

# ***ANNEX II + III: TECHNICAL SPECIFICATIONS + TECHNICAL OFFER***

**Contract title: Supply of equipment for relevant institutions within the SoHo System in Serbia**

**p 1 /...**

**Publication reference: < NEAR/BEG/2021/EA-OP/0180>**

**Columns 1-2 should be completed by the contracting authority**

**Columns 3-4 should be completed by the tenderer**

**Column 5 is reserved for the evaluation committee**

Annex III - the contractor's technical offer

The tenderers are requested to complete the template on the next pages:

- Column 2 is completed by the contracting authority shows the required specifications (not to be modified by the tenderer),
- Column 3 is to be filled in by the tenderer and must detail what is offered (for example the words ‘compliant’ or ‘yes’ are not sufficient)
- Column 4 allows the tenderer to make comments on its proposed supply and to make eventual references to the documentation

The eventual documentation supplied should clearly indicate (highlight, mark) the models offered and the options included, if any, so that the evaluators can see the exact configuration. Offers that do not permit to identify precisely the models and the specifications may be rejected by the evaluation committee.

The offer must be clear enough to allow the evaluators to make an easy comparison between the requested specifications and the offered specifications.

**Unless otherwise specified, the requirements in these Technical Specifications are presented as a minimum standard which the offered goods must meet.**

## LOT 2 - Support Laboratory Equipment for Transfusion and Transplantation Establishment

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
2.1	<b>AUTOMATED SYSTEM FOR BLOOD DONOR INFECTIOUS DISEASES SCREENING (throughput min. 400 mandatory tests/hour)</b>  <b>Quantity 1</b>			
	<ul style="list-style-type: none"> <li>Automated immunoassay analyser for donor screening, with assays mandatory for blood donor screening (HBV, HIV, HCV, Syphilis)</li> <li>Chemiluminescent technology</li> <li>Sample type: serum, plasma</li> <li>Specificity for mandatory donor screening assays in Serbia- min. 99,85%</li> <li>Full traceability for all reagents, controls, calibrators, solutions, consumables and operators</li> <li>Throughput for mandatory assays for donor screening:</li> <li>400 tests per hour per one unit</li> <li>Sample load up capacity:</li> <li>400 samples per unit</li> <li>Reagent kit size:</li> <li>100 tests/cartridge</li> <li>Possibility to run urgent samples- STAT /priority positions</li> <li>Time for urgent sample testing for all</li> </ul>	<p><i>Manufacturer's name:</i></p> <p><i>Product type, model:</i></p> <p><i>Specifications:</i></p>		

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	<p>mandatory donor screening assays- <math>\leq 1</math> h</p> <ul style="list-style-type: none"> <li>• Possibility to load and unload supplies and reagents on system without stopping or pausing the system.</li> <li>• Possibility to use different type of blood collection sample tubes on same sample carriers</li> <li>• Automated barcode reading from sample in rack, without positioning sample bar code in specific position</li> <li>• All reagents, controls, calibrators labelled with barcode and/or RFID</li> <li>• Refrigerated reagent carousel</li> <li>• Automated retesting function (in duplicate)</li> <li>• All reagents, controls, calibrators ready to use</li> <li>• Possibility for automated controls and calibration ordering</li> <li>• Sample clot and bubble detection</li> <li>• Technology to minimize carryover</li> <li>• Sample result storage on analyser <math>\geq 100.000</math></li> <li>• Alert (sound and/or visual) that can provide urgent notice to staff</li> <li>• Analyser readiness 24/7</li> <li>• Predictive technology to secure the potential to reduce downtime, prevent workflow interruptions and secure increase uptime</li> </ul>			

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	<ul style="list-style-type: none"> <li>Bidirectional host interface (HL7 and/or ASTM)</li> </ul>			
2.2	<b>PORTABLE RAPID HEMOGLOBIN SCREENING DEVICE FOR BLOOD DONOR</b>  <b>Quantity: 15</b>			
	<ul style="list-style-type: none"> <li>A device for quantitative determination of full blood hemoglobin</li> <li>Determination of hemoglobin by full-blood absorbance method at the isochoric point Hb / HbO<sub>2</sub></li> <li>The original hemoglobin calibration is required without the need for additional calibration</li> <li>Measurement of blood samples: capillary, venous or arterial blood</li> <li>Measurement range: 1.0–25.6 g/dL (10–256 g/L, 0.62–15.9 mmol/L)</li> <li>Measurement time: maximum 1 minute</li> <li>Sample volume: up to 10 microliters</li> <li>Analyzer storage temperature: 0 – 50°C</li> <li>Operating temperature: 10 - 35°C</li> <li>Storage temperature: 0 – 50°C</li> <li>Weight: up to 700g (device with all its accessories, compartment and batteries)</li> <li>Power supply with AC Adapter and/or USB and/or Lithium-Ion battery</li> <li>Integrated barcode reader or possibility to connect</li> </ul>			

1. Item Number	2. Specifications Required	3. Specifications Offered	4. Notes, remarks, ref to documentation	5. Evaluation Committee's notes
	<ul style="list-style-type: none"> <li>Quality control testing: Built-in self-test, optional liquid controls</li> <li>Interface: possibility for data transfer to a PC; Possibility of subsequent transfer of data to the Blood Bank program.</li> <li>Export data in an ASCII file, CSV file format for communication with any standard blood bank program.</li> </ul>			
2.3	<b>PLATELET INCUBATOR WITH AGITATOR</b>  <b>Quantity: 9</b>			
	<ul style="list-style-type: none"> <li>Table Top or Floor model Incubator</li> <li>Capacity for 192 platelet bags</li> <li>Temperature range: +20 °C to +35°C</li> <li>Temperature variation at 22 °C ± 1°C</li> <li>Auto-Stop/Start for ensuring continuous agitation with automatic stop when doors are opened</li> <li>Doors with the key lock option</li> <li>Microprocessor temperature controller with built-in alarm/monitor</li> <li>Single stainless steel monitoring probe</li> <li>Bacteria-resistant, powder-coated or stainless steel interior, exterior, and door handles</li> <li>, Tempered glass door</li> <li>LCD or LED digital display</li> <li>Manual alarm test</li> <li>Controller lockout</li> </ul>			

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	<ul style="list-style-type: none"> <li>• Dry contact alarm connection</li> <li>• Audible and visual alarms of low and high temperature</li> <li>• Fixed alarm volume and type</li> <li>• Power failure alarm</li> <li>• Roll out drawers for easy access to the agitators inside</li> <li>• Two shelves for two agitators</li> <li>• Battery back-up in case of power failure</li> <li>• 7-Days thermal temperature graphic recorder</li> <li>• Two platelet agitators with minimum capacity of 96 platelet bags each</li> <li>• Removable drawers perforated or grids.</li> <li>• Label holders</li> <li>•</li> </ul>			
2.4	<b>BLOOD CELL COUNTER</b>  <b>Quantity: 4</b>			
	<ul style="list-style-type: none"> <li>• Automated hematology analyzer</li> <li>• Flow/fluorescent cytometry technology</li> <li>• Leukocyte differential count, reticulocyte count and body fluids analysis for IVD use in clinical laboratories</li> <li>• Sample volume in manual mode: <math>\leq 120\mu\text{L}</math></li> <li>• Body Fluid results: WBC-BF, RBC-BF, MN#/%, PMN #/%</li> <li>• Results: WBC, RBC, HGB, HCT, MCV, MCHC, , RDW, , PLT</li> <li>• Differential results (No and %): NEUT,</li> </ul>			

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	<p>LYMPH, MONO, EOS, BASO</p> <ul style="list-style-type: none"> <li>• Platelet results: PLT, MPV, PDW, PCT</li> <li>• Reticulocyte results: 4 parameters, morphology differentiation of NRBC within RBC population</li> <li>• Throughput: CBC/DIFF 120 samples/hour</li> <li>• PC: Ethernet connection</li> <li>• Software: MS Windows or equivalent compatible operational system</li> <li>• LCD display, screen 19"</li> <li>• Data management capacity for archiving 10 000 samples (including scatter gram and histogram)</li> <li>• Printer: ink jet color printer with networking option</li> <li>• Bar code reader option, equipped with compatible software</li> </ul>			

## Installation and other services for Lot No2

Specifications Required		Specifications Offered	Notes, remarks, ref to documentation	Evaluation Committee's notes YES/NO
<b>Installation</b>	Installation performed by contractor or authorised service provider; All the equipment must include all necessary parts and standards for its installation			
<b>Testing</b>	Testing of all basic function on a set of producer's standard samples commonly used for the corresponding instrument.			
<b>Education</b>	Theoretical education about basic functions of instrument, software and maintenance in Serbian or interpretation should be provided for 2 doctors and 3 technicians during 5 days performed by a manufacturer's licensed instructor no sooner than 1 month before installation.			
<b>Start-up Training</b>	Practical start-up training for 5 end users after installation and testing in all basic functions of the instrument on set of standard samples, commonly used for the corresponding instrument . Duration of training 1 day.			
<b>Manuals</b>	Instruction manual in Serbian			
<b>Certificates and documentation</b>	CE mark; Certificates conform to standards as specified in EU Directive 2002/98/EC; GMP (Good Manufacturing Practice)documentation; all in English language.			



Specifications Required		Specifications Offered	Notes, remarks, ref to documentation	Evaluation Committee's notes YES/NO
Warranty	365 days after provisional acceptance in accordance with the conditions laid down in Article 32 of the General Conditions.			

### **Annex II + III: Technical Specifications + Technical Offer - part II – Place of delivery/Acceptance**

Item	ARTICLE	Place of acceptance
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Item 1-4	All items	<p>EQUIPMENT FOR TRANSFUSION ESTABLISHMENT</p> <p><i>For the Transfusion Establishment, exact number the place of acceptances is 8:</i></p> <p><i>1. Blood Transfusion Institute of Serbia, Sveti Sava str.39, 11000 Belgrade;</i></p> <p><i>2. Blood Transfusion Institute Nis, Bulevar Dr Zorana Djindjica str.48, 18000 Nis;</i></p> <p><i>3. Institute for Blood Transfusion of Vojvodina, Hajduk Veljka str. 9a, 21000 Novi Sad;</i></p> <p><i>4. Institute for Blood Transfusion Kragujevac, Zmaj Jovina str. 30, 34000 Kragujevac;</i></p> <p><i>5. General Hospital Užice, Miloša Obrenovića str.17, 31000 Užice;</i></p> <p><i>6. General Hospital Subotica, Izvorska str. 3, 24000 Subotica;</i></p> <p><i>7. KBC Zemun, Vukova str. 9, 11080 Zemun;</i></p> <p><i>8. Military Medical Academy, Crnotravska str. 17, 11000 Belgrade.</i></p>
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