

CERTIFICATE OF ANALYSIS	STREP A CASSETTE
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REF

4280220 20 Test	4280225 25 Test	x
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Cont	Strep A test device	Strep A Reagent A	LOT I608017		2018-07
	Sterile swabs	Strep A Reagent B		IVD	
	Workstation	Positive Control	2-30 °C		
	Tube test	Negative Control			
	Droppers				

PHYSICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
CASSETTE	APPEARANCE	COMPACT CASSETTE	PASS

(PASS / FAILURE)

FUNCTIONALITY TEST

Test	Solution	Specifications	Test results	Pass
Positive control	1.0 x 10 ⁶ org/mL Strep C	Negative	Negative	Pass
Sensitivity control	1.0 x 10 ⁵ org/mL Strep A	Positive	Positive	Pass
	1.0 x 10 ⁶ org/mL Strep A	Positive	Positive	Pass

This lot was tested by test methods described in the manufacturer's package insert.

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
	(APPROVED / NOT APPROVED)	31 August 2016 Quality Control Dept.

