

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX1 IgM

Code	91028		
LOT.NO	242	2025-04	2024-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007200	MICROPLATE	674	2025-05	1
PF93925	007190	CUT OFF CONTROL	221	2025-07	1
PF93900/HSV	C5020	NEGATIVE CONTROL	812	2025-07	1
PF93923	007220	POSITIVE CONTROL	209	2025-07	1
PF91721	007230	ANTIGEN	221	2026-09	6
PF93611	009660	DILUENT 2	232	2025-05	1
PF93603	1035	WASHING BUFFER 10x	468	2025-06	1
PF93602	1032/RISK0	STOP SOLUTION	218-6	2025-06	1
PF93619	1034	SUBSTRATE-HS	383	2025-05	1
PF30055	007180	CONJUGATE	228	2025-04	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.262	< 0,6 Cut Off
CUT OFF CONTROL	0.522	≥ 0.200
POSITIVE CONTROL	1.151	> 1,5 Cut Off
CV %	12%	≤ 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: 31.01.2024

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. 242
DATE OF TEST 30/01/2024

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE

A) UNIFORMITY BETWEEN PLATES

1st PLATE

2nd PLATE

B) UNIFORMITY WITHIN PLATE

FOUND

EXPECTED

OD 450 nm 3.021
CV% 2%
OD 450 nm 2.794
CV% 9%

< 20%

< 20%

OD 450 nm 3.057
CV% 5%

< 15%

OD 450 nm 0.483
accepted
accepted

≥ 0.200

According to specification

According to specification

OD 450 nm 0.053
OD 450 nm 0.262
OD 450 nm 0.522
OD 450 nm 1.151

≤ 0.100

< 0,6 Cut Off

≥ 0.200

> 1,5 Cut Off

No. 6
OD 450 nm 0.575
CV% 12%

≤ 15%

E) HOMOGENEITY OF CUT OFF

F) PRECISION OF FILLING PROCESS

SATISFACTORY

UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 30.1.2024

Signed: [Signature]
Released: Q.C.Manager