MONOLISA HBs Ag ULTRA CONFIRMATORY
CERTIFICATE OF ANALYSIS
72408

PRODUCT NUMBER : 72408	NAME : MONOLISA HBS AG ULTRA CONFIRMATORY	LOT : 2E0065

(c) conforming
(nc) not conforming

					C	NC
1)	**PACKAGING CONFORMANCE**					
	Control of labels	.....			C	
	Expiration date	.....	2023-10-22		C	
	Lot number	.....			C	
2)	**PACKAGE INSERT CONFORMANCE**					
	With kit reagents	.....			C	
3)	**KIT CONFORMANCE**	QT	LOT	EXP. DATE		
	Number of components per kits	4			C	
RA	Anti HBs positive diluent	1	2D0076	2023-10-22	C	
RB	Negative diluent	1	2D0076	2023-10-22	C	
RC	Sample diluent	1	2D0076	2023-10-25	C	
	Package insert	1			C	

CONFORMING

Steenvoorde, the 2022/05/17

I. LIMOGES

BIO-RAD
DATE 22.05.24
VISA Conca D.
QUALITY CONTROL

Digitally signed by Levința Alexandru
Date: 2023.07.28 10:41:02 EEST
Reason: MoldSign Signature
Location: Moldova

LOT : 2E0065

		C	NC
4) PHYSICAL PRODUCT CONTROL			
* All criteria and parameters (aspect, volumes) were checked and found conforming		C	
5) BIOBURDEN CONTROL	**STANDARDS**		
* Each reagent to be tested was checked and found conforming			
RA :	Conforming	C	
RB :	Conforming	C	
RC:	Conforming	C	
6) ACTIVITY CONTROL			
Equipment Pipettes :	MC	-	-
Incubator :	E8462	-	-
Washer :	L14059	-	-
Reader:	L15254	-	-
7) RESULTS			
Standards : lot = **10**	Conforming	C	
EFS AgHBs PANEL lot = 34.230225	Conformity reviewed by GMED	C	
FALSE POSITIVE PANEL lot = 01	Conforming	C	

The RA and the RB products contain human source material. Each serum and plasma donor unit has been tested and found non reactive for HBs Ag, HIV 1 and HIV 2 Ab and HCV Ab.

CONFORMING **~~NOT CONFORMING~~**

TL

GMED
GROUPE LNE

NOTIFICATION
relative à la
VERIFICATION DES PRODUITS FABRIQUES
Directive 98/79/CE Dispositifs médicaux de diagnostic in vitro
Transposée par l'ordonnance n°2001-198 du 1er Mars 2001

NOTIFICATION
relating to
VERIFICATION OF MANUFACTURED PRODUCTS
Directive 98/79/EC in vitro diagnostic medical devices
(ordonnance n°2001-198 du 1er Mars 2001)

DOSSIER NUMERO / *DOSSIER NUMBER* : **P604413 / 22-L3**

IDENTIFICATION DU PRODUIT / *PRODUCT IDENTIFICATION*

NOM DU PRODUIT / *BRAND NAME*	**MONOLISA ® Ag HBs ULTRA Confirmatory (72408)**
PARAMETRES / *PARAMETERS*	**Hépatite B : Antigène HBs (confirmation)**
NUMERO DE LOT / *BATCH NUMBER*	**2E0065**
TAILLE DU LOT / *BATCH SIZE*	**675 kits**
DATE DE FABRICATION / *DATE OF MANUFACTURE*	**2022-04-25**
DATE DE PEREMPTION / *EXPIRATION DATE*	**2023-10-22**

IDENTIFICATION DU FABRICANT / *MANUFACTURER IDENTIFICATION*

NOM / *NAME*	**BIO-RAD**	
INTERLOCUTEURS / *PERSON TO CONTACT*	**Contact1 : Catherine CARON** **Contact2 : Sylviane COSSEZ**	EMAIL : **catherine.caron@bio-rad.com** EMAIL : **SQIDDContactG_Med@bio-rad.com** FAX / *FAX* : /
ADRESSE / *ADDRESS*	**3 bd Raymond POINCARE – 92430 MARNES-LA-COQUETTE**	

SPECIFICATIONS DE CONTROLE RETENUES PAR LE FABRICANT / *SPECIFICATIONS RESPECTED BY THE MANUFACTURER*

DATE DE RECEPTION DU RAPPORT DE CONTROLE DE LOT *RECEPTION OF THE BATCH RELEASE REPORT ON*	**4 & 18 mai 2022**
SPECIFICATIONS INTERNES / *IN-HOUSE SPECIFICATIONS*	**PROD VS 229 IP (Version n°6)** **PVS 72408 01 (Version n°4)**
SPECIFICATIONS DU PANEL DE REPRODUCTIBILITE / *CONTROL PANEL SPECIFICATIONS*	**Panel EFS HBs Ag (DQ119) Lot 34.230225**
SPECIFICATIONS TECHNIQUES COMMUNES / *COMMON TECHNICAL SPECIFICATIONS*	**Exigences 3.4**

VERIFICATION / *VERIFICATION*

Sur la base des enregistrements du fabricant relatifs au lot ci-dessus visé, GMED a vérifié que les résultats des contrôles transmis sont :

On the basis of the manufacturer's records relating to the batch defined here above, GMED has checked that the quality control results:

☒ **CONFORMES** / ***ARE IN CONFORMITY***
☐ **NON CONFORMES** / ***ARE NOT IN CONFORMITY***

} **aux spécifications ci-dessus mentionnées** / ***with the above-mentioned specifications***

LIBERATION DE LOT / *BATCH RELEASE*

DATE / ***DATE***: 24 MAI 2022 | ☒ **AVIS FAVORABLE** / ***ACCEPTED*** | ☐ **AVIS DEFAVORABLE** / ***REJECTED***

SIGNATURES / *SIGNATURES*

VERIFICATION TECHNIQUE ***TECHNICAL VERIFICATION***	**SIGNATURE DU REPRESENTANT AUTORISE PAR GMED** ***GMED AUTHORISED REPRESENTATIVE***
NOM / NAME: **Mélanie PETT** Mélanie PETT	**Pour le Président,** ***For the President,*** **Ségolène COLRAT** Chef de Projet Certification DIV *IVD Certification Project Manager* Ségolène COLRAT

Numéro de fax pour la libération de lot / *Fax number for batch release* : (+33) 1.30.16.25.74. *email :* gmed.ivd.batch.release@lne.fr