

CERTIFICATE OF ANALYSIS	ANTI – HCV CASSETTE
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REF

4230240

40 Test

x

Cont HCV test device
Disposable specimen droppers
HCV Sample diluent

LOT F0624N5B00B 2019-06
 2-30 °C

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

ANALYSIS	Solution	SPECIFICATIONS	RESULTS
Positivity: - 2 positive samples - 1 whole blood positive	Positive	Positive	PASS
Negative specimens (20)	Negative	Negative	PASS
LOD : - L1 - L2 - L3	Positive Positive Positive / Negative	Positive Positive Negative	PASS
Precision	10 replicates	Uniformed band	PASS
Buffer	Negative	Negative	PASS
Background : - Female blood (10 replicates) - Male blood (10 replicates)	Clear	Clear	PASS
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 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, Alícia Abellan Quality Control Dept. 22 August 2017
	(APPROVED / NOT APPROVED)	

