

CERTIFICATE OF ANALYSIS	hCG - LATEX
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REF	2610005	50 Tests	2610081	1 L	2926150	X
	2610015	100 Tests	2610082	0,25 L	2926155	X
			2610085	5L	2926181	X
					2926182	X

Cont	R		LOT	29524		2018-09
	Control (+)	x		2-8°C	IVD	
	Control (-)					

PHYSICAL AND CHEMICAL CHARAC YTERISTICS

REAGENT	TEST	SPECIFICATIONS	RESULTS
hCG-LATEX (R)	APPEARANCE	Homogeneous suspension free of macroscopic or flaky particles.	ACCEPTED
	COLOUR	White	
	pH	7.4 +/- 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
hCG-LATEX (R)	Sensitivity, against Reference Material 3 rd International hCG Standard 75/357 (WHO)	200-100 IU/L	ACCEPTED
	Positive Control	3+	
	Negative Control	Negative	
CONTROL (+)	Tested with hCG-Latex	3+	ACCEPTED
CONTROL (-)	Tested with hCG-Latex	Negative	ACCEPTED

(ACCEPTED / N/A)

STABILITY TEST (10 days at 37°C)

REAGENT	TOLERANCE	RESULT
hCG-LATEX	After a stability study, the specifications remain unchanged	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 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 2016-05-17 Quality Control Dept.
	(APPROVED / NOT APPROVED)	

