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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

132



2024-06



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	175	2024-06	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	457	2024-08	1
PF93602	1032/RISK0	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%

Evaluation 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: 11.05.2023

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

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

OD 450 nm 2.030
CV% 2%

EXPECTED

< 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
- B) Index of Negative and Positive Sera
- C) Sensitivity with working calibrators

OD 450 nm 0.529
accepted
accepted

≥ 0.200
According to specification
According to specification

3. FINAL CONTROL date: 09/05/2023

- A) Blank
- B) Negative Control
- C) Calibrator 1 (Cut Off)
- D) Calibrator 2
- E) Calibrator 3

OD 450 nm 0.052
OD 450 nm 0.002
OD 450 nm 0.520
OD 450 nm 1.263
OD 450 nm 1.928

≤ 0.100
< 0,6 Cut Off
≥ 0.200
≥ 0.500
≥ 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