

CERTIFICATE OF ANALYSIS	DENGUE Ag CASSETTE
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REF

4276240	40 Test	X
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Cont	Test device	LOT	F0916L12C01B		2017-09
	Disposable specimen droppers		2-30 °C		
	Sample diluent				

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 WB positive samples	Both positive Positive	Both positive Positive
NEGATIVITY	20 negative samples	All negative	All negative
LOD	Dengue type 1 - L2 Dengue type 2 - L5 Dengue type 3 - L8 Dengue type 4 - L11	Positive Positive Positive Positive	Positive Positive Positive Positive
Precision	10 replicates	Uniformed band	Uniformed band
Sample diluent	DENGUE Ag CASSETTE	Negative	Negative
Background	Female blood (10 replicates) Male blood (10 replicates)	Clear	Clear

(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, Mercè Oriol QA/RA Manager 08/10/2015
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