PREBID QUERIES/CLARIFICATIONS ASKED BY BIDDERS AND IT'S RECOMMENDATIONS/REPLIES NIB REF: HITES/PCD/NCI-AIIMS/28/18-19; PREBID MEETING HELD ON: 27.08.2018

	Bloc	d Collection	Blood Collection Monitor (item at al. no. 2)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE
Point 1 Page 48	Should have facility to preset total volume of blood to be collected and accordingly monitor and display amount collected. It should have facility to clamp to stop the collection of blood as soon as preset volume is collected and not allow over collection. Should have the facility for LIS integration (preferably wireless).	Equipment point	The same does not comply in our category, but there is no major impact on the functioning of the device and its application	The requirement stays unchanged.
Point 8, page 48	Oscillation 16 +/-(2) rpm	Equipment point	Our device is with oscillation of 12 +/- 2rpm and the same is effective for the better rriving of articoagulant with the blood	To be amended as: "Oscillation 12 - 16 rpm"
Page 49, Para 14	14. Should be USFDA or European CE approved product.	AN.	NA	To be amended as : "It should have USFDA or European CE certification"
Page 48, Para 11	11. Every Bio-mixer should be provided with carry box with handle.	V	NA	To be amended as: "Every Bio-mixer should be provided with manufacturer provided carry box with handle."
Page 48		Υ Y	NA	Added Para: The biomixer should be able to integrate with LIS for cata management.

Page 1 of 34

ingham

1

8

Page 2 of 34

		2	Tube Stripper (item at sl. no. 4)	
ender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 8 para 49	Point 8 Should have provision for manual para tube sealing by aluminium rings 49	Equipment Point	Our hand stripper are designed without spring and the same is with roller mechanism which ensure the uniform functioning of the device	The requirement stays unchanged.

	1			
	COMMITTEE RECOMMENDATION	To be amended as: "2.1 Equipment should have ISO 13485 certification and Manufacturer should have ISO 9001 certification."	To be amended as: "Should be rechargeable battery operated compact (less than 3 Kg) hand held type, not bench top type. It should have a portable hand unit with coaxial cable of 1.5 - 2 meter."	To be amended as: "Sealing time should not be >2 sec. It should be able to make 50-60 seals/ hr and with No warm-up time."
Dielectric Tube Sealer - Handheld (item at sl. no. 5)	REPRESENTATION RECEIVED FROM THE FIRMS	NA	Ą	NA
Sealer - Hai	NAME OF THE FIRM	AN	∀ Z	NA
Dielectric Tube S	TENDER SPECIFICATION	2.1 Manufacturing should be compliant with ISO 13485, and both manufacturer and distributor/service provider should be ISO 9001:2008 compliant.	5. Should be rechargeable battery operated compact (less than 3 Kg) hand held type, not bench top type.	6. Sealing time should not be >2 sec
	Tender Page & Para	Page 50 , Para 2.1	Page 50 , Para 5	Page 50 , Para 6

Page 3 of 34

To be amended as: "No. of seals per charge should be 500-700 continuous seals from a fully charged battery."	To be amended as: "Charger should be compatible with Input voltage: 240V 50 Hz Single phase AC. It shall meet IEC-60601-1-2 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility"
δ	AN
A	A
11. No. of seals per charge should be more than NA 1200 continuous seals from a fully charged battery.	12. Charger should be compatible with Input voltage: NA 240V 50 Hz Single phase AC.
Page	Page
50 ,	50 ,
Para	Para
11	12

	COMMITTEE RECOMMENDATION	To be amended as: "Blood Bank Refrigerator - 400 L"	To be amended as: "Storage Capacity: Should be at least 400 Liters capacity and should be able to accommodate minimum 350 triple bags of 350 ml and 450ml capacity."	The requirement stays unchanged.
Blood Bank Refrigerator - 700 L (item at sl. no. 6)	REPRESENTATION RECEIVED FROM THE FIRMS	NA	Not comply with 700 litres capacity. Comply with 300L capacity to store 360 nos of 450ml blood bags and 510 nos of 350ml blood bags, hence in ferms of number of bags the device complies and is superior either	Not available, but all safety measures are applied to ensure effective functioning according to the global standards.
Blood Bank	NAME OF THE FIRM	NA	Equipment Point	Equipment Point
	TENDER SPECIFICATION	Heading: Blood Bank Refrigerator - 700 L	Storage Capacity: Should be at least 700 Liters capacity and should be able to accommodate minimum 350 triple bags of 350 ml and 450ml capacity.	Independent safety thermostat to avoid negative temperatures
	Tender Page & Para	Page 50	Point 1, Page 50	Point8, page 50

Page 4 of 34

To be amended as: "While in operation, the noise level must not exceed 90 dB."	To be amended as: "Equipment should be USFDA or European CE certified."	Clarified as: The vendor may add it as an accessory second item in the BOQ
TPPL equicment comply with ess than 80 dB, the same is a marginal difference and we expect it to be considered for evaluations	NA	Our observation is how to put the cost of temperature recorder paper cost in the BOQ as we are unable to access the BOQ. We have been informed that BOQ will be uploaded after the pre bid meeting.
Equipment Point	NA V	Span Healthcare Pvt Ltd
While in operation, the noise level must not exceed 60 dB.	18. Should be USFDA or European CE approved product.	Should have 1000 nos. of seven days graphic temperature recorder along with data logging device. The cost of the temperature recorder chart paper will be included in the total cost of the equipment for financial comparison.
Point 14,page 50	Point 18, Page 51	Point 10, Page 51

		Refrigerate	Refrigerated Blood Bag Centiliuge - 12 bags (item at sl. no. 8)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE
Point 19,page 53	Point Should be USFDA or 19,page European CE approved 53	Thermo Sh fisher cer Scientific no. Jus	Should be USFDA or European CE CERTIFIED product. The CE certificate should be used to be amended as: certificate should be used to be amended as: "Equipment should be amende	To be amended as: "Equipment should be US-FDA or European CE certified."

Self Pages of 34

The requirement stays unchanged.	
Manufacturer should be SO 3001 certified and should have ISO 13485 certification for quality standards. It shall meet IEC-60601-1-2 (Or Equivalent 3 S) General Requirements of Safety for Electromagnetic Compatibility or IEC 61010-2-020 (Or Equivalent BIS) salety standards particular for Centrifuges, a certificate from an agency recognized by International Electrotechnical Comm ssion (IEC) along with agency recognition certificate should be submitted.	Justification: IEC 61010-2-02C document attached for your ready reference is specific to laboratory centrifuges (page 3) which defines specific method like the Most Critical Accident Consideration (page 25), Crash Test (7.7.2.2 page 15 & 16), Movement of the Centrifuge (7.4.101 Imbalance page 13), Lid Lock Reliability Test (7.3.101 * page 11) and other specific requirements for roons (7.7.1 page 14). Centrifuge is a high tech product involving huge vinetic shergy and operator safety is a must. Also attached the IEC 61010-2-020 certificate and agency recognition certificate for your ready reference. Benefits: For safety of postagor and to provide safe working environment for entire blood bank.
Thermo fisher Scientific	
Manufacturer should be ISO 9001 certified and should have ISO 13485 certification for quality standards. It shall meet IEC-60601-1-2 (Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility	
Point 20,page 53	

SPECIFICATION	NAME OF REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point Should be USFDA or Thermo 19, page European CE approved fisher 53 Scientific	Thermo Should be USFDA or European CE CERTIFIED product. The CE certificate should be from Notified body with 4 digit identification Scientific no. Justification:-Minimum requirement for safety Benefits:-Safety for coerafor and patient	To be amended as: "Equipment should be US-FDA or European CEcertified."

(Jan Jan	0	_		1
				an an	
				C. O. O. O.	3

,	UbUT-T- unchanged.	ivalent	e from		plnods			ır ready	,			id Lock		h tech	8	ency				
Manufacturer should be ISC 9001certified and should have ISO	2 (Or Equivalent BIS) General Requirements of Safety for	Electromagnetic Compatitility or IEC 61010-2-020 (Or Equivalent	BIS) safety standards Fartcular for Centrifuges, a certificate from	an agency recognized by International Electrotechnical	Commission (IEC) along with agency recognition certificate should	be submitted		Justification :- IEC 61010-2-020 dccument attached for your ready	reference is specific to aboratory centrifuges (page 3) which	defines specific method like the Most Crtical Accident	Consideration (page 2E), Crash Test (7.7.22 page 15 & 16),	Movement of the Centrfuce (7.4 1C1 Impalance page 13), Lid Lock	Reliability Test (7.3.101.1 bage 11) and other specific	requirements for rotors (7.7.1 page 14) Centrifuge is a high tech	product involving huge kinetc energy and operator safety is a	must. Also attached the IEC 61010-2-020 certificate and agency	recognition certificate for your ready reference.	Benifits:-For safety of operator and to provide safe working	environment for entire blood bank.	
Thermo	Scientific								7		N I									
Manufacturer should be ISO 9001certified and	should have ISO 13485	certification for quality	standards. It shall meet	IEC-60601-1-2 (Or	Equivalent BIS) General	Requirements of Safety	ior Electromagnetic	Compatibility												

Point 20,page 53

Page 7 of 34

23	
1	

TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE HRMS	COMMITTEE RECOMMENDATION
Design of shelves : The agitator must be noiseless (< 60db)	Equipment point	Our device comply with 700B. It is a marginal point for consideration, and the same has no Fuge impact on the total noiseless feature of the device	To be amended as: "While in operation, the noise level must not exceed 90 dB."
Capacity: 150-200 random donor platelet units	Equipment point	we Comply with storage of 100 bags only with capacities specifically as option in 96/48/24 units. The same would be helpful in handling sπall π of units as well as and when required. And two units with about 100 units size capacity can assist further assist for safer storage of products in terms of dependency on a single unit with large vo ume capacity.	The requirement stays unchanged.
Must have at least 2 temperature sensors with digital temperature (LED) display with 0.1 °C graduation	Equipment point	the device al sady has sensors for temperature and display of temperature	The requirement stays unchanged.
15. Should be US-FDA or European CE approved product.	NA	NA	To be "Deleted"

Page 8 of 34

	PI (48	atelet Agitato random dono	Platelet Agitator cum Incubator (Upright Model) (48 random donor platelet units) item al sl. no. 11)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REFRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 5c, page 57	Must have at least 2 temperature sensors with digital temperature (LED) display with 0.1 °C graduation.	Equipment point	The d∋vice already has sensors for temperature and display of temperature.	The requirement stays unchanged.
Point 7, pag 57	Must have Battery backup for temperature recordings which is especially needed during power failure/fluctuations. Additional Battery backup for alarm must be there so that alarm will not fail in case of power failure, and must be able to sustain the alarm.	Equipment point	it is nor available the device.	The requirement stays unchanged.
Y Y	NA	Equipment point	The device is having all the respective features except one/two points as mention above	Clarified as: "The vendor must comply with all the required specification."
Page 58	15. Should be USFDA or European CE approved product.	NA	NA	To be amended as: "Equipment should have USFDA or European CE certification"

Page 9 of 34

	COMMITTEE RECOMMENDATION	The requirement stays unchanged.	To be "Deleted"	The requirement stays unchanged. Clarified as: The vendor may add it as an accessory second item in the BOQ.	The requirement stays unchanged. Clarified as: The vendor may add it as an accessory second item in the BOQ.	To be amended as : "Equipment should have USFDA/ CE/ISO certification."
Plasma thawing bath (item at sl. no. '2)	REPRESENTATION RECEIVED FROM THE FIRMS	Our Observation is to change the same to 2-16 bags of Plasma for keeping provisions of thawing even with minimum quantity of plasma bags collected.	This features in provided with a timer for the alarm. It does not give alarm after the plasma bags are thawed.	Not provided.	Not provided.	NA
sma thawing	NAME OF THE FIRM	Span Healthcare Pvt Ltd	Equipment Point	Equipment Point	Equipment Point	V
Pla	TENDER SPECIFICATION	Should be able to thaw 12-16 plasma bags within 30-45 mins.	Should give an alarm when the plasma bags are thawed	The firm must supply a Cover (PVC) to keep the unit covered when not in use.	The firm must supply system compatible plastic pouches for holding the plasma bags to be thawed to avoid cross-contamination in case of leakage and direct contact with the water	16. The quoted model should have FDA or CE or ISO certificate and copy of the same should be enclosed along with the technical bid.
	Tender Page & Para	Point 3, page 58	Point 4, page 59	Point 12,page 59	point 13, page 59	Page 59

Page 10 of 34

		Water Bath (Water Bath (item at sl. no. 13)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 59	 Should be double walled chamber with inner chamber made of stainless steel and the outer is made of thick sheet and duly powder coated. 	Equipment Point	Does not provice in the specific	The requirement stays unchanged.
Page 59	 (3). The cavity between the two chambers should be filled with high quality mineral glass wool. Dome shaped cover with knob to be provided. 	Equipment Point	HA.	The requirement stays unchanged.
Page 60	1.(4)Temperature should be controlled at increments of 1° C or less and is controlled by thermostat from room temperature to 100° C with an accuracy of ± 1° C.	Equipment Point	¥	The requirement stays unchanged.
Page 60	1.(8)Mercury thermometer to read up 100° C.	Equipment Point	Hot comply	The requirement stays unchanged. Clarified as: The vendor may add it as an accessory second item in the BOQ
Page 60	2.(1)Should be supplied with removable stainless trays for accommodating test tubes and flasks to fit the water bath.	Equipment Point	it is not provided.	Clarified as: 2.(1)Should be supplied with removable stainless racks for accommodating test tubes and flasks to fit the water bath. The vendor may add it as an accessory second item in the BOO
Page 60		NA	P.A	Added Para:- Equipment should have USFDA or European CE certification. Manufacturer should have ISO certification.
4	So and the se	Page	Page 11 o⁻ 34	A Luce

Luega

TENDER SPECIFICATION THE FIRM Heading "S.No:-15 Deep Treezer (-40°C) 700 L" Upright model with internal capacity 700 liters or more. Should be provided with data should have minimum boint must have automated defrost or a heating device on frame to avoid condensation Tenezer (-40°C) 700 L" The same is advantageous as the risk for product damage can be reduced due 20 non functioning of bigger single unit Dr, also the size is effective for the setup with maximum centers. System should have minimum Equipment Data can be collabed from the device. System should have minimum Equipment point lit is not comply writhout device. It must have automated defrost or a heating device on frame to avoid condensation Z6. Should be USFDA or European CE approved product.			Deep	Deep Freezer (-40°C) TOC L (item at sl. no. 15)	
Heading "S.No:-15 Deep Freezer (40°C) 700 L" Upright model with internal capacity 700 liters or more. Should be provided with data boint be provided with data should have minimum vibrations, and noise level should be versed 70 db. It must have automated defrost or a heating device on frame to avoid condensation 26. Should be USFDA or European CE approved Freezer with a capacity of 400 L. The same is adv.=nagects as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. The same is adv.=nageous as the risk for product. As amage can be educed due to not functioning of bigger single unit DF, also the size is effective for the setup with maximum centers. Should be provided with data and inclination of product.	Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Upright model with internal Equipment We have a deep freezer with a capacity of 400L. Capacity 700 liters or more. Should be provided with data equipment our device is with the noise capacity less that 80db. Should be provided with data equipment our device is with the noise capacity less that 80db. It must have automated defrost or a heating device on point frame to avoid condensation frame to avoid condensation equipment expected from the device. Should be USFDA or more. It must have automated defrost or a heating device on point frame to avoid condensation frame to avoid condensation product.	Page 61	Heading "S.No:-15 Deep Freezer (-40°C) 700 L"	NA	NA	To be amended as : "S.No:-15 Deep Freezer (-40°C) 400 L"
Should be provided with data logger device. System should have minimum Equipment vibrations, and noise level should not exceed 70 db. It must have automated defrost or a heating device on frame to avoid condensation broduct.	Point 3,page 61	Upright model with internal capacity 700 liters or more.	Equipment point	We have a deep freezer with a capacity of 400L. The same is advantageous as the risk for product damage can be reduced due to non functioning of bigger single unit DF, also the size is effective for the setup with maximum centers.	To be amended as : "Upright model with internal capacity 400 liters or more."
System should have minimum Equipment our device is with the noise capacity less that 80db. should not exceed 70 db. It must have automated defrost or a heating device on frame to avoid condensation frame to avoid condensation broduct.	it age	Should be provided with data logger device.	Equipment point	Data can be coll∋cted from the device.	The requirement stays unchanged.
It must have automated Equipment It is not comply with our device. defrost or a heating device on frame to avoid condensation 26. Should be USFDA or European CE approved product.	e t 18	System should have minimum vibrations, and noise level should not exceed 70 db.	Equipment point	our device is with the noise capacity less that 80db.	To be amended as : "System should have minimum vibrations, and noise level should not exceed 90 db."
26. Should be USFDA or NA NA European CE approved product.	it e 61	It must have automated defrost or a heating device on frame to avoid condensation	Equipment point	It is not comply with our device.	The requirement stays unchanged.
	e 62	26. Should be USFDA or European CE approved product.	AN	NA	To be amended as : "Equipment should have USFDA or European CE certification."

Page 12 of 34

		Deep freeze	Deep freezer(-80) 700L (item at sl. no. 16)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 62	Heading "S.No:-16 Deep Freezer (- 80°C) 800 L"	NA	NA	To be amended as : "S.No:-16 Deep Freezer (-80°C) 400 L"
Point 3,page 62	Vertical model with internal capacity 800 L or more.	Equipment point	Equipment our device is with capacity of max 400L & it is suggested for better utilization of device and lesser dependency on a single unit of deep freezer.	To be amended as : "Vertical model with internal capacity 400 L or more."
Point 18,page 63	It must have automated defrost or a heating device on frame to avoid condensation	Equipment point	The same does not comply with our device.	The requirement stays unchanged.
Page 63	25. Should be USFDA or European CE approved product	NA	NA	To be amended as : "Equipment should have USFDA or European CE certification."

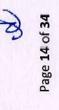
	Diele	ctric Tube se	Dielectric Tube sealer (Bench top) (item at sl. no. 17)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 12,page 63	Should be light weight not more than 6 Kg.	Equipment point	our device is also Icw weigh with 7.45kg weight. And is highly effective in its application to perform seales.	To be amended as: "Should be light weight not more than 8 Kg."
point 13,page 63	13. It should give alarm in case of detection of wet tube, leakage and sealing defect	Equipment point	Equipment it is not available with the device.	To be amended as: "Deleted"
-6	A September 1	30	Page 13 of 34 M	SAN DE

point 3, 3. The sealing time should be between	¥	NA	To be amended as:
page of 0.0-2 seconds. It should be able to			"3. The sealing time should be within
make / 0-80 seals/ hr.			2 seconds. It should be able to make
			atleast 40 seals/ hr."

		Manual Plasm	Manual Plasma Extractor (item at ≰l. no. 18)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THEF RMS	COMMITTEE RECOMMENDATION
Page 64	6. Certifications: Product certification: CE class IIA or US FDA certified.	N	NA	To be amended as: "6. It should have European CE class IIA or US FDA certification"

		Bla	Blast Freezer (item at sl. no. 29)	
Fender Page &	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 66		NA	NA	Added Para:- "Equipment should be USFDA or European CE certified"

	Bio	logical X-ray bas	Biological X-ray based blood irradiator (item at sl. no.22)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
		NA	NA	Added Para:- " Equipment should be USFDA or European CE certified"
4		£ 2	Page 14 of 34	A STATE OF THE STA





To be amended as: "The system MUST have X-ray tube output limits up to 160 kV, 26 mA and/or 3 kW."	To be amended as: "The X-ray tubes should have life span of at least 5 years."	To be amended as: "It should have self contained / external cooling system with or without requirement of external water supply."	To be amended as: "Canister volume should be able to accommodate a minimum of 3 to 6 blood bags each of 300 ml at a time."	To be amended as: "The system may include a positioning function for beam and specimen alignment."
The system MUST have X-ray tube output limits up to 160 kV, 26 mA and/or 3 kW.	The X+rey tubes should have life span of at least 5 years.	It should have self contained / external cooling system with or withou: requirement of external water supply	Canister volume should be able to accommodate a minimum of 3 to 6 blood bags each of 300 ml at a time	The system may include a positioning function for beam and specimen alignment. (Not required as the canister is in a fixed location)
M/s. Team Best Theratronics	M/s. Team Best Theratronics	M/s. Team Best Theratronics	M/s. Team Best Theratronics	M/s. Team Best Theratronics
The system MUST have X-ray tube output limits up to 220 kV, 30 mA and/or 3 kW.	The X-ray tubes should have life span of at least 5 years/5000 hours.	It must have self-contained cooling system without requirement of external water supply.	Canister volume should be able to accommodate a minimum of 6 to 8 blood bags each of 300 ml at a time	The system MUST include a positioning function for beam and specimen alignment.
Page no.67, Para 3	Page no.67, Para 4	Page no.67, Para 7	Page no.67, Para 8	Page no.67, Para 10

Page 15 of 34

. no. 23)	COMMITTEE RECOMMENDATION	The requirement stays unchanged.	Added Para:- "Equipment should be European CE or USFDA certified"
Fully Automated Random Access Chemiluminescence (item at sl. no. 23)	REPRESENTATION RECEIVED FROM THE FIRMS	All leading companies have the throughput ranging between 80-100 lests per hour. By not considering the change unknown companies having smaller throughput are more preferred as the tender is based on one bidder one complete project. Potential vulnerability of non-standard equipment gaining entry will be compromised for the setup.	All reputed manufacturers of Chemiluminiscence System are US FDA and European CE certified. It is necessary to ask for the same certificate as this is very critical equipment because the Blcod Bank will be completely dependent on the results of screening the highly critical parameters.
Itomated Ran	NAME OF THE FIRM	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd
Fully At	TENDER SPECIFICATION	The instrument should have throughput of at least 40 tests/hr.	
	Tender Page & Para	Page 69, Point 2.	Page 70

	anie Top Ce	24 Table Top Centringe (Item at St. no. 24)	
TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
18. Should be USFDA or European CE approved product.	NA	NA	To be amended as : "Equipment should have USFDA or European CE certification."
A STATE OF THE STA	36	Page 16 of 34	A Company

		Reagent Re	Reagent Refrigerator (item at sl. 10. 25)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Point 8,page 71	Independent safety thermostat to avoid negative temperatures.	Equipment Point	it covers all the interations safety parameters but this point does not comply with our device.	The requirement stays unchanged.
Point 10,page 71	Internal temperature hold over time in case of power failure should be at least 1.5 hours	Equipment Point	Not trezed.	The requirement stays unchanged.
Page 71	Page 71 16. Should be USFDA or European CE approved product.	NA	NA	To be amended as : "Equipment should have USFDA or European CE certification"

	Mici	o pipette set	icro pipette set (Manual ∈djustable) (ite n at sl. no. 26)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 72	14. Should be US FDA or European CE approved.	NA	AN	To be amended as: "Equipment should have USFDA or European CE certification."

8

Page 17 of 34

		Multi	Multichannel Pipette (item al sl. no. 27)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE HRMS	COMMITTEE RECOMMENDATION
Page 73		NA	NA	Added Para: "Equipment should have USFDA or European CE certification."

		Digital pH I	Digital pH Meter litem at sl no. 28)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page no 73	14. Should be USFDA or European CE NA approved product.	NA	NA	To be amended as: "Equipment should have USFDA or European CE certification."

TENDER SPECIFICATION

Page 18 of 34

	Fully Automat	ed Immuno-	Fully Automated Immuno-Haematology (IH) platform (item at sl. no. 30)	. no. 30)
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 77	13. Should be USFDA or European CE approved product.	NA	NA	To be amended as: "Equipment should have USFDA or European CE certification."

Blood Bank Refrigerator 300-550 L (1em at sl. no. 31)	N THE FIRM FROW "HE FIRMS COMMITTEE RECOMMENDATION	sed melt Equipment it complies with all the 31 points The requirement stays unchanged. Point except the specific functioning.
Blood Bank Refri	TENDER SPECIFICATION THE FIRE	Automatic defrosting and condensed melt Equipmer water evaporation.
	Tender Page & Para	Point A 2.9, w page 77

			91
× .	COMMITTEE RECOMMENDATION	To be amended as: "Continuous and/or Intermittent Flow Blood Cell Separator."	2
Apheresis Machine (Rem at st. no. 32)	REPRESENTATION RECEIVED FROM THE FIRMS	Our observation is to mentan intermittent flow also. Instrument must alveys be intermittent while using single needle, it should always be intermittent/continuates flow for the benefit of donor. Also the extracorporeal volume should be less than a unit of blood normally donated by any healthy donar which is less than 450 mi.	Page 19 of 34
Ap	NAME OF THE FIRM	Span Healthcare Pvt Ltd	<i>S</i>
	TENDER SPECIFICATION	Continuous Flow Blood Cell Separator.	3
	Tender Page & Para	Point 1, page 78	

zo a. 30 disposable platelet	A	"Dalatad" To be
pheresis kits should be provided		00000
with the system		

	Bio-S	Safety Cabine	Bio-Safety Cabinet (item at sl. no. 35)	
Tender Page & Para	TENDER SPECIFICATION	NAME OF THE FIRM	REPRESENTATION RECEIVED FROM THE FIRMS	COMMITTEE RECOMMENDATION
Page 82, Point 1.	Floor model, horizontal flow, well lighted, work space, low vibration and noise. Easy to maneuver due to caster wheel provision. Overall dimension of workspace should be approximately 1200mmx600mmx600mm. Class 2A type.	NA N	Ϋ́	To be amended as: "Tabletop model, well lighted, work space, low vibration and noise. Easy to maneuver due to caster wheel provision. Overall dimension of workspace should be approximately 1200mmx600mmx600mm. Class 2A type."

Electronic Analytical Balance (item at sl. no. 38)	NAME OF REPRESENTATION RECEIVED FROM THE FIRM THE FIRM COMMITTEE RECOMMENDATION	nt Equipment Transparent case not provided, but it does Point not affect the functioning of the device.	Equipment Manual calibration is dcne. The requirement stays unchanged. Point	A Page 20 of 34 M
Elect	TENDER SPECIFICATION THE F	Electronic balance with transparent Equipricase.	2. Digital display of weight and Equiprother parameters should be there.	J.
	Tender Page & Para	Point 1 ,page 83	Point 2,page 83	3



			anh laino	orner queries related to Equipment	
S No.	Item	Item Description	Name of the firm	Representation received from firms	Committee Recommendation
_	Donor couch in Donor / Bleed		Span Healthcare Pvt Ltd	7 nos specified	It is Clarified as:
	Room				 The quantity of following items are amended as below
2	Balance qty - 6 nos for Aphaeresis I ah	Aphaeresis machine qty - 7	Span Healthcare Pvt Ltd	Please clarify the disconnect	SI No.2. Blood Collection Monitor - 8 Nos SI No.3. Blood Donor Couch - 14 Nos
					II. The quantity of item SI.no 32, Aphaeresis Machine remains unchanged as 7 Nos.
3	Bio Safety Cabinet	Location -where it is proposed to be put up.	Span Healthcare Pvt Ltd	Please confirm if the beck up room will also be as per some cleanliness levels and will maintain differential pressures for operator safety.	Clarified as: It has to be as per D & C Act, (Drug and Cosmetic Act) WHO Guidelines (Design Guidelines for Blood Centres), NACO and CDISCO Guidelines.
4	Bio Safety Cabinet	Specifications in Tender say it to be Floor Model while the Equipment List says it to be Table top model.	Span Healthcare Pvt Ltd	Please clarify the disconnect	Clarified as: The technical specification of the item has been amended to 'Tabletop model'.
5	Bio Safety Cabinet	Horizontal Flow	Span Healthcare Pvt Ltd	Please clarify / re-confirm.	This point 'Horizontal Flow' stands 'Deleted'.

96 Page 21 of 34

Span Healthcare Please clarify or exhaust to be left within room or to be routed outside. This will have a bearing Cuidelines for Blood Centres). NACO and	CDISCO Guidelines.
Please clarify or exhaust to be left within room or to be routed outside. This will have a bearing	on the Lab Design Air Management.
Span Healthcare Pvt Ltd	
Type II A	
Bio Safety Cabinet	
9	

				General Queries	
S. No	Page No & Point No	Existing Point	Existing Point Name of the firm	Representation received from limns	Committee Recommendation
_	AN	N	Span Healthcare Pvt Ltd	Please clarify the point regarding £ir Conditioned services as the sama facility is provided by the Hospital than what is going to be the role of the vendor in maintanee as the facility is already given the Air Conditioning by the Hospital.	No such specific point in the tender. Hence not considered this point.
2	Ψ Z	Ą	Span Healthcare Pvt Ltd	What will happen if we have to recast some walls and floors where we have to develop the facility as per our design approved by your office? Any specific colours required to be considered for partitions / floors or walls because pastel colours are normally used in Blood Banks.	No such specific point in the tender. Hence not considered this point.
က	Page 47, Para-I, Point No.14	NA N	Span Healthcare Pvt Ltd	Please provide the details of the Pneumatic Tube System Vendor for the pneumatic work as mentioned by you for cost calculation at our end.	It is clarified as: Pneumatic system has already been ordered hence no cost is accord on Blood Bank Vendor.

St. page 22 cf 34

No such specific point in the tender. Hence not considered this point.	Clarified as: "No change considered."	Clarified as: "No change considered."	Clarified as: "No change considered."	Clarified as: "No change considered."	318
Please clarify that manufacturer Agreement Letter will be a common letter and not for every equipment because the bidder is solely responsible for the warranty period and there are many instruments which are arranged by the bidder to meet your tendered requirements and the association is limited for the institution only.	Biological X-Ray based Blood Irradiator needs to be installed only on the Ground Floor as per the availability of the space but it is not recommended for higher floors. The weight and radiation compliance prohibits the structure of the Blood bank	Warranty of the facilities like HVAC / Infection control should be with the hospiral facility supervisor and not with the vendor / bidder as the same can-rot be one.	Tender document does not mention for providing NAT facility but initial drawing and site does mention the same. If it remains in abeyance currently, later space provisions will be compromised instead of space utilization more effectively as mentioned in the tender document.	Permission to quote alternate models meeting the tender spec fications from the same manufacturer. Our observation is to keep the same open for the bidder because there are limited manufacturers who offer alternate models with same specifications and moreover it is the responsibility with the bidder to maintain high quality being quoted as single bid	St Page 23 cf 34 20
Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	20)
¥	67 NA	NA	A	WA (E)	
4 K	5 Page 67		4	8 Page 14, Clause no.16(1)	£\

				security.	
9	NA	NA	Span Healthcare Pvt Ltd	All the instruments requiring chart paper for print out; it is desired by the tenderer to provide the same by the vendor free of cost for a period of 5 years during the warranty period. This appears to be a non- conforming statement as the responsibility of the same must not be with the vendor however the vendor can supply initial 3-4 months of stock so that hospital can make purchases as per the requirement from various economical resources.	No change considered. Www

of

d

· See

Page **24** of **34**

Sie

Legg Begg

													7					
The second secon	Clarified as:	"No change considered."	,															
	lealthcare 2. Request a written clarification of the following Clarified as:	items:	a. That both intermittent and cortinuous flow	cell separators be permitted to the bidder	b. Whether all authorizations have to be from	the ORIGINAL MANUFACTURES or whether	their subsequent agreement to ensure	performance is adequate this is because many	companies will not be able to accept the	tenderers as AUTHORIZED DISTRIBUTORS in	time to submit the tencer because of their	compliance process (SPAN is fine in this	aspect across the spectrum of poducts, this is	NOT AN ISSUE for us bur we a∋ bringing it up	in any case)	c. Whether both Gel-based AND micro-plate	based technologies have been oeemed	acceptable by the committee
	Span Healthcare	Pvt Ltd																
414	NA																	
NIA.	NA NA																	
4	2																	

		N N	Room design related Queries	ries	
S 0	S Item / Lab NO. Name	Clarification	Name of the firm	Febresentation received from	Committee Recommendation
	QC Lab	No space / not earmarked in the layout provided.	Span Healthcare Pvt Ltd	Pease clarify location	Clarified as: "The design of the Blood Bank should be as per D & C Act, (Drug and Cosmetic Act) WHO Guidelines (Design Guidelines for

Page 25 of 34

到级

Blood Centres), NACO and CDISCO Guidelines. Vendors are permitted to modify existing structure, as per their required design."				Clarified as: "The design of the Blood Bank should be as per D & C Act, (Drug and Cosmetic Act) WHO Guidelines (Design Guidelines for Blood Centres), NACO and CDISCO Guidelines.
Meeting room too is merged the space is small. Further as per SGNP requirements, Ante Room & Locks, Change Rooms etc will also be required.	Ne propose adding Irradiator Room D it.	San be built by merging the 3 rooms adjacent to the issue courter. Meetings can be held on the outer periphery itself without the people / doctors having to go or bass in ite the work areas / Labs.	Please clarify. Need it to be someplace near to outside corridor as the imms from this room will go directly outside to incinerator / bioned ca waste if & as required.	Heed tt a same to be near the periphery wall as this will need dedicated outdoor units and they will need to be placed / hung outside with free access to open air.
Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Hea thcare Pvt Ltd
Too small space provided.	Small space.		Location	Location
Component Lab	NAT Lab	Meeting Room	discard Room	Cold Room
5	9	4	2	9

Page **26** of **34**

2

Si Company

		-			
7	Office Room	Location	Span Healthcare Pvt Ltd	Please confirm. Is it proposed to be Vendors are permitted near / adjacent the issue counter.	Vendors are permitted to modify existing
∞	Faculty Office	Location	Span Healthcare Pvt Ltd	Please confirm. Is it proposed to be near / adjacent the issue counter.	structure, as per their required design."
တ	Staff Common Room	Location	Span Healthcare Pvt Ltd	Please confirm. Is it proposed to be near / adjacent the issue counter.	

				Queries related	Queries related to Turnkey Works	
S no.	Pg No.	Item No.	S no. Pg No. Item No. Item Description	Name of the firm	Representation received from firms	Committee Recommendation
	86	Ann 3	turnkey works description			
-		4	Makes of HVAC items	Span Healthcare Pvt Ltd	none of the same makes AHU etc which will be used in the facility for Air management / filtration	Clarified as: "In such case, any AHU provided by the supplier will be accepted."
2	66	7	Sufficiency of Tender	Span Healthcare Pvt Ltd	Cannnot be open ended . Some battery limits have to be set for scope / quantities/ price .	Clarified as: "No change considered."
æ		O	Communication System	Span Healthcare Pvt Ltd	Requirec PA system for 9 areas including Mic/Speckers. PA system is a part of the Fire Alarm System with 1 central mic and speakers all across. If required separately with set of 1 mic and speakers in each area, please confirm.	Clarified as: "This communication system is for internal communication of staffs."

Page 27 of 34

Clarified as: "cGMP guidelines to be followed wherever and as recommended by NACO, WHO and D&C guidelines."	Amended as : "Lighting - LED 300-350 Lux"	Amended as : "toughened glass windows"	Clarified as: "No change considered."	Clarified as: "Zoning concept if any, as per D & C Act, (Drug and Cosmetic Act) WHO Guidelines (Design Guidelines for Blood Centres), NACO and CDISCO Guidelines."
Please confirm on the cleanliness levels required Further please also confirm if restricted access required to these labs. This will entail constructing set of Garmen change rooms / ante rooms and graded positive / negative pressures as required	Please =confirm as normally the clean rooms / also have a embient lighting levels of 300-350 lux at work surface ht.	All windows are sealed and double glazed with toughened glass. However, the Lab area does not have any wall exposed to outside and any light coming in will be from adjoining corridors etc. Labs do not have any curtains. We could provision for frosted also (one side) for whichever windows as confirmed by you.	mentioned about sprinklers / Hose and Pressure Pumps for Fre fighting. Fire fighting system will be for the entire building and cannot be segregated for the Blood Bank	Please da-fy on the same
Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd
cGMP Guidelines to be followed for Component Lab , NAT lab & TTI lab	Lighting - LED 500 lux	toughened glass windows with curtains	Fire fighting	Air-conditioning - Zoning Concept
10	13			41
	100			101
4	2	O	2	ھ

Page 28 of 34 (1)

			6 5			
Clarified as: "Inlet temperature of chilled water is 7 degC."	Clarified as: "Hot water is not supplied by NCI-AIIMS."	Clarified as: "AERB Approvals to be taken as applicable."	Clarified as: "Space will be provided by the institute as per requirement at an appropriate location."	Clarified as: "HVAC design, as per D & C Act, (Drug and Cosmetic Act) WHO Guidelines (Design Guidelines for Blood Centres), NACO and CDISCO Guidelines."	Clarified as: "No change considered."	Clarified as: "ETP inlet line will be provided at one point near the Blood Bank area."
Noted. Please confirm on the temperature as well.	Please confirm on the availability of the same as well.	Please clarify for which area as the same comes up for Radio pharmacy or adiation areas only	Space to keep the extra AHUs which will come up for the various areas.	Separate AHUs for different areas .	Being mentioned in tender. Proposed ocation / space.	Discard Room being talked about in sander. Also there could be some liquid wastes. Please confirm on the ETP required/ provision for the same with a separate crain line.
Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd	Span Healthcare Pvt Ltd
Chilled Water (CHW)	Hot Water (HW)	AERB approvals	AHU Location / Space		Discard Room	ЕТР
		9				
		120				
o	10	7	12	13	14	15

Page 29 of 34

(In turnkey works Annexure-3) Added Para

and conduct a detailed assessment with recard to any Civil, Electrical & HVAC changes required in Blood Bank area as per tender requirements. The bidder should quote for turnkey works only for the additional/differential Turnkey works of Blood Bank have been ex≡cuted to a large extend. The bidders are required to visit the site works required in the blood bank area to mest the tencer requirements.

identified after site visit. However, no additional turnkey work should be quoted for on account of a different Any makes and models given in the tender are to be used by the bidder while executing turnkey works make and model already used at the existing Blood Bank site.

	ed from Committee Recommendation	The following para from MAF stands 'Deleted'. TO SOURCE TO STALL TO SOURCE	
Commercia Queries	Representation received from firms	AUTHORISATION- TENDER CONTAINS EQUIPMENTS WHICH ARE NOT MANLEACTURED BY ANY SINGLE CON-NAY AND HAS TO SOURCE FRCY MANY SIPPLIERS. AUTHORISATION FOR ALL EQUIPMENTS. ARE NOT POSSIBLE AND ALSO RESTRICS NOT TO GET BEST EQUIPMENTS. AUTHORISATION MAY BE APPLICAELE TO MAJOR EQUIPMENTS. AMINIMUM WORK ORDER EQUIOMENTS ONLY. AUTHORISATION OF AUTHORISED DISTRIB JTOR DF MANUFACTURERE SHALL ALSO	RF ZI CWED
Com	Name of the firm	SR Biohealth	
	Existing Point	Bidder has quoted for goods manufactured by other manufacturer(s) without the required Manufacturer's Authorization Form as per Section XIII.	(
	Point No	27.4 (V)	The second second
	Pag e No	6	
	S S		

Page 30 cf 34

Clarified as: Part supply shall not be entertained.	Clarified as: "No change considered."	Clarified as: "No change considered."
SINCE THERE ARE NJMBER OF EQUIPMENTS, 75% PAYMENT OF SUPPLIED EQUIPMENTS SHALL BE RELEASED IN FARTS AS AND WHEN EQUIPMENTS SUPPLIED.	Page Number-36- Point 21.1-(A): Payment TerrsTender document terms says that payment will be disbursed as: 75% against submission of 3RC and 25% against final acceptance of the delivery. Observation is the same will be applicable for site renovation or it is against the instrument which will be supplied after the facility is completed.	PAYMENT- B4LANCE PAYMENT OF 25% SHALL BE RELEASED AFTER SUCCESSFJL INSTALLATION AND NOT LINKED TO TRIAL BECAUSE BLOOD BANK HAS LICENSING FORMALITIES WHICH ARE FART OF HOSPITAL RESPONSIBLITY AND ARE BEYOND OUT CONTEOL.
SR Biohealth	Span Healthcare Pvt Ltd	SR Biohealth
On delivery: 75% payment of the contract price shall be paid on receipt of goods in good condition and upon the submission of the	(i) Original copies of supplier's invoice showing contract number, goods description, quantity, packing list, unit price and total amount;	Balance 25% payment would be made against "Installation and Acceptance Certificate" of goods to be issued by the End User subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or
24.7	POINT (A	21.1 POINT (B)
	36	37
	2	က

Page 31 of 34 A

A.

	To be amended as 'Blood Bag Refrigerator' instead of 'Blast Freezer'	Amended as: PERFORMANCE STATEMENT (For the period of last seven years)	Being considered	Clarified as: "No change considered."
	WORK /SUPPLY CF BLAST FREEZER- BLAST FREEZER IS NOT A ROUTINE PRODUCT WHICH IS NOT TAKEN BY MOST BLOOD BANKS HENCE SHALL NOT BE PART OF QUALIFICATION OF BIDDER.	CONSIDER THE PERIOD OF LAST 7 YEARS INSTEAD OF 5 YEARS (EXTEND THE _AST DATE OF SUBMISSION TO 30TH SEPTEMBER 2018 AT LEAST	SHOULD BE SEPARATE TENDER AS EQUIPMENT COMPANIES ARE " NOT EXPERT IN THIS.
	SR Biohealth	SR Biohealth	SR Biohealth	SR Biohealth
otherwise. "Installation and Acceptance Certificate" need to be issued by the concerned End User after installation, commissioning, testing and successful trial run (if applicable).	Blast freezer- 1 (one) no.	PERFORMANCE STATEMENT (For the period of last five years)	Last date of submission 14.09.2018	CIVIL/ELECTRICAL/TUR N KEY WORK AS PER ANNEXURE 3
	Point 3.d	Page 122, PROFOR MA 'A'	Point 1	
	121	122	3	
	4	လ	9	7

2

Page **32** of **34**

A Celebration of the Celebration

Clarified as: "Yearwise price format for consumables shall be made available in Pricebid format."	Coep B
1 Require that the tenderers provide arnual prices for each item quoted. NCI could provide annual volumes in acvance, or consistently use the same volume for the evaluation of ALL the vendors (the formula would be NCI will provice annual volumes of disposables MULTIPLY it by the proceed for each year - say Aprillowarch for ten consecutive years for each of the products for each of the tenderers 2. Evaluate the entire project based on: a. Infrastructure and build-out of the blood bank b. Cost of the aquipment bid for the set-up c. Cost of the disposables over the ten years in constant rupee terms 3. However if we are all evaluated on the The Total of the being acceptable, from the winning tenderer	Page 33 of 34
Span Healthcare Pvt Ltd	ar a
1. The current format of the tender requires that the prices be frozen in INR for the entire period. While this may be for creating a clear reasoning from a budgetary process, it will create a lot of pressure on the tenderer because: a. All tendered prices would have to be based on the forecasted USD over a ten (10) year period. Since none of the tenderers are experts in FX forecasting, this will mean the prices will not be reflective of anything but a wild guesss b. When this is combined with the stated intent of the tender management team that NCI reserves the right to purchase disposables quoted by the tenderer (which is then a part of the overall evaluation of the tender), this will cause the tender to have no control over the business – which cannot and should not be the intent of the tender	
	0
· · · · · · · · · · · · · · · · · · ·	

	1. Each component supplied should have a value assessed to it. When it is delivered, 75% is released and when it is installed 25% is released – for that specific component 2. Break out the supplies into segments (BOQ) – Collection, Separation, Screening, Storage, Processing etc., with payments for each segment made based on 75% upon delivery enc 25% on installation 3. Gracuate the payments into 75% (Delivery), 15% (Installed) with 10% hed over until the ENTIRE PROLECT EQUIPMENT is delivered AND installed. The last one ensures that there is significant money at stake for the completion – but the cost of investmen: required on the Tenderer fails because of working capital	Clarified as: "No change considered."
Span Healthcare Pvf Ltd	Span Healthcare Pvf Ltd	
		iare.

Page 34 of 34