

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



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

Proben Nr.	Erwartet / expected		Probenzusammensetzung / Sample composition
533A 241015 01	+	61/71	<i>Helicobacter pylori</i> (~ 2x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533A 241015 02	+++	61/71	<i>Helicobacter pylori</i> (~ 2x10 ⁶ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533A 241015 03	++	61/71	<i>Helicobacter pylori</i> (~ 2x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
533A 241015 04	∅	62	<i>Escherichia coli</i> K12

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

<i>n</i> = 59	Proben Nr. (Sample no.)				Inhibition				
	01	02	03	04	01	02	03	04	
Befund <i>Result</i>									
Positiv	58¹⁾	59¹⁾	58¹⁾	2	n.d.	0	0	0	0
Negativ	1	0	1	56	nein <i>no</i>	59	539	59	59
Fraglich <i>Questionable</i>	0	0	0	1	ja <i>yes</i>	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	
	01		02		03		04	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
Bruker-HAIN GenoType HelicoDR (n= 12)	12	100	12	100	12	100	12	100
CerTest VIASURE H pylori + Clari. (n= 3)	3	100	3	100	2	67	1[§]	50
Ingenetix H. pylori ClariRes (n= 3)	3	100	3	100	3	100	3	100
Seegene Allplex H. pylori + ClariR (n= 13)	13	100	13	100	13	100	13	100
LightMix Helicobacter 23S Kit (n= 2)	2	100	2	100	2	100	2	100
RIDAGENE H. pylori (n= 11)	10	91	11	100	11	100	10	91
<i>In house</i> PCR assay (n= 10)	10	100	10	100	10	100	10	100
Other commercial tests (n= 5)	5	100	5	100	5	100	5	100

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).

§ Fraglich *Due to reporting questionable results, the number of true results has been reduced*

Comments:

1. Fifty-four of the 59 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of two laboratories, all reported results were correct.