

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



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
533 231024 01	++	<i>Helicobacter pylori</i> (~ 1x10⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
533 231024 02	∅	<i>Escherichia coli</i> K12
533 231024 03	+++	<i>Helicobacter pylori</i> (~ 1x10⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533 231024 04	+	<i>Helicobacter pylori</i> (~ 1x10⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n</i> = 52	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	52 ¹⁾	0	52 ¹⁾	47 ¹⁾	n.d.	0	0	0	0
Negativ	0	52	0	5	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 results among various NAT methods.

NAT-Methode [Code] (total number *)	NAT richtig positiv <i>True positive results</i>						NAT richtig negativ	
	01		03		04		02	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Bruker-HAIN GenoType HelicoDR (n = 13)	13	100	13	100	9	69	13	100
CerTest VIASURE H .pylori + Clari. (n = 3)	3	100	3	100	3	100	3	100
Ingenetix H. pylori ClariRes (n = 2)	2	100	2	100	2	100	2	100
Amplidiag H. pylori + ClariR (n = 1)	1	100	1	100	1	100	1	100
Seegene Allplex H. pylori + ClariR (n = 8)	8	100	8	100	8	100	8	100
LightMix Helicobacter 23S Kit (n = 2)	2	100	2	100	2	100	2	100
RIDAGENE H. pylori (n = 10)	10	100	10	100	10	100	10	100
<i>In house</i> PCR assay (n = 10)	10	100	10	100	9	90	10	100
Other commercial tests (n = 3)	3	100	3	100	3	100	3	100

Comments:

- Forty-nine of the 52 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of one laboratory, all reported results were correct.