



No.N.1-187/2014-SRRD/IDKL

Dated the 12.08.2014

M/s Meril Diagnostics Pvt. Ltd.,
Survey No. 135/2/B, Bilakhia House,
Muktanand Marg,
Chala, Vapi-396191
Gujarat

Subject: Testing of One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV
manufactured by M/s Meril Diagnostics Pvt. Ltd. Gujarat.

Sir,

Pursuant to letter No. Testing/NIB/2013/72212-13/B1, Gandhinagar, dated 23.8.2013 from the Commissioner, Food & Drugs Control Administration, Gandhinagar, Gujarat State and your letter no. MDS/2014/086, dated 15.07.2014 the under mentioned samples of MERISCREEN HCV, manufactured by M/s Meril Diagnostics Pvt. Ltd, Vapi, Gujarat State, have been tested and found to be of Standard Quality. The Certificate of Analysis is attached.

S.No.	Name of the Product	Batch/Lot No.	Mfg. date	Exp. date	Analytical Report No.
1.	One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV	MI071404R	07/2014	12/2015	661/IDL/2014, Dated 11.08.2014
		MI071405R	07/2014	12/2015	663/IDL/2014, Dated 11.08.2014
		MI071406R	07/2014	12/2015	662/IDL/2014, Dated 11.08.2014

Yours faithfully

(Ashis Barua)
JTO & Oi/c SRRD

Copy to respective product files



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Certificate No.T-2011

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry of Health & Family Welfare)
A-32, Sector-62, NOIDA-201 307

F. No: N.1-187/2014-SRRD/IDKL

Date: 11.08.2014

CERTIFICATE OF ANALYSIS

1. Date of sample receipt: **18.07.2014**
2. Start date of analysis: **04.08.2014**
3. Analytical Report No. : **661/IDL/2014**
4. Name of the Product: **One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV**
5. Name of the Manufacturer: **M/s MERIL DIAGNOSTICS PVT. LTD. VAPI, GUJRAT**
6. Batch/ Lot No: **MI071404R**
7. Manufacturing date: **07/2014**
8. Expiry date: **12/2015**
9. Whether Legal/ Regulatory/ Non regulatory: **REGULATORY**

S.No.	Test(s) Conducted	Specifications	Results
1.	Sensitivity	$\geq 99.0\%$	• True Positive (TP)= 100 • False Negative (FN) = 00 • Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100/ 100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0\%$	• True Negative (TN) = 481 • False Positive (FP) = 00 • Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(481/481+ 00)\} \times 100$ = 100 %

10. **CONCLUSION: THE BATCH/ LOT NO: MI071404R OF THE ABOVE NAMED PRODUCT One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV AS PER REQUIREMENT (S) OF CDSCO LETTER NO: 26-1/MISC/2003-DC DATED: 12.06.03 IS OF STANDARD QUALITY.**

for *[Signature]*
11/08/14

Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 11.08.2014

[Signature]

Signature of the Lab. Head
Name: Dr. Reba Chhabra
Designation: S-I & Lab. Head
Date: 11.08.2014



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CERTIFICATE OF ANALYSIS

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3. Analytical Report No. : **663/IDL/2014**
4. Name of the Product: **One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV**
5. Name of the Manufacturer: **M/s MERIL DIAGNOSTICS PVT. LTD. VAPI, GUJRAT**
6. Batch/ Lot No: **MI071405R**
7. Manufacturing date: **07/2014**
8. Expiry date: **12/2015**
9. Whether Legal/ Regulatory/ Non regulatory: **REGULATORY**

S.No.	Test(s) Conducted	Specifications	Results
1.	Sensitivity	$\geq 99.0\%$	• True Positive (TP)= 100 • False Negative (FN) = 00 • Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100/ 100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0\%$	• True Negative (TN) = 481 • False Positive (FP) = 00 • Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(481/481+ 00)\} \times 100$ = 100 %

10. **CONCLUSION: THE BATCH/ LOT NO: MI071405R OF THE ABOVE NAMED PRODUCT One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV AS PER REQUIREMENT (S) OF CDSCO LETTER NO: 26-1/MISC/2003-DC DATED: 12.06.03 IS OF STANDARD QUALITY.**

for *Signature*
11/08/14

Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 11.08.2014

Signature

Signature of the Lab. Head
Name: Dr. Reba Chhabra
Designation: S-I & Lab. Head
Date: 11.08.2014



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CERTIFICATE OF ANALYSIS

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3. Analytical Report No. : **662/IDL/2014**
4. Name of the Product: **One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV**
5. Name of the Manufacturer: **M/s MERIL DIAGNOSTICS PVT. LTD. VAPI, GUJRAT**
6. Batch/ Lot No: **MI071406R**
7. Manufacturing date: **07/2014**
8. Expiry date: **12/2015**
9. Whether Legal/ Regulatory/ Non regulatory: **REGULATORY**

S.No.	Test(s) Conducted	Specifications	Results
1.	Sensitivity	$\geq 99.0\%$	• True Positive (TP)= 100 • False Negative (FN) = 00 • Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100/ 100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0\%$	• True Negative (TN) = 481 • False Positive (FP) = 00 • Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(481/481+ 00)\} \times 100$ = 100 %

10. **CONCLUSION: THE BATCH/ LOT NO: MI071406R OF THE ABOVE NAMED PRODUCT One Step Rapid Test for detection of Anti-HCV MERISCREEN HCV AS PER REQUIREMENT (S) OF CDSCO LETTER NO: 26-1/MISC/2003-DC DATED: 12.06.03 IS OF STANDARD QUALITY.**

for *Dr. Charu M Kamal*
11.08/14

Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 11.08.2014

Dr. Reba Chhabra

Signature of the Lab. Head
Name: Dr. Reba Chhabra
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