

PCR-/NAT *Helicobacter pylori*
(RV 533) Mai 2020



Tabelle 1: Probenzusammensetzung und erwartetes Ergebnis.

Sample composition and expected results.

	<i>Erwartet / expected</i>		<i>Probenzusammensetzung / Sample composition</i>
2015331	++	61/71	<i>Helicobacter pylori</i> (~ 5x10 ⁴ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2015332	+++	61/71	<i>Helicobacter pylori</i> (~ 5x10 ⁵ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)
2015333	∅	62	<i>Escherichia coli</i> K12
2015334	+	61/71	<i>Helicobacter pylori</i> (~ 1x10 ³ CFU/mL) Clarithromycin resistant (GGA mut. in 23S rDNA)

Tabelle 2: Häufigkeit der Mitteilung verschiedener Befunde.

Absolute numbers of reported individual results.

<i>n = 51</i>	Probennummer (Sample no.)				Inhibition			
	2015331	2015332	2015333	2015334	2015331	2015332	2015333	2015334
Befund <i>Result</i>								
Positiv	51 ¹⁾	51 ¹⁾	0	42 ¹⁾²⁾	n.d.	0	0	0
Negativ	0	0	51	8 ²⁾	nein <i>no</i>	51	51	51
Fraglich <i>Questionable</i>	0	0	0	1 ²⁾	ja <i>yes</i>	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	
	2015331		2015332		2015334		2015333	
	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%	Absolut <i>Absolute</i>	%
HAIN GenoType HelicoDR (n = 20)	20	100	20	100	14	70	20	100
Ingenetix H.pylori ClariRes (n = 3)	3	100	3	100	3	100	3	100
RIDAGENE H.pylori (n = 4)	4	100	4	100	4	100	4	100
Other commercial tests (n = 11)	11	100	11	100	10	91	11	100
<i>In house</i> PCR assay (n = 13)	13	100	13	100	11	84	13	100

Comments: 1) Forty-two of the 51 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 2 laboratories, all reported results were correct.
 2) As sample # 2025334 contained a low number of *Helicobacter pylori* target organisms, negative PCR results were not rated "false negative" in this EQAS distribution.