

E0110 A novel RT-PCR for the detection of *H. pylori* and identification of clarithromycin resistance mediated by mutations in the 23S rRNA gene

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Background: *H. pylori* resistance to clarithromycin has steadily increased over the past 20 years in Europe, seriously jeopardizing treatment success with the guideline-proposed first line therapy that contains macrolides.

Materials/methods: In this study we evaluated the commercially available LightMix[®] RT-PCR assay for *Helicobacter pylori* detection and identification of clarithromycin (CLR) resistance in culture and clinical specimens (gastric biopsies and stool). The *H. pylori* LightMix[®] RT-PCR detects a 97bp long fragment of the 23S rRNA gene and allows the identification of 3 distinct point mutations conferring CLR resistance via melting curve analysis. The performance of the *H. pylori* LightMix[®] RT-PCR was evaluated using *H. pylori* reference strains (n=60) that showed a broad range of phenotypical resistance to CLR (Minimum inhibitory concentrations from 0.016 to 256 mg/L).

Results: We found high concordance (95%) between phenotypical CLR resistance screening by E-Test[®] and the Lightmix[®] RT-PCR. Discrepant results were verified by sequencing of the 23S rRNA gene that always confirmed the results obtained by Lightmix[®] RT-PCR. Furthermore, *H. pylori* was detected in clinical biopsy and stool specimens by Lightmix[®] RT-PCR that always identified the correct *H. pylori* genotype.

Conclusions: Our data shows that there is a strong association between specific mutations in the 23S rDNA and CLR resistance. The RT-PCR proved to be an exceptional tool for a fast and reliable detection of *H. pylori*. Furthermore, it allows for CLR resistance screening within a few hours prior to the prescription of an antibiotic therapy and should drastically reduce the cases of treatment failure as CLR is just administered if no resistance is detected. These improved detection rates and antibiotic susceptibility information is especially important when *H. pylori* culture is unsuccessful.