

CONSORTIUM of NRLs for KIT QUALITY

Under NACP

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Tel : 020-27331200, 27331210
Fax No.: 0091-20-27121071

To,

Date: 26-04-2022

Ms. Akanksha Jain

Asst. General Manager (Quality Assurance)

Central Medical Services Society

(Autonomous Body under MoH & FW, Govt. of India)

IInd Floor, Vishwa Yuvak Kendra.

Pt. Uma Shankar Dikshit Marg, Teen Murti Road,

Opposite Police Station Chanakyapuri, New Delhi-110021

Dear Ms. Jain,

This is in reference to your request for evaluation of Meriscreen HIV 1-2 WB (Lot No.: MI032239, Mfg. date: 2022/03: Expiry date: 2024/02) from Meril Diagnostics Pvt. Ltd. received on 08/04/2022 at ICMR-National Institute of Cholera and Enteric Diseases, Kolkata.

Please find attached the evaluation report of the same herewith.

Thanks & Regards,

Agniva Majumdar
26/04/2022

Dr. Agniva Majumdar

Scientist "C"

ICMR-National Institute of Cholera and Enteric Diseases.



Agniva
26/04/2022

Consortium Members

National AIDS Research Institute (NARI)

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National Centre for Diseases Control (NCDC)

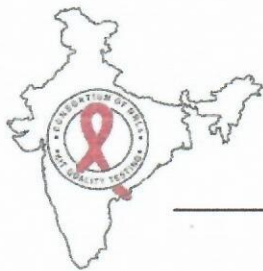
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KIT EVALUATION REPORT

A) General Information

1. Consortium kit ID : K-22-05
2. Date of receipt of kit : 08/04/2022
3. Name of the kit : MERISCREEN HIV 1-2 WB
4. Manufacturer : Meril Diagnostics Pvt. Ltd.
5. Batch number/lot No. : MI032239
6. Date of manufacture : 2022/03
7. Date of expiry : 2024/02
8. Assay Principle : Immuno-chromatography
9. No. of invalid assays* : None

*Comments : NIL

B) Details of the panel

1. Panel type : HIV Panel
2. Panel ID : ConQHIV20/01
3. Panel size : 500
4. Panel composition : 100 confirmed positive samples, and
400 confirmed negative samples



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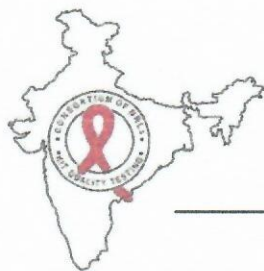
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Consortium kit ID: K-22-05
Batch No.: MI032239

C) Criteria for Acceptance of sensitivity and specificity for HIV as per CDSCO
letter no. 29/Misc/4/2016-DC (65):

• Sensitivity: 100%

• Specificity: $\geq 98\%$

D) Results:

Sensitivity and Specificity of the kit:

Test kit	Standard Test		
	Positive	Negative	Total
Positive.	100	00	100
Negative	00	400	400
Total	100	400	500

• Sensitivity = 100%

• Specificity = 100%

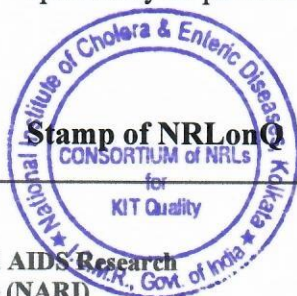
E) Kit Appraisal

	Rating	Poor	Satisfactory	Good
Kit instructions	Clarity			√
	Presentation			√
	Content			√
	Safety instructions			√
Reagent volume				√
Packing				√
Labeling				√
Ease of performance				√
Interpretation clarity				√

Comments: Nil

F) Summary and Conclusion of report:

The Sensitivity for this kit is 100% and the Specificity is 100%, meeting the criteria of sensitivity and specificity as per CDSCO guidelines. Thus, the kit (Batch No.: MI032239) is of Standard Quality.



Signature and date

In-charge- NRL on Q

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