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,
The Project Director
West Bengal State AIDS Prevention and Control Society
Swasthya Bhavan
Salt Lake, Sec- V
Kolkata-700091

Date: 18-01-2023

Subject: Evaluation of HIV (RAPID) Test Kits.

Dear Sir,

I am sending you the evaluation report of the HIV Rapid Kit, Lot No DHR2212047 (Kit ID: K-22-72) manufactured by Oscar Medicare Pvt. Ltd., which we have accepted for evaluation at our lab 28-12-2022.

The details of evaluation mentioned in separate pages attached herewith.

Kind regards.

Majumdar 18/01/2023

Dr. Agniva Majumdar
Scientist "C"
ICMR-National Institute of Cholera and Enteric Diseases.

18/01/2023

Consortium Members

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KIT EVALUATION REPORT

A) General Information

1. Consortium kit ID : K-22-72
2. Date of receipt of kit : 28/12/2022
3. Name of the kit : HIV-1 & HIV-2 Test
4. Manufacturer : Oscar Medicare Pvt. Ltd.
5. Batch number/lot No. : DHR2212047
6. Date of manufacture : 12-2022
7. Date of expiry : 11-2024
8. Assay Principle : Immuno-chromatography
9. No. of invalid assays* : 00

*Comments : Nil

B) Details of the panel

1. *Panel type* : HIV Panel
2. *Panel ID* : ConQHIV22/01
3. *Panel size* : 500
4. *Panel composition* : 100 confirmed positive samples, and 400 confirmed negative samples

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Consortium kit ID: K-22-72
Batch No.: DHR2212047

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.	92	00	92
Negative	08	400	408
Total	100	400	500

- **Sensitivity = 92%**
- **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:

F) Summary and Conclusion of report:

The Sensitivity for this kit is **92%** and the Specificity is **100%.** Hence the kit **does not meet** the criteria of **Sensitivity** as per CDSCO guidelines".

18/01/2023

Stamp of NRLonQ

Anujumdar 18/01/23

Signature and date
In-charge- NRL on Q

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1. Analytical Report No. : K-22-72
2. Name of the Product : HIV-1 & HIV-2 Test
3. Batch/Lot No. : DHR2212047
4. Name of the manufacturer : Oscar Medicare Pvt. Ltd.
5. Manufacturing Date : 12-2022
6. Expiry date : 11-2024

Remarks for →	Complying / Not complying
HIV (RAPID) TEST KIT 1st, 2nd & 3rd ANTIGEN	
Specific Requirement:	
1. The supplier should supply 600 tests x 2 sets free of cost from each batch for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocol of each batch is to be attached	Complying
2. A 'Cold Chain indicator' is to be supplied with the kits with the following specification: • *A cumulative time/temperature indicator to indicate the exposure to high temperature above 8 degree C* • *Should be mounted on card with clear instruction of interpretation* • *The card should be self adhesive and placed on each kit box to monitor heat exposure during transit and storage of the kits till its expiry* • *The cumulative time-temperature indicator technology used should be qualified* ***by US-FDA and/or prequalified by WHO.*** • ***The indicator should change color uniformly, irreversibly and the rate of reaction should be predictable by appropriate kinetic parameters.*** ***The color change should have a well-defined start point and end point that can be correlated to the heat stability of the kit.***	No comments
3) Bar-coding details are enclosed as Annexure I in Technical Specifications.	No comments
HIV (RAPID) TEST KIT 1st, 2nd & 3rd ANTIGEN	
The Purchaser can select anyone of the principle given on page **95-98** of Bid document under Technical Specification for 1st test. For 2nd line of testing, principle and or antigen would be different from the 1st test. The principle and or antigen for 3rd line of testing will be selected, which is different from 1st and 2nd line of testing.	No comments

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Consortium kit ID: K-22-72 ***Batch No.: DHR2212047***

	Remarks for →	Complying / Not complying
HIV (RAPID) TEST KIT		
1. The indigenous HIV antibody rapid test kits should have a valid license issued by the competent authority defined under Drugs & Cosmetics Act, 1940 after appropriate evaluation by the centers approved by DCG (I). The imported rapid test kits should have the approval of the statutory authority in the country of Origin/manufacture and should satisfy the requirements of Drugs & Cosmetics Act in India.		No comments
2. The assay should be able to detect antibodies of HIV1, HIV2 and all the subtypes **prevalent in the Indian sub continent by detection of antibodies** by the agglutination method.		No comments
3. The assay should have sensitivity of 100% or more and specificity of 98% or more as per data from an identified national reference laboratory.		**Not Complying:** Sensitivity is **92%**
4. The assay should have solid phase coated with synthetic and/ or recombination or both types of antigens of HIV1 & HIV2.		Complying
5. Total procedure time should not be more than 30 minutes.		Complying
6. The manufacturers should ensure that : a. The test should be packed such that there is a provision to conduct single test at a time. b. The assay components should include HIV positive and negative serum controls sufficient for conducting 20% of the tests (10% negative and 10% positive controls). c. The pack size of HIV rapid test kits should not be more than 50 tests per Kit.		Complying
7. The rapid kit should have a shelf life of minimal 12 months at the port of discharge of consignees end whichever is applicable.		No comments
8. The supplier/ local agent should have the facility to store kits at 2^{O} C to 8^{O}C.		No comments
9. The supplier should supply Tests for at least 600 tests free of cost from each lot for random evaluation at the identified laboratories for pre-dispatch lot verification. Protocols for each batch to be attached		Complying
10. Literature, detailing the components, methodologies, validity criteria, performance characteristics, storage conditions, manufacturing and expiry dates should be provided with each test		Complying

18/01/2023

Stamp of NRL on Q

Signature of the Lab. Authority
Name: Dr. Agniva Majumdar
Date: 18-01-2023

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