



QUALITY ASSURANCE DEPARTMENT

Certificate of Kit Performance

CoproStrip™ H. Pylori

Catalog No: F41221

Kit Lot No: C0906100

Expiry Date: 2024-05

1. Description of components

Components	Code	Lot No	Expiry Date
H. pylori Devices	FC 41221-02	P-301	2024-05
Stool collection buffer	FC 41221-03	P-301	2024-05

2. KIT PERFORMANCE

Sensitivity test

Dilution	1	1/2	1/4	1/8	1/16	1/32	1/64	1/128	1/256	1/512	1/1024	1/2048	0
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
-	-	NT	NT	NT

Pass / Fail

Kit approved by

QC Manager: Larisa

Date: 02.10.2022

QA Manager: [Signature]

Date: 02.10.2022