

**PCR-/NAT *Helicobacter pylori*
 (RV 533) Mai 2015**



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1515331	+++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
1515332	∅	62	<i>Escherichia coli</i> K12
1515333	++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
1515334	∅	62	<i>Campylobacter jejuni</i> (~ 1x10 ⁵ CFU/mL)

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

<i>n = 45</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	1515331	1515332	1515333	1515334	1515331	1515332	1515333	1515334	
Befund <i>Result</i>									
Positiv	45 ¹⁾	0	45 ¹⁾	0	n.d.	0	0	0	0
Negativ	0	44	0	45	nein <i>no</i>	45	44	45	45
Fraglich <i>Questionable</i>	0	1	0	0	ja <i>yes</i>	0	1	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 [25] (n = 20)	40	40 / 40	100	39	39 / 39 [§]	100
Ingenetix ClariRes [26] (n = 3)	6	6 / 6	100	6	6 / 6	100
Commercial assay [27] (n = 2)	4	4 / 4	100	4	4 / 4	100
<i>In house</i> PCR assay [28] (n = 19)	38	38 / 38	100	38	38 / 38	100
Andere / k.A. / other [29] (n = 2)	4	4 / 4	100	4	4 / 4	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⁾ Thirty nine of the 45 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 1 laboratory, all reported results were correct.