

CERTIFICATE OF ANALYSIS

HBsAg CASSETTE

REF 4255240 40 Test X

Cont HBsAg test device
Disposable specimen droppers

LOT
F0623N2G01B
2-30 °C

F0623N2G01B



2019-06

IVD

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

ANALYSIS	SPECIFICATIONS	TEST RESULTS
Positivity 10 positive samples	All positive	All positive
Negativity 20 negative samples	All negative	All negative
Precision 10 replicates	Uniformed band	Uniformed band
LOD Level 1	Positive	Positive
LOD Level 2	Positive	Positive
LOD Level 3	Positive / Negative	Negative
Flow rate	In 2 minutes	In 2 minutes
RESULTS	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, 22 August 2017 Alícia Abellan Quality Control Dept.
	(APPROVED / NOT APPROVED)	

