

**Minutes of Roundtable on NAT Screening held on 12/12/2012,
H&FW Department, GNCTD**

In continuation to EOI issued by the department and the interest received thereupon a roundtable with the interested participants was held on 12-12-2012 at 3.00 PM at conference Hall No.1, Delhi secretariat on NAT Screening.

The session was chaired by Spl. Secretary (Health) alongwith the Technical Committee on NAT. Among the interested parties, following were present:

- 1) Hemogenomics Pvt. Ltd., Bangalore
- 2) Dr. Lal Pathlabs, Corporate office, Gurgaon
- 3) Terumo Penpol Ltd., Trivandrum
- 4) Dr. Dangs Lab Pvt. Ltd., New Delhi
- 5) Dr. Khanna's Pathcare Pvt. Ltd., New Delhi
- 6) Bangalore Medical System
- 7) Santokba Durlabhji Memorial Hospital cum Medical Research Institute, Jaipur
- 8) Indraprastha Apollo Hospital, Sarita Vihar, Delhi
- 9) Roche Diagnostic India Pvt. Ltd.
- 10) Dr. Garg Labs Pvt. Ltd.
- 11) SRL Diagnostic

Following members of Technical committee were present. :-

- 1) Director Health Services, GNCTD – chairperson
- 2) Dr. Bharat Singh, Director, SBTC. - Convenor
- 3) Dr. V.G. Ramachandran, Prof. (Microbiology), UCMS.
- 4) Dr Chattopadhyay, NCDC (National Centre for Disease Control).
- 5) Dr. A.K. Gupta, Addl. Project Director, DSACS.
- 6) Dr. Sangeeta Pathak, Max Hospital, Saket Delhi

A brief of the round table for record is as under: -

The participants were welcomed with brief round of introduction followed by the short presentation on key aspects of the proposed NAT screening project (copy of presentation is placed opposite).

After the presentation, the interested parties were invited to offer their queries/suggestions, which in brief are recorded as under:

- (1) Choice of methods (Individual donor testing, v/s pool testing): - Some participants in their opening remarks suggested choosing one or other method for this project. The opinion was however divided, on the choice of method, some advocating IDT & others advocating pool, based mainly on commercial aspects with a some suggesting IDT as technically superior and some suggesting minipool as practical and equally good choice for Indian context. There were other participants who were neutral to the choice of technology. It was informed that both methods are approved for use with nearly same results & are followed worldwide including USA where the pool size is 16. The issue

- being technical, is noted for the technical experts to give their recommendation on the matter to the department.
- (2) It was pointed that if a sample in pool turns positive then those blood units will be locked. This issue is noted for experts.
 - (3) An issue of including HIV-I and/or HIV-2 under NAT screening was raised. Some of the participants suggested that NAT test may include HIV-II, besides HIV-I. Whereas some of the participants were of the opinion that HIV-I is more relevant in Indian context as almost all the case are HIV-I, although there may be isolated case reports of HIV-II, therefore, the NAT screening may include atleast HIV-I, since ELISA for both tests will also be done (on a query it was clarified that current ELISA will continue to be used for both HIV-I & HIV-II and NAT will be additional safety net). The issue being technical, is noted for the technical experts to give their recommendation to the department.
 - (4) Some participants suggested that discriminatory test may not be conducted on same platform since this is not a practice. The issue was discussed and it is decided that the discriminatory test shall have to be done, however it may be done on a different platform, for academic purposes, in the follow up.
 - (5) One of the participants suggested that the legal liability in case of false reporting should not rest with the Service provider. It was suggested that although negligible but there is a chance for false results for which the Service provider may not be liable. The issue was discussed threadbare and it was noted that the Service provider has to follow the SOP/protocols & ensure quality assurance through manufacturers recommendations/ internal quality control and external quality assurance (through proficiency organization acceptable to the Govt). These testing and validation mechanisms are the responsibility of the Service provider and therefore legal liability should rest with the service provider. Service provider is expected to procure necessary product liability/professional indemnity insurance & indemnify the Govt. towards the same. It was appreciated that this is standard practice and Service provider is legally liable for services rendered.
 - (6) Some participants suggested that there should be one lab with backup at same location & this lab should be developed as a state of art facility to show case as a model lab as it is expected that lab, once in place will be visited by Technical experts & stakeholders from many parts of India as well as abroad. For this lab, upto 1000 sq feet space may be provided. Some of the participants, however suggested having one lab with additional/backup labs at one or more locations as logistics are important component of this project. The education /research can be provided at all the 3 labs and 400 to 500 sq feet of space may suffice for one lab. The participants noted that space may be acquired for storage of the samples for future reference, although there is no mandatory requirement at present under

NABL/Govt. guidelines. The issue on the no. of labs & storage requirement is noted for the technical committee experts.

- (7) A query was raised regarding mode of delivery of results & TAT (turn around time). It was clarified that the result will be communicated online, like it is followed by private labs which give result online. These online reports will be followed by hardcopies. Regarding the TAT the participants informed that it may take approximately 8 Hrs to test the sample & issue the result. Participants were informed that such operational issues will be addressed in the RFP document.
- (8) One participant suggested that they have in house NAT Lab which may be used for this project without creating a new lab. It was clarified that for this project, NAT lab including any backup/additional lab shall be setup in the GNCTD hospital/blood bank & will run under direct supervision of the blood bank incharge.
- (9) One participant, Terumo Penpol Ltd., Trivandrum informed the group about their technology regarding blood bags which reduce pathogen load. While this may not be relevant to NAT screening but it is relevant for overall safety of blood.
- (10) One participant, requested for giving IPR to the Service provider. It was discussed and clarified that the IPR of all the database generated will rest with the Govt. The Service provider will be acknowledged in any paper published by the Govt. institution.
- (11) One of the participant, suggested that the financial eligibility criteria may be kept at approximately 4 to 5 crore (average 3 year turnover), further, the consortium member may be allowed to join hands with the L1 as there are only 2 manufacturer who are likely to participate & in case any other party wins the bid, it will have to procure the equipment either from these two manufactures. The participant further stressed that the payment by the Govt. should be made timely. It was clarified that issue regarding consortium will be worked into & payments shall be made timely. The PQ criteria are designed to shortlist just adequate number of highly capable bidders as the project is highly specialised & prestigious.
- (12) Technical committee members were requested to examine the issues noted and suitably recommend/advise the government.

The roundtable ended with thanks to Chair.

Sd/-
OSD (Health)
H&FW, GNCTD