

IO 09- 020-V



CODE 91055

CODE

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT EPSTEIN BARR VCA IgG

LOT. 122

DATE OF TEST 21/12/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm	2.551
	CV%	7% < 20%
2nd PLATE	OD 450 nm	n/a
	CV%	n/a < 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm	2.708
	CV%	7% <15%
2. BULK CONTROL date: 13/12/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm	0.311 ≥ 0.200
B) Index of Negative and Positive Sera		accepted According to specification
C) Sensitivity with working calibrators		accepted According to specification
3. FINAL CONTROL date: 21/12/2023		
A) Blank	OD 450 nm	0.050 ≤ 0.100
B) Negative Control	OD 450 nm	0.011 ≤ 0,6 Cut Off
C) Calibrator 1 (Cut Off)	OD 450 nm	0.602 ≥ 0.200
D) Calibrator 2	OD 450 nm	2.311
E) Calibrator 3	OD 450 nm	3.431 ≥ 1.000
F) HOMOGENEITY OF CUT OFF	No.	6
	OD 450 nm	0.652
	CV%	3% ≤ 15%
G) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 21/12/2023

Signed:

Released: Q.C.Manager