

# Evaluation of the new immunochromatographic test bioNexia® *H. pylori* Ag for rapid diagnosis of *Helicobacter pylori* in stools

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## Introduction

The interest for non-invasive diagnostic of *Helicobacter pylori* is increasing. Beside the urea breath test and serology, it was shown that *H. pylori* antigens and DNA are excreted in the stools where they can be detected.

## Aim

The aim of this study was to determine the accuracy (sensitivity and specificity) of a new rapid test (bioNexia® *H. pylori* Ag, bioMérieux, Marcy l'Etoile, France), an immunochromatographic test (ICT), in comparison to invasive tests.

## Material & Methods

Patients inclusion criteria:

- Endoscopy performed to get gastric biopsies and obtention of stools planned in 3 centres in the Bordeaux metropole: Hôpital St André - Hôpital Suburbain du Bouscat - Clinique Bordeaux Nord
- No previous eradication therapy prescribed

Tests performed in the 3 centres:

- On gastric biopsies : rapid urease test (RUT)

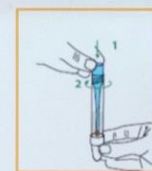
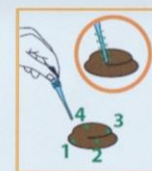
Tests performed in the central laboratory:

- On stools : 2 ICTs bioNexia *H. pylori* Ag (bioMérieux) and RAPID HpStAR™ (Oxoid)
- On gastric biopsies : 1) culture on Pylori agar (bioMérieux) and on in-house medium after grounding. The plates were incubated for 10 days before discarding them if no growth. Suspected colonies were tested for oxidase, catalase and urease.  
2) in-house real-time PCR

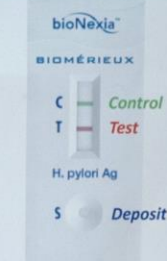
## Composite reference used:

- A patient was categorized *H. pylori* positive if the culture was positive, and in case of negative culture, if both the RUT and the real-time PCR were positive

## bioNexia® *H. pylori* Ag



10-15 min



## Results

131 patients included : 36 *H. pylori* positive (27,4%)

Reference	RUT	Culture	PCR	bioNexia	Oxoid	N	RUT	Culture	PCR	bioNexia	Oxoid	N
Reference positive n = 36 +	+	+	+	+	+	20	-	-	-	-	-	73
bioNexia n = 37 +	+	+	+	+	-	2	-	-	-	-	+	12
Oxoid n = 47 +	+	+	+	-	+	1	-	-	-	+	-	2
	+	+	+	-	-	1	-	-	-	+	+	1
Reference negative n = 95 -	-	+	+	+	+	7	+	-	-	-	-	2
bioNexia n = 94 -	-	+	+	-	+	2	-	-	+	+	+	3
Oxoid n = 84 -	-	+	+	-	-	1	-	-	+	+	+	3
	+	-	+	+	+	1	-	-	+	+	+	3

## Performances

	Sensitivity (%)	Specificity (%)	Positive Predictive Value (%)	Negative Predictive Value (%)
bioNexia	86	94	84	95
Oxoid	86	83	66	94

## Conclusion

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. The limit of the study is the choice of a low sensitivity test (RUT) to be included in the composite reference.