

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.
Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1615331	+++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1615332	∅	62	<i>Helicobacter felis</i> (~ 1x10 ³ CFU/mL)
1615333	+	61/72	<i>Helicobacter pylori</i> (~ 1x10 ³ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1615334	∅	62	<i>Escherichia coli</i> K12

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.
Absolute numbers of reported individual results.

<i>n = 48</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1615331	1615332	1615333	1615334	1615331	1615332	1615333	1615334	
Befund <i>Result</i>									
Positiv	48 ¹⁾	5	46 ¹⁾	0	n.d.	0	0	0	0
Negativ	0	42	2	48	nein <i>no</i>	48	48	48	48
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>	%
Hain GenoType Helico [20] (n = 18)	35	35 / 36	97	35	35 / 36	97
Ingenetix ClariRes [21] (n = 4)	8	8 / 8	100	8	8 / 8	100
Commercial assay [27] (n = 9)	17	17 / 18	94	17	17 / 17 [§]	100
In house PCR assay [28] (n = 17)	34	34 / 34	100	30	30 / 34	88
Andere / k.A. / other [29] (n = 1)	2	2 / 2	100	2	2 / 2	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⁾ Forty of the 48 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 3 laboratories, all reported results were correct.