

PCR-/NAT *Helicobacter pylori*
(RV 533) November 2016



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1625331	∅	62	<i>Escherichia coli</i> K12
1625332	+	61/71	<i>Helicobacter pylori</i> (~ 1x10 ³ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1625333	++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1625334	++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 38</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<i>1625331</i>	<i>1625332</i>	<i>1625333</i>	<i>1625334</i>	<i>1625331</i>	<i>1625332</i>	<i>1625333</i>	<i>1625334</i>	
<i>Befund Result</i>									
Positiv	0	38 ¹⁾	38 ¹⁾	38 ¹⁾	n.d.	1	1	1	1
Negativ	38	0	0	0	nein no	37	37	37	37
Fraglich Questionable	0	0	0	0	ja yes	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>	%
Hain GenoType Helico [20] (n = 17)	51	51 / 51	100	17	17 / 17	100
Ingenetix ClariRes [21] (n = 3)	9	9 / 9	100	3	3 / 3	100
Commercial assay [27] (n = 7)	21	21 / 21	100	7	7 / 7	100
<i>In house</i> PCR assay [28] (n = 13)	39	39 / 39	100	13	13 / 13	100

* 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⁾ Thirty-four of the 38 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.