CORRIGENDUM No. 01

Request for Proposal for Selection of an Agency for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh
*(Corrigendum No - 01 - to RFP Ref. No.: **S. No. N.H.M./Store/2022/5235** & Tender ID: **2022_DHS_214454_1**)*

1. This is regarding the NIT issued on 02/08/2022 Selection of an Agency to for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh, in leading newspaper and uploaded on MP Tender Website https://mptenders.gov.in.

2. In lieu of the released RFP, the Technical Committee after due consideration recommends following amendments in the Tender document for now:

S. No.	Tender Reference	Reference	Amendments
1.	**NIT**	**Dates (as published in the RFP)** - Document Download/ Sale End Date: 22nd August 2022, Monday, 04:00 PM - Bid Submission Start Date: 17th August 2022, Wednesday, 12:00 PM - Bid Submission End Date: 22nd August 2022, Monday, 04:00 PM - Bid Opening Date: 23rd August 2022, Tuesday, 05:00 PM	**Amendment** *"After the publication of the Corrigendum No. 01, the revised timelines/ dates for key events are as follows:* - *Document Download/ Sale End Date: 01st September 2022, Thursday, 04:00 PM* - *Bid Submission Start Date: 25th August 2022, Thursday, 12:00 PM* - *Bid Submission End Date: 01st September 2022, Thursday, 04:00 PM* - *Bid Opening Date: 02nd September 2022, Friday, 05:00 PM"*

3. All changes/ modifications in Tender document as above are binding to all Bidder(s)
4. Other terms and conditions of the Tender document shall remain the same

Mission Director
National Health Mission, Madhya Pradesh

CORRIGENDUM No. 02

Request for Proposal for Selection of an Agency for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh
*(Corrigendum No - 02 - to RFP Ref. No.: **S. No. N.H.M./Store/2022/5235** & Tender ID: **2022_DHS_214454_1**)*

1. This is regarding the NIT issued on 02/08/2022 Selection of an Agency to for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh, in leading newspaper and uploaded on MP Tender Website https://mptenders.gov.in.

2. In lieu of the released RFP, the Technical Committee after due consideration recommends following amendments in the Tender document for now:

S. No.	Tender Reference	Reference	Amendments
1.	Section 2, Clause 2.6.9, (o), Page No. 24	The base rate would be separate for the 02 (two) categories of blood banks to be established as mentioned in the scope of work. For the purposes of this RFP, the National Blood Transfusion Council ("**NBTC**") approved processing charges for Blood and Blood Components have been picked up as base rate for quoting of percentage (%) discount by the Bidder (s). The base rates for both the category of blood banks would be as mentioned below: - Category 01 = INR 1,100/- (one thousand one hundred only): applicable for existing 19 blood banks of the state - Category 02 = INR 2,350/- (two thousand three hundred fifty only): applicable for the 18 new blood banks to be established within the state	**Amendment:** *"The base rate would be separate for the 02 (two) categories of blood banks to be established as mentioned in the scope of work. For the purpose of this RFP, the National Blood Transfusion Council ("**NBTC**") approved processing charges for Blood and Blood Components have been picked up as base rate for quoting of percentage (%) discount by the Bidder (s). The base rates for both the category of blood banks would be as mentioned below:* - *Category 01 = **INR 1,550/-** (one thousand five hundred fifty only): applicable for existing 19 blood banks of the state* - *Category 02 = **INR 2,350/-** (two thousand three hundred fifty only): applicable for the 18 new blood banks to be established within the state"*
2.	Section 2, Clause 2.8.4, Page No. 27		**Amendment:** ***"**Please refer to Annexure I attached with this Corrigendum**"***
3.	Section 3, Clause 3.1, S. No. 4, Page No. 29	The Bidder(s) must have an experience of end-to-end management of blood banks (collection, testing, storage, separation and distribution aspects) services for at least 01 (one) project/ contract with a State Govt., PSUs, or Semi Govt. ventures across any of the last 03 (three) Financial Years (i.e., 2019-20, 2020-21 and 2021-22)	**Amendment:** *"This clause has been deleted from the RFP henceforth"*

S. No.	Tender Reference	Reference	Amendments
		Note: Experience of end-to-end management for providing Blood Bank services implies the Bidder (s) has procured necessary licenses/ certifications, installed equipment for processing, testing, and separation of Blood and related components, and handled storage & distribution of blood products etc. as responsibilities in the project	
4.	Section 3, Clause 3.1, S. No. 5, Page No. 29	The Bidder(s) should have an average annual financial turnover of INR 05 (five) Crores from end-to-end management of Blood Banks services in the 03 (three) Financial Years i.e., 2018- 19, 2019-20, and 2020-21	**Amendment:** *"The Bidder(s) should have an average annual financial turnover of INR 05 (five) Crores from healthcare services in the 03 (three) Financial Years i.e., 2018- 19, 2019-20, and 2020-21"*
5.	Section 4, Clause No. 4.2.1 (C) (1), Page No. 36	Added	**Amendment:** *"The Selected Agency shall not be required to conduct every test on the unit of blood to be processed. In case any special test(s) shall be required to be conducted, the charges pertaining to the same, shall be payable as per the rates mentioned in notification issued by NBTC"*
6.	Section 4, Clause No. 4.2.1 (B) (3), Page No. 36	(a) **Refrigerated Centrifuge with Separator** – The Selected Agency shall place 01 (one) New USFDA/ European (CE) certified Refrigerated Centrifuge with Separator for centrifugation purposes and compliant to the minimum technical specifications provided in Annexure – 16 at each of the Blood Banks (b) **Automated Component Separator -** The Selected Agency shall place 01 (one) New USFDA/ European (CE) certified Centrifuge & Automated Components Separator fully automatic machine for Component separation and leukoreduction, and compliant to the minimum technical specifications provided in Annexure – 16 at each of the Blood Banks (c) **Chemiluminescence Immunoassay (CLIA) methodology Fully automatic machine** –The Selected Agency shall place 01 (one) New USFDA/ European (CE) certified CLIA fully automatic machine for identifying Transfusion Transmitted Infection (TTI) and compliant to the minimum technical specifications provided in Annexure – 16 at each of the Blood Bank (d) **Semi-automatic Cross Matching Machine with Incubator** – The Selected Agency shall place 01 (one) New USFDA/ European (CE) certified Cross Matching Semi-automatic Machine for Cross matching of Blood, and compliant to the minimum technical specifications provided in Annexure – 16 at each of the Blood Banks	**Amendment:** *"**(a) Refrigerated Centrifuge with Separator:** The Selected Agency shall place 01 (one) New Refrigerated Centrifuge with Separator certified by USFDA/ European (CE)/ Declaration of Conformity of CE for centrifugation purposes at each of the Blood Banks and compliant to the minimum technical specifications provided in Annexure – II* ***(b) Automated Component Separator -** The Selected Agency shall place 01 (one) New Centrifuge & Automated Components Separator fully automatic machine certified by USFDA/ European (CE)/ Declaration of Conformity of CE for Component separation and leukoreduction at each of the Blood Banks, and compliant to the minimum technical specifications provided in Annexure – II* ***(c) Chemiluminescence Immunoassay (CLIA) methodology Fully automatic machine (Chemiluminescence/ Electro-Chemiluminescence/ Fluorescence technology)** –The Selected Agency shall place 01 (one) New CLIA fully automatic machine (Chemiluminescence/ Electro-Chemiluminescence/ Fluorescence technology) certified by USFDA/ European (CE)/ Declaration of Conformity of CE for identifying Transfusion Transmitted Infection (TTI) at each of the Blood Banks and compliant to the minimum technical specifications provided in Annexure – II*

S. No.	Tender Reference	Reference	Amendments
			(d) Semi-automatic Cross Matching Machine with Incubator *– The Selected Agency shall place 01 (one) New Cross Matching Semi-Automatic Machine USFDA/ European (CE)/ Declaration of Conformity of CE for Cross matching of Blood at each of the Blood Banks, and compliant to the minimum technical specifications provided in Annexure – II"*
7.	SECTION 4, Clause 4.2.1, (B) (3), Page No. 36	Added	**Amendment:** "*Note: The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") post installation for all the prescribed blood bank equipment's (as per **Annexure-II** attached with this Corrigendum no. 02); subsequent to the gap analysis done and as per the requirement for maintaining the operations of all the blood banks. Also, the Selected Agency has to install new machines only (old/ refurbished machines shall not be installed) across all the locations as mentioned under the scope of the work of RFP*"
8.	Section 4, Clause 4.2.1 (E) (2), Page No. 38	The Selected agency shall develop a BBIMS for the management and real-time monitoring of all the processes connected with Blood collection, storage, separation, transportation and distribution as well as to manage stock of blood and components on real time basis for all the blood banks. The BBIMS provided by the Selected Agency shall be able to perform a range of core functions such as - Workflow management; Record keeping; Inventory management and Reporting etc.	**Amendment:** *"The Selected agency shall develop a BBIMS (license version only) for the management and real-time monitoring of all the processes connected with Blood collection, storage, separation, transportation and distribution as well as to manage stock of blood and components on real time basis for all the blood banks. The BBIMS provided by the Selected Agency shall be able to perform a range of core functions such as - Workflow management; Record keeping; Inventory management and Reporting etc. The Selected Agency would be required to produce necessary documents for usage of Licensed Version applications to avoid any copyright or patent violation* *The Selected Agency shall be responsible for any upgradations/ customizations required in the BBIMS, along with purchase and renewal of any required licenses. No other additional fees would be paid for any of the requisite mandatory licenses and customizations required in BBIMS as per the requirements of NHM-MP. The Selected Agency would be responsible for doing any customizations in the BBIMS as suggested by NHM-MP during the Contract Period* *The Selected Agency shall provide login credentials for NHM-MP on the BBIMS for viewing and downloading of data/ reports, verification of records, reporting & audit purposes"*

S. No.	Tender Reference	Reference	Amendments
9.	SECTION 4, Clause No. 4.4.4, (d), Page No. 49	supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer and as per the laid down quality criteria of being USFDA/ CE (European) certified only	**Amendment:** *"Supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer and as per the laid down criteria for machines of being USFDA/ CE (European)/ Declaration of Conformity of CE certified only"*
10.	SECTION 4, Clause 4.5.11, Page No. 51	In the event the Selected Agency takes possession/carries away any asset belonging to NHM-MP, then NHM-MP will be entitled to forfeit the Performance Security in addition to taking any other recourse available under the law, including blacklisting the Agency	**Amendment:** "*The outgoing Agency shall only withdraw such assets (blood bank equipments, reagents, consumables, software etc.), which bears the ownership/ authorship of the Agency and was developed/ procured/ installed by the Agency for the purpose of providing services under this RFP for the Contract Period. No asset shall be taken away by the outgoing Agency that is under the ownership of NHM-MP (blood bank equipments, reagents, consumables, software, IT hardware/ equipments etc.). In an event, the outgoing Agency takes possession/ carries away any asset belonging to NHM-MP, then NHM-MP will be entitled to forfeit the Performance Security in addition to taking any other recourse available under the law, including blacklisting the Agency"*
11.	SECTION 5, Clause 5.1.1, (c), Page No. 53	No separate payments to be made for license (s) acquisition, installation of equipment's, reagents, consumables, recurrent controls and calibration costs, for the equipment provided by the Selected Agency, any consumables, IT hardware/ software expenses, transportation and supply costs, manpower deployed, for the services provided by the Selected Agency as per this RFP. The cost for the same shall be borne by the Selected Agency and has to be accounted for in the Financial Proposal	**Amendment:** "*No separate payments to be made for license(s) acquisition, installation of equipment's, reagents, consumables, recurrent controls including Daily/ Weekly/ Monthly/ Yearly Quality Control ("QC") measures and calibration costs, for the equipment provided by the Selected Agency, any consumables, IT hardware/ software expenses, transportation and supply costs, manpower deployed, for the services provided by the Selected Agency as per this RFP. The cost for the same shall be borne by the Selected Agency and has to be accounted for in the Financial Proposal"*
12.	Section 8, Annexure-16, Point no. 04 (A) (3), Page No. 105	Annexure-16 - Specifications of the Blood Processing Equipment to be provided by the Agency under the Project	**Amendment:** *"Please refer to Annexure-II attached with Corrigendum No. 02"*

3. All changes/ modifications in Tender document as above are binding to all Bidder(s)
4. Other terms and conditions of the Tender document shall remain the same

Mission Director
National Health Mission, Madhya Pradesh

Prebid Query Responses under the Request for Proposal for
Selection of an Agency for the Establishment, Operation & Management of Blood Banks for National Health Mission, Madhya Pradesh
Ref. No.: S. No. N.H.M./Store/2022/5235; Tender ID 2022_DHS_214454_1
(Prebid meeting – 08th August 2022, 01:00 PM via video conferencing)

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
1.	Innowave IT Infrastructures Ltd	Section 3, Clause No. 3.1, S. No. 2, Page No. 28 & 29	**Existence of the firm** The Bidder(s) should be in existence and engaged in the business of establishment, operation & management of Blood Bank Services in India in the last 03 (three) completed Financial Years (i.e., 2019-20, 2020-21, 2021-22) and must be in existence at the time of Proposal submission i.e., on Proposal Due Date (In case of sole Bidder, it should be met by the sole Bidder itself. Whereas in case of Consortium, the Lead member should fulfil the relevant criterion)	Since in all other clauses of qualification criterion it is been asked that either lead bidder or consortium partner can full fill it. So, consider this for the requested criteria as well. Any of the member of consortium partner can fulfill the criteria	No change required
2.	Innowave IT Infrastructures Ltd	Section 4, Clause No. 4.2.1 (B) (3), Page No. 36	1) Refrigerated centrifuge 2) Automated component separator 3) CLIA methodology fully automated machine 4) Semi-automatic crossmatching machine with Incubator	Mention in this point Should be from New USFDA/European (CE) machine	The Selected Agency has to install new machines only (old/ refurbished machines shall not be installed) across all the locations as mentioned under the scope of the work of RFP **Amendment:** *"**(a) Refrigerated Centrifuge with Separator:** The Selected Agency shall place 01 (one) New Refrigerated Centrifuge with Separator certified by USFDA/ European (CE)/ Declaration of Conformity of CE for centrifugation purposes at each of the Blood Banks and compliant to the minimum technical specifications provided in Annexure – II*

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
					(b) ***Automated Component Separator*** *- The Selected Agency shall place 01 (one) New Centrifuge & Automated Components Separator fully automatic machine certified by USFDA/ European (CE)/ Declaration of Conformity of CE for Component separation and leukoreduction at each of the Blood Banks, and compliant to the minimum technical specifications provided in Annexure – II* ***(c) Chemiluminescence Immunoassay (CLIA) methodology Fully automatic machine*** *(Chemiluminescence/ Electro-Chemiluminescence/ Fluorescence technology) – The Selected Agency shall place 01 (one) New CLIA fully automatic machine (Chemiluminescence/ Electro-Chemiluminescence/ Fluorescence technology) certified by USFDA/ European (CE) / Declaration of Conformity of CE for identifying Transfusion Transmitted Infection (TTI) at each of the Blood Banks and compliant to the minimum technical specifications provided in Annexure – II* ***(d) Semi-automatic Cross Matching Machine with Incubator*** *– The Selected Agency shall place 01 (one) New Cross Matching Semi-Automatic Machine USFDA/ European (CE)/ Declaration of Conformity of CE for Cross matching of Blood at each of the Blood Banks, and compliant to the minimum technical specifications provided in Annexure – II"*

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
3.	Innowave IT Infrastructures Ltd	Section 4, Clause No. 4.2.1 (D) (2), Page No. 37	**Manpower Requirement** Only 1 Supervisor and 1 BCTV Attendant is asked	This should be 1 supervisor and minimum 2 BCTV attender should be there	No change required
4.	Innowave IT Infrastructures Ltd	Section 7, Clause No. 7.15, Page No. 62	Sub-Contracting is not allowed	However, there are some activities like DC/ DR, biohazard disposal is to be sub-contracted	No change required
5.	Innowave IT Infrastructures Ltd	Section 4, Clause No. 4.4.3 (g), Page No. 48	The Selected Agency shall maintain Annual Maintenance Contracts ("AMC") / Comprehensive Maintenance Contract ("CMC") for all laboratory equipment procured and installed by the Agency or procured and installed by the NHM-MP for the Contract Period	The AMC and CMC details with commercials of already procured and installed by NHM-MP is required.	The Selected Agency shall be required to conduct the gap assessment of the existing Blood banks as per Section 4, Clause 4.1.1 (1) Page No. 33 of the RFP, in order get the requisite details regarding the installed equipments
6.	Sadguru Kripa Shaikshanik Sanstha	Section 3, Clause No. 3.1, S. No. 3, Page No. 29	**Work Experience** The Bidder(s) must have an experience of end-to-end management of blood bank services (collection, testing, storage, separation and distribution aspects) services for at least 02 (two) projects/ contracts across the last 03 (three) Financial Years (i.e., 2019-20, 2020-21, 2021-22) Note: Experience of end-to-end management for providing Blood Bank services implies the Bidder (s) has procured necessary licenses/ certifications, installed equipment for processing, testing, and separation of Blood and related components, and handled storage &, distribution of blood products etc. as responsibilities in the project	Request to consider experience of end-to-end management of blood bank services (Collection, testing, storage, separation and distribution aspects) services for at least 01 (One) projects/contracts across the last 03 (three) Financial Years (i.e., 2019-20, 2020-21, 2021-22). Also request to consider for NABH certified bidder as a qualification criterion with at least last three financial years. **Explanation** Some of bidder having One blood Bank but serving to many blood storage centers and Government hospital blood bank requirement as and when required, same data can be provided. Also, tender authority will get more number of bidders with these criteria. If NABH Blood bank participates in this tender, patient will get more benefit compare to non-NABH blood bankers experience. NABH experience bidder can provide quality healthcare global standard and it will increase	No change required

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
				patient experience positively. And this will be the mark for international recognition.	
7.	Sadguru Kripa Shaikshanik Sanstha	Section 3, Clause No. 3.1, S. No. 4, Page No. 29	The Bidder(s) must have an experience of end-to-end management of blood banks (collection, testing, storage, separation and distribution aspects) services for at least 01 (one) project/ contract with a State Govt., PSUs, or Semi Govt. ventures across any of the last 03 (three) Financial Years (i.e., 2019-20, 2020-21 and 2021-22) Note: Experience of end-to-end management for providing Blood Bank services implies the Bidder (s) has procured necessary licenses/ certifications, installed equipment for processing, testing, and separation of Blood and related components, and handled storage &distribution of blood products etc. as responsibilities in the project	Request to consider Government/Private blood bank experience At Least One Project/Contract. - If consider for Private experience also, this will benefit for tender authority to get maximum number of Bidders for this tender with good discount. - Across India there is very few states who are outsourcing blood centers to private agency, hence very few bidders will participate in this tender. - Due to Last two years pandemic situation of COVID-19. there were no such kind of tender across India.	**Amendment** *"This clause stands deleted from the RFP henceforth"*
8.	Sadguru Kripa Shaikshanik Sanstha	Section 2, Clause No. 2.6.9, (o), Page No. 24	The base rate would be separate for the 02 (two) categories of blood banks to be established as mentioned in the scope of work. For the purposes of this RFP, the National Blood Transfusion Council ("**NBTC**") approved processing charges for Blood and Blood Components have been picked up as base rate for quoting of percentage (%) discount by the Bidder (s). The base rates for both the category of blood banks would be as mentioned below: • Category 01 = INR 1,100/- (one thousand one hundred only): applicable for existing 19 blood banks of the state	Request to increase base charges for both categories, since as per NBTC recent guidelines; charges are higher for testing thru chemiluminescence, and this type of testing is mandatory by tender authority (Mentioned on Page Number 36)	**Amendment** *"The base rate would be separate for the 02 (two) categories of blood banks to be established as mentioned in the scope of work. For the purpose of this RFP, the National Blood Transfusion Council ("**NBTC**") approved processing charges for Blood and Blood Components have been picked up as base rate for quoting of percentage (%) discount by the Bidder (s). The base rates for both the category of blood banks would be as mentioned below:*

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
			• Category 02 = INR 2,350/- (two thousand three hundred fifty only): applicable for the 18 new blood banks to be established within the state		• *Category 01 = **INR 1,550/-** (one thousand five hundred fifty only): applicable for existing 19 blood banks of the state* • *Category 02 = **INR 2,350/-** (two thousand three hundred fifty only): applicable for the 18 new blood banks to be established within the state"*
9.	Bio-Rad Laboratories (I) Pvt. Ltd.	Section 4, Clause No. 4.2.1 (B) (3) (c), Page No. 36	Chemiluminescence Immunoassay (CLIA) methodology Fully automatic machine	4th Gen ELISA should also be added into specification. As per NACO recommendations 4th generation ELISA Kit for HIV and HCV should be used for donor screening. 4th Generation kits reduce the window period and help in picking up of early seroconversion sample. 4th Gen HCV is only available in ELISA platform.	No change required
10.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 4, Clause No. 4.2.1 (C) (1), Page No. 36	Reagents and Consumables: (1) Responsibility of Selected Agency	Need clarity on tests to be performed: Reverse & Forward Grouping is for sure but whether Ab screening, Ab identification, phenotyping is required is not sure (3 cell or 11 cell). Consumable specification should be mentioned. Vendor should provide the compatibility letter of reagent and consumables. With proper specification of consumables, NHM will be able to select the good quality products. Compatibility letter will ensure that the result got with the instrument and consumables will be perfect and will be whole sole responsibility of vendor supplying consumables	**Amendment** *"The Selected Agency shall not be required to conduct every test on the unit of blood to be processed, in case any special test(s) shall be required to be conducted, the charges pertaining to the same, shall be payable as per the rates mentioned in notification issued by NBTC"*
11.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 8, Annexure-16, Point no. 04 (A) (2), Page No. 105	Technical Specification of Gel card centrifuge	Max speed of the centrifuge should be 1600 +/- 10 RPM. 1600 10 RPM is not required.	**Amendment** *"Please refer to Annexure II attached with Corrigendum No. 02"*
12.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 8, Annexure-16,	Technical Specification of Gel card centrifuge	Max RCF should be 279 +/- 1 % g. 279 1 % g is not correct terminology	**Amendment**

S. No.	Bidder's Name	RFP Reference	Clause Details	Queries with Justification	Response
		Point no. 04 (A) (3), Page No. 105			*"Please refer to Annexure II attached with Corrigendum No. 02"*
13.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 8, Annexure-16, Point no. 04 (A), Page No. 105	Technical Specification of Gel card centrifuge	European CE certificate should be mandatory to assure quality of instrument. European CE certificate should be mandatory so that NHM can select the best quality products	**Amendment** *"Please refer to Annexure II attached with Corrigendum No. 02"*
14.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 8, Annexure-16, Point no. 04 (B) (2), Page No. 106	Technical Specification of Gel Card Incubator	Should maintain temperature at 37°C +/-1°C. 37°C 1°C is not correct terminology	**Amendment** *"Please refer to Annexure II attached with Corrigendum No. 02"*
15.	Bio-Rad Laboratories (I) Pvt. Ltd	Section 8, Annexure-16, Point no. 04 (B), Page No. 106	Technical Specification of Gel Card Incubator	European CE certificate should be mandatory to assure quality of instrument. European CE certificate should be mandatory so that NHM can select the best quality products	**Amendment** *"Please refer to Annexure II attached with Corrigendum No. 02"*

Annexure I

Selection basis for L-1 Bidder

The methodology to be followed for selecting the eligible L-1 Bidder would be as follows:

(a) For instance, suppose 03 (three) Bidders have submitted their Proposals. Once they are qualified Bidders based on the evaluation of the Technical Proposal, the Financial Proposal will be opened and the calculation methodology to be followed for selection of Bidder would be as follows:

BIDDER 1	BIDDER 2	BIDDER 3
Percentage (%) discount offered on NBTC approved processing charges for Blood and Blood Components: **(1) Category 01:** (a) Base rate: 1,550/- (b) Discount offered: 10% (c) Discounted processing charge: 1,395/- **(2) Category 02:** (a) Base rate: 2,350/- (b) Discount offered: 08% (c) Discounted processing charge: 2,162/- **(3) Total of discounted processing charge for category 01 and 02** = 1 (c) + 2 (c) = 1,395+ 2,162 = **INR 3,557/-**	Percentage (%) discount offered on NBTC approved processing charges for Blood and Blood Components: **(1) Category 01:** (a) Base rate: 1,550/- (b) Discount offered: 15% (c) Discounted processing charge: 1,318/- **(2) Category 02:** (a) Base rate: 2,350/- (b) Discount offered: 10% (c) Discounted processing charge: 2,115/- **(3) Total of discounted processing charge for category 01 and 02** = 1 (c) + 2 (c) = 1,318+ 2,115 = **INR 3,433/-**	Percentage (%) discount offered on NBTC approved processing charges for Blood and Blood Components: **(1) Category 01:** (d) Base rate: 1,550/- (e) Discount offered: 12% (f) Discounted processing charge: 1,364/- **(2) Category 02:** (d) Base rate: 2,350/- (e) Discount offered: 14% (f) Discounted processing charge: 2,021/- **(3) Total of discounted processing charge for category 01 and 02** = 1 (c) + 2 (c) = 1,364 + 2,021 = **INR 3,385/-**

In the scenario depicted above, Bidder 3 shall be the L-1 Bidder since the total discounted processing charges across both categories is the lowest. The discounted processing charges shall be inclusive of all estimated costs related to operationalization of the different categories of Blood Banks and operationalization of Blood Collection & Transportation Vans as specified in the scope of work section.

Note:

(i) The notional values as expressed in the table above is intended purely for explanation purposes only

(ii) Cost of operational expenditure (fuel, toll charges, repair & maintenance charges, lubricant etc.) for operating the BCTVs under the Project during the Contract Period shall be included in the percentage (%) discount quoted by the Bidder (s) on the base rates for each category of blood banks

Annexure - II

SPECIFICATIONS OF THE BLOOD PROCESSING EQUIPMENT TO BE PROVIDED BY THE AGENCY UNDER THE PROJECT

A. REFRIGERATED CENTRIFUGE

S. No.	Technical Specification
1.	For separation of the blood component like packed cell, platelet rich plasma, platelet concentrates plasma
2.	Microprocessor-controlled system to make operation automatic
3.	Programmable memory: Memory with tamper proof facility
4.	Stainless steel chamber: Easy to clean, corrosion resistant with provision of both drain and condensed water collection container
5.	CFC free refrigerant
6.	Swing bucket blood bank rotor: With metal buckets, 6 x 2000 ml, wind shielded. Suitable adapters for 12 blood bags of 350 ml and 450 ml
7.	Removable plastic cups to hold single/double/triple/quadruple Blood bag with partitions in every bucket
8.	Insert with hook adapter to spin bubbly coat or small volume of blood and balancing weight for insert
9.	Equipped with automatic lid lock
10.	Centrifugal force: 5000-6000 g
11.	Speed variation: Microprocessor-controlled rotor speed to within 10 rpm of set value. Acceleration and deceleration profile shall be available
12.	Temperature range: -10°C to + 40 °C
13.	Microprocessor controlled rotor temperature with 1°C of set temperature regardless of the centrifuge speed
14.	Programmable time: 0-99 minutes with minimum resolution of 1 minute
15.	Digital display of temperature, speed and time, minimum no. of 3-digit resolution
16.	Motor imbalance detection: Automatic shutdown of centrifuge if rotor load is out of balance with appropriate indicator, should incorporate alarm for imbalance detection lid interlock, over temperature, rotor over speed
17.	Power requirement 220/240 voltage, 50 Hz single-phase AC supply
18.	The equipment shall be suitable for operation from 0 to 40 °C at 90% relative humidity. Electronic circuitry Shell tropicalized for this ambient condition
19.	The equipment should be latest on the production line and must not be refurbished. The Agency shall also provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") with all relevant details relating to the equipment post-installation of the equipment at the blood bank
20.	Noise levels within 60 DB
21.	The equipment shall have lockable castors
22.	Protection of data: in the event of power interruption or complete failure data should remain stored
23.	Should have a provision for external connectivity
24.	It shall have a security lock to prevent unintentional switch off and also unauthorized opening of equipment
25.	Automatic line voltage corrector/voltage stabilizer: A line voltage corrector of appropriate rating should form part of standard configuration. copper wound single phase automatic line voltage corrector conforming to IS:9815(Pt. l)/94 with latest amendments of equivalent International standard fitted with a voltmeter and switch to indicate output/input voltage as under: ▪ Capacity/rating: 10 KVA: As per the requirement of the equipment ▪ Input Voltage: 140 to 280 Volts, 50 Cycles

S. No.	Technical Specification
	▪ Output Voltage: 220 Volts ±10% Volts. Input-output voltmeter and ampere meter. Protection: High-Low Voltage Cut-off, overload and short-circuit protection ▪ The equipment should be supplied with 2-meter cord at input and fitted with plugs of appropriate rating (15 Amp.) ▪ Make of the line voltage corrector shall be indicated
26.	Certifications: ▪ Product certification: USFDA/ European (CE) certified / Declaration of Conformity of CE ▪ Quality Certification: ISO Certified ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of blood units processed in the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spareparts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracyof calibration, etc. will not be paid for)*

B. AUTOMATED COMPONENT PROCESSOR (AUTOMATED PLASMA SEPARATOR)

S. No.	Technical Specification
1.	The equipment should be able to express the blood components, from primary bag into various satellite bags automatically, after initial manual loading of the bag system on to the machine
2.	The equipment must be compatible with any blood bag including top and bottom
3.	The equipment should have built in weighing mechanisms to measure the weight of various components separated (Plasma, Red cells and Platelets).
4.	It should give at least one log leukoreduction for red cells and platelets
5.	The equipment should have an integrated system of sealing heads and optical sensors to automatically control the flow of various blood components (Plasma, Platelets and red cells) in satellite tubing's
6.	The equipment should have a control panel with display system to indicate various procedural steps
7.	The tube sealing should be of radio frequency type
8.	The equipment should have the provision to store and transfer the blood component details including the identification number of the donor unit to a central facility
9.	The equipment should have built in alarm system to indicate the completion of the procedure
10.	The equipment should be latest on the production line and must not be refurbished. The Agency shall also provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") with all relevant details relating to the equipment post-installation of the equipment at the blood bank
11.	Electrical Supply: ▪ Voltage - 220 to 240 V AC ▪ Frequency - 50/60 Hz ▪ Compatible UPS, to complete the ongoing procedure, with a back-up supply for at least half an hour, should be supplied with the equipment
12.	Certifications: ▪ Product certification: USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified

S. No.	Technical Specification
	▪ Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of blood units processed in the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spareparts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracyof calibration, etc. will not be paid for)*

C. FULLY AUTOMATED CLIA ANALYZER

S. No.	Technical Specifications
1.	The machine should be brand new fully automated, random access immunoassay system
2.	The complete system should be latest on the production line and must not be refurbished. The Agency shall also provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") with all relevant details relating to the equipment post-installation of the equipment at the blood bank
3.	Should be based on Chemi Luminescence/ Electro-Chemiluminescence/ Fluorescence technology
4.	The equipment and all reagents should be European CE/IVD/USFDA and CDSCO approved
5.	Any necessary up-gradation in the equipment required in future will be the Selected Agency responsibility
6.	Parameters/ Investigations: 4th generation HIV Ag/Ab, HBsAg, Anti-HCV, HBV Core Ab, Syphilis-essential parameters and CMV, HTLV, SARSCOV 2 are desirable
7.	Sample: Human serum (including serum collected in serum separator tubes) or plasma collected in potassium EDTA, heparin, sodium citrate, CPDA-1, CPD, CP2D
8.	Throughput should be a minimum of 60 samples or more / hour
9.	The system should have the capability to do the assay in continuous, random batch and STAT mode
10.	Should have capacity to load a minimum of 15 or more Reagents packs of different parameters at a time
11.	Reagent packs should be ready to use with automatic onboard reagent mixing to avoid manual intervention & human relatederrors
12.	On board reagent stability of minimum 4 weeks with calibration stability of minimum 4 weeks should be there
13.	The system should not have to be stopped to reload new reagent kits
14.	The system should have single point data entry and result viewing with wide touchscreen monitor
15.	Continuous printing facility of patient results, QC and calibration details should be available
16.	Option of taking back-up of patient results and QC reports on external services and USB devices should be possible
17.	Onboard reagent inventory with automatic tracking and notification of remaining tests, onboard stability and expiration, calibration and storage conditions for each pack should be there. Reagent expiry should be minimum 4 months when supplied
18.	Reagent compartment with the required temperature for the reagent kits supplied by bidder should be available
19.	Should have access to samples during operation. Sample volume required should be 10-150 µL depending upon the analyte
20.	Should have facility to do Pre-dilution of samples
21.	Equipment should be able to work with all types of sample containers including standard primary tubes (both vacuum and non-vacuum tubes), System should accommodate multiple sample tube size / sample cups
22.	Universal barcode reader should be able to read multiple barcode type

S. No.	Technical Specifications
23.	Stat prioritization should be available on the system without interrupting the routine run. Dedicated STAT position should beavailable
24.	System should be able to perform assays with zero carry over
25.	System should perform assays in discrete disposable cuvettes/cells
26.	All disposables and consumables (All controls, calibrators, wash reagents, assay diluents, disposable sample probe tips, reactioncuvettes and other consumables necessary for investigations) should be included in the cost
27.	Should have on board sample auto dilution facility
28.	Should have Clot detection, bubble detection and low sample detection facility, hemolysis and icteric sample detection facility
29.	Should have lot to lot calibration for each assay. The calibrator and controls should cover all investigations/ parameters mentioned above. Certificate of Traceability for calibrators, traceable to national/ international reference standards to be submitted by the Selected Agency. 4th generation controls for relevant assays should be provided
30.	Reaction time should be within 10 – 60 minutes for the listed parameters
31.	System should have automatic reflex testing
32.	Should have facility for continuous random access, including loading and unloading of reagents, other consumables and samples without stopping the analyzer
33.	Servicing instruments by remotely capturing operational data available in the system
34.	Random access calibration should be possible
35.	Provision of inbuilt QC monitoring system by L J plots and Westgard and Configurable QC based rules should be available
36.	It is the responsibility of the agency to integrate the software of the equipment with the existing HIS of the hospital for interfacing the results, free of cost. All necessary hardware and software required for connecting the equipment to the hospital network shall be provided by the Selected Agency
37.	HIS port, Ethernet port and USB port should be available along with the equipment
38.	Real time monitoring of QC violations and turnaround time for samples should be available
39.	Instrument should provide integrated process control that monitors from sample aspiration to assay processing and report thesame. Operator should be able to see the report for any discrepancies and able to take print out for audit purpose
40.	On board sample data storage capacity should be a minimum of 10,000 and above patient results
41.	Should be able to work with Voltage: 200-240 V and Frequency 47- 60 Hz.
42.	UPS - 3KVA with 30 minutes battery backup should be supplied with equipment. Appropriate battery backup should be arranged and maintained by the agency with no extra cost
43.	The required plumbing/water plant facility should be provided and the same shall be maintained by the Selected itself. All prerequisites for installation and operational of machine will be fulfilled by the Selected Agency
44.	Floor drain kit should be set up by the Selected Agency to route waste directly to floor drain. All prerequisites for installation and operational of machine will be fulfilled by the Selected Agency
45.	The Selected Agency should inspect the site before installation and prepare the site for installation and proper functioning of the equipment round the clock, free of cost
46.	The Selected Agency shall be responsible for installation, commissioning and trial runs providing free trial kits for all tests along with respective calibrator and control
47.	The Select Agency should provide one kit per parameter at no cost for trial and training purpose. The equipment being installed should be validated in-house and documents for Installation qualification/Operational Qualification/Performance Qualification has to be provided to NHM-MP

<table>
<tr><th>S. No.</th><th>Technical Specifications</th></tr>
<tr><td>48.</td><td>Three levels of internal QC should be provided by the agency from an FDA-approved third-party manufacturer six monthly</td></tr>
<tr><td>49.</td><td>NABL standard must be adhered for running QCs</td></tr>
<tr><td>50.</td><td>The Agency shall undertake daily Quality Control for the equipment. In event of failure of Quality Control, the cost for any processing charges per blood bag processed and for trouble shooting shall be borne by the Agency only</td></tr>
<tr><td>51.</td><td>A unit from the same manufacturer with a throughput equivalent to that of main equipment should be provided as standby equipment, free of cost if required in case of breakdown/ not rectified within two days from the date of receipt of complaint</td></tr>
<tr><td>52.</td><td>The expected sensitivity and specificity of the assays are as follows:
<table><tr><th>Test</th><th>Sensitivity</th><th>Specificity</th></tr><tr><td>HIV</td><td>100%</td><td>99.5%</td></tr><tr><td>HBsAg</td><td>100%</td><td>99.5%</td></tr><tr><td>HCV</td><td>100%</td><td>99.5%</td></tr><tr><td>Syphilis</td><td>100%</td><td>99.5%</td></tr></table></td></tr>
<tr><td>53.</td><td>Certifications:
Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE
Quality Certification: ISO Certified
Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)</td></tr>
</table>

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of tests performed on the instrument at the rate agreed upon. (*Instrument, other equipment, maintenance of all these equipment, spare parts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracy of calibration, etc. will not be paid for*)

D. GEL CARD CENTRIFUGE AND INCUBATOR FOR CROSS MATCHING

(1) Gel Card Centrifuge:-

S. No.	Technical Specifications
1.	Capacity: Swing out rotor should accommodate 12 or more standard Gel cards
2.	Max speed of the centrifuge should be 1600 ±10 RPM
3.	Max RCF should be 279 ±1 % g
4.	Should have audio visual alarms for Imbalance, end of cycle and any other errors
5.	Should have single hand rotor removal for cleaning
6.	Should have LCD display with touch keypad
7.	Motor should be Brushless
8.	Net weight should be less than 20 kg
9.	Power supply should be 220-240 volts, 50 Hz, Single phase
10.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO Certified. ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

(2) Gel Card Incubator:-

S. No.	Technical Specifications
1.	Incubator should accommodate 12 or more Gel cards and 12 or more test tubes simultaneously
2.	Should maintain temperature at 37°C ±1°C
3.	Time limit adjustable up to 60 minutes
4.	Should have programs to adjust incubation temperature & time as specified by gel card
5.	Should have audio visual alarms for high / low temperature and end of cycle
6.	Should have Auto pop-up card mechanism for card removal, when lid is opened
7.	Should have LCD display with touch keypad
8.	Power supply: 220-240 volts, 50 Hz, single phase
9.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO Certified ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of tests performed on the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spare parts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracy of calibration, etc. will not be paid for)*

E. LIST AND TECHNICAL SPECIFICATIONS OF OTHER EQUIPMENT (APART FROM THE 04 MENTIONED ABOVE)

(1) Deep Freezer- 40°C

S. No.	Technical Specifications
1.	Purpose of Equipment: To freeze and store plasma
2.	Type of Equipment: Compression freezer with CFC-free refrigerant
3.	Capacity : As required by the blood bank (i.e., minimum of 200 blood bags)
4.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V_2 A- 1.4301) ▪ External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness) ▪ CFC-free insulation ▪ Design: Upright Type ▪ Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110° ▪ Insulation and gasket should be silicone ▪ Separate inner doors to prevent cold loss ▪ Drawers: Roll out type ▪ Heating device on frame to avoid condensation
5.	Electrical Characteristics: ▪ Input voltage: 220/24OV SOHZ ▪ A line voltage corrector of appropriate rating should form part of configuration
6.	Minimum Compressor Starting Voltage: 22% below nominal Voltage

S. No.	Technical Specifications
7.	Internal temperature Control: ▪ Electronic temperature control ▪ Operating temperature reachable lowest up to -45°C with setting accuracy of ±1 °C whatever the load ▪ Fan air cooling ▪ Automatic defrost within safe temperature range ▪ Casing & door should have insulation panel with polyurethane foam
8.	Refrigeration ▪ Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -40 C ▪ Option for duct from equipment to connect to common main duct to throw hot air out of the room ▪ Refrigerant CFC free/ green gas ▪ Optional: Access port for CO_2 backup system for refrigeration
9.	External Ambient Temperature: Performs in an ambient temperature of 10°C to 40°C
10.	Hold over time: 2 hrs. at ambient temperature
11.	Cooling Down Time: ▪ A full load of plasma packs at +25°C takes a maximum of 5 hrs. for all the packs to reach below -5°C ▪ A full load of plasma packs at +25°C takes a maximum of 30 hrs. for all the paces to reach below -20°C
12.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1°C graduation ▪ Temperature recording device: ▪ Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. There should be a method to check alarm system ▪ Seven days inkless graphic temperature recorder with range of OOC to -50°C with data logger, with supply of free charts for a period of warranty. ▪ Battery backup for alarm and temperature recording device. ▪ Provision to connect with central (temperature) monitoring system ▪ Mounted on Lockable Castor wheels ▪ Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm. ▪ Desirable: o Noise factor should not exceed 60 decibels. o Should have compressor running time < 60 to 70%
13.	Additional Requirements ▪ All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards ▪ Complete with comprehensive set of spare parts including a spare ▪ compressor, refrigerant gas cylinder etc. and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately ▪ Necessary catalogues, technical write up in English shall be provided by the Agency, both in hard and soft copies ▪ Performance, efficiency, other factors such as distortion etc. as applicable be also furnished ▪ Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished. ▪ Certifications: o Product certification : USFDA/ European (CE) certified// Declaration of Conformity of CE o Quality Certification: ISO certified

S. No.	Technical Specifications
	○ Electrical Safety Equipment meets electrical safety specifications such as that of IEC (Class I)

(2) <u>Deep Freezer -80°C</u>

S. No.	Technical Specifications
1.	Purpose of Equipment: To freeze and store plasma
2.	Type of Equipment: Compression freezer with CFC-free refrigerant
3.	Capacity : As required by the blood bank (i.e., minimum of 200 bags)
4.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V_2 A- 1.4301) ▪ External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness) ▪ CFC-free insulation ▪ Design: Upright Type ▪ Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110° ▪ Insulation and gasket should be silicone. A Separate inner door to prevent cold loss ▪ Drawers: Roll out type ▪ Heating device on frame to avoid condensation
5.	Electrical Characteristics: ▪ Input voltage: 220/24OV 50Hz ▪ A line voltage corrector of appropriate rating should form part of configuration.
6.	Minimum Compressor Starting Voltage: 22% below nominal Voltage
7.	Internal Temperature Control: ▪ Electronic temperature control ▪ Operating temperature reachable lowest up to -86°C with setting accuracy of f1 °C whatever the load ▪ Fan air cooling ▪ Automatic defrost within safe temperature range ▪ Casing & door should have insulation panel with polyurethane foam > 80mm thickness
8.	Refrigeration**:** ▪ Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -800C ▪ Refrigerant CFC free/ green gas ▪ Optional: Access port for COC backup system for refrigeration. ▪ Optional for duct from equipment to connect to common main duct to throw hot air out of the room
9.	External Ambient Temperature: Performs in an ambient temperature of +1°C to +40°C
10.	Hold over time: 2 hrs. at ambient temperature
11.	Cooling Down Time: ▪ A full load of plasma packs at +25°C takes a maximum of 5 hrs. for all the packs to reach below -5° C ▪ A full load of plasma packs at +25 °C takes a maximum of 30 hrs. for all the packs to reach below - 20° C
12.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1° C graduation ▪ Temperature recording device

S. No.	Technical Specifications
	▪ Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. There should be a method to check alarm system ▪ Seven days inkless graphic temperature recorder with range of OEC to -50° C with data logger, with supply of free charts for a period of warranty ▪ Battery backup for alarm and temperature recording device ▪ Provision to connect with central (temperature) monitoring system ▪ Mounted on Lockable Castor wheels ▪ Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration to alarm ▪ Desirable: o Noise factor should not exceed 60 decibels o Should have compressor running time < 60 to 70%
13.	Additional Requirements ▪ All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards ▪ Complete with comprehensive set of spare parts including a spare compressor, refrigerant gas cylinder etc. and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately ▪ Necessary catalogues, technical write up in English shall be provided by the Agency, both in hard and soft copies. ▪ Performance efficiency, other factors such as distortion etc. as applicable be also furnished ▪ Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished ▪ Certifications: o Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE o Quality Certification: ISO certified o Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

(3) Platelet Incubator & Platelet Agitator

(i) Purpose of Equipment: To continuously agitate platelet concentrates in an incubator in an even suspension in a plasma bag

(ii) Type of Equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating with GFC-free refrigerant gas and insulation material

(iii) Certifications:
- Product certification: USFDA/ European (CE) certified/ Declaration of Conformity of CE
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

S. No.	Technical Specifications - Platelet Incubator
1.	Should have a provision to store the agitator

S. No.	Technical Specifications - Platelet Incubator
2.	Should have a single transparent outer door for clear visibility
3.	Should be able to maintain a temperature of 22+20C, Set temperature of 22^C
4.	Should have a digital temperature indicator.
5.	Seven-day inkless chart recorder with battery back-up for minimum of 2 hours for continuous operation during power failure
6.	Single digital temperature sensor for both recording and controlling
7.	Should have audible visual high/low alarm for temperature control, battery on/low, sensor failure, agitator off, power failure, compressor and system
8.	Should have forced air circulation method for the uniformity of the temperature at all sides of the incubator.
9.	Chamber mounted electrical outlet for agitator should be available
10.	Power supply: 220-240 volts at 50 Hz.
11.	Facility to connect with central (temperature) monitoring system

S. No.	Technical Specifications - Platelet Agitator
1.	Construction: ▪ Internal: Stainless steel (min. 304 grade) ▪ External: Corrosion Resistant, at least 1mm thickness ▪ Capacity: Designed to hold random platelet packs or aphaeresis platelet packs or a mixture of both types (minimum 48 random platelet concentrate packs). ▪ Transparent Door ▪ Design of Shelves: Shelves are made of non-slip, corrosion resistant material, Coated with bacteria resistant material, perforated to ensure air circulation and with sufficient clearance to minimize noise ▪ Gentle side to side agitation at 3.6-4 cm side to side, 60- 70 ▪ strokes/ minute ▪ Heavy duty ball bearing gear motor for noise less and continuous operation for 24 hours a day throughout the year ▪ Motor with internal fan
2.	Temperature: ▪ 7-day chart recorder with free charts till warranty period. ▪ Temperature controller with sensor
3.	Refrigeration: Non-CFC air cooled refrigeration
4.	Safety features: ▪ Audio alarm for temperature fluctuation ▪ Auto stop for agitation when the door is opened ▪ Power failure alarm
5.	Push buttons switch with pause function for temporary stoppage of the motion
6.	Power supply: 220-240 volts at 50 Hz

(4) Sterile Connecting Device

S. No.	Technical Specifications
1.	Blood Bag Tube Sealer is a compact equipment to seal the Blood Bag pilot tubing
2.	The system should be heavy duty and be able to seal the blood bag etc. quickly and effectively
3.	Should be simple to handle
4.	System should gently seal the tubing with no hemolysis using radio frequency.
5.	Should be capable of making wide seal of 2 mm thickness.

S. No.	Technical Specifications
6.	Should be for bench-top use
7.	The sealing time should not be more than 2 seconds
8.	Sealing trigger should be automatic
9.	Should also have extended portable hand unit Sealing hand should be with coaxial cable of 1.5-2.0 meter.
10.	Should have indication lamps for “Sealing Process" on handle as well as main unit.
11.	No warm-up time should be required.
12.	Should ensure easy separation of tube segments after the sealing
13.	System should run on both mains and battery (more than 10hrs. back up and charger).
14.	Back up battery should seal more than 500 seals on PVC- tubes in continuous mode.
15.	The unit shall be capable of operating continuously in ambient temperature of 10 - 40° C and relative humidity of 15-90%
16.	Power input: 220-240V/ 50 Hz AC Single phase or 380-400V AC 50 Hz Three phase fitted with appropriate Indian plugs and sockets.
17.	Suitable Auto voltage corrector with spike protector should be available
18.	Electrodes should be well protected by a cover
19.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified ▪ Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock ▪ Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

(5) Blood Mixer and Collector

S. No.	Technical Specifications
1.	The system is used to collect donated blood from the donor at the same time mixing the blood for quality collection of blood
2.	It is meant for stationary and mobile use. Gentle end to end mixing and control of collection time to give high quality blood suitable for all blood bags.
3.	Volume Setting: Pre-selection of volume to be collected. Tarring of bag volume before collection. Tarring range: 0 — 600 g. Automatic storage and recall of set volume. Measure volume with best accuracy
4.	LED indication on commencement of collection
5.	LED indication and audible alarm at the end of collection
6.	Indication of time taken for collection
7.	Indication of blood flow with audio alarm when blood flow is hinge or lower than desired
8.	Continuous display of collected volume, flow and time during collection
9.	Automatic clamping at termination of preset volume collection
10.	Automatic release of bag when lifted.
11.	Continuous agitation of blood bags during collection: 12 - 16 rpm
12.	Equipment carry case for BCM should be provided for portability
13.	Should operate on mains as well as rechargeable battery. On battery it should operate for a minimum of 5-8 hours
14.	The unit shall be capable of operating continuously in ambient temperature of 10 -40° C and relative humidity of 15-90%
15.	Power input to be 220-240VAC, 50Hz,/440 V 3 Phase as appropriate fitted with Indian plug
16.	Resettable over current breaker shall be fitted for protection
17.	Suitable Automatic Voltage regulator/stabilizer meeting ISI specifications should be supplied. Broad

S. No.	Technical Specifications
	specifications are: Automatic Type Input 150-280V Output 220 V +/- 7 % , 50 Hz . Single phase, AC with automatic 2-4 sec Cut Off and 6-9 minutes restart delay. Quick start arrangements for bypassing the start delay. Suitable MCB on input voltmeter and indicators on Front Panel. Input Pore Cable with 15 A Plug and six-way output terminal strip for two outlets
18.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified ▪ Electrical Safety. Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock ▪ Shall meet IEC-60601-1-2 :2O01(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

(6) <u>Blood Bank Refrigerator/ Serology Refrigerated for Blood Banks (200 Bags Capacity)</u>

S. No.	Technical Specifications
a)	**Name & Coding:** ▪ GMDN name - Refrigerators ▪ GMDN code - CT1897
b)	**General Use:**
1.	Clinical purpose - A refrigerator for storing whole blood or red cell packs in a blood bank. A refrigerator for storing various reagents and /or patient samples
c)	**Technical Characteristics:**
1.	Technical characteristics (specific to this type of device) - Compression type refrigerator that uses CFC free refrigerant gas.
2.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) ▪ External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation ▪ Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the label side visible ▪ Door: Glass door, Automatic closing of the front door below opening angle of 90 ° and opening angle limited to 110° ▪ Insulation and gasket should be silicon ▪ Polyurethane insulation should be minimum 80mm thickness ▪ Door opening audio and visual display alarm
3.	Temperature Range: 2 ° C to 6 ° C and adjustable with setting accuracy of ±0.1 ° C with set temperature of 4 ° C. User parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F temperature choice
4.	Minimum Compressor Starting Voltage: 22% below nominal voltage
5.	Internal Temperature Control: Electronic temperature control, range +2 ° C to +6 ° C with setting accuracy of ±1 ° C whatever the load, Fan air cooling
6.	External Ambient Temperature: Performs in an ambient temperature of +10 ° C to +40 ° C
7.	Hold over time: A full load of blood packs at +4 ° C (±1 ° C) takes at least 30 minutes to rise to above +6 ° C. Internal temperature hold over time in case of power failure should be at least 1.5 hrs.
8.	Cooling Down Time: A full load of plasma packs at +25 ° C takes a maximum of 13 hrs. for all the packs to reach below +6 ° C
9.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1°C graduation, Temperature recording device, Microprocessor control for operation with integrated audio-visual temperature alarm function with

S. No.	Technical Specifications
	digital monitoring display. ▪ Independent safety thermostat to avoid negative temperatures. ▪ At least 2 temperatures sensors: Sensor for temperature monitoring shown on front display, sensor for managing use of compressor
10.	Temperature recording device: ▪ Visual and audible alarm system indicating unsafe temperatures. ▪ Battery backup for alarm system indicating unsafe temperatures. ▪ Seven days graphic temperature recorder with range of -10 ° C to +20 ° C with supply of free charts for a period of one year ▪ Ideal compressor running time of 27% at room temperature. ▪ Door locks should be available. ▪ Audio and visual alarm for variation in temperature, Interior lightening, ▪ Auto defrosting
11.	Capacity - As required by the blood bank (200 plasma bags of 350/450 mL each)
12.	Settings - Manual
13.	User's interface - Manual
14.	Software and/or standard of communication(wherever required) - Built in
d)	**Physical Characteristics:** ▪ Dimensions (metric) NA ▪ Weight (lbs., kg) NA ▪ Configuration NA ▪ Noise (in dBA) Noise factor should not exceed 60 decibels. ▪ heat dissipation NA ▪ Mobility, portability NA
e)	**Energy Source (Electricity, UPS, Solar, Gas, Water, CO2 ....):** ▪ Power Requirements input voltage - 220/240V 50Hz ▪ Battery operated - NA ▪ Tolerance (to variations, shutdowns) - NA ▪ Protection - A line voltage corrector of appropriate rating will form part of standard configuration. ▪ Power consumption - NA ▪ Other energy supplies – NA
f)	**Accessories, Spare Parts, Consumables:** Accessories & spare parts - Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately
g)	**Environmental and Departmental Considerations:** ▪ Atmosphere / Ambiance (air conditioning, humidity, dust ...) o Capable of being stored continuously in ambient temperature of 0 to 50° C and relative humidity of 15 to 90% o Capable of operating continuously in ambient temperature of 10 to 40° C and relative humidity of 15 to 90% ▪ Additional Requirements - All equipment should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished ▪ User's care, Cleaning, Disinfection & Sterility issues - Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant
h)	**Standards and Safety:** ▪ Product certifications - USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality certifications ISO 13485 certified

S. No.	Technical Specifications
	▪ Electrical Safety Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
i)	**Training and Installation:** ▪ Pre-installation requirements: nature, values, quality, tolerance - NA ▪ Requirements for sign-off - NA ▪ Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) - Training of users in operation and basic maintenance shall be provided
j)	**Warranty and Maintenance**: ▪ Warranty 2 years ▪ Maintenance tasks 3 years CMC ▪ Service contract clauses, including prices - Downtime: 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
k)	**Documentation:** ▪ **Operating Manuals, Service Manuals, Other Manuals -** Necessary Catalogues, Technical Write Up in English shall be provided by the agency, both in hard and soft copies

Note:

1. All the machines/ equipments to be installed by the Selected Agency should be new only and not old or refurbished. In case, the same are found to be old/ refurbished, the number of units processed shall not be paid for the respective duration
2. WRT all the machines/ equipments to be installed by the Selected Agency, the Agency shall also provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") with all relevant details relating to the equipment post-installation of the equipment at the blood bank

CORRIGENDUM No. 03

Request for Proposal for Selection of an Agency for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh
*(Corrigendum No - 03 - to RFP Ref. No.: **S. No. N.H.M./Store/2022/5235** & Tender ID: **2022_DHS_214454_1**)*

1. This is regarding the NIT issued on 02/08/2022 Selection of an Agency to for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh, in leading newspaper and uploaded on MP Tender Website https://mptenders.gov.in.

2. In lieu of the released RFP, the Technical Committee after due consideration recommends following amendments in the Tender document for now:

S. No.	Tender Reference	Reference	Amendments
1.	**NIT**	**Dates (as published in the Corrigendum No. 02)** - *Document Download/ Sale End Date: 01st September 2022, Thursday, 04:00 PM* - *Bid Submission End Date: 01st September 2022, Thursday, 04:00 PM* - *Bid Opening Date: 02nd September August 2022, Friday, 05:00 PM"*	**Amendment** *"After the publication of the Corrigendum No. 03, the revised timelines/ dates for key events are as follows:* - *Document Download/ Sale End Date: 12th September 2022, Monday, 04:00 PM* - *Bid Submission End Date: 12th September 2022, Monday, 04:00 PM* - *Bid Opening Date: 13th September August 2022, Tuesday, 05:00 PM"*

3. All changes/ modifications in Tender document as above are binding to all Bidder(s)
4. Other terms and conditions of the Tender document shall remain the same

Mission Director
National Health Mission, Madhya Pradesh

CORRIGENDUM No. 04

Request for Proposal for Selection of an Agency for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh
*(Corrigendum No. - 04 - to RFP Ref. No.: **S. No. N.H.M./Store/2022/5235** & Tender ID: **2022_DHS_214454_1**)*

1. This is regarding the NIT issued on 02/08/2022 Selection of an Agency to for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh, in leading newspaper and uploaded on MP Tender Website https://mptenders.gov.in.

2. In lieu of the released RFP, the Technical Committee after due consideration recommends following amendments in the Tender document for now:

S. No.	Tender Reference	Reference	Amendments
1.	Section 4, Clause 4.2.1 (E) (1), Page No. 38	(c) Bar Code/ RFID Printer and Reader - The Selected Agency shall install Bar-Code printers at the Blood Banks under the purview of the RFP. The Selected Agency may also provide pre-printed bar-coded stickers/ labels or pre-printed bar-coded vacutainers at the Blood Banks. Moreover, the Selected Agency shall be solely responsible for ensuring the availability and maintaining the buffer stock of such stickers/ labels or vacutainers at the Blood Banks for all the processes to be conducted as part of scope of work in the RFP (d) Printer cartridges, Stationery, Consumables etc. as per requirement for maintaining operations of computers, printers, bar-code/ rfid readers etc.	**Amendment:** *"(c) RFID labels/ tags, reader, Printers/ system - The Selected Agency shall install RFID labels/ tags, RFID scanner/ reader and RFID printer/ system at the Blood Banks under the purview of the RFP. The Selected Agency may also provide vacutainers, RFID tags, RFID readers, and RFID printers/ system at the Blood Banks. Moreover, the Selected Agency shall be solely responsible for ensuring the availability and maintaining the buffer stock of such labels/ tags or vacutainers at the Blood Banks for all the processes to be conducted as part of scope of work in the RFP* *(d) Printer cartridges, Stationery, Consumables etc. as per requirement for maintaining operations of computers, printers, RFID scanners, printers/ system and readers etc."*
2.	Section 2, Clause 2.6.9, point (h), Page No. 23, Section 4, Clause 4.2. (A), point (i), Page No. 35, Clause 4.3.1, Stage (03), point (iii) (v), Page No. 41, Stage (05), point (i), Stage (06), point (v), Page No. 42, Stage (07) point (v), Page No. 43,	Bar Code labels, reader, printers	**Amendment** *"In all these respective and related clauses for Bar Code labels, reader, printers should be read as RFID Labels/tags, RFID reader/ scanner, RFID printers/ system* *For the purpose of this RFP, the requirements for Bar Code labels, Bar-code reader, Bar-code printers shall stand deleted henceforth and RFID Labels/tags, RFID*

S. No.	Tender Reference	Reference	Amendments
	Section 5, Clause 5.1.2, Point (a), Page No. 54, Section 8, Annexure-18, Point (2), Page No. 117, Annexure-20, Clause 31.2 Point (a), Page No. 134 & any other related Clause to Bar Code		*reader/ scanner, RFID Printers/ system shall only be installed and used under the purview of this RFP."*
3.	Section 4, Clause 4.2.1, (B) (3), Page No. 36 and S. No. 07 of Corrigendum No. 02	"Note: The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") post installation for all the prescribed blood bank equipment's (as per **Annexure-II** attached with this Corrigendum no. 02); subsequent to the gap analysis done and as per the requirement for maintaining the operations of all the blood banks. Also, the Selected Agency has to install new machines only (old/ refurbished machines shall not be installed) across all the locations as mentioned under the scope of the work of RFP"	**Amendment** "*Note: The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") (as per Format attached as **Annexure-I** with this Corrigendum); at the time of installation for all the prescribed blood bank equipment's (specifications of equipments provided in **Annexure-II** attached with this Corrigendum); subsequent to the gap analysis done and as per the requirement for maintaining the operations of all the blood banks. Also, the Selected Agency has to install new machines only (old/ refurbished machines shall not be installed) across all the locations as mentioned under the scope of the work of RFP* *The designated officer of NHM-MP shall verify the details of OEMAF submitted by the Selected Agency at the time of installation and issue an inspection/ certification report post installation regarding the installation and functioning of all the equipment at the Blood Banks"*

3. All changes/ modifications in Tender document as above are binding to all Bidder(s)
4. Other terms and conditions of the Tender document shall remain the same

Mission Director
National Health Mission, Madhya Pradesh

ANNEXURE I: BIDDER'S AUTHORISATION LETTER

(To be submitted on the letterhead of the OEM)

To,

Mission Director,
National Health Mission - Madhya Pradesh (NHM-MP)
Link Road No.03, In front of Patrakar Colony,
Bhopal 462003 Madhya Pradesh

Sub: RFP Ref. No. S. No. N.H.M./Store/2022/5235 dated 01st August 2022 for "Request for Proposal for Selection of an Agency for the Establishment, Operation & Management of Blood Banks for NHM-MP"

Dear Sir/Madam,

We, _____ (*insert name of the OEM*)_____, hereby confirm and declare that:

1. M/s. _____ (*insert name and address of authorised dealer/agent*) _____is our authorized dealer/agent for _____
2. M/s. _____ (*insert name and address of authorised dealer/agent*) _____ have fully trained and experienced service personnel to provide the said services.

Yours sincerely,

Authorized Signature
[In full and initials with Seal]:
Name and Title of Signatory:
Name of OEM (*Firm/ Organization's name*):
Address:
Telephone:
Email:

Note:
1. This letter of authorization should be on the letterhead of the manufacturing firm and should be signed by a top executive of the manufacturing firm.
2. Original letter shall be submitted at the time of installation of the equipment by the Selected Agency

Annexure - II

SPECIFICATIONS OF THE BLOOD PROCESSING EQUIPMENT TO BE PROVIDED BY THE AGENCY UNDER THE PROJECT

A. REFRIGERATED CENTRIFUGE

S. No.	Technical Specification
1.	For separation of the blood component like packed cell, platelet rich plasma, platelet concentrates plasma
2.	Microprocessor-controlled system to make operation automatic
3.	Programmable memory: Memory with tamper proof facility
4.	Stainless steel chamber: Easy to clean, corrosion resistant with provision of both drain and condensed water collection container
5.	CFC free refrigerant
6.	Swing bucket blood bank rotor: With metal buckets, 6 x 2000 ml, wind shielded. Suitable adapters for 12 blood bags of 350 ml and 450 ml
7.	Removable plastic cups to hold single/double/triple/quadruple Blood bag with partitions in every bucket
8.	Insert with hook adapter to spin bubbly coat or small volume of blood and balancing weight for insert
9.	Equipped with automatic lid lock
10.	Centrifugal force: 5000-6000 g
11.	Speed variation: Microprocessor-controlled rotor speed to within 10 rpm of set value. Acceleration and deceleration profile shall be available
12.	Temperature range: -10°C to + 40 °C
13.	Microprocessor controlled rotor temperature with 1°C of set temperature regardless of the centrifuge speed
14.	Programmable time: 0-99 minutes with minimum resolution of 1 minute
15.	Digital display of temperature, speed and time, minimum no. of 3-digit resolution
16.	Motor imbalance detection: Automatic shutdown of centrifuge if rotor load is out of balance with appropriate indicator, should incorporate alarm for imbalance detection lid interlock, over temperature, rotor over speed
17.	Power requirement 220/240 voltage, 50 Hz single-phase AC supply
18.	The equipment shall be suitable for operation from 0 to 40 °C at 90% relative humidity. Electronic circuitry Shell tropicalized for this ambient condition
19.	The equipment should be latest on the production line and must not be refurbished. The equipment should be latest on the production line and must not be refurbished. The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") (as per Format attached as Annexure-I of Corrigendum No. 04) at the time of installation of the equipment at the blood bank
20.	Noise levels within 60 DB
21.	The equipment shall have lockable castors
22.	Protection of data: in the event of power interruption or complete failure data should remain stored
23.	Should have a provision for external connectivity
24.	It shall have a security lock to prevent unintentional switch off and also unauthorized opening of equipment
25.	Automatic line voltage corrector/voltage stabilizer: A line voltage corrector of appropriate rating should form part of standard configuration. copper wound single phase automatic line voltage corrector conforming to IS:9815(Pt. l)/94 with latest amendments of equivalent International standard fitted with a voltmeter and switch to indicate output/input voltage as under: ▪ Capacity/rating: 10 KVA: As per the requirement of the equipment

S. No.	Technical Specification
	▪ Input Voltage: 140 to 280 Volts, 50 Cycles ▪ Output Voltage: 220 Volts ±10% Volts. Input-output voltmeter and ampere meter. Protection: High-Low Voltage Cut-off, overload and short-circuit protection ▪ The equipment should be supplied with 2-meter cord at input and fitted with plugs of appropriate rating (15 Amp.) ▪ Make of the line voltage corrector shall be indicated
26.	Certifications: ▪ Product certification: USFDA/ European (CE) certified / Declaration of Conformity of CE ▪ Quality Certification: ISO Certified ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of blood units processed in the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spareparts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracyof calibration, etc. will not be paid for)*

B. AUTOMATED COMPONENT PROCESSOR (AUTOMATED PLASMA SEPARATOR)

S. No.	Technical Specification
1.	The equipment should be able to express the blood components, from primary bag into various satellite bags automatically, after initial manual loading of the bag system on to the machine
2.	The equipment must be compatible with any blood bag including top and bottom
3.	The equipment should have built in weighing mechanisms to measure the weight of various components separated (Plasma, Red cells and Platelets).
4.	It should give at least one log leukoreduction for red cells and platelets
5.	The equipment should have an integrated system of sealing heads and optical sensors to automatically control the flow of various blood components (Plasma, Platelets and red cells) in satellite tubing's
6.	The equipment should have a control panel with display system to indicate various procedural steps
7.	The tube sealing should be of radio frequency type
8.	The equipment should have the provision to store and transfer the blood component details including the identification number of the donor unit to a central facility
9.	The equipment should have built in alarm system to indicate the completion of the procedure
10.	The equipment should be latest on the production line and must not be refurbished. The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") (as per Format attached as Annexure-I of Corrigendum No. 04) at the time of installation of the equipment at the blood bank
11.	Electrical Supply: ▪ Voltage - 220 to 240 V AC ▪ Frequency - 50/60 Hz ▪ Compatible UPS, to complete the ongoing procedure, with a back-up supply for at least half an hour, should be supplied with the equipment
12.	Certifications:

S. No.	Technical Specification
	▪ Product certification: USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified ▪ Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of blood units processed in the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spareparts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracyof calibration, etc. will not be paid for)*

C. FULLY AUTOMATED CLIA ANALYZER

S. No.	Technical Specifications
1.	The machine should be brand new fully automated, random access immunoassay system
2.	The complete system should be latest on the production line and must not be refurbished. The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") (as per Format attached as Annexure-I of Corrigendum No. 04) at the time of installation of the equipment at the blood bank
3.	Should be based on Chemi Luminescence/ Electro-Chemiluminescence/ Fluorescence technology
4.	The equipment and all reagents should be European CE/IVD/USFDA and CDSCO approved
5.	Any necessary up-gradation in the equipment required in future will be the Selected Agency responsibility
6.	Parameters/ Investigations: 4th generation HIV Ag/Ab, HBsAg, Anti-HCV, HBV Core Ab, Syphilis-essential parameters and CMV, HTLV, SARSCOV 2 are desirable
7.	Sample: Human serum (including serum collected in serum separator tubes) or plasma collected in potassium EDTA, heparin, sodium citrate, CPDA-1, CPD, CP2D
8.	Throughput should be a minimum of 60 samples or more / hour
9.	The system should have the capability to do the assay in continuous, random batch and STAT mode
10.	Should have capacity to load a minimum of 15 or more Reagents packs of different parameters at a time
11.	Reagent packs should be ready to use with automatic onboard reagent mixing to avoid manual intervention & human relatederrors
12.	On board reagent stability of minimum 4 weeks with calibration stability of minimum 4 weeks should be there
13.	The system should not have to be stopped to reload new reagent kits
14.	The system should have single point data entry and result viewing with wide touchscreen monitor
15.	Continuous printing facility of patient results, QC and calibration details should be available
16.	Option of taking back-up of patient results and QC reports on external services and USB devices should be possible
17.	Onboard reagent inventory with automatic tracking and notification of remaining tests, onboard stability and expiration, calibration and storage conditions for each pack should be there. Reagent expiry should be minimum 4 months when supplied
18.	Reagent compartment with the required temperature for the reagent kits supplied by bidder should be available
19.	Should have access to samples during operation. Sample volume required should be 10-150 µL depending upon the analyte
20.	Should have facility to do Pre-dilution of samples

S. No.	Technical Specifications
21.	Equipment should be able to work with all types of sample containers including standard primary tubes (both vacuum and non-vacuum tubes), System should accommodate multiple sample tube size / sample cups
22.	Universal barcode reader should be able to read multiple barcode type
23.	Stat prioritization should be available on the system without interrupting the routine run. Dedicated STAT position should beavailable
24.	System should be able to perform assays with zero carry over
25.	System should perform assays in discrete disposable cuvettes/cells
26.	All disposables and consumables (All controls, calibrators, wash reagents, assay diluents, disposable sample probe tips, reactioncuvettes and other consumables necessary for investigations) should be included in the cost
27.	Should have on board sample auto dilution facility
28.	Should have Clot detection, bubble detection and low sample detection facility, hemolysis and icteric sample detection facility
29.	Should have lot to lot calibration for each assay. The calibrator and controls should cover all investigations/ parameters mentioned above. Certificate of Traceability for calibrators, traceable to national/ international reference standards to be submitted by the Selected Agency. 4th generation controls for relevant assays should be provided
30.	Reaction time should be within 10 – 60 minutes for the listed parameters
31.	System should have automatic reflex testing
32.	Should have facility for continuous random access, including loading and unloading of reagents, other consumables and samples without stopping the analyzer
33.	Servicing instruments by remotely capturing operational data available in the system
34.	Random access calibration should be possible
35.	Provision of inbuilt QC monitoring system by L J plots and Westgard and Configurable QC based rules should be available
36.	It is the responsibility of the agency to integrate the software of the equipment with the existing HIS of the hospital for interfacing the results, free of cost. All necessary hardware and software required for connecting the equipment to the hospital network shall be provided by the Selected Agency
37.	HIS port, Ethernet port and USB port should be available along with the equipment
38.	Real time monitoring of QC violations and turnaround time for samples should be available
39.	Instrument should provide integrated process control that monitors from sample aspiration to assay processing and report thesame. Operator should be able to see the report for any discrepancies and able to take print out for audit purpose
40.	On board sample data storage capacity should be a minimum of 10,000 and above patient results
41.	Should be able to work with Voltage: 200-240 V and Frequency 47- 60 Hz.
42.	UPS - 3KVA with 30 minutes battery backup should be supplied with equipment. Appropriate battery backup should be arranged and maintained by the agency with no extra cost
43.	The required plumbing/water plant facility should be provided and the same shall be maintained by the Selected itself. All prerequisites for installation and operational of machine will be fulfilled by the Selected Agency
44.	Floor drain kit should be set up by the Selected Agency to route waste directly to floor drain. All prerequisites for installation and operational of machine will be fulfilled by the Selected Agency
45.	The Selected Agency should inspect the site before installation and prepare the site for installation and proper functioning of the equipment round the clock, free of cost
46.	The Selected Agency shall be responsible for installation, commissioning and trial runs providing free trial kits for all tests along with respective calibrator and control

<table>
<tr><th>S. No.</th><th>Technical Specifications</th></tr>
<tr><td>47.</td><td>The Select Agency should provide one kit per parameter at no cost for trial and training purpose. The equipment being installed should be validated in-house and documents for Installation qualification/Operational Qualification/Performance Qualification has to be provided to NHM-MP</td></tr>
<tr><td>48.</td><td>Three levels of internal QC should be provided by the agency from an FDA-approved third-party manufacturer six monthly</td></tr>
<tr><td>49.</td><td>NABL standard must be adhered for running QCs</td></tr>
<tr><td>50.</td><td>The Agency shall undertake daily Quality Control for the equipment. In event of failure of Quality Control, the cost for any processing charges per blood bag processed and for trouble shooting shall be borne by the Agency only</td></tr>
<tr><td>51.</td><td>A unit from the same manufacturer with a throughput equivalent to that of main equipment should be provided as standby equipment, free of cost if required in case of breakdown/ not rectified within two days from the date of receipt of complaint</td></tr>
<tr><td>52.</td><td>The expected sensitivity and specificity of the assays are as follows:
<table>
<tr><th>Test</th><th>Sensitivity</th><th>Specificity</th></tr>
<tr><td>HIV</td><td>100%</td><td>99.5%</td></tr>
<tr><td>HBsAg</td><td>100%</td><td>99.5%</td></tr>
<tr><td>HCV</td><td>100%</td><td>99.5%</td></tr>
<tr><td>Syphilis</td><td>100%</td><td>99.5%</td></tr>
</table>
</td></tr>
<tr><td>53.</td><td>Certifications:
Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE
Quality Certification: ISO Certified
Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)</td></tr>
</table>

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of tests performed on the instrument at the rate agreed upon. (*Instrument, other equipment, maintenance of all these equipment, spare parts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracy of calibration, etc. will not be paid for*)

D. GEL CARD CENTRIFUGE AND INCUBATOR FOR CROSS MATCHING

(1) Gel Card Centrifuge:-

S. No.	Technical Specifications
1.	Capacity: Swing out rotor should accommodate 12 or more standard Gel cards
2.	Max speed of the centrifuge should be 1600 ±10 RPM
3.	Max RCF should be 279 ±1 % g
4.	Should have audio visual alarms for Imbalance, end of cycle and any other errors
5.	Should have single hand rotor removal for cleaning
6.	Should have LCD display with touch keypad
7.	Motor should be Brushless
8.	Net weight should be less than 20 kg
9.	Power supply should be 220-240 volts, 50 Hz, Single phase
10.	Certifications:

S. No.	Technical Specifications
	▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO Certified. ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

(2) <u>Gel Card Incubator:-</u>

S. No.	Technical Specifications
1.	Incubator should accommodate 12 or more Gel cards and 12 or more test tubes simultaneously
2.	Should maintain temperature at 37°C ±1°C
3.	Time limit adjustable up to 60 minutes
4.	Should have programs to adjust incubation temperature & time as specified by gel card
5.	Should have audio visual alarms for high / low temperature and end of cycle
6.	Should have Auto pop-up card mechanism for card removal, when lid is opened
7.	Should have LCD display with touch keypad
8.	Power supply: 220-240 volts, 50 Hz, single phase
9.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO Certified ▪ Electrical Safety: Equipment meets electrical safety specification such as that of IEC (Class 1)

Note:- Instrument will be placed on rental basis and the institution will only make payment for the number of tests performed on the instrument at the rate agreed upon. *(Instrument, other equipment, maintenance of all these equipment, spare parts, reagents, consumables, Preventive Maintenance Kits, calibrators, tests performed for calibration and ensuring accuracy of calibration, etc. will not be paid for)*

E. LIST AND TECHNICAL SPECIFICATIONS OF OTHER EQUIPMENT (APART FROM THE 04 MENTIONED ABOVE)

(1) <u>Deep Freezer- 40°C</u>

S. No.	Technical Specifications
1.	Purpose of Equipment: To freeze and store plasma
2.	Type of Equipment: Compression freezer with CFC-free refrigerant
3.	Capacity : As required by the blood bank (i.e., minimum of 200 blood bags)
4.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V_2 A- 1.4301) ▪ External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness) ▪ CFC-free insulation ▪ Design: Upright Type ▪ Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110° ▪ Insulation and gasket should be silicone ▪ Separate inner doors to prevent cold loss ▪ Drawers: Roll out type

S. No.	Technical Specifications
	▪ Heating device on frame to avoid condensation
5.	Electrical Characteristics: ▪ Input voltage: 220/24OV SOHZ ▪ A line voltage corrector of appropriate rating should form part of configuration
6.	Minimum Compressor Starting Voltage: 22% below nominal Voltage
7.	Internal temperature Control: ▪ Electronic temperature control ▪ Operating temperature reachable lowest up to -45°C with setting accuracy of ±1 °C whatever the load ▪ Fan air cooling ▪ Automatic defrost within safe temperature range ▪ Casing & door should have insulation panel with polyurethane foam
8.	Refrigeration ▪ Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -40 C ▪ Option for duct from equipment to connect to common main duct to throw hot air out of the room ▪ Refrigerant CFC free/ green gas ▪ Optional: Access port for CO_2 backup system for refrigeration
9.	External Ambient Temperature: Performs in an ambient temperature of 10°C to 40°C
10.	Hold over time: 2 hrs. at ambient temperature
11.	Cooling Down Time: ▪ A full load of plasma packs at +25°C takes a maximum of 5 hrs. for all the packs to reach below -5°C ▪ A full load of plasma packs at +25°C takes a maximum of 30 hrs. for all the paces to reach below -20°C
12.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1°C graduation ▪ Temperature recording device: ▪ Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. There should be a method to check alarm system ▪ Seven days inkless graphic temperature recorder with range of OOC to -50°C with data logger, with supply of free charts for a period of warranty. ▪ Battery backup for alarm and temperature recording device. ▪ Provision to connect with central (temperature) monitoring system ▪ Mounted on Lockable Castor wheels ▪ Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm. ▪ Desirable: o Noise factor should not exceed 60 decibels. o Should have compressor running time < 60 to 70%
13.	Additional Requirements ▪ All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards ▪ Complete with comprehensive set of spare parts including a spare ▪ compressor, refrigerant gas cylinder etc. and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately ▪ Necessary catalogues, technical write up in English shall be provided by the Agency, both in hard and soft copies ▪ Performance, efficiency, other factors such as distortion etc. as applicable be also furnished

S. No.	Technical Specifications
	▪ Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished. ▪ Certifications: o Product certification : USFDA/ European (CE) certified// Declaration of Conformity of CE o Quality Certification: ISO certified o Electrical Safety Equipment meets electrical safety specifications such as that of IEC (Class I)

(2) <u>Deep Freezer -80°C</u>

S. No.	Technical Specifications
1.	Purpose of Equipment: To freeze and store plasma
2.	Type of Equipment: Compression freezer with CFC-free refrigerant
3.	Capacity : As required by the blood bank (i.e., minimum of 200 bags)
4.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V_2 A- 1.4301) ▪ External: Solid Outer Cabinet Corrosion Resistant (at least 1mm thickness) ▪ CFC-free insulation ▪ Design: Upright Type ▪ Door: Solid door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110° ▪ Insulation and gasket should be silicone. A Separate inner door to prevent cold loss ▪ Drawers: Roll out type ▪ Heating device on frame to avoid condensation
5.	Electrical Characteristics: ▪ Input voltage: 220/24OV 50Hz ▪ A line voltage corrector of appropriate rating should form part of configuration.
6.	Minimum Compressor Starting Voltage: 22% below nominal Voltage
7.	Internal Temperature Control: ▪ Electronic temperature control ▪ Operating temperature reachable lowest up to -86°C with setting accuracy of f1 °C whatever the load ▪ Fan air cooling ▪ Automatic defrost within safe temperature range ▪ Casing & door should have insulation panel with polyurethane foam > 80mm thickness
8.	Refrigeration**:** ▪ Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -800C ▪ Refrigerant CFC free/ green gas ▪ Optional: Access port for COC backup system for refrigeration. ▪ Optional for duct from equipment to connect to common main duct to throw hot air out of the room
9.	External Ambient Temperature: Performs in an ambient temperature of +1°C to +40°C
10.	Hold over time: 2 hrs. at ambient temperature
11.	Cooling Down Time: ▪ A full load of plasma packs at +25°C takes a maximum of 5 hrs. for all the packs to reach below -5° C

S. No.	Technical Specifications
	▪ A full load of plasma packs at +25 °C takes a maximum of 30 hrs. for all the packs to reach below - 20° C
12.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1° C graduation ▪ Temperature recording device ▪ Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. There should be a method to check alarm system ▪ Seven days inkless graphic temperature recorder with range of OEC to -50° C with data logger, with supply of free charts for a period of warranty ▪ Battery backup for alarm and temperature recording device ▪ Provision to connect with central (temperature) monitoring system ▪ Mounted on Lockable Castor wheels ▪ Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration to alarm ▪ Desirable: o Noise factor should not exceed 60 decibels o Should have compressor running time < 60 to 70%
13.	Additional Requirements ▪ All equipment should specify Design qualifications, Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national / international standards ▪ Complete with comprehensive set of spare parts including a spare compressor, refrigerant gas cylinder etc. and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately ▪ Necessary catalogues, technical write up in English shall be provided by the Agency, both in hard and soft copies. ▪ Performance efficiency, other factors such as distortion etc. as applicable be also furnished ▪ Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished ▪ Certifications: o Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE o Quality Certification: ISO certified o Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

(3) Platelet Incubator & Platelet Agitator

(i) Purpose of Equipment: To continuously agitate platelet concentrates in an incubator in an even suspension in a plasma bag

(ii) Type of Equipment: Flatbed agitator fitted inside a temperature-controlled incubator operating with GFC-free refrigerant gas and insulation material

(iii) Certifications:
- Product certification: USFDA/ European (CE) certified/ Declaration of Conformity of CE
- Quality Certification: ISO certified

- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

S. No.	Technical Specifications - Platelet Incubator
1.	Should have a provision to store the agitator
2.	Should have a single transparent outer door for clear visibility
3.	Should be able to maintain a temperature of 22+20C, Set temperature of 22^C
4.	Should have a digital temperature indicator.
5.	Seven-day inkless chart recorder with battery back-up for minimum of 2 hours for continuous operation during power failure
6.	Single digital temperature sensor for both recording and controlling
7.	Should have audible visual high/low alarm for temperature control, battery on/low, sensor failure, agitator off, power failure, compressor and system
8.	Should have forced air circulation method for the uniformity of the temperature at all sides of the incubator.
9.	Chamber mounted electrical outlet for agitator should be available
10.	Power supply: 220-240 volts at 50 Hz.
11.	Facility to connect with central (temperature) monitoring system

S. No.	Technical Specifications - Platelet Agitator
1.	Construction: ▪ Internal: Stainless steel (min. 304 grade) ▪ External: Corrosion Resistant, at least 1mm thickness ▪ Capacity: Designed to hold random platelet packs or aphaeresis platelet packs or a mixture of both types (minimum 48 random platelet concentrate packs). ▪ Transparent Door ▪ Design of Shelves: Shelves are made of non-slip, corrosion resistant material, Coated with bacteria resistant material, perforated to ensure air circulation and with sufficient clearance to minimize noise ▪ Gentle side to side agitation at 3.6-4 cm side to side, 60- 70 ▪ strokes/ minute ▪ Heavy duty ball bearing gear motor for noise less and continuous operation for 24 hours a day throughout the year ▪ Motor with internal fan
2.	Temperature: ▪ 7-day chart recorder with free charts till warranty period. ▪ Temperature controller with sensor
3.	Refrigeration: Non-CFC air cooled refrigeration
4.	Safety features: ▪ Audio alarm for temperature fluctuation ▪ Auto stop for agitation when the door is opened ▪ Power failure alarm
5.	Push buttons switch with pause function for temporary stoppage of the motion
6.	Power supply: 220-240 volts at 50 Hz

(4) <u>Sterile</u> Connecting Device

S. No.	Technical Specifications
1.	Blood Bag Tube Sealer is a compact equipment to seal the Blood Bag pilot tubing
2.	The system should be heavy duty and be able to seal the blood bag etc. quickly and effectively

S. No.	Technical Specifications
3.	Should be simple to handle
4.	System should gently seal the tubing with no hemolysis using radio frequency.
5.	Should be capable of making wide seal of 2 mm thickness.
6.	Should be for bench-top use
7.	The sealing time should not be more than 2 seconds
8.	Sealing trigger should be automatic
9.	Should also have extended portable hand unit Sealing hand should be with coaxial cable of 1.5-2.0 meter.
10.	Should have indication lamps for “Sealing Process" on handle as well as main unit.
11.	No warm-up time should be required.
12.	Should ensure easy separation of tube segments after the sealing
13.	System should run on both mains and battery (more than 10hrs. back up and charger).
14.	Back up battery should seal more than 500 seals on PVC- tubes in continuous mode.
15.	The unit shall be capable of operating continuously in ambient temperature of 10 - 40° C and relative humidity of 15-90%
16.	Power input: 220-240V/ 50 Hz AC Single phase or 380-400V AC 50 Hz Three phase fitted with appropriate Indian plugs and sockets.
17.	Suitable Auto voltage corrector with spike protector should be available
18.	Electrodes should be well protected by a cover
19.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified ▪ Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock ▪ Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

(5) Blood Mixer and Collector

S. No.	Technical Specifications
1.	The system is used to collect donated blood from the donor at the same time mixing the blood for quality collection of blood
2.	It is meant for stationary and mobile use. Gentle end to end mixing and control of collection time to give high quality blood suitable for all blood bags.
3.	Volume Setting: Pre-selection of volume to be collected. Tarring of bag volume before collection. Tarring range: 0 — 600 g. Automatic storage and recall of set volume. Measure volume with best accuracy
4.	LED indication on commencement of collection
5.	LED indication and audible alarm at the end of collection
6.	Indication of time taken for collection
7.	Indication of blood flow with audio alarm when blood flow is hinge or lower than desired
8.	Continuous display of collected volume, flow and time during collection
9.	Automatic clamping at termination of preset volume collection
10.	Automatic release of bag when lifted.
11.	Continuous agitation of blood bags during collection: 12 - 16 rpm
12.	Equipment carry case for BCM should be provided for portability
13.	Should operate on mains as well as rechargeable battery. On battery it should operate for a minimum of 5-8 hours
14.	The unit shall be capable of operating continuously in ambient temperature of 10 -40° C and relative humidity of 15-90%

S. No.	Technical Specifications
15.	Power input to be 220-240VAC, 50Hz,/440 V 3 Phase as appropriate fitted with Indian plug
16.	Resettable over current breaker shall be fitted for protection
17.	Suitable Automatic Voltage regulator/stabilizer meeting ISI specifications should be supplied. Broad specifications are: Automatic Type Input 150-280V Output 220 V +/- 7 % , 50 Hz . Single phase, AC with automatic 2-4 sec Cut Off and 6-9 minutes restart delay. Quick start arrangements for bypassing the start delay. Suitable MCB on input voltmeter and indicators on Front Panel. Input Pore Cable with 15 A Plug and six-way output terminal strip for two outlets
18.	Certifications: ▪ Product certification : USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality Certification: ISO certified ▪ Electrical Safety. Equipment meets electrical safety specifications such as that of IEC (Class I) or Class II type-B device to protect against electric shock ▪ Shall meet IEC-60601-1-2 :2O01(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility

(6) Blood Bank Refrigerator/ Serology Refrigerated for Blood Banks (200 Bags Capacity)

S. No.	Technical Specifications
a)	**Name & Coding:** ▪ GMDN name - Refrigerators ▪ GMDN code - CT1897
b)	**General Use:**
1.	Clinical purpose - A refrigerator for storing whole blood or red cell packs in a blood bank. A refrigerator for storing various reagents and /or patient samples
c)	**Technical Characteristics:**
1.	Technical characteristics (specific to this type of device) - Compression type refrigerator that uses CFC free refrigerant gas.
2.	Construction: ▪ Internal: Stainless steel (min. 22g) (S.S. V2 A- 1.4301) ▪ External: Solid outer Corrosion Resistant (at least 1mm thickness), CFC free insulation ▪ Drawers: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are held in a vertical position with the label side visible ▪ Door: Glass door, Automatic closing of the front door below opening angle of 90 ° and opening angle limited to 110° ▪ Insulation and gasket should be silicon ▪ Polyurethane insulation should be minimum 80mm thickness ▪ Door opening audio and visual display alarm
3.	Temperature Range: 2 ° C to 6 ° C and adjustable with setting accuracy of ±0.1 ° C with set temperature of 4 ° C. User parameter settings: set point, high alarm point, low alarm point, buzzer off time, C/F temperature choice
4.	Minimum Compressor Starting Voltage: 22% below nominal voltage
5.	Internal Temperature Control: Electronic temperature control, range +2 ° C to +6 ° C with setting accuracy of ±1 ° C whatever the load, Fan air cooling
6.	External Ambient Temperature: Performs in an ambient temperature of +10 ° C to +40 ° C
7.	Hold over time: A full load of blood packs at +4 ° C (±1 ° C) takes at least 30 minutes to rise to above +6 ° C. Internal temperature hold over time in case of power failure should be at least 1.5 hrs.
8.	Cooling Down Time: A full load of plasma packs at +25 ° C takes a maximum of 13 hrs. for all the packs to reach below +6 ° C

S. No.	Technical Specifications
9.	Temperature Monitoring: ▪ Digital temperature (LED) display with 0.1°C graduation, Temperature recording device, Microprocessor control for operation with integrated audio-visual temperature alarm function with digital monitoring display. ▪ Independent safety thermostat to avoid negative temperatures. ▪ At least 2 temperatures sensors: Sensor for temperature monitoring shown on front display, sensor for managing use of compressor
10.	Temperature recording device: ▪ Visual and audible alarm system indicating unsafe temperatures. ▪ Battery backup for alarm system indicating unsafe temperatures. ▪ Seven days graphic temperature recorder with range of -10 ° C to +20 ° C with supply of free charts for a period of one year ▪ Ideal compressor running time of 27% at room temperature. ▪ Door locks should be available. ▪ Audio and visual alarm for variation in temperature, Interior lightening, ▪ Auto defrosting
11.	Capacity - As required by the blood bank (200 plasma bags of 350/450 mL each)
12.	Settings - Manual
13.	User's interface - Manual
14.	Software and/or standard of communication(wherever required) - Built in
d)	**Physical Characteristics:** ▪ Dimensions (metric) NA ▪ Weight (lbs., kg) NA ▪ Configuration NA ▪ Noise (in dBA) Noise factor should not exceed 60 decibels. ▪ heat dissipation NA ▪ Mobility, portability NA
e)	**Energy Source (Electricity, UPS, Solar, Gas, Water, CO2 ....):** ▪ Power Requirements input voltage - 220/240V 50Hz ▪ Battery operated - NA ▪ Tolerance (to variations, shutdowns) - NA ▪ Protection - A line voltage corrector of appropriate rating will form part of standard configuration. ▪ Power consumption - NA ▪ Other energy supplies – NA
f)	**Accessories, Spare Parts, Consumables:** Accessories & spare parts - Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer. The make, rating, model, description, specifications, price, quantity of each item shall be furnished separately
g)	**Environmental and Departmental Considerations:** ▪ Atmosphere / Ambiance (air conditioning, humidity, dust ...) o Capable of being stored continuously in ambient temperature of 0 to 50° C and relative humidity of 15 to 90% o Capable of operating continuously in ambient temperature of 10 to 40° C and relative humidity of 15 to 90% ▪ Additional Requirements - All equipment should specify Design qualifications, Installation qualifications, Operational qualifications and performance qualifications, validation and calibration reports should have traceability towards applicable national/ international standards. Performance, efficiency, other factors such as distortion etc. as applicable be also furnished. Complete construction, details in respect of material specification, thickness, finish etc. are to be furnished ▪ User's care, Cleaning, Disinfection & Sterility issues - Complete unit to be easily washable and sterilizable using both alcohol and chemical disinfectant
h)	**Standards and Safety:**

S. No.	Technical Specifications
	▪ Product certifications - USFDA/ European (CE) certified/ Declaration of Conformity of CE ▪ Quality certifications ISO 13485 certified ▪ Electrical Safety Equipment meets electrical safety specifications of IEC 60601-1 and 60601-2 (as relevant)
i)	**Training and Installation:** ▪ Pre-installation requirements: nature, values, quality, tolerance - NA ▪ Requirements for sign-off - NA ▪ Training of staff (medical, paramedical, technicians) OPTIONAL (Depending upon scope of work order) - Training of users in operation and basic maintenance shall be provided
j)	**Warranty and Maintenance**: ▪ Warranty 2 years ▪ Maintenance tasks 3 years CMC ▪ Service contract clauses, including prices - Downtime: 48 hours or after penalty clause will be active. Local clinical staff / authorized officer on behalf of purchaser to affirm completion of installation
k)	**Documentation:** ▪ **Operating Manuals, Service Manuals, Other Manuals -** Necessary Catalogues, Technical Write Up in English shall be provided by the agency, both in hard and soft copies

Note:

1. All the machines/ equipments to be installed by the Selected Agency should be new only and not old or refurbished. In case, the same are found to be old/ refurbished, the number of units processed shall not be paid for the respective duration
2. WRT all the machines/ equipments to be installed by the Selected Agency, The Selected Agency shall provide a duly signed and stamped Original Equipment Manufacturer Authorization Form ("**OEMAF**") (as per Format attached as Annexure-I of Corrigendum No. 04) at the time of installation of the equipment at the blood bank

CORRIGENDUM No. 05

Request for Proposal for Selection of an Agency for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh
*(Corrigendum No – 05- to RFP Ref. No.: **S. No. N.H.M./Store/2022/5235** & Tender ID: **2022_DHS_214454_1**)*

1. This is regarding the NIT issued on 02/08/2022 Selection of an Agency to for the Establishment, Operation and Management of Blood Banks for National Health Mission, Madhya Pradesh, in leading newspaper and uploaded on MP Tender Website https://mptenders.gov.in.

2. In lieu of the released RFP, the Technical Committee after due consideration recommends following amendments in the Tender document for now:

S. No.	Tender Reference	Reference	Amendments
1.	**NIT**	**Dates (as published in the Corrigendum No. 03)** - *Document Download/ Sale End Date: 12th September 2022, Monday, 04:00 PM* - *Bid Submission End Date: 12th September 2022, Monday, 04:00 PM* - *Bid Opening Date: 13th September 2022, Tuesday, 05:00 PM"*	**Amendment** *"After the publication of the Corrigendum No. 05, the revised timelines/ dates for key events are as follows:* - *Document Download/ Sale End Date: 19th September 2022, Monday, 04:00 PM* - *Bid Submission End Date: 19th September 2022, Monday, 04:00 PM* - *Bid Opening Date: 20th September 2022, Tuesday, 05:00 PM"*

3. All changes/ modifications in Tender document as above are binding to all Bidder(s)
4. Other terms and conditions of the Tender document shall remain the same

Mission Director
National Health Mission, Madhya Pradesh