



ANALYSIS CERTIFICATE

Dengue-CHIK cassette

REF	4274240	40 Test	x		
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Cont	40 Dengue-CHIK test device	LOT F0617M2A04DB	 2018-06
	40 Capillar Tubes (5 µl)		
	40 Plastic Droppers	 2-30 °C	IVD
	2 Sample diluent		

CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULT
Dengue-CHIK CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

FUNCTIONALITY TEST

TEST	SPECIFICATIONS	RESULTS
POSITIVE CONTROL	2 Den IgG+IgM positive samples	POSITIVE
	2 CHIK IgM positive samples	POSITIVE
	1 Den whole blood positive samples	POSITIVE
	1 CHIK whole blood positive samples	POSITIVE
NEGATIVE CONTROL	20 negative samples	NEGATIVE
PRECISION	Den 10 replicates	Uniformed Band
	CHIK 10 replicates	Uniformed Band
Background	Female blood. 10 replicados	Clear
	Male blood. 10 replicados	Clear

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 15 July 2016 Quality Control Dept.
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