

CERTIFICATE OF ANALYSIS	Helicobacter pylori Ag Cassette
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REF	4245122	25 Test	x
	CT42451	20 Test	

LOT F1104N2F00
 2-30°C

2019-11
IVD

FUNCTIONALITY

Test	ACCEPTANCE		RESULTS
	Level	Criteria	
Positivity	10 positive samples	All positive	All positive
Negativity	20 negative samples	All negative	All negative
LOD	10 ng/mL	Positive	Positive
	5 ng/mL	Positive	Positive
	2.5 ng/mL	Positive/Negative	Negative
Precision	10 replicates	Uniformed band	Uniformed band
Sample diluent	SB-R0192	Negative	Negative

This lot was assayed by the test method described in the manufacturer's package insert. These results are applicable to this lot and subsequent sublots, for which a capital letter has been assigned after the lot number.

This Certificate of Analysis is a computer printout and has therefore not been signed by hand.

This lot meets our specifications and is released for sale	APPROVED	Signed Date of Manufacture: Mercè Oriol Quality Control Dept. 14 December 2017
	(APPROVED / NOT APPROVED)	

