

PCR-/NAT *Helicobacter pylori* (RV 533) Nov 2025



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

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
533A 251014 01	Ø	62	<i>Helicobacter salomonis</i> (~ 5x10 ⁵ CFU/mL)
533A 251014 02	++	61/ 71	<i>Helicobacter pylori</i> (~ 5x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533A 251014 03	Ø	62	<i>Escherichia coli</i> K12
533A 251014 04	+++	61/ 72	<i>Helicobacter pylori</i> (~ 5x10 ⁵ 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				
Befund Result		01	02	03	04		01	02	03	04
Positiv		6	51 ⁽²⁾	3	51 ⁽²⁾	n.d.	0	0	0	0
Negativ		46	1	49	1	nein no	52	52	52	52
Fraglich Questionable		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 True positive results				NAT richtig negativ True negative results			
	02		04		01		03	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Bruker-HAIN GenoType HelicoDR (n = 13)	13	100	13	100	12	92	13	100
CerTest VIASURE H pylori + Clari. (n = 1)	1	100	1	100	1	100	1	100
Ingenetix H. pylori ClariRes (n = 3)	3	100	3	100	1	33	3	100
Seegene Allplex H. pylori + ClariR (n = 13)	13	100	12	92	12	92	12	92
TIB Molbiol Modular Helicob. 23S rRNA (n = 1)	1	100	1	100	1	100	1	100
r-Biopharm RIDAGENE H. pylori (n = 7)	6	86	7	100	6	86	6	86
In house PCR assay (n = 9)	9	100	9	100	9	100	8	89
Other commercial tests (n = 5)	5	100	5	100	4	80	5	100

Comments:

1. The following tests are listed under "Other commercial tests": Bioeksen H.pylori/Clarithromycin Resistance qPCR Kit (1x), Sansure Biotech Helicobacter pylori Clarithromycin resistant Diagnostic Kit (1x), FRIZ Biochem (1x) and Savvygen H. pylori and Antibiotic Resistance Kit (1x).
2. Fifty of the 52 participants reported results for molecular Clarithromycin-susceptibility testing. Excluding the laboratories with false positive and false negative results, all reported results were correct.