



QUALITY ASSURANCE DEPARTMENT

Certificate of Kit Performance

CoproStrip™ H. Pylori

Catalog No: F41221

Kit Lot No: D0598700

Expiry Date: 2025-03

1. Description of components

Components	Code	Lot No	Expiry Date
H. pylori Devices	FC 41221-02	P-310	2025-03
Stool collection buffer	FC 41221-03	P-310	2025-03

2. KIT PERFORMANCE

Sensitivity test

Conc (ng/mL)	50	25	12.5	6.25	3.12	1.56	0.78	0.39	0.19	0.09	0.05	0.02	0
Result (t=10')	+	+	+	+	+	+	+	+	+	-	-	-	-

Specificity test

Positive Material				
1	2	3	4	5
+	+	+	+	+
6	7	8	9	10
+	+	+	+	+

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Negative Material				
1	2	3	4	5
-	-	-	-	-
6	7	8	9	10
-	-	-	-	-
11	12	13	14	15
-	-	-	-	-
16	17	18	19	20
-	-	-	-	-

Pass / Fail

Kit approved by

QC Manager: _____

Date: 04.06.2023

QA Manager: P. Libi Heylikher

Date: 04.06.2023