / 11	100
Andere / k.A. / other [29] (n=6)	17	17 / 18	94	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. 2) 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 #1725452 contained a low number of *Clostridium difficile* target organisms, negative PCR results were not rated “false negative” in this EQAS distribution.