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Evaluation of the new immunochromatographic test BioNexia H. pylori Ag for rapid diagnosis of Helicobacter pylori antigen

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Background: The aim of this study was to evaluate a new immunochromatographic test (ICT), bioNexia® *H. pylori* Ag (bioMérieux) in comparison to tests requiring endoscopy (culture, real-time PCR, and rapid urease test: RUT) and another ICT: RAPID Hp StAR™ (Oxoid)Please copy and paste the corresponding text here

Material/methods: Patients for whom an upper digestive endoscopy was planned in 3 centres in the Bordeaux metropole, France and who did not receive previous eradication treatment and fulfilled the usual inclusion criteria were included in the study. Gastric biopsies were obtained for RUT, culture and PCR. In addition, stools were obtained and also tested centrally with the 2 ICTs: RAPID Hp StAR™ and bioNexia® *H. pylori* Ag. A patient was considered *H. pylori* positive if culture was positive or, in the case of a negative culture, if both RUT and real-time PCR were positive. Standard statistical tests were performed.

Results: 131patients were included, 36 were *H. pylori* positive and 95 *H. pylori* negative according to the above mentioned reference. bioNexia *H. pylori* Ag® detected 31 out of 36 *H. pylori* positive specimens while it detected 89 out of 95 *H. pylori* negative specimens (sensitivity 86%, specificity 94%, PPV 84%, NPV 95%). With the same samples, RAPID Hp StAR™ performances were: sensitivity 86%, specificity 83%, PPV 66%, and NPV 94%.

Conclusions: bioNexia® *H. pylori* Ag is a convenient test for a rapid diagnosis of *H. pylori*. Its specificity is excellent as well as its PPV which emphasizes its interest in areas or population of high *H. pylori* prevalence.