CONSORTIUM OF NRLs FOR KIT QUALITY

ABOUT US:

Anti-HIV antibody tests are performed for diagnosis of HIV infection, surveillance of HIV infection and screening blood to protect the blood recipient from transfusion transmitted infections (TTIs). The other routinely tested TTI infections are HBV and HCV. The evaluation of diagnostic kits for TTIs was an important aspect of obtaining good quality kits.

Hence a Consortium of four NRLs under initiative was established in 2008 with the help of NACO which provides Quality Evaluation of ELISA and Rapid diagnostic kits for HIV, HBV and HCV.

The four institutes involved in this activity are accredited by NABL, India for HIV, HBV and HCV serology. The institutes are:

- National AIDS Research Institute (NARI), Pune (evaluating institute and Secretariat)
- National Institute of Cholera and Enteric Diseases (NICED), Kolkata
- National Centre for Disease Control (NCDC), Delhi
- National Institute of Mental Health and Neurosciences (NIMHANS), Bengaluru.

The consortium became functional in 2010. A well characterized panel of 100 reactive (positive either for HIV, HBV or HCV) and 400 nonreactive (negative for all three infections) is developed and the same panel is being used by all the member institutes. Till date, the consortium has evaluated more than 700 kits received from different procurement agencies for the national programme, SACS which has resulted in availability of the quality kits for use in the national program.

KIT EVALUATION PROCESS:

The requests for evaluation are sent to National AIDS Research Institute (NARI), Pune (Consortium Secretariat) on consortium.nari@gmail.com which assigns the evaluation to one of the consortium members by rotation.

Charges: The cost for evaluations is Rs. 50,000 (Fifty Thousand only) per batch of kit.

Documents to be submitted along with the kits.

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<tr>
<td>1.</td>
<td>Has the kit been referred by a referring agency NACO?</td>
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<td>2.</td>
<td>Cold chain, Gross packaging and seal intact?</td>
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<td>3.</td>
<td>A total of 15 ELISA test kits (1400 test) or 1400 rapid tests supplied?</td>
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<td>4.</td>
<td>A production and Quality control protocol has been attached?</td>
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<td>5.</td>
<td>Licensing and batch released certificate* from the country of origin have been submitted?</td>
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6. A kit insert in English language comprising of details of the product, steps for performance of the test, calculation & interpretation of the result has been provided?* Certified and Authenticate copies of documents  □ Yes  □ No

**CONTACT US:**

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