

**PCR-/NAT *Helicobacter pylori*
 (RV 533) Mai 2024**



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

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
533A 240521 01	∅	62	<i>Campylobacter jejuni</i> (~ 1x10 ⁵ CFU/mL)
533A 240521 02	+++	61/ 71	<i>Helicobacter pylori</i> (~ 5x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533A 240521 03	∅	62	<i>Escherichia coli</i> K12
533A 240521 04	+++	61/ 72	<i>Helicobacter pylori</i> (~ 1x10 ⁶ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

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

n = 53	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04		01	02	03	04
Befund <i>Result</i>									
Positiv	1	53 ¹⁾	1	53 ¹⁾	n.d.	0	0	0	0
Negativ	52	0	52	0	nein no	53	53	53	53
Fraglich <i>Questionable</i>	0	0	0	0	ja yes	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>			
	02		04		01		03	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Bruker-HAIN GenoType HelicoDR (n = 14)	14	100	14	100	13	93	13	93
CerTest VIASURE H .pylori + Clari. (n = 1)	1	100	1	100	1	100	1	100
Ingenetix H. pylori ClariRes (n = 2)	2	100	2	100	2	100	2	100
Seegene Allplex H. pylori + ClariR (n = 11)	11	100	11	100	11	100	11	100
LightMix Helicobacter 23S Kit (n = 1)	1	100	1	100	1	100	1	100
RIDAGENE H. pylori (n = 8)	8	100	8	100	8	100	8	100
In house PCR assay (n = 13)	13	100	13	100	13	100	13	100
Other commercial tests (n = 3)	3	100	3	100	3	100	3	100

Comments:

1. The following tests are listed under "Other commercial tests": Bioeksen H.pylori/Clarithromycin Resistance qPCR Kit (1x) and Savvygen H. pylori and Antibiotic Resistance Kit (1x).
2. Forty- seven of the 53 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of two laboratories, all reported results were correct.