

PCR-/NAT *Helicobacter pylori*
(RV 533) November 2022



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
2225331	++	61/72	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
2225332	∅	62	<i>Escherichia coli</i> K12
2225333	++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2225334	∅	62	<i>Helicobacter felis</i> (~ 1x10 ⁵ CFU/mL)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 49</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>					
<i>Befund Result</i>	2225331	2225332	2225333	2225334	2225331	2225332	2225333	2225334		
Positiv	49 ¹⁾	0	49 ¹⁾	6	n.d.	0	0	0	0	
Negativ	0	49	0	43	nein <i>no</i>	49	49	49	49	
Fraglich <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 Anwenden 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>			
	2225331		2225333		2225332		2225334	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
HAIN GenoType HelicoDR (n = 15)	15	100	15	100	15	100	15	100
Ingenetix H. pylori ClariRes (n = 2)	2	100	2	100	2	100	2	100
Amplidiag H. pylori + ClariR (n = 2)	2	100	2	100	2	100	0	0
Seegene Allplex H. pylori + ClariR (n = 6)	6	100	6	100	6	100	6	100
LightMix Helicobacter 23S Kit (n = 3)	3	100	3	100	3	100	0	0
RIDAGENE H. pylori (n = 8)	8	100	8	100	8	100	8	100
<i>In house</i> PCR assay (n = 10)	10	100	10	100	10	100	9	90
Other commercial tests (n = 3)	3	100	3	100	3	100	3	100

Comments:

1. Forty-six of the 49 participants reported results for molecular Clarithromycin-susceptibility testing. All reported results were correct.
2. Unter "Andere kommerzielle Testsysteme" sind folgende Testsysteme aufgeführt: VIASURE H.pylori + Clarithromycin resistance Real Time PCR Detection Kit von CerTest (2x).