

**PCR-/NAT *Helicobacter pylori*  
 (RV 533) November 2011**



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
1125331	<b>++</b>	61/71	<i>Helicobacter pylori</i> (~ 1x10 <sup>4</sup> CFU/mL) Clarithromycin resistant (GGA mut. in 28S rDNA)
1125332	<b>Ø</b>	62	<i>Helicobacter salomonis</i> (~ 1x10 <sup>4</sup> CFU/mL)
1125333	<b>Ø</b>	62	<i>Helicobacter bizzozeronii</i> (~ 1x10 <sup>3</sup> CFU/mL)
1125334	<b>(Ø)</b>	62	<i>Helicobacter felis</i> (~ 1x10 <sup>3</sup> CFU/mL)

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

<i>n = 41</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	<b>1125331</b>	<b>1125332</b>	<b>1125333</b>	<b>1125334</b>	<b>1125331</b>	<b>1125332</b>	<b>1125333</b>	<b>1125334</b>	
<b>Befund</b> <i>Result</i>									
<b>Positiv</b>	40 <sup>1)</sup>	6	3	7 <sup>2)</sup>	n.d.	0	0	0	0
<b>Negativ</b>	1	35	38	34	nein <i>no</i>	41	41	41	41
<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>		
	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>	<b>Absolut</b> <i>Absolute</i>	<b>Relativ</b> <i>Relative</i>	<b>%</b>
<b>Ingenetix ClariRes Assay [26] (n= 3)</b>	<b>3</b>	3 / 3	<b>100</b>	<b>9</b>	9 / 9	<b>100</b>
<b>Commercial assay [27] (n = 12)</b>	<b>12</b>	12 / 12	<b>100</b>	<b>33</b>	33 / 36	<b>92</b>
<b>In house PCR assay [28] (n = 24)</b>	<b>23</b>	23 / 24	<b>96</b>	<b>60</b>	60 / 72	<b>83</b>
<b>Andere / k.A. / other [29] (n = 2)</b>	<b>2</b>	2 / 2	<b>100</b>	<b>5</b>	5 / 6	<b>83</b>

**Comments:** <sup>1)</sup> Twenty-nine of the 41 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.

<sup>2)</sup> Positive PCR results with sample # 1125334 were not rated as false-positive in the course of issuing the corresponding QC certificates.