

CERTIFICATE OF ANALYSIS	ROSE BENGAL
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REF

2210005	100 tests	x	2210010	100 tests (w/o control)	x	2210081 (1 L)	x	2921280 (500 mL)	
2210015	5 mL	x				2210082 (0.25 L)	x	2921281 (100 mL)	
			2922150	1 mL		2210085 (5 L)	x	2921282 (50 mL)	

Cont	R	X
	Control (+)	X
	Control (-)	X

LOT	22096
	2-8°C

	2019-07
IVD	

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
ROSE BENGAL (R)	APPEARANCE	Liquid suspension free of macroscopic particles. Homogeneous.	ACCEPTED
	COLOUR	Bright Rose colour.	
	pH	3.6 ± 0.2	
CONTROL (+)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)	APPEARANCE	Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

REAGENT	TEST	SPECIFICATIONS	RESULTS
ROSE BENGAL (R)	Sensitivity, against Reference Material. 2 ^o International anti-Brucella abortus serum (NIBS-WHO)	20-30 IU/mL	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with Rose Bengal	3+	ACCEPTED
CONTROL (-)	Tested with Rose Bengal	Negative	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST (7 days at 37°C)

REAGENT	TOLERANCE	RESULT
ROSE BENGAL	After a stability study, the specifications remain unchanged	ACCEPTED
CONTROL (+)		ACCEPTED
CONTROL (-)		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 Date of Manufacture Pilar Montolio 2017-07-10 Quality Control Dept
	(APPROVED / NOT APPROVED)	

