Subject: National Blood Transfusion Council (NBTC) norms for sending TTI reactive blood bags by licensed blood centres.

General Norms

1. Licensed blood centre shall be permitted to send Transfusion-Transmissible Infection (TTI) sero-reactive blood bags to identified Reference Laboratories, Indigenous diagnostic kit manufacturers, and Proficiency Testing (PT) providers in the Public, private (Indigenous), and Charitable sectors for preparation of seroconversion panels, Quality Control panels, and manufacture of Indigenous diagnostic/screening kits.

2. No Objection Certificate (NOC) for the same shall be issued by the respective State Blood Transfusion Councils after receipt of the application from the concerned organization identifying blood centres who would supply the blood bags.

3. The blood bags shall be issued free of cost to public sector reference laboratories/government-approved External Quality Assessment Scheme (EQAS) providers (without levy of any processing charges). In the case of indigenous manufacturers, the charges can be levied as per the government-approved applicable processing charges for whole blood.

4. The organization receiving such blood bags shall undertake in writing to ensure proper transport and disposal of the remainder of infective material in accordance to the extant rules including Biomedical Waste Management (BMW) rules, preventing the issuing blood centre of any such responsibility.

5. Records of such a transaction shall be maintained at licensed blood centres as per the format prescribed by National Blood Transfusion Council (NBTC)/ State Blood Transfusion Council (SBTC).

6. For any research purpose the proposal has to be sent to the Indian Council of Medical Research (ICMR) through proper channels, with appropriate ethics clearance.

7. All licensed blood centres would take the informed consent of the blood donors at the time of blood donation that their blood/ blood components/ products may be used for the purposes of preparation of panels, scientific research, and Indigenous manufacture to address all ethical concerns.

Norms specific to Indigenous manufacturers of kits and medical devices:

1. Transfusion-Transmissible Infection (TTI) sero reactive blood bags shall be issued to Indigenous manufacturers of kits and medical devices with a valid manufacturing license from the State Licensing Authority and Central License Approving Authority as well as to Indigenous manufacturers of diagnostic raw materials like antigens and antibodies.

2. When the manufacturers apply for a manufacturing license, auditors from the Central Drugs Standard Control Organization (CDSCO), shall check Risk management protocols and records for the usage, handling, and disposal of infectious materials in use, at the manufacturing facility. To ensure employee health safety and environmental protection.

3. Each such firm shall submit an affidavit to the licensed blood centre and copy to the respective State Licensing Authority and Central License Approving Authority stating that the firm shall utilize the collected TTI sero reactive blood as a raw material for preparing In vitro diagnostic (IVD) reagents and shall not divert the material for purposes other than IVD usage.

4. The applicants (Manufacturer/Test License holder) shall be required to submit an undertaking to the concerned blood centre, stating that they would adhere to the Biomedical Waste Management Rules, 2016 laid down for biohazardous materials, while collecting, transporting, storing, using and discarding such sera.

5. Blood centres incur a certain amount of charges on each unit of blood bag for its testing and processing and hence blood centers shall be permitted to invoice the manufacturers for unused sero-reactive units to compensate for expenses incurred on each unit of blood bag for its testing and processing.

6. The blood centre shall maintain a record of the number of blood bags given to the manufacturers and similar records shall be kept by the manufacturers for traceability from the collection point till the manufacture of the Kits.

7. The manufacturer shall hand over a receipt at the time of collection of the blood bag/s to the firm which shall mention:

a. TTI reactive blood bag number
b. Number of units
c. Date of collection
d. Complete address and contact details of both parties

e. The same shall be signed and stamped by both parties and copies retained.

8. The manufacturer shall maintain the following records:

a. Reconciliation record of the blood collected and its usage at all times.

b. Quantity of the antigen used for the manufacture of the kits to avoid the misuse of the TTI reactive blood bag.

9. The applicant (manufacturer) shall approach SBTC (State Blood Transfusion Council) to get approval for the collection of reactive blood bags/ samples from the blood centres of that State/UTs.

10. Once the approval is sought from SBTC. The MoU shall be signed between the approved manufacturer and the blood centre for the above purpose, and the same shall be informed to SBTC.

11. Data confidentiality should be maintained while supplying the Sero-positive blood bags by licensed blood centres.