Patient' data		Gold standar t	H. pylori	H. pylori -IgG	
ID	RUT	Culture	Histopathology	status ^a	ELISA ^b
25	Positive	Positive	Positive	Positive	Positive
34	Positive	Negative	Positive	Positive	Positive
87	Positive	Positive	Positive	Positive	Positive
91	Positive	Positivo	Negative	Positive	Positive
100	Positive	Positive	Positive	Positive	Positive
101	Positive	Negative	Positive	Positive	Positive
104	Positive	Positive	Negative	Positive	Positive
111	Positive	Negative	Positive	Positive	Positive
114	Positive	Positive	Positive	Positive	Positive
115	Positive	Negative	Positive	Positive	Positive
116	Positive	Positive	Positive	Positive	Positive
117	Positive	Negative	Positive	Positive	Positive
118	Positive	Positive	Positive	Positive	Positive
121	Positive	Positive	Positive	Positive	Positive
130	Positive	Positive	Negative	Positive	Positive
136	Positive	Positive	Positive	Positive	Positive
141	Positive	Positive	Positive	Positive	Positive
144	Positive	Positive	Positive	Positive	Positive
146	Positive	Positive	Positive	Positive	Positive
154	Positive	Negative	Positive	Positive	Positive
163	Positive	Negative	Positive	Positive	Positive
164	Positive	Negative	Positive	Positive	Positive
170	Positive	Negative	Positive	Positive	Positive

Table S1. Report of diagnostic test results obtained for each patients with dyspeptic symptoms enrolled in the primary optimization in-house ELISA using samples from *H. pylori*-positive cases (n=23) and *H. pylori*-negative controls (n=23).

Patient' data	Gold standar tests			H. pylori	H. pylori -IgG
ID	RUT	Culture	Histopathology	status ^a	ELISA ^b
5	Negative	Negative	Positive	Negative	Negative
11	Negative	Negative	Negative	Negative	Negative
16	Negative	Negative	Negative	Negative	Negative
22	Negative	Negative	Negative	Negative	Negative
70	Negative	Negative	Negative	Negative	Negative
98	Negative	Negative	Negative	Negative	Negative
105	Negative	Negative	Negative	Negative	Negative
106	Negative	Negative	Negative	Negative	Negative
107	Negative	Negative	Negative	Negative	Negative
109	Negative	Negative	Negative	Negative	Negative
124	Negative	Negative	Negative	Negative	Negative

125	Negative	Negative	Negative	Negative	Negative
126	Negative	Negative	Negative	Negative	Negative
138	Negative	Negative	Negative	Negative	Negative
147	Negative	Negative	Negative	Negative	Negative
149	Positive	Negative	Negative	Negative	Negative
159	Negative	Negative	Negative	Negative	Negative
160	Negative	Negative	Negative	Negative	Negative
166	Positive	Negative	Negative	Negative	Negative
168	Positive	Negative	Negative	Negative	Negative
177	Positive	Negative	Negative	Negative	Negative
179	Negative	Negative	Negative	Negative	Negative
182	Negative	Negative	Negative	Negative	Negative
185	Negative	Negative	Negative	Negative	Negative

Legend and specifications

^a*H. pylori* status was defined by histopathology (standard histological examination with hematoxilin-eosin & giemsa stain), RUT and bacterial culture on Columbia agar plates under microaerophilic conditions. Patients were classified as *H. pylori*-infected if at least two of the gold standard tests were positives, otherwise they were considered *H. pylori*-noninfected [22].

^b Patient sera samples were analyzed using a commercially available *H. pylori* IgG ELISA (IBL International, Hamburg, Germany), previously validated [26], according to the manufacturer's instructions.

Item		Page	
	No	Recommendation	number
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or	2
		the abstract	
		(<i>b</i>) Provide in the abstract an informative and balanced summary of what	2
		was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation be-	2-3
Duenground/futionale	2	ing reported	23
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of	4
	-	recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection	4
ĩ		of participants	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders,	4-6
		and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measure-	8*	For each variable of interest, give sources of data and details of methods	5-7
ment		of assessment (measurement). Describe comparability of assessment	
		methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	4-7
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If appli-	7
		cable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for	7
		confounding	
		(b) Describe any methods used to examine subgroups and interactions	6
		(c) Explain how missing data were addressed	-
		(d) If applicable, describe analytical methods taking account of sampling	-
		strategy	
		(<u>e</u>) Describe any sensitivity analyses	-
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study-eg numbers po-	8
		tentially eligible, examined for eligibility, confirmed eligible, included in	
		the study, completing follow-up, and analysed	
		(b) Give reasons for non-participation at each stage	4
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical,	9
		social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of	9
		interest	
Outcome data	15*	Report numbers of outcome events or summary measures	8-12

 Table S2. STROBE Statement—Checklist of items that should be included in reports of cross-sectional studies

Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted es-	8-12
		timates and their precision (eg, 95% confidence interval). Make clear	
		which confounders were adjusted for and why they were included	
		(b) Report category boundaries when continuous variables were catego-	8-12
		rized	
		(c) If relevant, consider translating estimates of relative risk into absolute	-
		risk for a meaningful time period	
Other analyses	17	Report other analyses done-eg, analyses of subgroups and interactions,	12
		and sensitivity analyses	
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-14
Limitations	19	Discuss limitations of the study, taking into account sources of potential	13
		bias or imprecision. Discuss both direction and magnitude of any poten-	
		tial bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives,	12-14
		limitations, multiplicity of analyses, results from similar studies, and	
		other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present	-
		study and, if applicable, for the original study on which the present article	
		is based	

Note. The STROBE checklist of items included in cross-sectional studies were adapted of guideline published by von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. "The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Guidelines for Reporting Observational Studies". Int J Surg. 2014;12:1495–9 (https://linkinghub.elsevier.com/retrieve/pii/S174391911400212X).

Variability intra-assay*						
Sample	Replicate 1	Replicate 2	Duplicate Mean	SD	CV%	
1	0.085	0.091	0.088	0.003	3.41	
2	0.091	0.075	0.083	0.008	9.64	
3	0.103	0.066	0.085	0.019	21.89	
4	0.087	0.069	0.078	0.009	11.54	
5	0.089	0.079	0.084	0.005	5.95	
6	0.100	0.080	0.090	0.010	11.11	
7	0.088	0.074	0.081	0.007	8.64	
8	0.092	0.074	0.083	0.009	10.88	
9	0.129	0.126	0.128	0.002	1.18	
10	0.138	0.117	0.128	0.011	8.24	
11	0.117	0.112	0.115	0.003	2.18	
12	0.143	0.118	0.131	0.013	9.58	
13	0.138	0.133	0.136	0.003	1.85	
14	0.159	0.111	0.135	0.024	17.78	
15	0.134	0.124	0.129	0.005	3.88	
16	0.137	0.120	0.129	0.008	6.50	
17	0.134	0.074	0.104	0.030	28.85	
18	0.137	0.074	0.105	0.032	29.91	
19	0.085	0.126	0.106	0.021	19.43	
20	0.091	0.117	0.104	0.013	12.50	
21	0.103	0.112	0.108	0.005	4.19	
22	0.129	0.091	0.110	0.019	17.27	
23	0.138	0.075	0.107	0.032	29.58	
24	0.654	0.813	0.734	0.080	10.84	
25	0.653	0.784	0.719	0.066	9.12	
26	0.622	0.826	0.724	0.102	14.09	
27	0.606	0.777	0.692	0.086	12.36	
28	0.631	0.788	0.710	0.079	11.06	
29	0.625	0.770	0.698	0.073	10.39	
30	0.628	0.737	0.683	0.055	7.99	
31	0.619	0.817	0.718	0.099	13.79	
32	0.630	0.786	0.708	0.078	11.01	
33	1.155	1.105	1.130	0.025	2.21	
34	1.161	1.063	1.112	0.049	4.41	
35	1.093	1.095	1.094	0.001	0.09	
36	1.178	1.092	1.135	0.043	3.79	
37	1.120	1.083	1.102	0.019	1.68	

Table S3. Coefficient of variability average intra-assay and inter-assay using a panel of sera samples from seropositive *H. pylori*-cases and seronegative *H. pylori*-controls (n=46)

38	1.099	1.032	1.066	0.034	3.14
39	1.209	1.114	1.162	0.048	4.09
40	1.172	1.119	1.146	0.027	2.31
41	1.147	1.085	1.116	0.031	2.78
42	1.770	1.973	1.872	0.102	5.42
43	1.743	2.009	1.876	0.133	7.09
44	1.729	1.906	1.818	0.088	4.87
45	1.652	1.891	1.772	0.120	6.75
46	1.705	1.936	1.821	0.116	6.34

*The Intra-Assay variability is reported as the average of the individuals CV and is calculated by

% $CV = SD \div duplicate mean x 100$

where:

SD- standard desviation of duplicates

CV- coefficient of variability

Intra-assay %CV (n=46) = average % CV = 9.4

			Variabi	ility Inter-a	ssay**			
	Sample	Absorbar	nce values	Plate	Mean	Mean of plates/day	SD	%CV
-	low	0.211	0.246					
	low	0.232	0.254	1	0.236			
day 1 -	low	0.187	0.215	-	0.010	-		
	low	0.22	0.229	2	0.213			
	low	0.202	0.214	2	2 0.205	—	0.008	3.744
1 2	low	0.208	0.195	5 0.205	0.205	0.219		
day 2 -	low	0.193	0.208	4	0.214	- 0.218		
	low	0.226	0.229	4	0.214			
	low	0.233	0.244	E	0.017			
day 2	low	0.292	0.097	5	0.217			
uay 5	low	0.092	0.102	6	0.225			
	low	0.6	0.106	0	0.225			
	medium	0.651	0.616	1	0.622	-		
n dare 1	medium	0.63	0.589	1	0.022			
uay 1	medium	0.679	0.619	2	0.640			
	medium	0.578	0.682	2	0.040			
	medium	0.626	0.667	3	0 705	- 0.652	0.037	5.728
day 2 -	medium	0.765	0.763	3	0.705			
uay 2	medium	0.759	0.783	4	0.710	0.052		
	medium	0.688	0.611	4	0.710	_		
	medium	0.626	0.619	5	0.628			
dav 3 -	medium	0.628	0.639	5	0.028	_		
uay 5	medium	0.641	0.604	6	0.606			
	medium	0.573	0.606	0	0.000			
	high	1.729	1.606	1	1 732			
dav 1 -	high	1.723	1.868	1	1.732	_		
uay 1	high	1.479	1.594	2	1 581			
	high	1.618	1.631	2	1.561	_		
	high	0.883	0.974	3	0.963		0.202	24 120
day 2 -	high	1.055	0.94	5	0.963	1.016		
uay 2	high	0.989	0.972	Δ	0.962	1.210	0.275	27.127
	high	0.955	0.933	4	0.902	_		
	high	1.003	0.902	5	0.997			
dav 3 -	high	1.025	1.059	5	0.997	_		
uay 5	high	1.12	1.068	6	1.061			
	high	1.048	1.008	6 1.0	1.001			

*The Inter-Assay variability is reported as the average of the high, medium and low % CV.

% CV = SD of plate means \div mean of plate/day x 100

Inter-assay %CV (n=6) = average of % CV=11.2