

No. T-11020/82/2017-NACO/CST  
Government of India  
Ministry of Health and Family Welfare  
National AIDS Control Organisation

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36 Janpath, New Delhi - 11001.  
Dated: 1<sup>st</sup> February, 2018

Office Memorandum

**Subject: Regarding routine viral load testing scale-up plan**

In supersession to the existing guidelines on monitoring of PLHIV on ART, it has been decided to introduce routine viral load testing to monitor patients on antiretroviral therapy (ART). Currently, the programme is using targeted viral load testing to confirm suspected treatment failure owing to clinical or immunological failure of the patient. Under routine viral load testing, the patients on ART will be monitored using viral load test at regular intervals. The result of this test will allow early detection of potential treatment failure. Detailed information and guidance for the ART centre staff is as below.

1. **Scale-up plan for viral load testing:** NACO has contracted M/s Metropolis Healthcare Limited, Mumbai under a public-private partnership (PPP) to provide viral load testing for patients across all ART centres in the country. This agency shall carry out 2,10,000 tests in the first year, starting from 8th February, 2018 and will potentially provide 4,25,000 and 6,80,000 tests in the second and third year of its operation respectively. NACO has also planned to set up ~80 public sector viral load laboratories across the country to support routine viral load testing.
2. **Eligibility of patients for viral load testing:** All HIV-1 and HIV-1&2 co-infected patients who are registered under the programme and have been on ART for at least 6 months are eligible for viral load testing. However, NACO plans to introduce routine viral load testing in a phased manner. Hence, the following patient groups will be given priority for testing in 2018:

- Priority Group 1:** Patients with suspected treatment failure (immunological or clinical). Please refer to annexure 1 for definition of immunological failure
- Priority Group 2:** All PLHIV on second and third line ART
- Priority Group 3:** All pregnant and breast feeding HIV positive women
- Priority Group 4:** All PLHIV identified as Key population

*Note: PLHIV with confirmed HIV-2 infection should not be referred for viral load testing.*

3. **Timing for Viral Load test:**
  - For patients on first line of treatment, viral load test should be conducted at 6 months and 12 months from the date of ART initiation in first year, and once every 12 months thereafter.
  - For second/third line patients, viral load test should be conducted once every 6 months after initiation on ART.

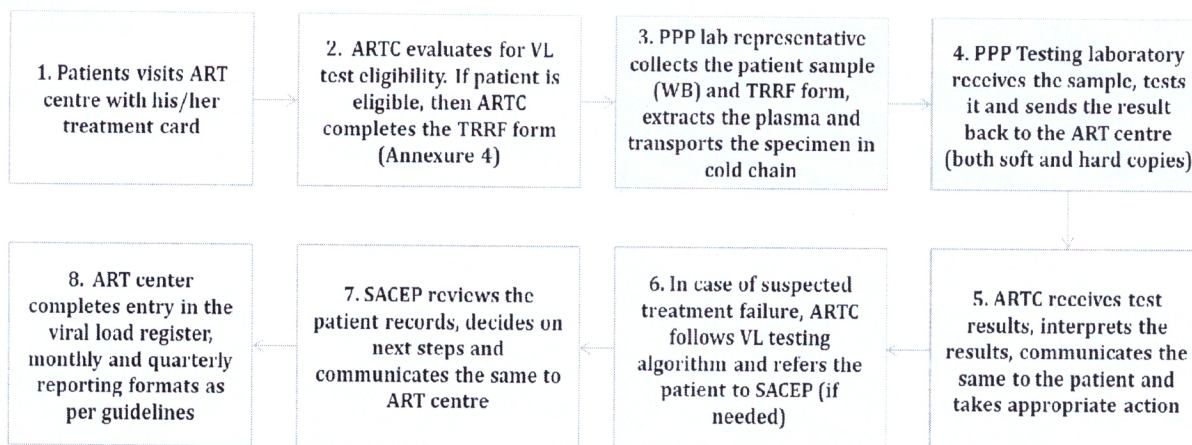
**Important:** CD4 testing should be continued for patients undergoing viral load tests. Please refer to annexure 2 for details on timing of patient monitoring tests.

The ART centre should ensure that viral load and CD4 tests are conducted on the same date (whenever possible).

4. **Interpretation of the result:** It is critical that appropriate action is taken after the ART center receives the viral load test result of the patient. Please refer to annexure 3 for flow chart regarding steps to be taken based on Viral load result. If a patient is suspected of virological failure, then he/she should be referred to SACEP over an email (e-referral) as soon as possible.



#### 5. Operational steps in routine viral load testing under PPP model:



**Sample collection schedule at ARTC:** The day(s) and timing of sample collection for VL testing at the ARTC will be communicated by NACO to all ARTCs in a follow-up communication

#### 6. Important Considerations for the routine viral load testing under PPP model:

- PPP agency will be responsible for arranging all consumables for sample collection, storage and transportation.
- PPP agency will also ensure that (a) soft copy of the VL test report is made available to ARTC within 24 hours of receipt of sample at testing facility
- Both the ARTC and testing lab will also be responsible for maintaining the viral load testing registers at their respective facilities and filling monthly reports as per the formats provided by the National programme (refer to annexure 5 for main formats). The ART centre is thus requested to extend necessary support to the staff of the agency, take receipt/ custody of consumables & equipment for sample collection (upon delivery by agency's transporter) and make working space available for PPP representative for sample collection on fixed day(s) of the week at the ART Centre. (For detailed roles and responsibilities of the ART centre staff, please refer to the "National Operational Guidelines for Viral Load Testing")
- ARTC should maintain a clear repository of the original TRRF forms (ARTC copy) for future audit purposes. The monthly review format for desk review of ARTC should be signed by ARTC SMO/MO and shared with SACS via email.
- SACS will be responsible for monitoring the entire viral load program, addressing any potential operational issues at the ART centre including printing of stationery, compiling monthly reports from all ART centres in the state/UT and sending them to NACO

Routine viral load testing will provide an early and more accurate indication of treatment failure and the need for a switch in ART regimen. However, the success of the viral load scale-up under the national programme depends on the abilities of the ART centres to identify the eligible PLHIV, conduct their viral load test and interpret the result as per the guidelines for timely diagnosis of treatment failures.

(Dr. R. S. Gupta)  
Dy. Director General (CST)  
02/02/2018

#### To:

Nodal Officer, All ART Centres

#### Copy to:

JD (CST)/ Officer In Charge (CST)  
All Regional Coordinators  
All Project Directors, SACS  
Programme Directors of CoE / PCoE

#### Copy for Information to:

PPS to AS, NACO  
PS to JS, NACO