

CERTIFICATE OF ANALYSIS	B-hCG cassette
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REF 4130040 40 Test X

Cont	Device
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LOT F0715N4D00 2019-07
 2-30 °C **IVD**

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
DEVICE	APPEARANCE	COMPACT DEVICE	PASS

(PASS / FAILURE)

ANALYSIS		SPECIFICATIONS	RESULTS
Sensitivity	6.25 mIU/ml	± / Negative	Negative
	12.5 mIU/ml	Positive	Positive
	25 mIU/ml	Positive	Positive
	50 mIU/ml	Positive	Positive
Specificity	50 negative samples	Negative	Negative
Prozone:	2000 mIU/ml	Positive	Positive
Pass / No Pass	PASS		

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, 22 August 2017 Alícia Abellan Quality Control Dept.
	(APPROVED / NOT APPROVED)	

