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Sede Legale e Amministrazione
20144 Milano (Italy) Via A. Solari 19 sc. 6

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgM

Code 91028

LOT.NO 239-D



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	666	2024-04	1
PF93925	007190	CUT OFF CONTROL	214	2024-07	1
PF93900/HSV	C5020	NEGATIVE CONTROL	781	2024-07	1
PF93923	007220	POSITIVE CONTROL	202	2024-07	1
PF91721	007230	ANTIGEN	220	2025-09	6
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISKO	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF30055	007180	CONJUGATE	221	2024-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.206	< 0,6 Cut Off
CUT OFF CONTROL	0.458	≥ 0.200
POSITIVE CONTROL	1.532	> 1,5 Cut Off
CV %	8%	≤ 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:

09.05.2023

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- 005-V



CODE 91028

CODE 91186

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 1 IgM
LOT.	239
DATE OF TEST	17/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

FOUND

OD 450 nm 1.799

CV% 4%

EXPECTED

< 20%

2nd PLATE

OD 450 nm 1.772

CV% 6%

< 20%

B) UNIFORMITY WITHIN PLATE

OD 450 nm 1.792

CV% 7%

< 15%

2. BULK CONTROL date:14/02/2023

A) Average OD of Cut Off Control

OD 450 nm 0.424

≥ 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: 17/02/2023

A) Blank

OD 450 nm 0.045

≤ 0.100

B) Average OD of Negative Control

OD 450 nm 0.206

< 0,6 Cut Off

C) Average OD of Cut Off Control

OD 450 nm 0.458

≥ 0.200

D) Average OD of Positive Control

OD 450 nm 1.532

> 1,5 Cut Off

E) HOMOGENEITY OF CUT OFF

No. 8

OD 450 nm 0.511

CV% 8%

≤ 15%

F) PRECISION OF FILLING PROCESS

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 20.02.2023

Signed:

Released: Q.C.Manager