

राष्ट्रीय जैविक संस्थान
स्वास्थ्य एवं परिवार कल्याण मंत्रालय

NATIONAL INSTITUTE OF BIOLOGICALS
Ministry of Health & Family Welfare, Government of India



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No.N.1-211/2013-SRRD/IDKL/1507

Dated the 21.8.2013

22

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

Subject: Testing of Meriscreen HBsAg manufactured by M/s Meril Diagnostics Pvt. Ltd.

Sir,

Pursuant to License No. G/29/7958, dated 26.3.2013 from the Commissioner, Food & Drugs Control Administration, Gujarat State and your letter No. MSD/1314/086, dated 31.7.2013 the under mentioned samples of Meriscreen HBsAg 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.	MERISCREEN HBsAg	M1041315R	04/2013	06/2014	356/IDL/2013, Dated 19.8.2013
		M1041316R	04/2013	06/2014	357/IDL/2013, Dated 19.8.2013
		M1071314R	07/2013	09/2014	358/IDL/2013, Dated 19.8.2013

Yours faithfully

(Ashis Barua)
JTO & Oi/c SRRD

Copy to:

F.No. N.1-212/2013-SRRD/IDKL

F.No. N.1-213/2013-SRRD/IDKL



Certificate No.T-2011

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

F. No: N.1-211/2013-SRRD/IDKL

Date: 19.08.13

CERTIFICATE OF ANALYSIS

1. Date of sample receipt: **05.08.13**
2. Start date of analysis: **12.08.13**
3. Analytical Report No. : **356/IDL/2013**
4. Name of the Product: **MERISCREEN HBsAg**
5. Name of the Manufacturer: **M/s MERIL DIAGNOSTICS PVT. LTD., GUJARAT, INDIA**
6. Batch/ Lot No: **MI041315R**
7. Manufacturing date: **04'2013**
8. Expiry date: **06'2014**

S.No.	Test(s) Conducted	SPECIFICATIONS (As per DCG(I) letter no: 26-1/Misc/2003-DC dated: 12.06.03)Specifications	Results
1.	Sensitivity	$\geq 99.0 \%$	<ul style="list-style-type: none">• True Positive (TP)= 100• False Negative (FN) = 00• Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100 /100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0 \%$	<ul style="list-style-type: none">• True Negative (TN) = 485• False Positive (FP) = 00• Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(485 /485+ 00)\} \times 100$ = 100 %

CONCLUSION: THE BATCH/ LOT NO: MI041315R OF THE ABOVE NAMED PRODUCT COMPLY THE REQUIREMENT (S) AND FOUND TO BE OF STANDARD QUALITY.

Charu
19/8/13
Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 19.08.13

Reba
Signature of the Lab. Head
Name: Dr. Reba Chhabra
Designation: S-II & Lab. Head
Date: 19.08.13



Certificate No.T-2011

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F. No: N.1-212/2013-SRRD/IDKL

Date: 19.08.13

CERTIFICATE OF ANALYSIS

1. Date of sample receipt: **05.08.13**
2. Start date of analysis: **12.08.13**
3. Analytical Report No. : **357/IDL/2013**
4. Name of the Product: **MERISCREEN HBsAg**
5. Name of the Manufacturer: **M/s MERIL DIAGNOSTICS PVT. LTD., GUJARAT, INDIA**
6. Batch/ Lot No: **MI041316R**
7. Manufacturing date: **04'2013**
8. Expiry date: **06'2014**

S.No.	Test(s) Conducted	SPECIFICATIONS (As per DCG(I) letter no: 26-1/Misc/2003-DC dated: 12.06.03)Specifications	Results
1.	Sensitivity	$\geq 99.0 \%$	<ul style="list-style-type: none">• True Positive (TP) = 100• False Negative (FN) = 00• Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100/100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0 \%$	<ul style="list-style-type: none">• True Negative (TN) = 485• False Positive (FP) = 00• Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(485/485 + 00)\} \times 100$ = 100 %

CONCLUSION: THE BATCH/ LOT NO: MI041316R OF THE ABOVE NAMED PRODUCT COMPLY THE REQUIREMENT (S) AND FOUND TO BE OF STANDARD QUALITY.

Charu
19/8/13
Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 19.08.13

Reba Chhabra
19/8/13
Signature of the Lab. Head
Name: Dr. Reba Chhabra
Designation: S-II & Lab. Head
Date: 19.08.13



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F. No: N.1-213/2013-SRRD/IDKL

Date: 19.08.13

CERTIFICATE OF ANALYSIS

1. Date of sample receipt: 05.08.13
2. Start date of analysis: 12.08.13
3. Analytical Report No. : 358/IDL/2013
4. Name of the Product: MERISCREEN HBsAg
5. Name of the Manufacturer: M/s MERIL DIAGNOSTICS PVT. LTD., GUJARAT, INDIA
6. Batch/ Lot No: MI071314R
7. Manufacturing date: 07'2013
8. Expiry date: 09'2014

S.No.	Test(s) Conducted	SPECIFICATIONS (As per DCG(I) letter no: 26-1/Misc/2003-DC dated: 12.06.03)Specifications	Results
1.	Sensitivity	$\geq 99.0 \%$	<ul style="list-style-type: none">• True Positive (TP)= 100• False Negative (FN) = 00• Sensitivity = $\{(TP/TP + FN)\} \times 100$ = $\{(100 / 100 + 00)\} \times 100$ = 100 %
2.	Specificity	$\geq 98.0 \%$	<ul style="list-style-type: none">• True Negative (TN) = 485• False Positive (FP) = 00• Specificity = $\{(TN/TN + FP)\} \times 100$ = $\{(485 / 485 + 00)\} \times 100$ = 100 %

CONCLUSION: THE BATCH/ LOT NO: MI071314R OF THE ABOVE NAMED PRODUCT COMPLY THE REQUIREMENT (S) AND FOUND TO BE OF STANDARD QUALITY.

Charu
19/8/13
Signature of the Analyst
Name: Dr. Charu M Kamal
Designation: S-III & Lab i/c
Date: 19.08.13

Reba Chhabra
Signature of the Lab. Head
Name: Dr. Reba Chhabra
Designation: S-II & Lab. Head
Date: 19.08.13