

CERTIFICATE OF ANALYSIS	DENGUE IgG/IgM CASSETTE
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REF

4273240	40 Test	X
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Cont Test device
Disposable specimen droppers
Sample diluent

LOT F0614M7I05DB 2018-06
2-30 °C IVD

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

ANALYSIS	SPECIFICATIONS	TEST RESULTS	RESULTS
POSITIVITY	2 IgG+IgM positive samples 2 IgG+IgM WB positive samples	Both positive	Both positive
NEGATIVITY	20 negative samples	All negative	All negative
LOD	L1 (IgG)	Positive	Positive
	L2 (IgG)	Positive	Positive
	L3 (IgG)	Positive / Negative	Positive / Negative
	L4 (IgM)	Positive	Positive
	L5 (IgM)	Positive	Positive
	L6 (IgM)	Positive / Negative	Positive / Negative
Precision	10 replicates	Uniformed band	Uniformed band
Sample diluent	DENGUE IgG/IgM CASSETTE	Negative	Negative
Background	Female blood (10 replicates)	Clear	Clear
	Male blood (10 replicates)		

(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, 15 July 2016 Mercè Oriol Quality Control Dept.
	(APPROVED / NOT APPROVED)	

