



Based on the Assistance Measure to Strengthen the Capacities of the Balkan Medical Task Force (BMTF) financed by the European Peace Facility through the ITF Enhancing Human Security (ITF), ITF would like to announce the following:

INVITATION NOTICE FOR SUBMISSION OF OFFERS FOR THE BIOCHEMICAL LAB -I-STAT/AMENDED

1. Publication reference:

Provision of the Biochemical Lab -I-stat

2. Procedure:

Participation is open on equal terms to private business entities (companies)

3. Contracting Authority:

ITF Enhancing Human Security (ITF)

4. Description of the Procurement of Equipment:

Please find detailed specification of the *Biochemical Lab -I-stat* in Annex 1

5. Eligibility and rules of origin

Participation is open on equal terms to private business entities (companies).

Offeror shall not be considered eligible if: (Ethics Clauses)

1. Any attempt by a candidate or offer to obtain confidential information, enter into unlawful agreements with competitors or influence the Commission or the Contracting Authority during the process of examining, clarifying, evaluating, and comparing offers will lead to the rejection of his candidacy or offer and may result in administrative penalties.
2. Without the Contracting Authority's prior written authorization, a Contractor and his staff or any other company with which the Contractor is associated or linked may not, even on an ancillary or subcontracting basis, perform other services, carry out works or supply equipment for the project. This prohibition also applies to any other projects that could, owing to the nature of the contract, give rise to a conflict of interest on the part of the Contractor.
3. When putting forward a candidacy or offer, the candidate or Offeror must declare that he is affected by no potential conflict of interest, and that he has no particular link with other Offerors or parties involved in the project. Should such a situation arise during performance of the contract, the Contractor must immediately inform the Contracting Authority.
4. The Contractor must at all times act honourably and impartially in accordance with the code of conduct of his profession. He must refrain from making public statements about the project or services without the Contracting Authority's prior approval. He may not commit the Contracting Authority in any way without its prior written consent.
5. For the duration of the contract, the Contractor and his staff must respect human rights and undertake not to violate the political, cultural, and religious mores of the recipient state.
6. The Contractor may accept no payment connected with the contract other than that provided for therein. The Contractor and his staff must not exercise any activity or receive any advantage inconsistent with their obligations to the Contracting Authority.
7. The Contractor shall refrain from any relationship likely to compromise his independence or that of his staff. If the Contractor ceases to be independent, the Contracting Authority may, regardless of injury, terminate the contract without further notice and without the Contractor having any claim to compensation.

8. The Contracting authority reserves the right to suspend or cancel project financing if corrupt practices of any kind are discovered at any stage of the award process. For the purposes of this provision, "corrupt practices" are the offer of a bribe, gift, gratuity, or commission to any person as an inducement or reward for performing or refraining from any act relating to the award of a contract or implementation of a contract already concluded with the Contracting Authority.

6. General terms

- **Delivery and training must be completed at the latest by November 30, 2024.**
- The offer shall be signed by a person or persons authorized to sign on behalf of the offeror using the Form provided in Annex II.
- The currency of donation is the Euro; therefore, prices of the offers should be expressed in EUR and VAT should be stated separately.
- The Balkan Medical Task Force – Participating Nation Serbia and N. Macedonia – are the recipient in this Invitation notice for submission of offers. The delivery location is:

**Centre of Medical Services, Military Healthcare Department,
Ministry of Defence of Republic of Serbia
2 Raška street, 1100 Belgrade,
Republic of Serbia**

AND

**Logistic Base of the AF of North Macedonia,
Boulevard Nikola Karev b.b., 1000 Skopje
Republic of North Macedonia**

- The Contracting Authority reserves the right to the final selection based on the funds available for the procurement and other specific requirements.
- Offeror in the offered technical specification must indicate a warranty deadline and potential options for extended warranty.
- Joint Venture, Consortium or Association or any other form of cooperation is not eligible for this contract.
- The Offer and all correspondence and documents related to this procedure exchanged by the Offeror and the Contracting Authority shall be written in English, which is the language of this procedure. Also, all correspondence for payments including pro-forma invoices, and final payment certificates shall be sent to the Contracting Authority in English or local language with English translation.
- This Invitation notice for submission of offers is governed by the laws of the Republic of Slovenia.
- The Offeror shall bear all costs associated with the preparation and submission of his Offer. In no case the Contracting Authority will be responsible or liable for such costs, regardless of the process or results of the Invitation notice for submission of offers procedure.
- The Offeror shall organize and deliver the goods in line with INCOTERMS - DDP (Delivered Duty Paid) to the above stated delivery location and recipient.

- Offeror shall quote all components of the Cost-Breakdown Bill of Quantities exclusive of taxes, customs and import duties. Any item without a price shall not be paid.
- Donor's specific conditions and requirements must be taken into consideration and fulfilled at all related administrative procedures.
- The Contracting Authority reserves the right to accept or reject any offer and/or cancel the whole process of offer selection and reject all offers. The Contracting Authority may do so at any time before informing the selected without any liability to the Offerors. The ITF reserves the right to initiate a new offer selection procedure.

7. The offer must include all the following information:

1. Form of Offer (Annex 2)
2. Affidavit Statement (Annex 3)
3. Extract from the register of companies
4. A Certificate of solvency (Bank statement) from the bank in which the transaction account is opened, which shall indicate that the current account was not blocked in the last 6 months on any grounds.
5. Statement on Non-Association (Annex 4)
6. Reference List (supported by relevant official documentation / confirmations) - list all the contracts/projects for the last twenty-four (24) months completed by your company, stating contract value for each, and the month and year completed.

8. Quality Control and Equipment Handover

The quality control and equipment handover will be agreed and coordinated between the selected Offeror, ITF, and end recipient Republic of Serbia and Republic of North Macedonia, Participating Nation of Balkan Medical Task Force upon arrival of equipment to the end destination.

9. Evaluation of Offers

Acceptable offers will be evaluated by the Contracting Authority applying the criteria of technical suitability, lowest price, and delivery deadline.

10. POC's

Please direct technical questions (if any) regarding this Invitation to:
Mr. Iztok Hočevar, Email: Iztok.hocevar@itf.si

Please direct administrative/procedural questions (if any) regarding this Invitation to:
Mr Iztok Hočevar, Project Manager
E-mail: iztok.hocevar@itf.si

11. Offer validity

The offered prices shall be valid for period of minimum 90 (ninety) days after the deadline for submission of offers and must be accompanied by an Offer Guarantee (issued by offerors bank) in the amount of 500 EUR. This guarantee will be released to unsuccessful Offeror(s) once the procedure has been completed and to the successful Offeror upon signature of the contract by all parties.

12. Advance Payment Guarantees

The successful contracted party will be asked to provide the advanced payment guarantee at the signing of the contract, The percentage of the advanced payment guarantee will be determined upon the advanced payment amount set in the contract. The advanced payment guarantee shall be valid from the date of the signing of the contract and until 30 days after the goods are delivered, installed and training conducted (if applicable). If the selected company fails to provide such a guarantee, the contract will be void and a new contract may be drawn up and sent to the company which has submitted the second-best admissible offer.

13. Deadline for submission of offers

The offers must be received by **ITF Enhancing Human Security, on email E-mail: Iztok.hocevar@itf.si** no later than **Friday, September 22, 2023 by 12:00 hrs (local time)**. Any offer delivered or received after this deadline will not be considered for further evaluation.

14. Appeal

After receipt of the notification letter on un-successful offer, the un-successful Offeror can complain to the decision of the Contracting Authority. The Appeal must be submitted in writing and be delivered within the deadline as stated in the notification letter. The Appeal must be addressed to the ITF Director and must be sent with registered mail or be delivered in-person. The confirmation of payment in amount of 500 EUR or equivalent in local currency has to be enclosed to the Appeal. The payment has to be made on the ITF account, obtained on www.itf.si. In the case of justified Appeal, the amount will be returned to the Offeror.

Annex I: List of Equipment with detailed technical specifications

TITLE: Biochemical Lab -I-stat

INSTRUCTIONS:

In columns **No.2** are given requirements of contracting authority. Columns No.3 and No.4 are mandatory for Offeror:

- **In column No.3** Offeror must write **MANDATORY answer** on contracting authority requirements from columns No.2. Full description and other technical specifications (Numbers/Quantity data, description, evidence, delivery schedule, pricing including transportation and training for users – the costs of all activities, certificate, written statement,);
- **In column No.4** Offeror specifies the number of **attachments or pages**, under which are attached technical specifications and documentation which confirm the requirements of contracting authority, **(MUST BE CLEARLY/APPROPRIATELY MARKED).**

Offeror must in the bid as proof for listed references in the column No. 2, submit manufacturers publications with technical specification and user data in English and Macedonian and Serbian language for the goods offered (if publications are in any other language translation in English or Macedonian and Serbian language must be submitted) and visual materials (if such visuals exist). In publications and visual material agreement binds must be clearly in accordance with all the demands. Provider must fulfil the demands.

Offeror's references in the table are binding for the offeror. References/Data/Information from the table will be used and taken in account for the evaluation and the analysis.

TITLE: Biochemical Lab -I-stat

SUPPLIER	
BRAND OR TYPE	
OFFERED BRAND AND MODEL (Complete designation)	

Equipment Items and Quantities:

Biochemical Lab -I-stat – 4 pieces

Technical Specification – Biochemical Lab -I-stat

1. Table No. 1 - GENERAL DETAILS/CRITERIA

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier – Actual Information	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
1.	GENERAL REQUIREMENT:		
1.1.	Blood Analyser at the patient's side or point-of-care testing (POCT)		
1.2.	Lightweight, portable, and easy to use. Testing and obtaining time-sensitive results at the patient's side. Delivers lab-quality, diagnostic results in minutes. The		

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier – Actual Information	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
	i-STAT 1 can connect to multiple data management systems.		
1.3.	Healthcare providers can monitor course of the disease.		

2. Table No.2 - STANDARDS AND TECHNICAL REQUIREMENTS

2.1. Biochemical Lab -I-stat

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier - Actual Information/Data	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
2.	REGULATIONS AND RULES IN SERBIA AND N. MACEDONIA		
2.1	In conformance/accordance with regulations which are set for Biochemical Lab -I-stat in Serbia and N. Macedonia. Supplier delivers quantity and quality certificate- certificate of conformity – homologation. Biochemical Lab -I-stat and its equipment must have manufacturers certificate of conformity which affirms its compliance with the relevant EU standards; Offeror must attach documents/certificates which prove affirms its compliance with the relevant EU standards.		
3.	GENERAL OVERVIEW		

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier - Actual Information/Data	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
3.1	Blood Analyser at the patient's side or point-of-care testing (POCT)		
4.	OPERATIONAL REQUIREMENTS		
4.1	Conditions for use		
4.1.1	<p>For demanding conditions</p> <p>Biochemical Lab I-stat shall have followed characteristics. In conformance/accordance with customer technical conditions and regulations listed in this document. All characteristics and requirements are for fully equipped Biochemical Lab I-stat, which is ready to use.</p>		
4.1.4	Healthcare providers can monitor course of the disease, patient's response to therapy and infections after surgery:		

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier - Actual Information/Data	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
	<ul style="list-style-type: none"> • Device weight less than 0,8 kg. • Testing and obtaining time-sensitive results at the patient's side. • Broad menu of test, options to use i-STAT test cartridges and different reagents for single use. • Must contain charging battery and lithium battery as an input. • Must run connected to electrification network and wireless on battery. • Must enable quantitative chemical and electrolyte blood analysis (NA, K, Cl, tCO₂, iCa, GLU, BUN, Crea and lactate). • Must enable gas blood analysis (pH, pCO₂, pO₂, tCO₂, HCO₃⁻ surplus base). • Must enable blood coagulation analysis (PT/INR, ACT). • Must enable quantitative chemical and electrolyte blood analysis. • Must enable quantitative heart-markers analysis (cTnI, CK-MB, BNP). 		

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier - Actual Information/Data	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
	<ul style="list-style-type: none"> • Complete analysis process must be finished in 20min. • Must enable possibility to overview to 3000 results in a backward basis. • Device must work/operate 24 hours without charging. • Printer for instant display of analysis results with reference values via wireless (Infrared - IR) • Option to send data from the field through electronic. • Protection case with foam for transportation of device and its equipment • Temperature operating range: from 16 to 30 C. • Instructions in English language • CE • IVD • Warranty certificate • Warranty min 4 years 		

No.	DESCRIPTION	INFORMATION Obligatory Answer of Supplier - Actual Information/Data	ATTACHMENTS Contract and Technical Specification Attachments (Annex Clarity)
	2	3	4
4.2	DIMENSIONS OF MACHINE/DEVICE		
4.2.1	Weight Approx. 0.8 kg		

5.	DOCUMENTATION (by delivery)		
5.1	<p>Instructions for use and basic maintenance of the machine/device and Instruction for added equipment. Supplier and customer shall agree when and how Instructions for use and basic maintenance of the machine will be delivered. Instruction for added equipment must be also part of the delivery.</p> <p>Instructions must be in English language. Content must cover:</p> <ul style="list-style-type: none"> - index, 		

<ul style="list-style-type: none">- warnings and hazards,- technical specifications of the machine/device,- description of the machine/device and functioning of systems,- machine/device handling,- description of functioning of systems and networks- handling of possible upgrade,- defects and disorders (tips and help, failure response),- daily check (check before use, between use and after use),- machine/device preparation (cleaning, washing, lubrication, adding lubricants and technical liquids if needed) with the purpose to have machine/device in constant readiness for use,- conditions of implementation of regular services and checks with detailed definition of necessary contents of services,- List of authorized services for machine/device		
--	--	--

	Instructions must be in English language and delivered in printed version (No. of machine + 4 copies) and in electronic version (4 copies) in file which is supported in Windows system.		
5.2	<p>Spare parts list of machine/device and additional equipment and tools. Catalogue must be in English language and delivered in printed version (No. of machine + 4 copies) and in electronic version (4 copies) in file which is supported in Windows system.</p> <p>Catalogue must enable availability to web database for spare parts, machine/device information and upgrade construction with equipment</p>		
6.	TRAINING (by delivery)		
6.1	Offeror will in coordination with customer by delivery organize training for machine/device handling and training for basic maintenance of the machine/device, upgrades and added equipment. Or organize online training, if agreed with customer. Price of training must be part of purchase price of the machine. Place and date of training shall be agreed between supplier and		

	customer. Training and instruction must be provided in a language that users can understand. Supplier shall provide certificates which confirm qualified machine/device handling and its equipment.		
	Offeror shall provide provisional timeframe of training within his first offer/proposal		
7.	WARRANTY AND SUPPORT		
7.1	<p>For device at least or min. 4 years from the day of quality check by the delivery of the machine/device</p> <p>For additional fixed and installed equipment min 24 months from the day of quality check by the delivery of the device</p> <p>Without any restrictions, exceptions, assumptions, or additional conditions</p> <p>Warranty is valid in EU and other European countries - Serbia and N. Macedonia</p>		
7.5	Services and specialist tooling net in North Macedonia in Serbia. Offeror must in his offer name at least 1 authorized service or tooling specialist. Supplier shall deliver addresses and data of authorized		

	service for the machine/device and service for equipment.		
7.6	Specialist tooling and spare parts. Ensure the maintenance of the machine/device in his lifetime. The requirement is defined based on demand of customer or on the deal in which both sides define maintenance of the machine. Offeror must add list of maintenance works/services, which must be carried out on daily, weekly, monthly, or periodically level.		
7.7	Spare parts The Offeror shall provide the Authority with comprehensive parts list giving part numbers in electronic format or in a form for easy and quick viewing (MS Excel). The parts list will be updated to reflect any supersessions, changes, or replacement. Price list shall be marked by date		
7.8	Gratis repairing within the warranty period. Organization of gratis service 24/7		
7.9	For simple repair and service deadline is 1 working day since takeover of the machine/device or as two parties agree		
7.10	For extensive repairs and service, the deadline is agreed between two parties		

7.11	Warranty documents are attached with delivery		
8.	REFERENCE		
8.1	<p>Offeror must in his proposal/offer attach:</p> <p>- List with dates and quantity of machines that have been sold. At least 30 machines/devices which are the same type as offered machine in last five years. Starting from the date which was set for submission of the tender.</p> <p>Both lists must contain costumers contacts details.</p> <p><u>Lists must be prepared separately (one for machine/device and one fort he added equipment).</u></p> <p><u>If the bidder does not prepare the references for number of machines/devices and added equipment he will be eliminated from the evaluation.</u></p>		

IMPORTANT: In points of technical specification where term » in confirmation/accordance » is referred (Biochemical Lab -I-stat and its equipment must have manufacturers certificate of conformity which affirms its compliance with the relevant EU standards; Offeror must attach documents/certificates which prove affirms its compliance with the relevant EU standards: Equipment and Consumables) the offeror must write answer YES, if the offer meets the requirements.

Relevant certificates must be part of the delivery and they will be proofed and checked on the delivery day and quality and quantity check. Offeror can attach relevant certificates to the proposal already in the Tendering process.

FORM OF INVITATION FOR SUBMISSION OF OFFERS

PROCUREMENT AND DELIVERY OF BIOCHEMICAL LAB -I-STAT

Date and Place: _____

1 SUBMITTED by

Name of Offeror	Nationality

2 CONTACT PERSON (for this offer)

Name	
Company	
Address	
Telephone	
Fax	
e-mail	

We, the undersigned, hereby declare that:

1. This Offer is valid for a period of **90 days** from the offer submission deadline.
2. We agree to abide by the ethics Clauses in the Invitation notice for submission of offers and, in particular, have no potential conflict of interests or any relation with other candidates or other parties in this procedure at the time of the submission of this offer.
3. We will inform the Contracting Authority immediately if there is any change in the above circumstances at any stage during the implementation of the contract. We also fully recognize and accept that any inaccurate or incomplete information deliberately provided in this application may result in our exclusion from this and other contracts funded by the Contracting Authority.

Name and first name: [.....]

Duly authorized to sign this Offer on behalf of:

[.....]

Place and date: [.....]

Stamp of the Organization/Legal entity:

This Invitation for submission of offers includes the following annexes:

[*Numbered list of annexes with titles*]

Annex 3

FORM OF AFFIDAVIT STATEMENT

Contract No: ITF- _____

STATEMENT

With moral and legal responsibilities, I can confirm that company/organization:

_____ (Name of the Company/Organization) are not bankrupt or being wound up, are having their affairs administered by the courts, have entered an arrangement with creditors, have suspended business activities or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations.

_____ (Name of the Company/Organization) are not the subject of proceedings for a declaration of bankruptcy, for winding-up, for administration by the courts, for an arrangement with creditors or for any similar procedure provided for in national legislation or regulations.

_____ (Name of the Company/Organization) declare that it is affected by no potential conflict of interest, and that he has no link with other Offerors or parties involved in the project. Should such a situation arise during performance of the contract, the Contractor must immediately inform the Contracting Authority.

_____ (Name of the Company/Organization) have not been convicted of an offence concerning professional conduct by a judgment which has the force of *res judicata*.

_____ (Name of the Company/Organization) are not guilty of grave professional misconduct proven by any means which the Contracting Authority can justify.

_____ (Name of the Company/Organization) have fulfilled obligations relating to the payment of social security contributions in accordance with the legal provisions of the country where they are established;

_____ (Name of the Company/Organization) have fulfilled obligations relating to the payment of taxes in accordance with the legal provisions of the country where they are established;

_____ (Name of the Company/Organization) they are not guilty of serious misrepresentation in supplying the information required by the Contracting Authority as a condition of participation in an invitation to offer or contract;

_____ (Name of the Company/Organization) have not been declared to be in serious breach of contract for failure to comply with obligations in connection with another contract with the same Contracting Authority or another contract financed with Community funds;

_____ (Name of the Company/Organization) are not in one of the situations allowing exclusion referred to in the Ethics Clauses in connection with the offer or contract.

If it is determined that the above statements are not accurate, we agree that the offer may be declared inadmissible by Contracting Authority, as administrative noncompliant.

Name and Surname: _____

Duly authorized to sign this offer:

Signature:

[.....]

Place and date:

Stamp of the Company/Organization:

STATEMENT OF NON-ASSOCIATION

Offerors should here include a statement that the Offeror (including subcontractors) is not associated, nor has been associated in the past, directly, or indirectly, with any other entity that has prepared specifications and documents for the Project or being proposed as Supervisor for the Contract (as stated in Annex 3).

Signature.....

(a person or persons authorized to sign on behalf of the Offeror)

Date