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Titel des Beitrags:
A novel line immunoassay based on recombinant virulence factors enables highly specific and sensitive serologic diagnosis of Helicobacter pylori infection.

Abstract:
Helicobacter pylori colonizes half of the world’s population, and infection can lead to ulcers, gastric cancer, and mucosa-associated lymphoid tissue (MALT) lymphoma. Serology is the only test applicable for large-scale, population-based screening, but current tests are hampered by a lack of sensitivity and/or specificity. Also, no serologic test allows the differentiation of type I and type II strains, which is important for predicting the clinical outcome. H. pylori virulence factors have been associated with disease, but direct assessment of virulence factors requires invasive methods to obtain gastric biopsy specimens. Our work aimed at the development of a highly sensitive and specific, noninvasive serologic test to detect immune responses to important H. pylori virulence factors. This line immunoassay system (recomLine) is based on recombinant proteins. For this assay, six highly immunogenic virulence factors (CagA, VacA, GroEL, gGT, HcpC, and UreA) were expressed in Escherichia coli, purified, and immobilized to nitrocellulose membranes to detect serological immune responses in patient’s sera. For the validation of the line assay, a cohort of 500 patients was screened,
of which 290 (58.0%) were H. pylori negative and 210 (42.0%) were positive by histology. The assay showed sensitivity and specificity of 97.6% and 96.2%, respectively, compared to histology. In direct comparison to lysate blotting and enzyme-linked immunosorbent assay (ELISA), the recomLine assay had increased discriminatory power. For the assessment of individual risk for gastrointestinal disease, the test must be validated in a larger and defined patient cohort. Taking the data together, the recomLine assay provides a valuable tool for the diagnosis of H. pylori infection.