



CERTIFICATE OF ANALYSIS	RUBA IgG / IgM Cassette
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REF	4217240	40 Test	x
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LOT	F0616M6A00B		2018-06
	2-30°C	IVD	

FUNCTIONALITY

Test	ACCEPTANCE		RESULTS
	Level	Criteria	
Positivity	20 positive samples	All positive	All positive
	1 IgG whole blood positive	Positive	Positive
	1 IgM whole blood positive	Positive	Positive
Negativity	20 negative samples	All negative	All negative
Precision	10 replicates test (IgG1)	Uniformed band	Uniformed band
	10 replicates test (IgG2)	Uniformed band	Uniformed band
	10 replicates test (IgM)	Uniformed band	Uniformed band
LOD (R0243)	L1 L2 (IgG 1)	Positive	Positive
	L3 (IgG 1)	Positive / Negative	Positive
	L4 L5 (IgG 2)	Positive	Positive
	L6 (IgG 2)	Positive / Negative	Positive
	L7 L8 (IgM)	Positive	Positive
	L9 (IgM)	Positive / Negative	Positive
Sample diluent	SB-R0243	Negative	Negative
Flow rate	Complete in 2 minutes		In 2 minutes

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

