Expression of Interest (EOI) for
Biological sample transport for HIV-1 Viral load testing under the National AIDS Control Program (NACP)
Profile of Organization and capability
Format for information related to Expression of Interest

The Chhattisgarh State AIDS Control Society (CGSACS) is a registered society under the Societies Registration Act, which receives fund from Govt. of India under Domestic Budgetary Support for implementation of National AIDS Control Programs (NACP) in the State of Chhattisgarh.

Expression of Interest are invited from eligible service providers for sample transport for HIV-1 Viral load testing under the National AIDS Control Program (NACP) in the state of Chhattisgarh. The service provider services related to biological specimen packaging and transportation from the designated ART center (sample collection site) and their delivery to the testing laboratories (Viral Load Testing Lab) as per the client approved linkage plan and timelines.

Objective:

To purchase services for sample transportation of biological samples across the State of Chhattisgarh. This document defines the technical and operational requirements of packaging and transportation of biological samples i.e. plasma and Dried Blood Spot (DBS) for HIV-1 viral load test under the national program.

Eligibility & Assessment Criteria:

- The service provider's capacity of having provisions for temperature and humidity-controlled logistics for plasma and DBS samples.
- The capability of the service provider in terms of supply chain management of materials (consumables and equipment) required for biological specimen packaging and transportation, provision of temperature and humidity-controlled transportation and deployment of competent personnel for carrying out the work.
- The capacity in terms of adequate physical infrastructure, robust processes, air & land connectivity network, appropriate tools to capture and share information on sample movement and a qualified/trained team that is experienced in handling large projects involving vast geographies and scale.
- Years of experience and prior work experience of providing similar services.

Requirements:

The EOI should be sent along with a capability statement including the profile of the organization relevant technical and geographical coverage along with the financial turnover for the last 3 financial years.

A format is shared below for providing the Capability statement. Any EOI with inadequate information, those which do not meet the above criteria, or those received after the closing date will not be short listed.

EOI should be as concise and focused as possible to give evidence of the above requirements including the capability statement and organization profiles.

They should be mailed in a sealed envelope through registered post/courier to the Project Director, Chhattisgarh State AIDS Control Society, State Health Training Centre, Budhapara, Raipur (C.G.) 492001, to arrive not later than 05 p.m. on 30/12/2021.

For Further Information

For further information, interested bidders are requested to visit the SACS website: https://www.cgsacs.com Or Contact the e-mail id: chhattisgarhsacs@gmail.com

Format for providing the Capability statement

Profile of Organization and capability: Format for information related to Expression of Interest

Section A: Basic Information

1. Name of the Agency/Supplier:

2. Postal Address:

3. Telephone:

4. Telex Fax Email

5. Legal status: Private ( ) Society ( ) Company ( ) Others (specify)

6. Registration Details: Registered on (Date)

7. Contact person:

8. Designation:

Section B: Organizational Background

9. Assets/Infrastructure of the agency/supplier

Category	Worth in rupees (eg. Land, building)

10 a. Please provide details, regarding the annual budget of your agency/supplier and attach the detailed audited statement for 3 years for NGOs and 1 year for CBO.

Year	Source of Funding	Amount (in Rs.)	List of activities	Activities similar to the TOR/Scope of Work	Geographical area of activities as mentioned in column no. 5
1	2	3	4	5	6

10. b.: Whether blacklisted/debarred by any agency (both government, private or World Bank/ UN bodies) in the past? If yes, provide details in an Affidavit.

10. c.: Whether any staff or board member of your agency is part of any NACO/SACS/TSU staffs currently or in the past. Please provide the above information in the form of an Affidavit.

Section C: Current key activities by the agency

11. Geographical location of Work

12. Please provide basic information on the key projects carried out by your agency since the last three years/one year (as applicable) (5 lines for each subject – attach separately) related to Biological sample transport for HIV-1 Viral load testing.

13. A brief write up on the activities of the agency currently runs (no more than two pages)

Section D: Documents Required

14. Copies of the following documents need to be provided with self-attestation by competent authority of the organization:

- Relevant registration of the agency
- Activity Report/Annual report (last 3years)

- Annual Audit Report last 3years
- Income Tax Return Document: (last 3years)
- Copy of the PAN Card
- Copies of the affidavit as required above
- Identification document of Authorized signatory submitting EoI (Govt. photo ID with address)
- Documents related to minimum financial turn over criteria (one crore)

15. Name of the person who filled this form:

Designation:

Address (with PIN Code):

Email address:

Biological sample transport for HIV-1 Viral load testing under the National AIDS Control Program (NACP)

Operational criteria for Pan-India temperature-controlled logistics

1. Background:

In its pursuit to implement the program effectively, NACO has up-scaled HIV-1 Viral Load testing for routine monitoring of patients on ART across the country. Viral load test provides early and accurate indication of treatment failure and the consequent need to switch to second-line drugs. It also improves the clinical outcomes as second-line ART is initiated earlier and thus reducing the accumulation of drug resistance mutations.

There are around 16700 PLHIVs receiving treatment at 08 ARTC centers (**Refer List of ARTCs - Annexure A)**. All patients on ART are monitored through HIV-1 Viral Load testing to assess the response to treatment. Those with higher HIV-1 Viral Load (>1000 Copies/ml) are evaluated for treatment failure in order to consider them for next line of Antiretroviral Treatment.

Currently, CGSACS is implementing routine HIV-1 Viral Load testing through 01 Viral Load Testing Centers in government-run facilities in the state (**VL lab list Refer Annexures B**).

HIV-1 VL test using plasma obtained from EDTA tubes is the most preferred sample type. Plasma sample requires strict specimen storage conditions as it is stable for only five days from the time of sample collection, at 2-8 ^{o} C. The plasma sample should be transported to the testing laboratory within a stipulated time. In situations where cold-chain availability between health facilities and testing sites is not feasible, like difficult terrains and far flung-areas which create barriers to VL services, DBS (Dried Blood Spot) specimen may be collected which is stable for 12 weeks at ambient temperature and controlled humidity conditions.

2. Scope of Services:

The scope of work includes biological specimen packaging and transportation from the designated ART center (sample collection site) and their delivery to the testing laboratories as per the client approved linkage plan and timelines. The service provider should have provisions for temperature and humidity-controlled Pan-India logistics for plasma and DBS samples. **(Refer Annexure C)**.

The responsibilities of the service provider extend from supply chain management of materials (consumables and equipment) required for biological specimen packaging and transportation, provision of temperature and humidity-controlled transportation and deployment of competent personnel for carrying out the work.

The service provider must have adequate physical infrastructure, robust processes, air & land connectivity network, appropriate tools to capture and share information on sample movement and a qualified/trained team that is experienced in handling large projects involving vast geographies and scale.

3. Operational Requirements for shipment of biological samples for HIV-1 VL test

a. The sample handling as per temperature and humidity requirements should be compliant with the National HIV-1 Viral Load guidelines
b. **Material to be transported**: Biological sample (Plasma & DBS)
c. **Category of material**: Biological substance Category B-UN3373
d. **Duration of sample transportation**:
    i. Plasma: delivery of samples to the testing lab at the earliest however not later than 5 days of sample collection
    ii. DBS: delivery of samples to the testing lab at the earliest, however not later than 10 days of sample collection maintaining the requirements for humidity control
e. **Temperature maintenance during sample transportation**:
    i. Plasma: cold chain transport (2-8 ºC)
    ii. DBS: ambient temperature and controlled humidity
f. **Packaging requirement**: The Service Provider should adhere to the national HIV-1 VL guidelines (Refer: NACO website) and applicable national and international guidelines such as Triple layer, UN-3373 packaging for infectious agent and WHO guidelines for safe transportation of material.
g. **Sample pick up site**: Sample collection sites identified by the client, refer **Annexure A**.
h. **Sample delivery site**: Viral load Labs, refer **Annexure B**.
i. **Sample referral and linkage patterns**: the client has defined the linkage patterns of sample collection sites with the viral load labs and frequency of pick up, refer **Annexure C**
j. Frequency of sample pick up: As defined in the **Annexure C**
k. The temperature data logger should be of the temperature range -10°C to 40°C and USFDA / CE and BIS approved. The service provider is required to provide technical specifications (and approval status as above) of temperature data loggers to be used during transportation of samples.
l. All consumables and equipment required for specimen packaging and transportation should be provided by the Service Provider.

m. The safe storage of all the consumables (including the personal protective equipment) and equipment required for above activities is the responsibility of the service provider.
n. The management of all Bio Medical Waste generated during this activity, in compliance to the biomedical waste management rules 2016, is the responsibility of the service provider.

4. Technical Requirements for shipment of biological samples for HIV-1 VL test

a. The Service Provider should have adequate experience and expertise to carry out packaging and transportation of plasma and DBS samples.
b. The Service Provider should engage qualified, trained and competent staff for sample packaging and transportation
c. The concerned nodal person of the sample collection site must be intimated through email/SMS before pickup person reaches sample collection site for pickup. The samples should not be delivered during non-working hours, weekends or on holidays unless prior arrangement with the receiving laboratory has been made.
d. The service provider must have all necessary licenses and approvals for the work undertaken
e. The service provider should have SOP for environment-friendly disposal mechanism of used packaging boxes & other materials used in logistics, adhering to the local/State guidelines and laws
f. An online system of specimen tracking must be made available

A. Packaging of plasma samples

a. Use validated Transport boxes to maintain 2-8-degree C during the duration of shipment.
b. It is desirable that the service provider has a network of multiple cold-rooms and freezers, for conditioning and decontamination of gel-packs, box preparation and for Gel-pack replenishment. The Gel-packs to be appropriately conditioned and decontaminated before usage.

B. Transport of Plasma samples

a. The samples should be transported in temperature ranges between 2- 8 ºC within five days of collection.
b. The documentation required for sample transportation is the responsibility of the service provider. A copy of documentation should also be provided to the in-charge of the sample collection site for record.
c. The data logger/temperature indicators should be provided in each transportation box for temperature monitoring during sample transportation.
d. In-transit status and key milestones shall be updated and made available by the Service Provider, on the real-time basis.
e. Service Provider shall have Pan-India logistic network connectivity.
f. Service Provider shall ensure delivery of temperature-controlled shipments within five days of sample collection.
g. At the time of the delivery of the samples to the lab, the record of data logger/temperature indicator should be accessible to the lab and at the national level.
h. If there is change in the approved linkage plan due to reasons such as non-functional lab, etc., a revised connectivity plan will be provided by the client on need basis.
i. The samples should not be packaged and transported or delivered during non-working hours, weekends or on holidays unless prior arrangement with the receiving laboratory has been made.
j. The Service provider is responsible for end to end monitoring of temperature during sample transportation.

C. Packaging for DBS specimens

a. The zip-lock bag containing the DBS cards from the sample collection site should be packed inside a water proof padded envelope.
b. Place the Test Requisition form (TRF), and the completed sample transportation log in the envelope.
c. Label the envelope with VL lab address and sender’s address with contact details.
d. Seal the envelope and label envelop with Biohazard label.

D. Transport of DBS specimen

a. The envelope containing the DBS cards should be transported to the linked viral load lab at ambient temperature and humidity-controlled conditions (with humidity indicator and desiccant).
b. The consignment should reach the VL lab not later than ten days of sample collection.

5. Monitoring and evaluation

The Service Provider will submit a monthly report on the following performance indicators:

a. Number of samples packaged and transported per month. Cumulative and facility wise disaggregated data for DBS and plasma sample
b. Number of shipments per month. Cumulative and facility wise disaggregated data for DBS and plasma
c. Average Turnaround Time from sample packaging and transportation to delivery at VL lab: Cumulative and facility wise disaggregated data for DBS and plasma
d. Number of shipments that missed the Turnaround Time. Cumulative and facility wise disaggregated data for DBS and plasma
e. Number of shipments not meeting the temperature requirements during plasma transportation. Cumulative and facility wise disaggregated data

The service provider must periodically monitor (internal audit) all the activities. This should be at least once in a year but at the start of operations more frequent internal audits must be done. The internal audit report with CAPA should be made available to the client on request. The client will have a system of scheduled and unannounced facility visits to check and verify the compliance to the requirements of the contract.

6. List of Annexures

1. Annexure A: List of sample collection sites (ART Centers) with PLHIV Load.
2. Annexure B: List of viral load Testing Centers.
3. Annexure C: Linkage plan of sample collection sites with the VL lab, sample type and frequency of sample pick-up.

Annexure A:

List of sample collection sites with PLHIV Load in Chhattisgarh:

SN	District	Sample Collection Site	Current PLHIV Load
1	Raipur	ART Centre, Dr. B.R. Ambedkar Memorial Hospital, Raipur	5225
2	Durg	ART Centre, District Hospital Durg	4569
3	Bilaspur	ART Centre, Chhattisgarh Institute of Medical Sciences (CIMS) Bilaspur	3641
4	Surguja	ART Centre, Govt. Medical College, Ambikapur	1058
5	Bastar	ART Centre, Govt. Medical College, Jagdalpur	1137
6	Korba	ART Centre, Govt. Medical College, Korba	410
7	Raigarh	ART Centre, Govt. Medical College, Raigarh	345
8	Rajnandgaon	ART Centre, Govt. Medical College, Rajnandgaon	320

Note: PLHIV Load is a dynamic figure and may vary from time to time.

Annexure B:

List of viral load Testing Centers in Chhattisgarh:

SN	District	Viral Load Testing Centre
1	Raipur	VL Lab, Department of Microbiology, II Floor, Pt. JNM Medical College, Jail Road, Raipur (C.G.).

Annexure C:

Linkage plan of sample collection sites with the VL lab, sample type and frequency of sample pick-up:

SN	District	Sample Collection Site	VL Lab (Where samples are to be transported)	Sample Type	Frequency of sample pick up
1	Raipur	ART Centre, Dr. B.R. Ambedkar Memorial Hospital, Raipur	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
2	Durg	ART Centre, District Hospital Durg	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
3	Bilaspur	ART Centre, Chhattisgarh Institute of Medical Sciences (CIMS), Bilaspur	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
4	Surguja (Ambikapur)	ART Centre, Govt. Medical College, Ambikapur	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
5	Bastar (Jagdalpur)	ART Centre, Govt. Medical College, Jagdalpur	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
6	Korba	ART Centre, Govt. Medical College, Korba	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
7	Raigarh	ART Centre, Govt. Medical College, Raigarh	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week
8	Rajnandgaon	ART Centre, Govt. Medical College, Rajnandgaon	VL Lab, Department of Microbiology, Pt. JNM Medical College, Raipur.	Plasma	Once in a week