

72346 - MONOLISA HBs Ag ULTRA 1 PLATE
CERTIFICATE OF ANALYSIS

PRODUCT NUMBER : 72346		NAME : MONOLISA HBs Ag ULTRA 1 PLATE		LOT N° : 3A0116		
1)	<u>PACKAGING CONFORMANCE</u>	(c) conforming (nc) not conforming		C	NC	
		Control of labels		C		
		Expiration date 2024-05-28		C		
		Lot number		C		
2)	<u>PACKAGE INSERT CONFORMANCE</u>	With kit reagents		C		
3)	<u>KIT CONFORMANCE</u>	Qt	LOT	EXP.DATE		
		Number of components per kit			11	C
		R1 Microtiter plates	1	2L0323	2024-05-28	C
		R2 Washing solution*	1	2M0350	2024-12-05	C
		R3 Negative control	2	3A0323	2024-07-05	C
		R4 Positive control	1	3A0323	2024-07-06	C
		R6 Conjugate diluent	1	3A0323	2024-06-27	C
		R7 Conjugate	1	2M0323	2024-07-04	C
		R8 Substrate buffer/TMB WW*	1	2M0621	2024-06-16	C
		R9 coloured Chromogen (TMB) *	1	2M0832	2024-06-11	C
		R10 Stopping solution 1N*	1	2L0563	2024-11-20	C
		Package insert	1			C

* R2, R8, R9 and R10 are generic reagents

CONFORMING
 Steenvoorde, the 23/01/24

P Bhuir

NBhuir



N° Lot : 3A0116

		C	NC
4) <u>PHYSICAL PRODUCT CONTROL</u> * All criteria and parameters (aspect, volumes, pH and conductivity) were checked and found conforming		C	
5) <u>BACTERIOLOGICAL CONTROL</u> * Each reagent to be tested was checked and found conforming		C	
6) <u>MICROBIOLOGICAL CONTROL</u> R4 : anti HIV 1 et anti HIV 2 anti HCV HBs Ag	Negative Negative Positive	C C C	
7) <u>ACTIVITY CONTROL</u> Equipment Pipettes : Incubator : Washer : Reader :	AD E657 L8490 L15254	- - - -	- - - -

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	STANDARDS	RESULTS	C	NC
8) RESULTS The following results were obtained with generic reagents : R2 : 2M0350 R8 : 2M0621 R9 : 2M0832 R10 : 2L0563				
R3	$0,010 \leq \overline{OD} \leq 0,065$	PL 1 : 0.015 PL 2 : 0.010	C C	
R4	$1,2 \leq \overline{OD} \leq 2,0$	PL 1 : 1.746 PL 2 : 1.620	C C	
CO = cut - off	OD Mean R3+0,050	PL 1 : 0.065 PL 2 : 0.060	- -	- -
- Analytical Sensitivity	Linear regression ≤ 0.09 ng/ml	PL 1 : 0.07	C	
Panel lot : 05				
- Specificity : 100 negative samples	No positive	No positive	C	
Panel lot : 17				
- EFS Panel : lot : 38.240601	Linear regression ≤ 0.130 UI/ml	Reviewed by G-med	C	

CONFORMING

NOT CONFORMING

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