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DIESSE DIAGNOSTICA SENESE SpA

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

QUALITY CONTROL CERTIFICATE

KIT NAME **ENZYWELL HERPES SIMPLEX 1+2 IgM**

Code 91021

LOT.NO 326 2025-01

2023-10

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	006190	MICROPLATE	672	2025-04	1
PF91520	006180	CONJUGATE	246	2025-01	1
PF93900/HSV	C4940	NEGATIVE CONTROL	804	2025-04	1
PF92022	005140	POSITIVE CONTROL	225	2025-04	1
PF91821	006150	CUT OFF CONTROL	238	2025-04	1
PF91621	006170	ANTIGEN	223	2026-03	6
PF93611	009660	DILUENT 2	231	2025-03	1
PF93603	1035	WASHING BUFFER 10x	464	2025-04	1
PF93602	1032/RISK0	STOP SOLUTION	218-5	2025-06	1
PF93619	1034	SUBSTRATE-HS	380	2025-03	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS	
NEGATIVE CONTROL	0.086	< 0,6 Cut Off	
CUT OFF CONTROL	0.428	≥ 0.200	
POSITIVE CONTROL	1.979	> 1,5 Cut Off	
CV %	10%	≤ 15%	

FOUND DECULTS

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: 03_11.623

WARNING: POTENTIAL BIOHAZARDOUS MATERIALI

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.