



CERTIFICATE OF ANALYSIS	TPHA
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REF	2520005	200 Tests	X	2925282	50 ml	
				2520090	1 L	X
				2520092	1 L	X
				2520094	1 L	X

Cont	R1 / R2 / R3	X
	Control (+)	X
	Control (-)	X

LOT 25348A
 2-8°C

 2019-10
IVD

PHYSICAL AND CHEMICAL CHARACTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
R1 TEST CELLS	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles. Dark red colour.	ACCEPTED
R2 CONTROL CELL			ACCEPTED
R3 BUFFER		Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (+)		Liquid solution. Clear and transparent.	ACCEPTED
CONTROL (-)		Liquid solution. Clear and transparent.	ACCEPTED

(ACCEPTED / N/A)

FUNCTIONALITY

TEST	SPECIFICATIONS	RESULTS
SENSITIVITY	Reactive control serum (CDC, USA) Known titer: 1:5120 ± 1 dil	ACCEPTED
CONTROL (+)	(+++)	ACCEPTED
CONTROL (-)	(-)	ACCEPTED

(ACCEPTED / N/A)

Components from human origin have been tested and found negative for the presence of antibody to HIV (1/2) as well as HBsAg and HCV. However, handle cautiously as potentially infectious.

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

These results are applicable to this lot and subsequent sublots, for which a capital letter has 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 2018-02-16 Quality Control Dept.
	(APPROVED / NOT APPROVED)	



