Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. TR-100 din 15.12.2023

Solicitantul TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Puskin 60/1, of. 4, tel./fax: 022-22-03-02, e-mail triumf.motiv@mail.ru, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Denumire generică (denumirea dispozitivului)	Modelul
Merilisa HCV	HPCELI-01
Merilisa HBsAg	HPBELI-01
Merilisa T3 ELISA	ITTELI-01
Merilisa T4 ELISA	ITFELI-01
Merilisa TSH ELISA	TSIELI-01

Se anexează următoarele acte:
DECLAȚIE DE CONFORMITATE CE
CERTIFICATUL DE CONFORMITATE CE
Scrisoare de autorizare de la producător

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:08:12 EET
Reason: MoldSign Signature
Location: Moldova

Data 15.12.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: TRIUMF MOTIV SRL, cu sediul or. Chișinău str. Puskin 60/1, of. 4,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

Denumire generică (denumirea dispozitivului)	Modelul
Merilisa HCV	HPCELI-01
Merilisa HBsAg	HPBELI-01
Merilisa T3 ELISA	ITTELI-01
Merilisa T4 ELISA	ITFELI-01
Merilisa TSH ELISA	TSIELI-01

Sunt autentice și corespund realității.

Numele, prenumele şi funcţia Jighili Tatiana, Administrator
Semnătura _____

Data _15.12.2023___

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:08:20 EET
Reason: MoldSign Signature
Location: Moldova

LETTER OF AUTHORIZATION

Date: June 10th, 2023

To Whom It May Concern:

Hereby, we

Company Name: Meril Diagnostics Pvt Ltd
Address: Muktanand Marg, Chala, Vapi, Gujarat. INDIA
Phone number: +91 260 2408000

Certify that:

Triumf Motiv SRL
Address: Republic Of Moldova, MD 2043-str. Grenoble 193, et.13, of.1
Phone number: (+373 22) 76 84 62, 76 88 41

Triumf-Motiv SRL is our authorized representative and distributor on the territory of the Republic of Moldova.

We allow this company to register our products with the competent authorities on the territory of the Republic of Moldova, as well as to promote, sell, distribute our products in the Republic of Moldova, and we will provide all necessary assistance to expand the market of medical supplies and devices of our brand Merilisa in your country.

This letter of authorization remains valid for five years, starting from June 20.2023 and expiring on March 09, 2028.

Signature:

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:08:17 EET
Reason: MoldSign Signature
Location: Moldova

MERIL DIAGNOSTICS PRIVATE LIMITED

Meril

Diagnostics

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL DIAGNOSTICS PVT. LTD.**
Manufacturer's Address:	Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.
Product Name:	_____ (The Immunology Reagents covered by this declaration are indicated in the Annex I)
Product Details:	**Control No.** DOC/IM/GEN/C/Rev.03/23.10.2019 Lot No.: _____ Mfg. Date: _____ Ref. No.: _____ Expiry Date: _____ Conforms to the applicable national and international standards.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All the supporting documentations are retained under the premises of the manufacturer.

General applicable directives:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
List of Standard Applied:	EN 13975:2003, EN 13640:2002, EN 13641:2002, EN 13612 : 2002, EN 14136:2004, EN 980:2008, EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-1: 2011, EN ISO 18113-2 : 2011, EN 15193:2009, EN 15194:2009, EN 17511:2003, EN 23640:2015, ISO 15223-1:2016
Conformity Assessment Route:	Annex: III of Directive /98/79/EC on In vitro Diagnostic Medical Devices
Device Classification:	Device other than those covered in Annex II of Directive 98/79/EC
European Authorized Representative:	Obelis s.a., Bd General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954 F +32.2.732.6003 E mail@obelis.net
Signature:	MERIL DIAGNOSTICS PVT. LTD. VAPI
Name:	Mr. K. Sridhar
Designation:	Senior General Manager
Date/Location:	**Date**: _____ **Location**: Vapi, Gujarat, INDIA

CE

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:07:28 EET
Reason: MoldSign Signature
Location: Moldova

Annex I

Sr. No.	Product Name	UMDNS Code	Product Code
1.	MERISCREEN hCG	19952	HCGRPD-01 RPDHCG-01 RPDHCG-02
2.	Merilisa T3 ELISA	19109	TTTELI-01
3.	Merilisa T4 ELISA	19110	TTFELI-01
4.	Merilisa TSH ELISA	19865	TSOELI-01
5.	Merilisa Cortisol ELISA	19131	COSELI-01
6.	Merilisa Free Estriol ELISA	19871	FESELI-01
7.	Merilisa Thyroglobulin ELISA	17398	ATGELI-01
8.	Merilisa Testosterone ELISA	19120	TSTELI-01
9.	Merilisa Estradiol ELISA	19115	ESTELI-01
10.	Merilisa Progesterone ELISA	19118	PSTELI-01
11.	Merilisa LH ELISA	19117	LHEELI-01
12.	Merilisa FSH ELISA	19116	FSNELI-01
13.	Merilisa 25OH Vitamin D Total ELISA	19142	VTDELI-01
14.	Merilisa Prolactin ELISA	19119	PRLELI-01
15.	Merilisa β HCG ELISA	19124	BHCELI-01
16.	Merilisa Free Testosterone ELISA	19869	FTSELI-01
17.	Merilisa FT3 ELISA	19862	FTTELI-01
18.	Merilisa FT4 ELISA	19111	FFFELI-01
19.	Merilisa DHEA-S ELISA	19114	DHSELI-01
20.	Merilisa Total IgE ELISA	17371	TIEELI-01
21.	Merilisa Insulin ELISA	19127	INSELI-01
22.	Merilisa C-Peptide ELISA	19126	CPTELI-01
23.	Merilisa ANA Screen	19038	ANAELI-01
24.	Merilisa Anti Phospholipid Screen	20107	APLELI-01
25.	Merilisa Anti dsDNA IgG ELISA	20075	DSDELI-01
26.	Merilisa Anti Cardiolipin IgM ELISA	20108	ACMELI-01
27.	Merilisa Anti Cardiolipin IgG ELISA	20108	ACGELI-01
28.	Merilisa Anti Cardiolipin Screen	20108	ACSELI-01
29.	Merilisa 17-OH Progesterone ELISA	19868	HPSELI-01
30.	LumiQuant LH – CLIA	19117	LUT CLI-01
31.	LumiQuant FSH – CLIA	19116	FOL CLI-01
32.	LumiQuant PROLACTIN – CLIA	19119	PLC CLI – 01
33.	LumiQuant PROGESTERONE – CLIA	19118	PRGCLI – 01
34.	LumiQuant TESTOSTERONE – CLIA	19120	TES CLI-01
35.	LumiQuant ESTRADIOL – CLIA	19115	ESTCLI – 01
36.	LumiQuant C- PEPTIDE – CLIA	19126	PEP CLI – 01
37.	LumiQuant INSULIN – CLIA	19127	INSCLI – 01
38.	LumiQuant T3 – CLIA	19109	TTTCLI-01
39.	LumiQuant T4 – CLIA	19110	TTFCLI-01
40.	LumiQuant TSH CLIA	19865	TSHCLI-01
41.	LumiQuant FT3 CLIA	19862	FTTCLI-01
42.	LumiQuant FT4 CLIA	19111	FTFCLI-01
43.	LumiQuant Anti-TG CLIA	17280	ATGCLI-01
44.	LumiQuant Anti-TPO CLIA	20098	TPOCLI-01
45.	Merilisa Anti-TG ELISA	17280	ATGELI-01
46.	Merilisa Anti-TPO ELISA	20098	ATPELI-01
47.	MeriScreen Dengue IgG / IgM	22367	DTARPD-01 RPDDAB-01
48.	MeriScreen Dengue NS1 Ag	Not Available	DTNRPD-02 DTNRPD-03 RPDDAG-01
49.	MeriScreen Dengue Onset	Not Available	DTCRPD-01

			DTCRPD-02 RPDDON-01
50.	Merilisa i T3	19109	ITTELI-01
51.	Merilisa i T4	19110	ITFELI-01
52.	Merilisa i TSH	19865	TSIELI-01
53.	MeriScreen Malaria PAN Ag	19527	RPDMPN-01
54.	Merilisa Malaria Pan Ag (pLDH)	19527	MPNELI-02
55.	MeriScreen Syphiline	19471	SYPRPD-01 SYPRPD-02 RPDSYP-01 RPTSYP-02 RPTSYP-03 RPDSYP-02
56.	Makesure T3 ELISA	19109	ITTELI-02
57.	Makesure T4 ELISA	19110	ITEELI-02
58.	Makesure TSH ELISA	19865	TSIELI-02
59.	Merilisa i 25-OH Vitamin D ELISA	19142	VTDELI-01
60.	Merilisa Anti-CCP ELISA	9419	CCPELI-01
61.	Merilisa Anti-MPO (pANCA) ELISA	20114	AMAELI-01
62.	Merilisa Anti-PR3 (cANCA) ELISA	20113	APAELI-01
63.	Merilisa AFP-ELISA	17259	AFPELM-01
64.	Merilisa CEA-ELISA	17293	CEAELM-01
65.	LumiQuant CA 15-3 CLIA	Not Available	BRSCLI-01
66.	LumiQuant CA 19-9 CLIA	Not Available	PNCCLI-01
67.	LumiQuant CA 125 CLIA	Not Available	OVACLI-01
68.	LumiQuant CEA CLIA	Not Available	CEACLI-01
69.	LumiQuant AFP-CLIA	7594	AFPCLI-01
70.	Pregios One Step Test For Hcg	19952	HCGRRT-02
71.	i-can One step Pregnancy Test Device	19952	-
72.	MERISCREEN hCG Dipstick	19952	HCGSTK-01 HCGSTK-02 RSTHCG-01 RSTHCG-02
73.	RapidSure Dengue IgG/IgM	22367	RPDDAB-02
74.	RapidSure Dengue NS1	Not Available	RPDDAG-02
75.	RapidSure Dengue Duo NS1+IgG/IgM	Not Available	RPDDON-02

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:08:43 EET
Reason: MoldSign Signature
Location: Moldova

Meril
Diagnostics

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL DIAGNOSTICS PVT. LTD.**
Manufacturer's Address:	Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.
Product Name:	Merilisa HBsAg
	Control No. CE-DOC/IM/GRA/001/ Rev.03/18.08.2021 GMDN Code: 48319
Product Details:	Ref. No.: HPBELI-03

Conforms to the applicable national and international standards.

1. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All the supporting documentations are retained under the premises of the manufacturer.
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per ISO 13485:2016/NS-EN ISO 13485:2016 & ISO 9001:2015
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 05 years for IVD reagents and kits after the last product has been manufactured.
5. Company &/or his authorized representative shall fulfill the obligations imposed by Annex I of Directive 98/79/EC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market

General applicable directives:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
List of Standard Applied:	EN 13975:2003, EN 13641:2002, EN 13612 : 2002, EN 14136:2004, BS EN 1041:2008+A1:2013, BS EN 62366-1:2015, EN ISO 13485:2016, ISO 14971:2019, EN ISO 18113-1: 2011, EN ISO 18113-2 : 2011, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 17511:2003, EN ISO 23640:2015, ISO 15223-1:2021, ISO 14644-1: 2015, ISO 14644-2: 2015, BS EN ISO 14644-3: 2019, ISO 14644-4: 2001
Conformity Assessment Route:	Annex: IV of Directive 98/79/EC on In vitro Diagnostic Medical Devices
Device Classification:	List A device as per Annex II of Directive 98/79/EC
European Authorized Representative:	Obelis s.a. Bd., General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954 F +32.2.732.6003 E mail@obelis.net
CE Certificate No.:	1434-IVDD-236/2020
CE Certificate Valid till:	27-05-2024
Notifying Body:	Polish Centre for Testing and Certification (CE1434)
Signature:	
Name:	Mr. Ram Kanoje
Designation:	Head, Quality Assurance
Date/Location:	**Date**: _____ **Location**: Vapi, Gujarat, INDIA

MERIL DIAGNOSTICS PVT. LTD. ★ VAPI ★

CE
1434

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:06:38 EET
Reason: MoldSign Signature
Location: Moldova

Meril
Diagnostics

DECLARATION OF CONFORMITY

Manufacturer's Name:	**MERIL DIAGNOSTICS PVT. LTD.**
Manufacturer's Address:	Second Floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India.
Product Name:	Merilisa HCV
Product Details:	Control No. CE-DOC/IM/GRA/003/ Rev.03/18.08.2021 GMDN Code: 48365 Ref. No.: HPCELI-01

Conforms to the applicable national and international standards.

1. We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All the supporting documentations are retained under the premises of the manufacturer.
2. Company undertakes to manufacture the products as per National/ International Standards and following quality management system as per EN ISO 13485:2012/ ISO 13485:2016 & ISO 9001:2008.
3. Company authorizes the notified body to carry out necessary inspection and agrees to supply the required information & data/documents from time to time.
4. Company agrees to make available all relevant Documents & Data of the products to the National and competent Authority for a period ending 05 years for IVD reagents and kits after the last product has been manufactured.
5. Company &/or his authorized representative shall fulfill the obligations imposed by Annex I of Directive 98/79/EC as amended & ensures & declares that the Company's Products shall meet all provision of the directive as applicable.
6. Company undertakes to keep up to date a systematic procedure to review experience gained during post production phase and to implement appropriate means to apply any necessary corrective action taking account of the nature & risk in relation to the product.
7. Company undertakes to notify immediately any malfunction /deterioration of the performance of the device to the appropriate authority and shall recall such devices already placed in the market

General applicable directives:	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
List of Standard Applied:	EN 13975:2003, EN 13641:2002, EN 13612 : 2002, EN 14136:2004, BS EN 1041:2008+A1:2013, BS EN 62366-1:2015, EN ISO 13485:2016, ISO 14971:2019, EN ISO 18113-1: 2011, EN ISO 18113-2 : 2011, EN ISO 15193:2009, EN ISO 15194:2009, EN ISO 17511:2003, EN ISO 23640:2015, EN ISO 15223-1:2021, ISO 14644-1: 2015, ISO 14644-2: 2015, BS EN ISO 14644-3: 2019, ISO 14644-4: 2001
Conformity Assessment Route:	Annex: IV of Directive 98/79/EC on In vitro Diagnostic Medical Devices
Device Classification:	List A device as per Annex II of Directive 98/79/EC
European Authorized Representative:	Obelis s.a. Bd., General Wahis 53, 1030, Brussels, Belgium. T +32.2.732.5954 F +32.2.732.6003 E mail@obelis.net
CE Certificate No.:	1434-IVDD-108/2018
CE Certificate Valid till:	12-07-2023
Notifying Body:	Polish Centre for Testing and Certification (CE1434)
Signature:	
Name:	Mr. Ram Kanoje
Designation:	Head, Quality Assurance
Date/Location:	**Date**: _____ **Location**: Vapi, Gujarat, INDIA

MERIL DIAGNOSTICS PVT. LTD. VAPI

CE 1434

CERTIFICATE OF ANALYSIS

PRODUCT NAME :	Merilisa HBsAg	**COA No:**	HPB23020
LOT NO.:	MI0923033	**PRODUCT CODE:**	HPBELI-01
DATE OF RELEASE :	18/09/2023	**MFG DATE.:**	2023.09.14
BATCH/LOT QTY :	2010 Kits	**EXP DATE.:**	2025.03.13
BATCH/LOT RELEASED QTY :	2005 Kits	**QC SAMPLED QTY :**	04 Kits
STORAGE AT 2°- 8°C (Do Not Freeze)			

KIT CONTAINS OF :

SR.NO.:	REAGENTS	QUANTITY
1	HBsAg antibody coated Microplate	1 X 96 Tests
2	Negative control	1 X 1.0ml
3	Positive Control	1 X 1.0 ml
4	Washing Solution (20X)	1 X 30.0ml
5	Conjugate (51X)	1 X 0.25 ml
6	Conjugate Diluent	1 X 8.0 ml
7	Substrate Solution	1 X 12.0 ml
8	Stop Solution	1 X 6.0 ml
ACCESSORIES :		
9	Adhesive strips	2 X 12 Strips
10	Pack Insert	1 Nos.

KIT PERFORMENCE TEST:

SR NO.:	TEST PARAMETERS	SPECIFICATIONS	OBTAINED RESULTS
1	Kit Negative Control	Absorbance (OD) < 0.100	Absorbance (OD) = 0.007
2	Kit Positive Control	Absorbance (OD) > 1.000	Absorbance (OD) = 2.295

SR NO.:	TEST PARAMETERS	SPECIFICATIONS	OBTAINED RESULTS
3.	**Diagnostic Specificity:**		
3.1	Carry out the test with 148 Nos. of Negative Human Serum / Plasma Samples.	should give absorbance less than the cut off value ($NC\bar{x}$ + 0.100) at 450nm using 630nm as reference wavelength by HBsAg ELISA using reagents of the same kit.	All 148 HBsAg negative serum / Plasma samples given absorbance less than the cut off value at 450 nm using 630 nm as reference wavelength by HBsAg ELISA using reagents of the same kit.

MERIL DIAGNOSTICS PVT. LTD. VAPI

SR NO.:	TEST PARAMETERS	SPECIFICATIONS	OBTAINED RESULTS
4.	**Diagnostic Sensitivity:**		
4.1	Carry out the test with 24 Nos. of HBsAg Positive Serum / Plasma Samples.	should give absorbance greater than the cut off value ($NC\bar{x}$ + 0.100) at 450 nm using 630nm as reference wavelength by HBsAg ELISA using reagents of the same kit.	All 24 HBsAg positive serum samples given absorbance greater than the cut off value at 450 nm using 630 nm as reference wavelength by HBsAg ELISA using reagents of the same kit.
5.	**End Point Dilution:**		
5.1	End point dilution of HBsAg positive serum sample [MQC 153]	Should give Positive result up to ≥1 :64000, end point dilution of HBsAg Positive Serum Sample. [MQC 153]	1:256000
6.	**Product Information**	**Verified or not**	
6.1	Lot Number :	Yes ☑ No ☐	
6.2	Mfg Date :	Yes ☑ No ☐	
6.3	Exp Date :	Yes ☑ No ☐	

Results : Sensitivity = 100 %

Specificity = 100 %

Conclusion : The above results are **complies** / ~~**Does not comply**~~ with in house standard specification as mentioned in the reference Doc.No.**TS/FG/HPBELI/QCI/016.**

	Tested By	Approved By
Signature :		
Date :	18/09/2023	18/09/2023
Name :	Jaglesh Patel	Manish Naik
Designation :	Se. Executive QC	Sr. Manager QC

MERIL DIAGNOSTICS PVT. LTD. ★ VAPI ★

PRODUCT NAME :	Merilisa HCV	COA No:	HPC23018
LOT NO.:	MI0823037	PRODUCT CODE:	HPCELI-03
DATE OF RELEASE :	19/08/2023	MFG DATE.:	2023.08.16
BATCH/LOT QTY :	2010 Kits	EXP DATE.:	2024.11.15
BATCH/LOT RELEASED QTY :	2005 Kits	QC SAMPLED QTY :	04 Kits
STORAGE AT 2°- 8°C (Do Not Freeze)			

KIT CONTAINS OF :

SR.NO.:	REAGENTS	QUANTITY
1	HCV antigen coated Microplate	1 X 96 Tests
2	Sample Diluent	1 X 12 ml
3	Negative control	1 X 0.400ml
4	Positive Control	1 X 0.400 ml
5	Washing Solution (20X)	1 X 30.0ml
6	Conjugate (51X)	1 X 0.400 ml
7	Conjugate Diluent	1 X 15 ml
8	Substrate Solution	1 X 12 ml
9	Stop Solution	1 X 6 ml
ACCESSORIES :		
10	Adhesive strips	2 X 12 Strips
11	Pack Insert	1 Nos.

KIT PERFORMENCE TEST:

SR NO.:	TEST PARAMETERS	SPECIFICATIONS	OBTAINED RESULTS
1	Kit Negative Control	Absorbance (OD) = < 0.100	Absorbance (OD) = 0.006
2	Kit Positive Control	Absorbance (OD)= > 1.000	Absorbance (OD) = 2.330

SR NO.:	TEST	SPECIFICATION	RESULTS
3.	Diagnostic Specificity:		
3.1	Carry out the test with Anti-HCV Negative Human Serum / Plasma Samples. [N=148]	should give absorbance less than the cut off value ($\overline{NCx}$ + 0.200) at 450nm using 630nm as reference wavelength by HCV ELISA using reagents of the same kit.	All 148 Anti-HCV negative human serum / Plasma samples given absorbance less than the cut off value at 450 nm using 630 nm as reference wavelength by HCV ELISA using reagents of the same kit.

MERIL DIAGNOSTICS PVT. LTD. KAPI

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Date: 2023.08.21 13:03:40 EEST
Reason: MoldSign Signature
Location: Moldova

SR NO.:	TEST	SPECIFICATION	RESULTS
4.	**Diagnostic Sensitivity:**		
4.1	Carry out the test with Anti-HCV Positive Serum / Plasma Samples. [N=24]	should give absorbance greater than the cut off value ($\overline{NCx}$ + 0.200) at 450 nm using 630nm as reference wavelength by HCV ELISA using reagents of the same kit.	All 24 Anti-HCV positive serum samples given absorbance greater than the cut off value at 450 nm using 630 nm as reference wavelength by HCV ELISA using reagents of the same kit.
5.	**Analytical Sensitivity:**		
5.1	End point dilution of Anti-HCV positive serum sample [MQC 154]	Should give Positive result up to ≥1 :160, end point dilution of Anti-HCV Positive Serum Sample. [MQC 154]	1:320
6.	**Product Information**	**Verified or not**	
6.1	Lot Number :	Yes ☑ No ☐	
6.2	Mfg Date :	Yes ☑ No ☐	
6.3	Exp Date :	Yes ☑ No ☐	

Results : Sensitivity = 100 %
Specificity = 100 %

Conclusion : The above product **Complies** / ~~**does not comply**~~ with our In-House Specification as mentioned in the Reference Doc.No.**TS/FG/HPCELI/QCI/089.**

	Tested By	Approved By
Signature :		
Date :	19/08/2023	19/08/2023
Name :	Vaibhav Patel	Manish Naik
Designation :	S.E. Executive/ QC	SR- Manager

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 114470 0002 Rev. 00

Holder of Certificate: **Meril Diagnostics Pvt.Ltd.**
Second Floor, D1-D3, Meril Park,
Survey No.135/2/B & 174/2, Muktanand Marg, Chala
Vapi 396191
INDIA

Certification Mark:

Scope of Certificate:

Design and Development, Manufacture and Distribution of In Vitro Diagnostic Reagents and Kits for Biochemistry, Hematology, Immunology and Molecular Biology including Point of Care Testing (POCT) Strips,
The Provision of Manufacturing and Distribution Service for Monoclonal & Polyclonal Antibody for In Vitro Diagnostic Immunology Reagents,
Manufacturing, Distribution, Installation and Servicing of In Vitro Diagnostic Instruments (Semi automated Biochemistry Analyzers, Full automated Biochemistry Analyzers, ELISA Processors, Hematology Analyzers, Coagulation Analyzers, Electrolyte Analyzers, Molecular Diagnostics Analyzers, Diabetic Management Analyzers and POCT Devices)

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 114470 0002 Rev. 00

Report No.: IND2021150_CN

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:10:51 EET
Reason: MoldSign Signature
Location: Moldova

Valid from: 2022-07-13
Valid until: 2025-03-13

Date, 2022-07-13

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 114470 0002 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Meril Diagnostics Pvt.Ltd.
Second Floor, D1-D3, Meril Park,, Survey No.135/2/B & 174/2,
Muktanand Marg, Chala, Vapi 396191, INDIA

see scope of certificate

-/-

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Meril Life Sciences Pvt. Ltd.

Main Site: Survey No. 135/2/A & 135/2/B and 174/2,
Vapi - 396191, Gujarat, India

See appendix for additional sites and additional site scopes

has been registered by Intertek as conforming to the requirements of:

ISO 14001:2015

Organization was certified by another Certification Body before 22/03/2021.

The management system is applicable to:

Manufacturing of Medical Devices like Balloon Catheters, Stents, Heart Valves and Tissue Valves.

Digitally signed by Jighili Tatiana
Date: 2023.12.15 12:10:39 EET
Reason: MoldSign Signature
Location: Moldova

Certificate Number:
0114155

Initial Certification Date:
07 April 2018

Last Certificate Expiry Date:
06 April 2021

Date of Last Recertification Audit:
31 March 2021

Certification Cycle Start Date:
21 May 2021

Issuing Date:
26 May 2021

Valid Until:
06 April 2024

[redacted]

Calin Moldovean
President, Business Assurance

Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

APPENDIX TO CERTIFICATE OF REGISTRATION

This appendix identifies the locations covered by the management system of:

Meril Life Sciences Pvt. Ltd.

This appendix is linked to the Main Certificate # 0114155 and cannot be shown nor reproduced without it.

Meril Diagnostics Private Limited

Survey No. 135/2/B and 174/2, Vapi - 396191, Gujarat, India

Manufacturing of Analyzers and Reagents for Clinical Biochemistry, Hematology, Immunology (ELISA & CLIA), Rapids, Blood Grouping Reagents Coagulation, Critical Care, Diabetes Management and Lab Consumables.

Meril Healthcare Private Limited

Survey No. 135/2/B and 174/2, Vapi - 396191, Gujarat, India

Manufacturing of Orthopedic Implants like Bone Plate, Bone Screw, Bone Nails, Hip and Knee Implants, Instruments for Hip and Knee.

Certificate

This is to certify that the

QUALITY MANAGEMENT SYSTEM

of

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Date: 2023.12.15 12:08:37 EET
Reason: MoldSign Signature
Location: Moldova

MERIL DIAGNOSTICS PVT. LTD.

Second Floor, D1- D3, Meril Park, Survey No. 135/2/B & 174/2,
Muktanand Marg, Chala, Vapi- 396191, Gujarat, India

has been assessed and found to be in conformance to the requirements of

ISO 9001:2015

This certificate is valid for the following activity:

Design, Development, Manufacture, Storage and Distribution of In-Vitro Diagnostic Biochemistry, Haematology, Immunology, Molecular Biology and POCT-Strips, Reagents & Kits. Design Development, Manufacture, Storage, Distribution, Installation and Servicing of In- Vitro Diagnostic Analyzers. Manufacturing and Supply of Raw Material (Animal Plasma/Serum) used for Production of Diagnostic Reagent and Kits, Purchase for Re-Sale of Elisa Processors, Coagulation Analyzers and POCT Devices

IAF Code: 19 NACE Code: 26.5, 26.6

Certificate No. : DI-21030501

Date of initial registration	05-03-2021
Date of this certificate	05-03-2021
Certificate Expiry	04-03-2022*
Recertification Due	04-03-2024

Auth Sign

*Registration is subject to the system being continually maintained to the above standard under regular surveillance.
To check the certification validity please visit our website- www.isplcert.com or contact at- isplcert@gmail.com

CB-QMS-022

Indraprastha SystemCert Pvt. Ltd.

Accredited by EIAC, A Member of International Accreditation Forum

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201, Jaina Tower-3, A-1, Janak Puri, New Delhi-110058, India, Ph +91 9990 477 631

If one of the Negative Control wells has an absorbance more than 0.10 O. D. above the mean of two, discard that value and calculate the new Negative Control mean from two remaining replicates.

Cut-off value

Calculate the Cut-off value by adding 0.10 to the mean of the Negative Control replicates.

Mean Negative Control = 0.010

Cut-off value = 0.010 + 0.100 = 0.110

QUALITY CONTROL

Results of an assay are valid if the following criteria for the controls are met:

Negative Control

The mean absorbance must be less than 0.10.

Positive Controls

The absorbance of each of the Positive Controls should be more than 1.0

Assays which do not meet these criteria should be repeated. In the unlikely event of the results repeatedly failing to meet either the Quality Control criteria or the expected performance of the test, please contact your representative.

INTERPRETATION OF RESULTS

Non-reactive Results

Samples giving an absorbance less than the Cut-off value are considered negative in the assay.

Reactive Results

Samples giving an absorbance equal to or greater than the Cut-off value are considered initially reactive in the assay.

Note: Samples which are found reactive should be retested in duplicate using the original source. Samples that are reactive in at least one of the duplicate retests are considered repeatedly reactive in Merilisa HBsAg and are presumed to contain HBsAg. Such samples should be further investigated and the presence of HBsAg confirmed by other tests. Samples that are non-reactive i.e. with an absorbance less than that of the Cut-off value, should be considered non-reactive for HBsAg.

LIMITATIONS OF PROCEDURE

1. The **Test Procedure** and **Interpretation of Results** must be followed.
2. This test has only been evaluated for use with individual serum, EDTA plasma or citrate plasma samples. Merilisa HBsAg has not been evaluated for any other purpose.
3. A negative result with an antibody detection test does not preclude the possibility of infection.
4. Non-repeatable reactive results may be obtained with any EIA procedure.
5. The most common sources of error are: a) Imprecise delivery of Sample, Conjugate or Substrate into the wells. b) Contamination of Substrate with Conjugate. c) Contamination with conjugates from other assays. d) Blocked or partially blocked washer probes. e) Insufficient aspiration leaving a small volume of Washing solution in the wells. f) Failure to ensure that the bottom surface of the wells is clean and dry, and that no air bubbles are present on the surface of the liquid in the wells before a plate is read. g) Failure to read at the correct wavelength or use of an incorrect reference wavelength.
6. The use of highly haemolysed samples, incompletely clotted sera, plasma samples containing fibrin or samples with microbial contamination may give rise to erroneous results.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of Merilisa HBsAg has been determined by in-house testing of 760 samples, Merilisa HBsAg assay demonstrated a specificity of 100 % and a sensitivity of 100%.

Merilisa HBsAg demonstrated the **analytical sensitivity of 0.4 PEIU/ml.**

BIBLIOGRAPHY

1. Blumberg, B.S., Sutnick, A.I., London, W.T., (1968) Hepatitis and leukemia: their relation to Australia antigen. Bull. N.Y. Acad. Med.; 44(12): 1566-1586.
2. Taylor, R.N., Fulford, K.M., (1976) Results of the Center for Disease control Proficiency Testing Program for the detection of hepatitis B surface antigen. J Clin Microbiol.; 4(1): 32-39.
3. Scheiblauer, H., El-Nageh, M., Diaz, S., Nick, S., Zeichhardt, H., Grunert, H.P., Prince, A.,(2009) Performance evaluation of 70 hepatitis B virus (HBV) surface antigen (HBsAg) assays from around the world by a geographically diverse panel with an array of HBV genotypes and HBsAg subtypes. Vox Sang.; 98: 403-414.

QA0I -701.09
Rev 00, Dt. 01/04/2013

Symbols used on Meril Diagnostics labels:

REF	Catalogue No	IVD	In Vitro Diagnostics
LOT	Batch No		Manufacturing Date
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage temperature

Meril Diagnostics

MERILISA HBsAg

Enzyme immunoassay for detection of HBsAg in human serum or plasma

For in vitro diagnostic use
Read this pack insert thoroughly before use

Product Code: HPBELI-01

INTENDED USE

MERILISA HBsAg is Enzyme immunoassay for the qualitative determination of Hepatitis B surface antigen in human serum or plasma by healthcare professional.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis B is a disease caused by a viral infection. Throughout the various serological markers appear infection among which is the HBsAg. In 1964, Blumberg et al. first detected HBsAg in the serum of an Australian Aboriginal an antigen reacted with an antibody serum from a haemophiliac patient New York. Hepatitis B virus (HBV) is an enveloped DNA virus. During infection, HBV produces an excess of hepatitis B surface antigen (HBsAg), which can be detected in the blood of infected individuals. HBsAg is the first serological marker after infection with HBV appearing one to ten weeks after exposure and two to eight weeks before the onset of hepatitis. HBsAg persists during this acute phase and clears late in the convalescence period. Failure to clear HBsAg within six months indicates a chronic HBsAg carrier state.

Merilisa HBsAg employs HBsAg specific antibody and is expected to detect HBsAg in human serum or plasma. Consequently potentially infectious samples of serum, EDTA plasma or citrate plasma can be identified.

PRINCIPLE OF THE PROCEDURE

Merilisa HBsAg is based on microwells coated with monoclonal anti-HBsAg Antibody. The Conjugate is polyclonal anti-HBsAg antibody labelled with horseradish peroxidase.

Samples and controls are incubated in the wells and HBsAg if present bind to the monoclonal anti-HBsAg antibody on the microwell. In a subsequent step, Conjugate is added which in turn binds to any specific antigen already bound to the antibody on the well. Unbound Conjugate is washed away and a solution containing 3, 3', 5, 5'-tetramethylbenzidine (TMB) and hydrogen peroxide is added to the wells. Wells with bound Conjugate develop a blue to bluish green colour which is converted to an yellow to orange colour when the reaction is stopped with sulphuric acid. After incubation the reactions are stopped with sulphuric acid and the colour is read spectrophotometrically. The intensity of colour produced in the wells is directly proportional to the concentration of HBsAg in the sample. Wells containing negative samples remain colourless.

REAGENTS

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

1. HBsAg Ab Coated Microplate

One plate of 96 microwells coated with monoclonal anti-HBsAg antibody. If less than the whole plate is being used allow the wells to reach room temperature (18 to 30°C) before removal from the bag. Place unused wells in the sealable storage bag provided and return to 2 to 8°C. Once opened, microwells should be used within one month.

2. Negative Control

Vial containing 1.0 ml of normal human serum with preservative. Negative control has been tested and found negative for anti-HIV 1+2, HBsAg, Anti-HCV and Syphilis.

3. Positive Control

Vial containing 1.0 ml of inactivated human serum in a buffer containing protein with preservative. Positive control has been tested and found negative for Anti-HIV 1+2, Anti-HCV and Syphilis.

4. Washing Solution (20X)

Bottle containing 20 times working strength Phosphate Buffer Saline Wash Solution with detergent. Add one volume of Washing Solution Concentrate to 19 volumes of distilled or deionised water to give the required volume. If the Crystals are observed in the Washing Solution (20X), dissolve crystals by keeping Washing Solution (20X) at 37°C until the crystals dissolves. Store the diluted Washing Solution at 18 to 30°C in a closed vessel under which conditions it will retain activity for one month.

5. Conjugate (51X)

Vial containing polyclonal Anti-HBsAg conjugated to HRP with protein stabilizers and preservatives. Bottle containing 51 times working strength conjugates. Add one volume of Conjugate Concentrate to 50 volumes of Conjugate Diluent to give the required volume.

6. Conjugate Diluent

Bottle containing solution consisting of buffer, bovine protein, preservatives and detergent.

Meril Diagnostics Pvt. Ltd., Survey No. 135/2/B, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, India.
Tel: +91 22 39350700; Fax: +91 22 39350777 **E:** diagnostics@merillife.com; **W:** www.merillife.com

Preparation Working conjugate solution

Dilute Conjugate (51X), 1:50 with Conjugate Diluent as per **Table1**.

Table 1:

No. of Strips	1	2	4	6	8	10	12
Conjugate Diluent, mL	0.5	1	2	3	4	5	6
Conjugate (51X), µL	10	20	40	60	80	100	120

Store the diluted Conjugate at 2 to 8°C in a closed vessel under which conditions it will retain activity for 48 hours.

7. Substrate Solution

Bottle containing colourless solution of 3, 3', 5, 5' tetramethylbenzidine and hydrogen peroxide and stabilizers.

8. Stop Solution

Bottle containing colourless solution of diluted mineral acid and stabilizers.

WARNINGS AND PRECAUTIONS

The reagents are for *in vitro* diagnostic use only.

For professional use only.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

SPECIMEN COLLECTION

Serum, EDTA plasma or citrate plasma samples may be used. Ensure that the serum samples are fully clotted. Remove any visible particulate matter from the sample by centrifugation.

SPECIMEN TRANSPORT AND STORAGE

Store the samples at 2 to 8°C. Samples not required for assay within 7 days should be stored frozen (-15°C or colder). Avoid multiple freeze-thaw cycles. After thawing ensure samples are thoroughly mixed before testing.

MATERIALS REQUIRED BUT NOT PROVIDED

1. **Freshly distilled or high quality deionised water** is required for dilution of Washing Solution for use in conjunction with automated washers.
2. **Calibrated Micropipettes and Multichannel micropipettes** of appropriate volume.
3. **Incubator** capable of maintaining the temperature limits required as per assay protocol.
4. **Instrumentation**
   a. Automated microplate strip washer.
   b. Microplate reader or Fully automated microplate processor.
   c. All instruments must be validated before use.
   d. Please contact your representative for details of recommended systems, software protocols for instrumentation and validation procedures.
5. **Disposable Reagent Troughs**.
6. **Sodium hypochlorite** for disposal of hazardous substance or remnants of the assay.

PRECAUTIONS

1. Potentially contaminated materials should be disposed of safely according to local requirements.
2. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated area swabbed with, for example, 1.0% sodium hypochlorite before work is continued. Sodium hypochlorite should not be used on acid-containing spills unless the spill area is first wiped dry. Materials used to clean spills, including gloves, should be disposed of as potentially biohazardous waste. Do not autoclave materials containing sodium hypochlorite.
3. Neutralised acids and other liquid waste should be decontaminated by adding a sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.
4. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.
5. The following reagents contain low concentrations of harmful or irritant substances: a) The Conjugate Diluent and Sample Diluent contain ProClinR300 which can be absorbed through the skin and is a sensitising agent.
6. Sulphuric acid used in Stop Solution is corrosive and should be handled with appropriate care. If either come into contact with the skin or eyes, wash thoroughly with water.
7. If any of the reagents come into contact with the skin or eyes wash the area extensively with water.
8. Do not use the reagents beyond the stated expiry date.
9. Follow Good Laboratory Practice to avoid microbiological contamination of reagents as this may reduce the life of the product and cause erroneous results.
10. Do not modify the **Test Procedure** or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. Do not reduce any of the recommended incubation times.
11. Allow all reagents and samples to come to 18 to 30°C before use. Immediately after use return reagents to the recommended storage temperature.
12. Do not expose reagents to strong light or hypochlorite fumes during storage or during incubation steps.
13. Do not allow wells to become dry during the assay procedure.
14. Do not cross-contaminate reagents. It is recommended to use dedicated separate pipettes for use with the Substrate Solution and Conjugate.
15. Do not touch or splash the rim of the well with Conjugate. Do not blow out from micropipettes; reverse pipetting is recommended whenever possible.
16. Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate.
17. Do not contaminate microwells with dust from disposable gloves.
18. Ensure the assay is run within the recommended temperature limits in the assay protocol.
19. Do not use CO_2 Incubators.
20. Do not store the Stop Solution in a shallow dish or return it to a stock bottle after use.
21. The possibility of cross contamination between assays needs to be excluded when validating assay protocols on instrumentation.

TEST PROCEDURE

Step 1: Prepare working **Conjugate solution** and **Washing solution**.

Step 2: Use only the number of wells required for the test. Avoid touching the tops or bottoms of the wells.

Step 3: Add 50 µl of **Samples and Controls** to the wells.

For each plate use the first column of wells for the assay Controls. Add the Controls to the designated wells after dispensing the samples. Pipette 50 µl of the Negative Control into each of three wells B1 to D1 and 50 µl of the Positive Control into wells E1 and F1 respectively. Do not add anything in Blank well (A1).

Use of a white background will aid visualisation of sample addition.

Step 4: Add 50 µl of **Conjugate** to all wells except blank well (A1).

Step 5: Cover the wells with adhesive strip(s) and **incubate** for **60 mins** at 37°C ± 1°C.

Step 6: At the end of the incubation, discard the content of the plate. Aspirate the contents of the wells and fill them completely (approximately 350 µl) with the diluted washing solution. Repeat the process of aspiration and washing **4 more times**. Ensure that each column of wells soaks for at least 30 seconds before the next aspiration cycle. After the last washing blot the microplate on absorbent tissue to remove any excess liquid from the wells.

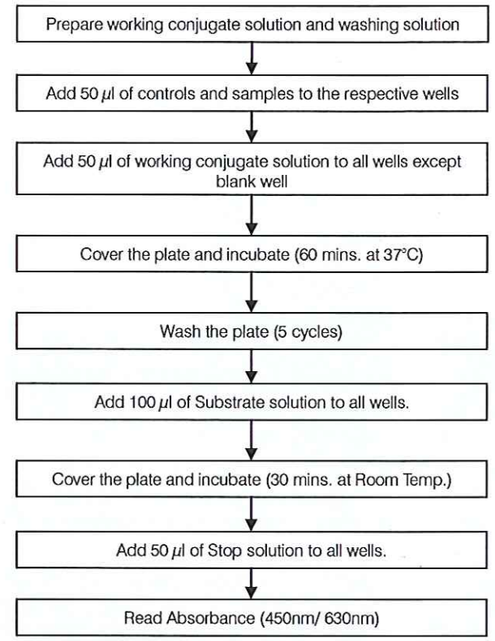
Step 7: Immediately after washing the plate, **add** 100 µl of **Substrate Solution** to each well.

Step 8: Cover the wells with adhesive strip(s) and **incubate** for **30 mins** at room temperature. Keep away from direct sunlight. A Blue or bluish green colour should develop in wells containing reactive samples.

Step 9: Add 50 µl of **Stop Solution** to each well.

Step 10: Within 15 minutes **read** the absorbance at 450 nm using 630 nm as the reference wavelength.

PROCEDURAL FLOW CHART



RESULTS

CALCULATION OF RESULTS

Each plate must be considered separately when calculating and interpreting results of the assay.

Approved software may be used for calculation and interpretation of results.

Negative Control

Calculate the mean absorbance of the Negative Controls.

Example:

Well 1 = 0.009, Well 2 = 0.010, Well 3 = 0.011

Total = 0.030

Mean Negative Control = 0.030/3 = 0.010

Approved software may be used for calculation and interpretation of results.
Negative Control
Calculate the mean absorbance of the Negative Controls.
Example:
Well 1 = 0.009, Well 2 = 0.010, Well 3 = 0.011
Total = 0.030
Mean Negative Control = 0.030/3 = 0.010
If one of the Negative Control wells has an absorbance more than 0.10 O. D. above the mean of two, discard that value and calculate the new Negative Control mean from two remaining replicates.

Cut-off value

Calculate the Cut-off value by adding **0.200** to the mean of the Negative Control replicates.
Mean Negative Control = 0.010
Cut-off value = 0.010 + **0.200** = 0.210

QUALITY CONTROL

Results of an assay are valid if the following criteria for the controls are met:

Negative Control

The mean absorbance must be less than 0.10.

Positive Control

The absorbance of each of the Positive Controls should be more than 1.0
Assays which do not meet these criteria should be repeated. In the unlikely event of the results repeatedly failing to meet either the Quality Control criteria or the expected performance of the test, please contact your representative.

INTERPRETATION OF RESULTS

Non-reactive Results

Samples giving an absorbance less than the Cut-off value are considered negative in the assay.

Reactive Results

Samples giving an absorbance equal to or greater than the Cut-off value are considered initially reactive in the assay.
Note: Samples which are found reactive should be retested in duplicate using the original source. Samples that are reactive in at least one of the duplicate retests are considered repeatedly reactive in Merilisa HCV and are presumed to contain antibodies to HCV. Such samples should be further investigated and the presence of antibodies against HCV confirmed by other tests. Samples that are non-reactive i.e. with an absorbance less than that of the Cut-off value, should be considered non-reactive for HCV antibodies.

LIMITATIONS OF PROCEDURE

1. The Test Procedure and Interpretation of Results must be followed.
2. This test has only been evaluated for use with individual serum, EDTA plasma or citrate plasma samples. Merilisa HCV has not been evaluated for any other purpose.
3. A negative result with an antibody detection test does not preclude the possibility of infection.
4. Non-repeatable reactive results may be obtained with any EIA procedure.
5. The most common sources of error are: a) Imprecise delivery of Sample, Conjugate or Substrate into the wells. b) Contamination of Substrate with Conjugate. c) Contamination with conjugates from other assays. d) Blocked or partially blocked washer probes. e) Insufficient aspiration leaving a small volume of Washing solution in the wells. f) Failure to ensure that the bottom surface of the wells is clean and dry, and that no air bubbles are present on the surface of the liquid in the wells before a plate is read. g) Failure to read at the correct wavelength or use of an incorrect reference wavelength.
6. The use of highly haemolysed samples, incompletely clotted sera, plasma samples containing fibrin or samples with microbial contamination may give rise to erroneous results.

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance of Merilisa HCV has been determined by in-house testing of 625 samples, Merilisa HCV assay demonstrated a specificity of ≥ 99.5 % and a sensitivity of 100%.

BIBLIOGRAPHY

1. Tang, E., (1991) **Hepatitis C virus. A review.**West Med.;155(2):164-168.
2. **Neville, J.A.**, et. al. (1997) Antigenic variation of core, NS3, and NS5 proteins among genotypes of hepatitis C virus. **J Clin Microbiol.** ;35(12):3062-3070.
3. Tokeshi, S., Sata, M., et. al.(1993) **Evaluation of first- and second-generation assays for detection of antibody to hepatitis C virus innon-A, non-B chronic liver diseases--evaluation of 1st and 2nd-generation assays in NANBH.** Kurume Med J.;40(1):27-32.
4. **Vrielink, H., Reesink, H.W.**, et. al. (1997) Performance of three generations of anti-hepatitis C virus enzyme-linked immunosorbent assays in donors and patients.**Transfusion** ;37(8):845-849.

QA0I -701.10
Ver 00, Dt. 01/04/2013

Symbols used on Meril Diagnostics labels:

REF	Catalogue No	IVD	In Vitro Diagnostics
LOT	Batch No		Manufacturing Date
	Expiry Date		Consult Instruction for Use
	Manufacturer		Storage temperature

Merilisa HCV

Enzyme immunoassay for the detection of antibodies to Hepatitis C Virus in human serum or plasma

Product Code : HPCELI-01

Meril Diagnostics

For in vitro diagnostic use
Read this pack insert thoroughly before use

INTENDED USE

MERILISA HCV is Enzyme immunoassay for the qualitative determination of antibodies to Hepatitis C Virus in human serum or plasma by healthcare professional.

SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C (HCV) is now recognised as the primary cause of transfusion associated hepatitis. HCV is a single stranded positive-sense RNA virus and is globally present. In acute presentation of HCV infection patients may develop jaundice, others may go on to develop chronic hepatitis with life threatening conditions such as cirrhosis and hepatocellular carcinoma. Diagnosis of HCV is mainly done by either direct detection of viral RNA by PCR or by detection of anti-HCV antibodies. Recombinant DNA techniques have been used to develop structural and non-structural proteins derived from HCV RNA with utility for antibody screening. Anti-HCV assays have evolved as from 1st generation products, which incorporated NS4 proteins, but the sensitivity was low and then 3rd generation assays evolved which incorporates core (structural), NS3 protease/helicase (non-structural), NS4 (non-structural) and NS5 replicase (non-structural) proteins. Studies report that the third generation assays demonstrate significant improvements in sensitivity, particularly with regard to increased reactivity with the NS3 antigen and earlier detection of seroconversion.
Merilisa HCV is expected to detect human IgG to the HCV proteins i.e., Core, NS3, NS4 and NS5.

PRINCIPLE OF THE PROCEDURE

Merilisa HCV is based on microwells coated with HCV specific recombinant protein i.e., core, NS3, NS4 and NS5 derived from HCV RNA. The Conjugate is monoclonal anti-human IgG labelled with horseradish peroxidase.

Samples and controls are incubated in the wells and antibodies to HCV if present bind to the antigens on the microwell; sample and any excess antibodies are then washed away. In a subsequent step, Conjugate is added which in turn binds to any specific IgG already bound to the antigen on the well. Unbound Conjugate is washed away and a solution containing 3, 3', 5, 5'-tetramethylbenzidine (TMB) and hydrogen peroxide is added to the wells. Wells with bound Conjugate develop a blue to bluish green colour which is converted to an yellow to orange colour when the reaction is stopped with sulphuric acid. After incubation the reactions are stopped with sulphuric acid and the colour is read spectrophotometrically. The intensity of colour produced in the wells is directly propotional to the concentration of antibody to HCV in the sample. Wells containing negative samples remains colourless.

REAGENTS

DESCRIPTION, PREPARATION FOR USE AND RECOMMENDED STORAGE CONDITIONS

1. HCV Ag. Coated Microplate

One plate of 96 microwells coated with HCV antigens. If less than the whole plate is being used allow the wells to reach room temperature (18 to 30°C) before removal from the bag. Place unused wells in the sealable storage bag provided and return to 2 to 8°C. Once opened, microwells should be used within one month.

2. Sample Diluent

Bottle containing buffered solution containing proteins stabilizer, preservative, detergents and indicator dye for sample addition.

3. Negative Control

Vial containing 0.3 ml of normal human serum with preservative. Negative control has been tested and found negative for anti-HIV 1+2, HBsAg, Anti-HCV and Syphilis.

4. Positive Control

Vial containing 0.3 ml of inactivated human serum in a buffer containing protein with preservative. Positive control has been tested and found negative for HBsAg, Anti-HIV 1+2 and Syphilis.

5. Washing Solution (20X)

Bottle containing 20 times working strength Phosphate Buffer Saline Wash solution with detergent. Add one volume of Washing Solution Concentrate to 19 volumes of distilled or deionised water to give the required volume. If the Crystals are observed in the Washing Solution (20X), dissolve crystals by keeping Washing Solution (20X) at 37°C until the crystals dissolves. Store the diluted Washing Solution at 18 to 30°C in a closed vessel under which conditions it will retain activity for one month.

Meril Diagnostics Pvt. Ltd., Survey No. 135/2/B, Muktanand Marg, Chala, Vapi – 396 191, Gujarat, India.
Tel: +91 22 39350700; Fax: +91 22 39350777 **E:** diagnostics@merillife.com; **W:** www.merillife.com

6. Conjugate (51X)
Vial containing Anti-human IgG conjugated to HRP with protein stabilizers and preservatives. Bottle containing 51 times working strength antibody conjugates. Add one volume of Conjugate Concentrate to 50 volumes of Conjugate Diluent to give the required volume.

7. Conjugate Diluent
Bottle containing solution consisting of buffer, bovine protein, preservatives and detergent.

Preparation of Working Conjugate Solution

Dilute Conjugate (51X), 1:50 with Conjugate Diluent as per **Table1**.

Table 1:

No. of Strips	1	2	4	6	8	10	12
Conjugate Diluent, mL	1.0	2.0	4.0	6.0	8.0	10	12
Conjugate (51X), µL	20	40	80	120	16	200	240

Store the diluted Conjugate at 2 to 8°C in a closed vessel under which conditions it will retain activity for 48 hours.

8. Substrate Solution
Bottle containing colourless solution of 3, 3', 5, 5' Tetramethylbenzidine, hydrogen peroxide and stabilizers.

9. Stop Solution
Bottle containing colourless solution of diluted mineral acid and stabilizers.

WARNINGS AND PRECAUTIONS

The reagents are for *in vitro* diagnostic use only.
For professional use only.

SPECIMEN COLLECTION, TRANSPORT AND STORAGE

SPECIMEN COLLECTION

Serum, EDTA plasma or citrate plasma samples may be used. Ensure that the serum samples are fully clotted. Remove any visible particulate matter from the sample by centrifugation.

SPECIMEN TRANSPORT AND STORAGE

Store the samples at 2 to 8°C. Samples not required for assay within 7 days should be stored frozen (-15°C or colder). Avoid multiple freeze-thaw cycles. After thawing ensure samples are thoroughly mixed before testing.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Freshly distilled or high quality deionised water is required for dilution of Washing solution for use in conjunction with automated washers.
2. Calibrated Micropipettes and Multichannel micropipettes of appropriate volume.
3. Incubator capable of maintaining the temperature limits required as per assay protocol.
4. Instrumentation
   a. Automated microplate strip washer.
   b. Microplate reader or Fully automated microplate processor.
5. All instruments must be validated before use. Please contact your representative for details of recommended systems, software protocols for instrumentation and validation procedures.
6. Disposable Reagent Troughs.
7. Sodium hypochlorite for disposal of hazardous substance or remnants of the assay.

PRECAUTIONS

1. Potentially contaminated materials should be disposed of safely according to local requirements.
2. Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated area swabbed with, for example, 1.0% sodium hypochlorite before work is continued. Sodium hypochlorite should not be used on acid-containing spills unless the spill area is first wiped dry. Materials used to clean spills, including gloves, should be disposed of as potentially biohazardous waste. Do not autoclave materials containing sodium hypochlorite.
3. Neutralised acids and other liquid waste should be decontaminated by adding a sufficient volume of sodium hypochlorite to obtain a final concentration of at least 1.0%. A 30 minute exposure to 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.
4. Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.
5. The following reagents contain low concentrations of harmful or irritant substances: a) The Conjugate Diluent and Sample Diluent contain ProClinR300 which can be absorbed through the skin and is a sensitising agent.
6. Sulphuric acid used in Stop Solution is corrosive and should be handled with appropriate care. If either come into contact with the skin or eyes, wash thoroughly with water.
7. If any of the reagents come into contact with the skin or eyes wash the area extensively with water. Do not use the reagents beyond the stated expiry date.
8. Follow Good Laboratory Practice to avoid microbiological contamination of reagents as this may reduce the life of the product and cause erroneous results.
9. Do not modify the Test Procedure or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. Do not reduce any of the recommended incubation times.
10. Allow all reagents and samples to come to 18 to 30°C before use. Immediately after use return reagents to the recommended storage temperature.
11. Do not expose reagents to strong light or hypochlorite fumes during storage or during incubation steps.
12. Do not allow wells to become dry during the assay procedure.
13. Do not cross-contaminate reagents. It is recommended to use dedicated separate pipettes for use with the Substrate Solution and Conjugate.
14. Do not touch or splash the rim of the well with Conjugate. Do not blow out from micropipettes; reverse pipetting is recommended whenever possible.
15. Ensure that the bottom of the plate is clean and dry and that no bubbles are present on the surface of the liquid before reading the plate.
16. Do not contaminate microwells with dust from disposable gloves.
17. Ensure the assay is run within the recommended temperature limits in the assay protocol.
18. Do not use C02 Incubators.
19. Do not store the Stop Solution in a shallow dish or return it to a stock bottle after use.
20. The possibility of cross contamination between assays needs to be excluded when validating assay protocols on instrumentation.

TEST PROCEDURE

Step 1: Prepare working Conjugate solution and Washing solution.

Step 2: Use only the number of wells required for the test. Avoid touching the tops or bottoms of the wells.

Step 3: Add 100 µl of Sample Diluent to each well. Do not add anything in Blank well (A1).

Step 4: Add 10 µl of Samples and Controls to the wells.

For each plate use the first column of wells for the assay Controls. Add the Controls to the designated wells after dispensing the samples. Pipette 10 µl of the Negative Control into each of three wells B1 to D1 and 10 µl of the anti-HCV Positive Controls into wells E1 and F1 respectively.

Use of a white background will aid visualisation of sample addition.

Step 5: Cover the wells with adhesive strip(s) and incubate for 30 mins at 37°C ± 1°C.

Step 6: At the end of the incubation, discard the content of the plate. Aspirate the contents of the wells and fill them completely (approximately 350 µl) with the diluted washing solution. Repeat the process of aspiration and washing 4 more times. Ensure that each column of wells soaks for at least 30 seconds before the next aspiration cycle. After the last washing blot the microplate on absorbent tissue to remove any excess liquid from the wells.

Step 7: Immediately after washing the plate, add 100 µl of Conjugate to all wells except blank well.

Step 8: Cover the wells with adhesive strip(s) and incubate for 30 mins at 37°C ± 1°C.

Step 9: At the end of the incubation time wash the plate as described in Step 6.

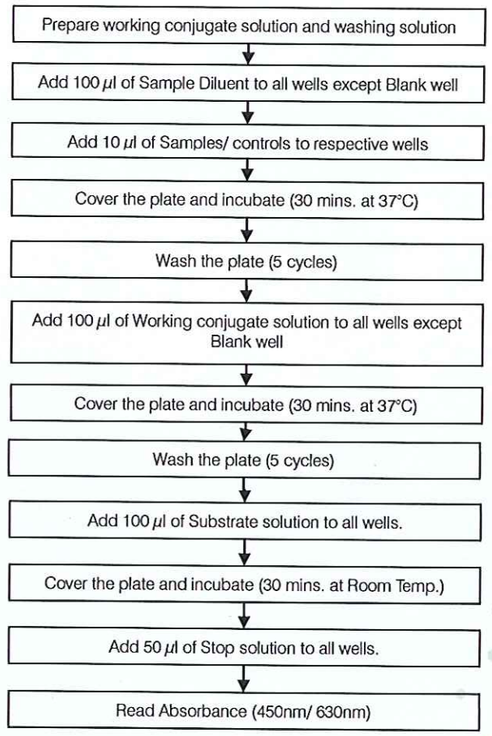
Step 10: Immediately after washing the plate, add 100 µl of Substrate Solution to each well.

Step 11: Cover the wells with adhesive strip(s) and incubate for 30 mins at room temperature. Keep away from direct sunlight. A Blue or bluish green colour should develop in wells containing reactive samples.

Step 12: Add 50 µl of Stop Solution to each well.

Step 13: Within 15 minutes read the absorbance at 450 nm using 630 nm as the reference wavelength.

PROCEDURAL FLOW CHART



RESULTS

CALCULATION OF RESULTS

Each plate must be considered separately when calculating and interpreting results of the assay.