

**PCR-/NAT *Helicobacter pylori***  
**(RV 533) Mai 2021**



**Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.**

*Sample composition and expected results.*

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
2115331	+++	61/72	<i>Helicobacter pylori</i> (~ 5x10 <sup>5</sup> CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
2115332	∅	62	<i>Campylobacter jejuni</i> (~ 5x10 <sup>4</sup> CFU/mL)
2115333	∅	62	<i>Escherichia coli</i> K12
2115334	+++	61/71	<i>Helicobacter pylori</i> (~ 5x10 <sup>5</sup> CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)

**Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.**

*Absolute numbers of reported individual results.*

<i>n = 51</i>	<i>Probennummer (Sample no.)</i>					<i>Inhibition</i>			
	2115331	2115332	2115333	2115334		2115331	2115332	2115333	2115334
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	50 <sup>1)</sup>	0	0	51 <sup>1)</sup>	n.d.	1	1	1	1
<b>Negativ</b>	1	51	51	0	nein <i>no</i>	50	50	50	50
<b>Fraglich</b> <i>Questionable</i>	0	0	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.*

<b>NAT-Methode</b> [Code] (total number *)	<b>NAT richtig positiv</b> <i>True positive results</i>				<b>NAT richtig negativ</b> <i>True negative results</i>			
	2115331		2115334		2115332		2115333	
	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%	<i>Absolut</i> <i>Absolute</i>	%
HAIN GenoType HelicoDR (n = 20)	20	100	20	100	20	100	20	100
Ingenetix H.pylori ClariRes (n = 3)	3	100	3	100	3	100	3	100
Seegene Allplex H.pylori + ClariR (n = 3)	3	100	3	100	3	100	3	100
RIDAGENE H.pylori (n = 7)	7	100	7	100	7	100	7	100
Other commercial tests (n = 5)	5	100	5	100	5	100	5	100
<i>In house</i> PCR assay (n = 13)	12	92	13	100	13	100	13	100

**Comments:** <sup>1)</sup> Forty-five of the 51 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 2 laboratories, all reported results were correct.