

# CONSORTIUM of NRLs for KIT QUALITY

Under NACP

E-mail: consortium.nari@gmail.com

Website: www.nari-icmr.res.in

Tel : 020-27331200, 27331210

Fax No.: 0091-20-27121071

To,

**Ms. Akanksha Jain**

**Asst. General Manager (Quality Assurance)**

**Central Medical Services Society**

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

**II<sup>nd</sup> Floor, Vishwa Yuvak Kendra.**

**Pt. Uma Shankar Dikshit Marg, Teen Murti Road,**

**Opposite Police Station Chanakyapuri, New Delhi-110021**

Date: 20-05-2022

Dear Ms. Jain,

This is in reference to your request for evaluation of Comb Aids-RS ADVANTAGE-ST (Lot No.: 4000026952, Mfg. date: 2022-04-14; Expiry date: 2024-04-14) from ARKRAY Healthcare Pvt. Ltd. received on 17/05/2022 at ICMR-National Institute of Cholera and Enteric Diseases, Kolkata.

Please find attached the evaluation report of the same herewith.

Thanks & Regards,

*Agniva Majumdar*  
20/05/2022

Dr. Agniva Majumdar

Scientist "C"

ICMR-National Institute of Cholera and Enteric Diseases.



*Sd/-*  
20/05/2022

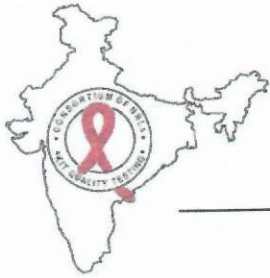
## Consortium Members

**National AIDS Research Institute (NARI)**  
Plot No. 73, 'G' Block,  
MIDC, Bhosari, Pune-411026  
Phone: 020-27331200  
Fax: 0091-20-27121071  
E-mail: consortium.nari@gmail.com

**National Centre for Diseases Control (NCDC)**  
22, Shamnath Marg,  
Delhi- 110054  
Phone: +91-11-23913148  
-23946893  
Fax: +91-11-23922677  
E-mail: dirnicd@bol.net.in  
dirnicd@del3.vsnl.net.in

**National Institute of Mental Health and Neuro Sciences (NIMHANS)**  
Hosur Road, Bangalore- 560029  
Phone: 080-26995126, 26995778  
Fax: +91-80-26564830, -6562121  
E-mail: anitasdesai@gmail.com  
dnn@nimhans.kar.nic.in

**National Institute of Cholera & Enteric Diseases (NICED)**  
P-33, CIT Road, Scheme- XM,  
Beliaghata, Kolkata- 700010  
Phone: 033-23501176, 23633374  
Fax: +91-33-23505066, -23532524  
E-mail: directorniced@icmr.org.in



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## KIT EVALUATION REPORT

### A) General Information

1. Consortium kit ID : K-22-13
2. Date of receipt of kit : 17/05/2022
3. Name of the kit : Comb Aids-RS ADVANTAGE-ST
4. Manufacturer : ARKRAY Healthcare Pvt. Ltd.
5. Batch number/lot No. : 4000026952
6. Date of manufacture : 2022-04-14
7. Date of expiry : 2024-04-14
8. Assay Principle : Dot Immunoassay
9. No. of invalid assays\* : 01

\*Comments : No pink coloured dot/ spot is visible in "control area" after completion of the test in one (01) comb. After repetition, this comb comes valid.

### 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

*Del.*  
20/05/2022



*JW*  
20/05/2022

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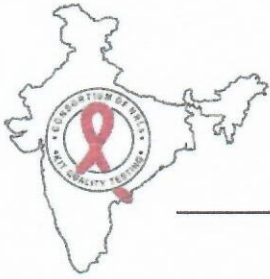
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dnn@nimhans.kar.nic.in

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**Consortium kit ID: K-22-13**

**Batch No.: 4000026952**

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

• Sensitivity: 100%

• Specificity: ≥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**

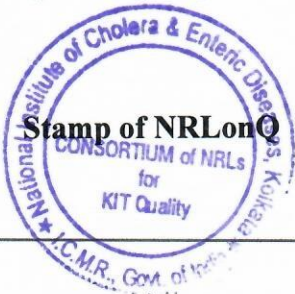
	Rating	Poor	Satisfactory	Good
Kit instructions	Clarity			√
	Presentation			√
	Content			√
	Safety instructions			√
Reagent volume				√
Packing				√
Labeling				√
Ease of performance				√
Interpretation clarity			√	

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.: **4000026952**) is of Standard Quality.

20/05/2022



Signature and date

In-charge- NRL on Q

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