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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 135-A



2025-04



2024-05

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93054	007000	MICROPLATE	033	2025-04	1
PF93571	006990	CONJUGATE	130	2025-08	1
PF93910	1036	NEGATIVE CONTROL	179	2025-06	1
PF91871	016590	CALIBRATOR 1	116	2025-11	1
PF30077	016600	CALIBRATOR 2	116	2025-11	1
PF92072	016610	CALIBRATOR 3	116	2025-11	1
PF93619	1034	SUBSTRATE-HS	383-1	2025-05	1
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	473	2025-08	1
PF93602	1032/RISKO	STOP SOLUTION	218-6	2025-06	1
PF30253	B5160	SAMPLE SORBENT 10	019	2025-11	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL (CAL 0)	0.009	< 0,6 CUT OFF
CUT OFF CONTROL (CAL 1)	0.407	≥ 0.200
POSITIVE CONTROL (CAL 3)	1.742	≥ 1.000
CALIBRATOR 2	1.049	≥ 0.500
CV %	5%	≤ 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:

2025.02.24

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. 135

DATE OF TEST 23/05/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND		EXPECTED
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.954	
	CV%	4%	< 20%
2nd PLATE	OD 450 nm	N/A	
	CV%	N/A	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450nm	1.963	
	CV%	4%	<15%
2. BULK CONTROL date: 21/05/2024			
A) Average OD of Cut Off Calibrator	OD 450 nm	0.408	≥ 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: 23/05/2024			
A) Blank	OD 450 nm	0.049	≤ 0.100
B) Negative Control	OD 450 nm	0.009	< 0,6 Cut Off
C) Calibrator 1 (Cut Off)	OD 450 nm	0.407	≥ 0.200
D) Calibrator 2	OD 450 nm	1.049	≥ 0.500
E) Calibrator 3	OD 450 nm	1.742	≥ 1.000
F) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.456	
	CV%	5%	≤15%
G) PRECISION OF FILLING PROCESS			



SATISFACTORY



UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date:

Signed:

Released: Q.C.Manager