

**PCR-/NAT *Helicobacter pylori*
 (RV 533) Mai 2014**



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

| | <i>Erwartet / expected</i> | | <i>Probenzusammensetzung / Sample composition</i> |
|---------|----------------------------|-------|--|
| 1415331 | ++ | 61/72 | <i>Helicobacter pylori</i> (~ 1x10 ⁵ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence) |
| 1415332 | + | 61/72 | <i>Helicobacter pylori</i> (~ 1x10 ⁴ CFU/mL) Clarithromycin susceptible (wildtype 23S rDNA sequence) |
| 1415333 | ∅ | 62 | <i>Helicobacter mustelae</i> (~ 1x10 ⁵ CFU/mL) |
| 1415334 | ∅ | 62 | <i>Escherichia coli</i> K12 |

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

| <i>n = 48</i> | Probennummer (Sample no.) | | | | Inhibition | | | | |
|--|---------------------------|------------------|---------|---------|-------------------|---------|---------|---------|----|
| | 1415331 | 1415332 | 1415333 | 1415334 | 1415331 | 1415332 | 1415333 | 1415334 | |
| Befund <i>Result</i> | | | | | | | | | |
| Positiv | 48 ¹⁾ | 48 ¹⁾ | 4 | 1 | n.d. | 2 | 2 | 2 | 2 |
| Negativ | 0 | 0 | 43 | 47 | nein <i>no</i> | 46 | 46 | 46 | 46 |
| Fraglich <i>Questionable</i> | 0 | 0 | 1 | 0 | ja <i>yes</i> | 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 <i>True positive results</i> | | | NAT richtig negativ <i>True negative results</i> | | |
|--|---|----------------------------|-----|---|----------------------------|-----|
| | Absolut <i>Absolute</i> | Relativ <i>Relative</i> | % | Absolut <i>Absolute</i> | Relativ <i>Relative</i> | % |
| Hain GenoType Helico [25] (n = 18) | 36 | 36 / 36 | 100 | 35 | 35 / 36 | 97 |
| Ingenetix ClariRes [26] (n = 3) | 6 | 6 / 6 | 100 | 6 | 6 / 6 | 100 |
| Commercial assay [27] (n = 4) | 8 | 8 / 8 | 100 | 7 | 7 / 8 | 88 |
| In house PCR assay [28] (n = 23) | 46 | 46 / 46 | 100 | 42 | 42 / 45 [§] | 93 |
| Andere / k.A. / other [29] (n = 1) | 2 | 2 / 2 | 100 | 2 | 2 / 2 | 100 |

[§] Due to reporting questionable results, the number of true results (denominator in the „relative“ column) has been reduced.

* Durch Mehrfachnennung oder fehlende Angabe kann die absolute Zahl der Ergebnisse (Tab. 2) von der Anzahl der Teilnehmer abweichen.
 Due to reporting results of multiple assay systems or missing specifications, the effective numbers are not correlating with the number of participants

Comments: ¹⁾ Thirty seven of the 43 participants reported results for molecular Clarithromycin-susceptibility testing. With the exception of 1 laboratory, all reported results were correct.