



CERTIFICATE OF ANALYSIS	ANTI – HIV 1/2 CASSETTE
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REF

4235240	40 Test	X
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Cont HIV test device Disposable specimen droppers HIV Buffer	LOT F0623N3E02B 	2-30 °C		2019-06
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IVD

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

ANALYSIS	SPECIFICATIONS	TEST RESULTS	RESULTS
POSITIVITY	2 HIV-1 positive samples 2 HIV-2 positive samples 1 HIV-1 WB positive samples 1 HIV-2 WB positive samples	Positive	PASS
NEGATIVE	20 Negative samples	Negative	PASS
LOD	L1 / L2 L3 L4 / L5 L6	Positive Positive / negative Positive Positive / negative	PASS
Precision	10 replicates (HIV-1) (HIV-2)	Uniformed band	PASS
Sample diluent	Negative	Negative	PASS
Background :	Clear	Clear	PASS
- Female blood (10 replicates) - Male blood (10 replicates)			
Flow rate.	Completion of run in membrane	In two minutes	PASS

(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 n°.

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

