

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



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

*Sample composition and expected results.*

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
2125331	+++	61/72	<i>Helicobacter pylori</i> (~ 5x10 <sup>5</sup> CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
2125332	∅	62	<i>Escherichia coli</i> K12
2125333	∅	62	<i>Escherichia coli</i> K12
2125334	++	61/72	<i>Helicobacter pylori</i> (~ 1x10 <sup>4</sup> CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

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

*Absolute numbers of reported individual results.*

<i>n</i> = 53	Probennummer (Sample no.)				Inhibition				
	2125331	2125332	2125333	2125334	2125331	2125332	2125333	2125334	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	52 <sup>1)</sup>	1	1	52 <sup>1)</sup>	n.d.	2	2	2	2
<b>Negativ</b>	1	52	52	1	nein <i>no</i>	51	51	51	51
<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.*

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>				NAT richtig negativ <i>True negative results</i>			
	2125331		2125334		2125332		2125333	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
HAIN GenoType HelicoDR (n = 20)	19	95	20	100	19	95	19	95
Ingenetix H. pylori ClariRes (n = 3)	3	100	3	100	3	100	3	100
Amplidiag H. pylori + ClariR (n = 2)	2	100	2	100	2	100	2	100
Sacace H. pylori Real-TM (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex H. pylori + ClariR (n = 4)	4	100	4	100	4	100	4	100
LightMix Helicobacter 23S Kit (n = 4)	4	100	4	100	4	100	4	100

<b>RIDAGENE H. pylori (n = 7)</b>	<b>7</b>	<b>100</b>	<b>7</b>	<b>100</b>	<b>7</b>	<b>100</b>	<b>7</b>	<b>100</b>
<b>In house PCR assay (n = 11)</b>	<b>11</b>	<b>100</b>	<b>10</b>	<b>91</b>	<b>11</b>	<b>100</b>	<b>11</b>	<b>100</b>
<b>Other commercial tests (n = 1)</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>	<b>1</b>	<b>100</b>

**Comments:** <sup>1)</sup> Forty-two of the 53 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.