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Sede Legale e Amministrazione
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Pag 1/1

QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO 234-F



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	666	2024-04	1
PF93900/HSV	C4960	NEGATIVE CONTROL	782-1	2024-07	1
PF92355	007280	POSITIVE CONTROL	203-1	2024-07	1
PF30056	011560	CONJUGATE	222-1	2024-04	1
PF91722	007300	ANTIGEN	226	2025-09	6
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457-1	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	375	2024-09	1
PF30057	011570	CUT OFF CONTROL	215-1	2024-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.089	< 0,6 Cut Off
CUT OFF CONTROL	0.344	≥ 0.200
POSITIVE CONTROL	2.308	> 1,5 Cut Off
CV %	3%	≤ 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:

22.06.2023

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 91025

CODE 91187

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 2 IgM
LOT.	234
DATE OF TEST	24/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

1. SOLID PHASE	FOUND	EXPECTED
A) UNIFORMITY BETWEEN PLATES		
1st PLATE	OD 450 nm 1.799 CV% 4%	< 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: 15/02/2023		
A) Average OD of Cut Off Control	OD 450 nm 0.455	≥ 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: 24/02/2023		
A) Blank	OD 450 nm 0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm 0.085	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm 0.342	≥ 0.200
D) Average OD of Positive Control	OD 450 nm 2.221	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No. 6 OD 450 nm 0.387 CV% 13%	≤ 15%
F) PRECISION OF FILLING PROCESS		

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 24.02.2023

Signed:

Released: Q.C.Manager