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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL EPSTEIN BARR VCA IgM

Code	91056		
LOT.NO	131-D	2024-04	2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93054	007000	MICROPLATE	028	2024-04	1
PF93571	006990	CONJUGATE	126	2024-04	1
PF93910	1036	NEGATIVE CONTROL	175	2024-06	1
PF91871	016590	CALIBRATOR 1	112	2024-07	1
PF30077	016600	CALIBRATOR 2	112	2024-07	1
PF92072	016610	CALIBRATOR 3	112	2024-07	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF93611	009660	DILUENT 2	229	2024-09	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISKO	STOP SOLUTION	215-5	2024-08	1
PF30253	B5160	SAMPLE SORBENT 10	015	2024-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.012	< 0,6 CUT OFF
CUT OFF CONTROL (CAL 1)	0.511	≥ 0.200
POSITIVE CONTROL (CAL 3)	1.174	≥ 1.000
CALIBRATOR 2	1.890	≥ 0.500
CV %	4%	≤ 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: 06.05.2023

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.	131
DATE OF TEST	27/01/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 2.204 CV% 4%	< 20%
2nd PLATE	OD 450 nm 2.086 CV% 4%	< 20%
B) UNIFORMITY WITHIN PLATE	OD 450nm 1.993 CV% 5%	<15%
2. BULK CONTROL date: 17/01/2023		
A) Average OD of Cut Off Calibrator	OD 450 nm 0.632	≥ 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: 27/01/2023		
A) Blank	OD 450 nm 0.054	≤ 0.100
B) Negative Control	OD 450 nm 0.012	< 0,6 Cut Off
C) Calibrator 1 (Cut Off)	OD 450 nm 0.511	≥ 0.200
D) Calibrator 2	OD 450 nm 1.174	≥ 0.500
E) Calibrator 3	OD 450 nm 1.890	≥ 1.000
F) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.565 CV% 4%	≤15%
G) PRECISION OF FILLING PROCESS		



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 30.01.2023

Signed:

Released: Q.C.Manager