

PCR-/NAT *Helicobacter pylori*
(RV 533) Mai 2023



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

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
533 230523 01	++	61/ 71	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533 230523 02	++	61/ 72	<i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
533 230523 03	∅	62	<i>Escherichia coli</i> K12
533 230523 04	∅	62	<i>Helicobacter mustelae</i> (~ 1x10 ⁵ CFU/mL)

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

n = 57	Proben Nr. (Sample no.)				Inhibition				
	Befund Result	01	02	03	04	01	02	03	04
Positiv	56 ¹⁾	55 ¹⁾	1	4 ¹⁾	n.d.	0	0	0	0
Negativ	0	1	55	51	nein no	57	57	57	57
Fraglich Questionable	1	1	1	2	ja yes	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 True positive results				NAT richtig negativ True negative results			
	01		02		03		04	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Bruker-HAIN GenoType HelicoDR (n = 17)	17	100	16	94	17	100	16	94
CerTest VIASURE H .pylori + Clari. (n = 2)	1 [§]	100	1 [§]	100	1 [§]	100	1 [§]	50
Ingenetix H. pylori ClariRes (n = 4)	4	100	4	100	4	100	4	100
Amplidiag H. pylori + ClariR (n = 1)	1	100	1	100	1	100	0	0
Seegene Allplex H. pylori + ClariR (n = 9)	9	100	9	100	9	100	9	100
LightMix Helicobacter 23S Kit (n = 1)	1	100	1	100	1	100	1	100
RIDAGENE H. pylori (n = 9)	9	100	9	100	8	89	9	100
In house PCR assay (n = 13)	13	100	13	100	13	100	11 [§]	92
Other commercial tests (n = 1)	1	100	1	100	1	100	1	100

[§] Fraglich Due to reporting questionable results, the number of true results has been reduced.

Comments:

1. Forty-nine of the 57 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of two laboratories, all reported results were correct.