

The DIRCETROATE OF ROYAL MEDICAL SERVICES THE INSTITUE OF BIOMEDICAL TECHNOLOGY Oncology Centre/ Annex 1. Stem Cell Lab Unit



Item 1		ell Lab Unit	

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

	Product Details
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
The country where the manufacturer is ba	ased
Delivery time	
Full warranty period	
FDA clearance OR CE Mark	

	Minimum Requirements	Compliance (Y/N), Brochure Notes Page No.
*The la	test highest-end model of the required range.	
	1. System and Design	
1	Turnkey project (construction works, electrical power supply, uninterrupted power supply UPS, water supply, RO system, waste and drain system, HVAC system and etc.) as annex2	
2	Establishing a well-functioning laboratory for the hematopoietic stem cells transplantation	
3	A well-planned, organized, and properly equipped laboratory supports research; and treatment activities by increasing efficiency and reducing lost time and wasted resources.	



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	Minimum Requirements	Compliance (Y/N), Brochure Notes Page No.
4	Proper planning of laboratory operations and proper design of the physical layout of the stem cell laboratory so that it meets the scope of planned operations for long-term returns in operational efficiency and effectiveness.	
5	designing a developed laboratory from the open area must consider the equipment, operators, and type of activities to be performed in order to achieve the best design	
6	Using a modular design, allows the laboratory to be expanded as needed by adding additional tissue culture modules	
7	Provide two designs for the system fit with the site	
8	Optimal utilization of space biggest workflow area and smallest dead area	
	2. Equipment's	
*	This section lists the minimal equipment required for the basic culture and characterization of Stem Cell Lab.	
*	All tools, equipment, facilities and etc. not listed and necessary for the system to operate effectively and completely, must be provided, and otherwise, the contractor is obligated to provide them free of charge.	
*	All tools, equipment, facilities and etc. must be compatible with high standard stem cell lab	
2.1	Basic equipment's	
1	Class II,A2 Biosafety Cabinet (BSC) Qty 1	
2	Laboratory refrigerator with deep freezer Qty 1	i i i i i i i i i i i i i i i i i i i
3	Micropipettes 2, 20, 200, and 1,000 μL Qty 1 each	
4	Vacuum flask/aspiration device. Qty 1	
5	Water bath (37°C). Qty 1	#\$\$*\;\;\;\;\;\;\;\;\;\;\;\;\;\;\;\;\;\;\
6	Orbital shaker Qty 1	
7	Tube stripper Qty 1	
8	Blood bag refrigerated centrifuge Qty 1	





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	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
	star hotel on full board basis) and any extra costs.		
2	For items where user training courses for the offered item are usually conducted abroad, offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for at least three operators; all costs inclusive, air tickets, boarding, commuting, accommodation (minimum 3-star hotel on full board basis)		
	and any extra costs		
3	The period of the training courses must be according to the manufacturer's program excluding traveling days and must be stated clearly in the technical offer.		
	Training Programs must conform to the following standards:		
	 User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive maintenance and calibration. 		
	2. Service training must comprise: theory, understanding, and use of service manual(s), calibration, preventive maintenance procedure, and practical troubleshooting and repair exercises, and must be conducted by		
4	professional instructors employed or authorized by the system manufacturer.		
	3. Service training must be conducted on a system of identical make, model, and configuration to that purchased by DRMS, and designated by the		
	manufacturer or the local agent for training purposes. 4. Certificates must be endorsed and officially sealed by the system manufacturer, legally empowering trainees		
	to engage in user and service activities according to operation and service manual(s).	1	
5	Where applicable, offers must include on-site user and service training.	;	



TORDAN ARMED FORCES



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	Minimum Requirements	Compliance (Y/N), Notes	Brochures Page No.
9	Inverted microscope with intermediate and high magnification		
2.2	Separation Equipment's		
1	FDA or CE approved CD34 selection and t-cell deplation device with high purity not less than 85% Qty 1		
2.3	Cryopreservation Equipment's		
1	Smart max device for cooling and mixing Qty 1		
2	Controlled rate freezer Racks for tubes and canister Qty 1		
3	Liquid nitrogen supplier tank for controlled rate freezer Qty 1		
4	Tank for 250-750 ml samples ,capacity not less than 300bags Qty 1		
5	Dry shipper Qty I		
6	Monitoring system Qty 1		
7	Bags sealer Qty I		
8	Automated and rechargeable pipette aid Qty 1		
	3. Support	· · · · · · · · · · · · · · · · · · ·	
1	Certified local application specialist (The number of the specialist team, certifications, Experiences and etc.)		
2	Certified local service specialist (The number of the specialist team, certifications, Experiences and etc.)		
3	External support (team support time, spare part support time, hotline support, link support and etc.)		
4	Periodic preventive maintenance schedule (PPM)		
5	Reference centers in the Middle East and North Africa (MENA)		
	4. Training		
1	For items where service training courses for the offered system are usually conducted abroad, offers must include a certified service training program at a reputable center abroad recognized by the manufacturer for at least two biomedical engineer or biomedical technician; all costs inclusive, air tickets, boarding, commuting, accommodation (minimum 3-		



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	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
	5. Pricing		
1	All components of the system must be priced separately.		
2	Any reagents, operating kits, calibrations, controls, accessories, and consumable items necessary to operate the offered system for 60 patients yearly must be clearly identified and priced separately. Prices fixed for a period of five years from the date of installation, any essential item not listed will be considered free of charge. Start-up kit for 10 cases excluding cases that need cell selection process		
3	Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation, and these prices will be taken by consideration of the comparison (lease contract).		

Annex 1:existing equipment :(No need)

	Equipment's	Qty	
1	CO2 incubator	1	
2	Biosafety Cabinet class II	1	
3	Centrifuge	1	
4	Balance	1	
5	Light Microscope	1	
6	Tube Sealer	1	
7	Vortex	1	
8	Hematology analyzer	1	
9	Blood Donor Chair	1	
10	Donation Bed	1	
11	Plasma Extractor 1		





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الاعمال الانشائية :Annex 2

- 1- فك الاسقف الموجودة حاليا مع الدكت والاناره
- 2- اعادة تاهيل الدكت للهواء بما يتناسب مع طبيعة الغرفة والعمل المرجو منها يحيث تحقق درجة حرارة في غرفة المختبر من 19-25م
 - 3- توريد و تركيب اسقف الجبسن بورد
- 4- توريد وتركيب مداخل الهواء (terminal HEPA filter with box) عدد 7 و (treturn) عدد المطلوبة class c
 - i. Number of air change 30AC/Hr.
 - ii. Differential pressure >10 Pa
 - iii. Temperature 19-25
 - 5- تركيب وتوريد وحدة هواء لا تقل عن 4 طن بحيث تكون نسبة Fresh Air من 15-20%
 - 6- دهان ايبوكسى للارضيات self-leveling بسمك 2-1.5 ملم
 - 7- دهان ايبوكسى للجدران والاسقف
 - 8- تركيب وحدات انارة IP55 LED
 - 9- تركيب 3 ابواب معدنية قياس 90*210
 - 10-تركيب قاطع سيكوريت سمك 10ملم مع فتحة Pass Box
 - 11- تركيب نظام انترلوك لبابين
 - 12-توريد وتركيب Stainless Steel Pass Box قياس 60*40*60 سم مع
 - 13-تركيب مروحة exhaust fan لتحقيق اتجاه حركة الهواء مع تركيب وحدة قياس فرق الضغظ
 - 2 عدد 2 قياس 1.5*60 عبم عدد 2 Stainless Steel Stepover توريد وتركيب
 - O2 sensors في منطقة عمل N2- تركيب
 - 16- اعمال الالكتروميكانيك
 - 17- اغلاق النوافذ الخارجية بالواح جبسن بورد
 - 18- عمل قواطع غرفة 2.5*2م للغيار و غرفة انترلوك 1.5 *2م
 - 19- هدم وفتح 3 ابواب واغلاق باب واحد



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SPECIAL TERMS

- Offers not complying with any of the <u>special terms or the technical specifications</u> shall be considered non-conforming with tender requirements.
- Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.
- 1. All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.
- 2. Required certificates:
- 2.1 For equipment of US origin, a copy of a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.
- 2.2 For equipment of other origins, a copy of either a CE certificate with the relevant CE number (MDD)/TÜV/BSI/UL OR a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.
- 2.3 Only for class I medical equipment, submission of a copy of the Declaration of Conformity certificate (MDD) for the offered model shall be accepted.
- 2.4 With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent / distributor for the offered item.
- 2.5 In all of the above cases (except 2.4) certificates must be formally endorsed by JFDA.
- 3. Country of origin:
- i. The country of origin of the main part (s) of the system must be one of the following:

 "USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France,

 Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia & Czech Republic.





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- ii. Accessories and consumables (as determined by the purchasing committee) may be manufactured in other countries and/or by different manufacturers.
- iii. All offered items must be approved for sale in the same country of origin.
- iv. Vendors must specify the origin of <u>all</u> offered items and accessories in the technical offer.
- v. Equipment manufactured by reputable companies based in any of the countries mentioned in (3.1) will be taken into consideration regardless of the manufacturing site only:
- a. <u>If</u> they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorized body must be included in the offer.

 OR
- b. If they are approved for sale in at least three of the countries mentioned in (3.1) (an original and officially endorsed free-sale certificate from an authorized body in those countries must be included in the offer).
- vi. Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.
- 4. Warranty:
- i. Offers must include a full warranty including spare parts and labor for a period of a minimum of 24 months from the date of installation.
- ii. If at any time during the warranty period the item becomes inoperative due to a technical fault the item must then be repaired by the supplier /local agent within a period of fourteen days from written notification, otherwise the supplier must replace the item with a new identical functioning one and will endure a penalty determined by the Royal Medical Services for each day of the downtime of the system. In case the item was replaced by a new one, the warranty period mentioned in (4.1.) above will start from the installation and commissioning date of the new item.
- 5. One set of the operation manual(s) and one set of the service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.
- 6. Where applicable, pre-installation shall be the sole responsibility of the supplier. Preinstallation shall include removal of old system(s), any civil work, electrical work or site

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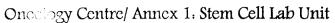
modification(s) necessary to accommodate the new system(s) according to manufacturers' specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).

- 7. Power requirements: where applicable either single-phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.
- 8. Technical offers must include clear original technical brochures/catalogs for all offered items.
- 9. Offers must include fully detailed technical offers and compliance sheets as a soft copy (
 either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact
 model/catalog number and country of origin of the offered item(s), full technical
 description/specifications and any accessories or options included in the offer.
- 10. Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a <u>Yes or NO</u> response to each point in the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.
- 11. Accessories and consumables:
- i. Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.
- ii. Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft conv (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, any expential item not listed will be considered free of charge.
- iii. Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- iv. Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free p-charge basis.
- 12. Spare Parts:



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- i. Technical offers must include a comprehensive and priced spare parts list as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any control item not listed will be considered free of charge.
- ii. Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- 13. Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years storing from the date of installation and commissioning.
- 14. Tender Awar . . .
- i. For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and it's' running cost (Total Cost of Ownership) over a period of seven years from the date of installation and commissioning. Only offers with the homest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.
- ii. Running cast reludes the value of consumables, accessories needed to operate the system over the same period well as the cost of any service contract (where applicable).
- **15.** For PC/Lapury—used systems:
- i. Complete reversion medium (CD/DVD/etc.) of the operating system and the application software must be sured.
- ii. Where locally splied computers or laptops are offered, only computers/laptops from

 Apple, hp/Compan. 1990 wo, Dell, Fujitsu or Toshiba will be accepted, offered models must be the

 latest available version upon delivery.
- iii. Where love West applied printers are offered only the following types and brands are accepted: IIP, 843 848, CKI, CANON, EPSON.
- 16. Pricing mass and de services of sale, shipment, transportation, delivery from port to the site or to Main Mass and tell and equipment into service.



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17.	Custom clearer	of goods shall be the responsibility of the Jordanian Armed Forces
(JA	F), however, sup	s shall bear all costs incurred by handling charges and any demurrage
cha	rges or extra expens	an incurred by the port's corporation (including expenses caused by delay
in p	resenting the need	ry shipment documents for either clearing or transporting the goods to
the	required location	entioned in the final order, delivery note-issuing charges, unloading
cha	rges, local shipping	carges, etc.). The supplier is also responsible for providing all relevant
shij	pping documents.	with the delivery order(s).

- 18. DRMS has the Whit to increase or decrease the awarded quantities by a percentage not exceeding 30% after the includer notification with the same prices, terms and conditions of the original contract n_i and n_i request and approval of the awarded party.
- 19. The supplier of furnish DRMS with a guarantee stamped and legalized by the Notary

 Public equals to (11) of the total value of the awarded equipment valid for twelve months from
 the date of final accessorice of the equipment by DRMS.

20. Training:

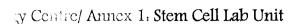
- i. For items with the provided training courses for the offered system are usually conducted abroad, offers which is the according service training program at a reputable center abroad recognized by the mass of these for at least one biomedical engineer or biomedical technician; all costs inclusive, air to a cost, commuting, accommodation (minimum 3-star hotel on full board basis) and any to a costs.
- ii. For items velocities and contrasts for the offered item are usually conducted abroad,

 offers must include a lifect of greator training program at a reputable center abroad recognized

 by the manufactives at lateral are operator; all costs inclusive, air tickets, boarding, commuting,

 accommodation (1) as Decreatories afull board basis) and any extra costs.
- iii. The period of the raining courses must be according to the manufacturer's program excluding traveling to the manufacturer in the technical offer.
- iv. Training the second conform to the following standards:

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User training must i. operation of the equi:

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prise understanding and use of operation manual(s), correct and safe ent, as well as user preventive maintenance and calibration.

Service training me ii. calibration, prevention and must be conducted manufacturer.

comprise: theory, understanding, and use of service manual(s), sintenance procedure, and practical troubleshooting and repair exercises, professional instructors employed or authorized by the system

iii. purposes.

Service training which conducted on a system of identical make, model, and configuration to that purchased by 1985 A, and designated by the manufacturer or the local agent for training

Certificates must be iv. empowering trainer manual(s).

v.

Arrest and officially scaled by the system manufacturer, legally resigning for every and service activities according to operation and service

Where applied to offers must include on-site user and service training.

21. For offers submitted in Jordanian Dinars, Payment will be either by wive Hansper or by cheque after Final acceptance of goods of my other way of Payment will be rejected.