


CERTIFICATE OF ANALYSIS	PROTEUS OX19
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REF	2107005	5 mL	X	2107081	X
	2108005	50 mL		2107082	X
				2107085	X

LOT 21904
 2-8°C

 2020-10

IVD

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
PROTEUS OX19	APPEARANCE	Homogeneous suspension, free of macroscopic particles.	ACCEPTED
	COLOUR	Blue	
	pH	8.2 +/- 0.2	

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST: SLIDE AND TUBE METHOD	SPECIFICATIONS	RESULTS
PROTEUS OX19	Sensitivity, against Internal Reference Material	Titer: Within tolerance range	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	

(ACCEPTED / N/A)

STABILITY TEST (14 days at 37°C)

REAGENT	TOLERANCE	RESULT
PROTEUS OX19	After a stability study, the specifications remain unchanged	ACCEPTED

(ACCEPTED / N/A)

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
	(APPROVED / NOT APPROVED)	Date of Manufacture Pilar Montolio 2018-03-23 Quality Control Dept.

