

CERTIFICATE OF ANALYSIS	HELICOBACTER PYLORI Ab CASSETTE
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REF	4260240	40 Test			
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Cont	H. pylori test device Disposable specimen droppers
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LOT	F0627N5F00DB	2019-06
4-30 °C		

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

ANALYSIS	SPECIFICATIONS	TEST RESULTS	RESULTS
Positivity: - 2 positive samples - 1 whole blood positive	Positive	Positive	PASS
Negative specimens (20)	Negative	Negative	PASS
LOD : - L1 - L2 - L3	Positive Positive Positive / Negative	Positive Positive Negative	PASS
Precision	10 replicates	Uniformed band	PASS
Sample diluent	Negative	Negative	PASS
Background : - Female blood (10 replicates) - Male blood (10 replicates)	Clear	Clear	PASS
Flow rate.	Completion of run in membrane	In two minutes	PASS

(PASS / FAILURE)

This lot was tested by test methods described in the manufacturer's package insert.

These results are applicable to this lot and sequential sublots, for which a capital letter have 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, Alicia Abellan 22 August 2017 Quality Control Dept.
	(APPROVED / NOT APPROVED)	

