

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgM

Code	91056		
LOT.NO	132-A	2024-07	2023-04

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93054	007000	MICROPLATE	030	2024-10	1
PF93571	006990	CONJUGATE	127	2024-07	1
PF93910	1036	NEGATIVE CONTROL	176	2024-11	1
PF91871	016590	CALIBRATOR 1	113	2024-10	1
PF30077	016600	CALIBRATOR 2	113	2024-10	1
PF92072	016610	CALIBRATOR 3	113	2024-10	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	458	2024-09	1
PF93602	1032/RISKO	STOP SOLUTION	215-5	2024-08	1
PF30253	B5160	SAMPLE SORBENT 10	016	2024-10	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.002	< 0,6 CUT OFF
CUT OFF CONTROL (CAL 1)	0.520	≥ 0.200
POSITIVE CONTROL (CAL 3)	1.928	≥ 1.000
CALIBRATOR 2	1.263	≥ 0.500
CV %	7%	≤ 15%

*Evaluatin of the method according to the package inset in the attached document
This batch has been manufactured and checked according to quality requirements.
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE: 19/05/2023

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.

IO 09- 021-V



CODE 91056
CODE _____

QUALITY CONTROL CERTIFICATE
Annex: Method Evaluation

NAME KIT	EPSTEIN BARR VCA IgM
LOT.	132
DATE OF TEST	09/05/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.030	
	CV% 2%	< 20%
2nd PLATE	OD 450 nm 1.968	
	CV% 2%	< 20%
B) UNIFORMITY WITHIN PLATE		
	OD 450nm 1.960	
	CV% 5%	<15%
2. BULK CONTROL date: 19/04/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.529	≥ 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: 09/05/2023		
A) Blank	OD 450 nm 0.052	≤ 0.100
B) Negative Control	OD 450 nm 0.002	< 0,6 Cut Off
C) Calibrator 1 (Cut Off)	OD 450 nm 0.520	≥ 0.200
D) Calibrator 2	OD 450 nm 1.263	≥ 0.500
E) Calibrator 3	OD 450 nm 1.928	≥ 1.000
F) HOMOGENEITY OF CUT OFF		
	No. 6	
	OD 450 nm 0.572	
	CV% 7%	≤15%
G) PRECISION OF FILLING PROCESS		

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 09.05.2023

Signed:
Released: Q.C.Manager