



CERTIFICATE OF ANALYSIS

Format No : SOP/QCD/IMG/021/F2-01
Supersedes No : SOP/QCD/IMG/021/F2-00

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	Nogativo 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 PERFORMANCE 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 ($NC\bar{x} + 0.200$) 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 Private Limited | CIN : U33110GJ2011PTC064994

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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 ($NC\bar{x} + 0.200$) 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 $\geq 1 : 160$, end point dilution of Anti-HCV Positive Serum Sample. [MQC 154]	1:320
6.	Product Information	Verified or not	
6.1	Lot Number :	Yes <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 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 :	<i>[Signature]</i>	<i>[Signature]</i>
Date :	19/08/2023	19/08/2023
Name :	Vishal Patel	Mauish Naik
Designation :	Sr. Executive	Sr-Manager



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