

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



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

Proben Nr.	Erwartet / expected	Probenzusammensetzung / Sample composition
533A 250520 01	+++	61/ 72 <i>Helicobacter pylori</i> (~ 5x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
533A 250520 02	Ø	62 <i>Escherichia coli</i> K12
533A 250520 03	++	61/ 72 <i>Helicobacter pylori</i> (~ 5x10 ⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)
533A 250520 04	+	61/ 72 <i>Helicobacter pylori</i> (~5x10 ³ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence)

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

n = 61	Proben Nr. (Sample no.)				Inhibition				
Befund Result	01	02	03	04		01	02	03	04
Positiv	61 ¹⁾	0	61 ¹⁾	59 ¹⁾	n.d.	0	0	0	0
Negativ	0	61	0	2	nein no	61	61	61	61
Fraglich Questionable	0	0	0	0	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	
	01		03		04		02	
	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%	Absolut Absolute	%
Bruker-HAIN GenoType HelicoDR (n = 16)	16	100	16	100	15	94	16	100
CerTest VIASURE H pylori + Clari. (n = 1)	1	100	1	100	1	100	1	100
Ingenetix H. pylori ClariRes (n = 4)	4	100	4	100	4	100	4	100
Seegene Allplex H. pylori + ClariR (n = 13)	13	100	13	100	13	100	13	100
r-Biopharm RIDAGENE H. pylori (n = 9)	9	100	9	100	9	100	9	100
In house PCR assay (n = 12)	12	100	12	100	11	92	12	100
Other commercial tests (n = 3)	6	100	6	100	6	100	6	100

Comments:

1. The following tests are listed under "Other commercial tests": r-Biopharm RIDA UNITY H. pylori and Resistance CF (1x), Bioeksen H.pylori/Clarithromycin Resistance qPCR Kit (1x), Sansure Biotech Helicobacter pylori Clarithromycin resistant Diagnostic Kit (1x) and Savvygen H. pylori and Antibiotic Resistance Kit (1x).
2. Fifty- one of the 61 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of one laboratory, all reported results were correct.