

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



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

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
2215331	+	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2215332	+++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁶ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2215333	∅	62	<i>Escherichia coli</i> K12
2215334	++	61/71	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)

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

<i>n = 53</i>	<i>Probennummer (Sample no.)</i>				<i>Inhibition</i>				
	2215331	2215332	2215333	2215334	2215331	2215332	2215333	2215334	
Befund <i>Result</i>									
Positiv	53 ¹⁾	53 ¹⁾	0	53 ¹⁾	n.d.	1	1	1	1
Negativ	0	0	53	0	nein <i>no</i>	52	52	52	52
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 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	
	2215331		2215332		2215334		2215333	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <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
Amplidiag H. pylori + ClariR (n = 2)	2	100	2	100	2	100	2	100
Seegene Allplex H. pylori + ClariR (n = 4)	4	100	4	100	4	100	4	100
LightMix Helicobacter 23S Kit (n = 2)	2	100	2	100	2	100	2	100
RIDAGENE H. pylori (n = 7)	7	100	7	100	7	100	7	100

In house PCR assay (n = 13)	13	100	13	100	13	100	13	100
Other commercial tests (n = 2)	2	100	2	100	2	100	2	100

Comments:

1. Forty-five of the 53 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of two laboratories, 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 (1x).