Annexure-1

19. Blood transportation box –medium 10 unit capacity

1 Description of Function

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
1.1	Cold Box is essential to carry whole blood from individual donors to blood bank or from blood bank to point of use within safe temperature range (2 to + 10 deg C) for a particular period known as cold life of the product		
1.2	Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use		

2 Operational Requirements

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
2.1	The small cold box , long range should be able to keep the Blood Bags safe while transporting to long distances for longer hours of time. Blood storage capacity of 10 units is required.		

3 Technical Specifications

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
3.1	External surface and internal lining material LLDPE-(Linear Low Density Polyethylene)		
3.2	Insulation material CFC-free Polyurethane		

3.3 Insulation thickness-90-120mm

3.4 Cold life without opening 90-160hrsat+ 43 degree C(or better)

3.5 Cold Box shall be CFC free and shall be marked CFC Free on the outside).

3.6 Each cold Box shall contain adequate icepacks

3.7 External dimensions 50x55x47 in cms

3.8 Internal dimensions 27x24x26 in cms

3.9 Lid type- Hinged

4 System Configuration Accessories, spares and consumables

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
4.1	Unit as specified		

5 Environmental factors

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
5.1	The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%		
5.2	Maximum Ice Melting Rate: More than 15 hrs cold life per kg of ice melted at 43 °C		

6 Power Supply

Sl	Name	Technical Specs quoted	Bidders Deviation if any

		by bidder	
	None		

7 Standards and Safety

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
7.1	Inspection and Laboratory Test Procedure to be carried out as per WHO Standard Test Procedure: B4/PROC/4		
7.2	The equipment should Conform to WHO Specifications B4/BC1		
7.3	Manufacturer should have ISO certification for quality standards.		

8 Documentation

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
8.1	Manufacturers certification of compliance of test procedures as per WHO Standards Test Procedures.		
8.2	Inspection Certificate from manaufacturer to be complying with WHO specification as specified above.		

20. Blood transportation box –large 50 unit capacity

1 Description of Function

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any

1.1 Cold Box is essential to carry whole blood from individual donors to blood bank or from blood bank to point of use within safe temperature range (2 to + 10 deg C) for a particular period known as cold life of the product

1.2 Purpose of Equipment: To carry whole blood from individual donors to blood bank or from blood bank to point of use

2 Operational Requirements

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
2.1	The Large cold box , long range should be able to keep the Blood Bags safe while transporting to long distances for longer hours of time. Blood storage capacity of 50 units is required.		

3 Technical Specifications

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
3.1	External surface and internal lining material LLDPE-(Linear Low Density Polyethylene)		
3.2	Insulation material CFC-free Polyurethane		
3.3	Insulation thickness 100-120 mm		
3.4	Cold life without opening 120-185 hrs at +43 degrees C (or better).		
3.5	Cold Box shall be CFC free and shall be marked CFC Free on the outside).		
3.6	Each cold Box shall contain adequate icepacks		
3.7	External dimensions 70 X 55 X50 in cms.		

3.8 Internal dimensions 50 X 34 X27 in cms.

3.9 Lid type –Hinged

4 System Configuration Accessories, spares and consumables

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
4.1	Large Cold Box- Large Range(including integrated lockable fittings)- qty-		

5 Environmental factors

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
5.1	Maximum Ice Melting Rate: More than 10 hrs per 1 kg ice melted during 43 °C cold life test		

6 Power Supply

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
	None		

7 Standards and Safety

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
7.1	Inspection and Laboratory Test Procedure to be carried out as per WHO Standard Test Procedure: B4/PROC/2		

7.2 The equipment should Conform to WHO Specifications B4/BC2

7.3 Manufacturer should have ISO certification for quality standards.

8 Documentation

Sl	Name	Technical Specs quoted by bidder	Bidders Deviation if any
8.1	Manufacturers certification of compliance of test procedures as per WHO Standards Test Procedures.		
8.2	Inspection Certificate from manaufacturer to be complying with WHO specification as specified above.		

21. Specification for Nucleic Acid Amplification Testing

s no.	Specification
1	Fully automated system- the system must be fully integrated and automated with process control from sample pipetting /preparation to result reporting with minimal end user intervention for the whole period of testing procedure
2	Assay performance : they should be able to detect accurately the following viral markers HIV-all HIV variant including subtypes HCV-genotype 1111,2,3,4,5,6 HBV-genotype A,B,C,D,E,and G Tenderer shall provide data with detail from reference centres showing assay performance of the reagent for the detection of the requirements list as above. Wider spectrum of viral genotype detection will be advantageous in tender assessment
3	Testing format-should be ID (Individual donor) NAT based system
	Instrument should have through put of Minimum 250 testing in 8 Hours by individual donor testing; 500 testing in 12 hours by individual donor testing. minimum 100 sample tubes processing capacity with ability for continuous sampler loading
4	Procedure should on transcription mediated amplification / PCR technique
5	Analytical sensitivity of the complete assay performed on system (with a 95% detection probability will be at least HIV :50 copies /ml HCV:10 IU/ml HBV:10 IU /ml
6	Multiplex nucleic Acid test for HIV, HCV and HBV (3 in 1)
7	An internal control must be added to each reaction tube to ensure that the assay integrity

	is maintained throughout the procedure
8	the kit should consist of all the ready to use reagent and chemical necessary for the complete NAT procedure
9	Each kit should contain positive and negative control calibration internal control and external control samples all other necessary chemicals for the completion of the NAT procedure.
10	Original product insert of the reagent assay kit should be provide in the test sample
11	Amplification should not be inhibited by any anticoagulant present in the technical bid.
12	the NAT test kit, test protocol and system should be approved by united states food and drug administration (US-FDA) or confirm to European standard (CE) and the competent India authority for use in blood screening. Tenderers shall submit relevant supporting document evidence for the above requirement.
13	All the ancillary equipment list required for making the system fully functional list should be provided
14	The supplier shall provide latest software to operate the system & data backup solution as a part of software to interact with hospital information system
15	The equipment should have up gradation facility
16	System should have be provided with on board laser printer (S) for hard copy printout of result
17	The supplier will make the system fully functional and provide all necessary kits, reagent required during the standardizing process
18	Supplier shall make necessary back up arrangement for testing samples in case of breakdown of equipment
19	The equipment/components of system shall be provided with uniterrupted power supply (online ups) devices which keep the system running for at least 30 min from the time of power failure without loss of any data
20	Each donor to be tested individually, the rate of reportable test to be fixed for 3 yrs
21	Quotation should include 1 yrs warranty with all the spares and CMC for next 5 years after expiry of warranty
22	Supplier shall provide onsite comprehensive training to the laboratory staff and support services till familiar and confident in using the system

22. Fully automated coagulation system

1 It should be fully automated coagulation analyzer.

2 It should be open system with batch and patient mode of operation.

3 It should be viscosity based detection system for Clotting test and optical system for chromogenic and immunoturbidimetric test.

4 It should be capable to run clotting assay, chromogenic assay , immunoturbidimetricsa assay.

5 It should be perameter- PT,APTT,TT,ATIII,HEPARIN,fidrinogen, fondaparinux, rivaroxaban,UFH and LMWH,D-Dimer,PC,PS,FVIII and FIX.

6 It should be throughput -50 PT test/hour and time to first patents result-PT/APTT/FIV=6 mts.

7 It should be 80 test methodologist available.
8 It should be reagent position- 16. All are temperature controlled and maintained from 15 to 19 degree C. Each reagent can be placed in several positions and analyzer will detect automatically without manual intervention
9 It should be positive barcode identification for reagent. Barcode identification for reagent name, lot no, expiry, on board stability
10 It should be 20 sample carrousels for primary tubes. Capable of adapting paediatric tube and microtainers.
12 It should be positive barcode identification for sample.
13 It should be 12 programmable tests for 1 sample.
14 It should be single probe for sample and reagent with LLD (liquid level detection).
15 It should be 220 unitary cuvettes on board with continuous loading capability.
16 It should pre calibrated assay for PT, FIV and D-Dimer.
17 It should be storage capable for calibration curves, automatic dilution for calibration.
18 It should be multi tasking software with touch screen with LCD display.
19 It should be 600 patient result and 1 year QC result in memory.
20 It should be QC management with levy jennings chart and wesdgard QC alarm.
21 It should be alarm for QC out range capability.
22 It should be availability of internal printer and capability to adopt external printer.
23 It should be LIS capability with BI directional transferring capacity.
24 It should be auto validation for patient result and calibration.
25 It should be auto rerun with operator's rules.