



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
<b>ACCESSORIES :</b>		
9	Adhesive strips	2 X 12 Strips
10	Pack Insert	1 Nos.

**KIT PERFORMANCE 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.	<b>Diagnostic Specificity:</b>		
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 Private Limited | CIN : U33110GJ2011PTC064994

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SR NO.:	TEST PARAMETERS	SPECIFICATIONS	OBTAINED RESULTS
4.	<u>Diagnostic Sensitivity:</u>		
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.	<u>End Point Dilution:</u>		
5.1	End point dilution of HBsAg positive serum sample [MQC 153]	Should give Positive result up to $\geq 1:64000$ , end point dilution of HBsAg Positive Serum Sample. [MQC 153]	1:256000
6.	<u>Product Information</u>	<u>Verified or not</u>	
6.1	Lot Number :	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
6.2	Mfg Date :	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
6.3	Exp Date :	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>

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 :	<i>Jagdish Patel</i>	<i>Mauish Naie</i>
Date :	<i>18/09/2023</i>	<i>18/09/2023</i>
Name :	<i>Jagdish Patel</i>	<i>Mauish Naie</i>
Designation :	<i>SE. Executive ce</i>	<i>SS. Manager ce</i>

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