מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

שירותי הבריאות הטובים בישראל

Request for Information (RFI) (regarding an automated system and reagents for performing celiac and ANCA tests) (hereinafter – the "Request")

1. General

1.1. Maccabi Health Services (hereinafter **"Maccabi")** is interested in receiving information regarding an automated system and reagents for performing celiac tests (TTG, DGP) and ANCA antibodies (MPO, 3PR) (hereinafter **"the products and/or services") ,** as specified

please.

1.2. The information must be filled out on the attached application form and sent to **Galit Peled** by email.

.17.06.2025 to peled_gali@mac.org.il

1.3. The publication of the request for information does not cancel Maccabi's right to continue previous engagements, in accordance with its sole discretion, with the Offeror, and the fact that the Offeror referred to this request does not mean that it intends to cancel and/or change and/or derogate from Maccabi's rights in accordance with previous agreements with it, including the exercise of options, if any.

1.4 It is hereby clarified that the purpose of the publication is to obtain information and should not be seen as any obligation on the part of Maccabi to hold negotiations. Or choose any supplier and/or contact any of the applicants. Maccabi reserves the right to publish another application and/or publish a request for quotes and/or not enter into any agreement with any of the applicants.

1.5 This request does not constitute an invitation to submit proposals and is not part of any tender procedures, therefore it does not create any obligation. To which of the respondents is Maccabi obligated to enter into a contract with any of the respondents as aforesaid and/or to publish a tender? The request is intended for informational purposes only, and Maccabi will consider its continued actions in accordance with the following considerations:

Professional and to the point.

1.6 If a tender process is held in the future, Maccabi will be entitled to change or add terms and requirements beyond those detailed in the application. This is all at its sole professional discretion and in accordance with its needs as they may be from time to time. Since the offeror is the owner of the offer The best economic bid does not guarantee victory. Victory will be declared after weighing price and quality as decided by Maccabi.

1.10 Maccabi may use any information (in whole or in part) provided as part of a response to this request for information. And the information provider will have no claims regarding copyrights of any kind.

1.11 The bidder undertakes to provide, free of charge, a device and reagents for the purpose of performing an evaluation. The evaluation will be performed on the devices that meet the detailed laboratory requirements. An evaluation protocol will be defined at a later stage, will include subject samples and quality control samples (approximately 100 samples for celiac testing and approximately 100 samples for ANCA antibodies) and will be coordinated with the Mega Lab management. All items required for the evaluation phase will be provided to Maccabi free of charge and at the expense of the supplier.

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

מכבי
שירותי הבריאות הטובים בישראל

2. General description of the professional requirements for the subject of the application:

2.1 Required product: Automated random access system and reagents for performing immunology tests

(The required tests and estimated monthly quantity are detailed in Appendix A). A proposal for implementation can be submitted

Celiac and/or ANCA antibody tests.

2.2 The bidder must attach a quality color prospectus and documents from the manufacturer: device brochures, quality standards, and documents

indicating the specifications of the relevant device.

2.3 Each of the sections in the table must be addressed:

Reference The offeror	Subject/Requirement	
	general:	1
	1.1 Proposed system including analytical characteristics (see Appendix B)	
	1.2 The proposing corporation and the name of	
	the manufacturer. 1.3 Experience in Israel and internationally in the use of reagents and the device must be detailed (see Section 3.11, 'Key Customers'). Contact details for the laboratories working with the device and the proposed reagents for the tests in question must be provided.	
	1.4 FDA and/or CE approvals and AMR approval must be attached for the proposed reagents/device. 1.5 The proposal must	
	include reagents or equipment for **two** Maccabi laboratories (in a general distribution of 60% in one laboratory and 40% in a second laboratory).	
	1.6 It should be specified whether the system can address both groups of tests together. (i.e. in Appendix A: Groups A and B) 1.7 Regarding Group A, it should	
	be specified whether the system detects a low IgA level as part of the test Celiac.	
	1.8 An estimated delivery time and the preparation period required by the supplier must be specified. Starting the system and performing the tests 1.9 It must be	
	specified whether any additional equipment is required, and if so, what it is.	
	Technical details for a proposal for the device and reagents: 3.1 The	**3**
	dimensions of the device (desktop/floor-standing), including a computer, if required, must be specified. 3.2 The	
	expected power for one device in a random mix of the variety of tests must be specified. listed in Table A.	
	3.3 The number of test types that can be run simultaneously must be specified. 3.4	
	Whether the proposed device will allow working with multiple reagent batches simultaneously must be specified. 3.5 The types of test	
	tubes, secondary/primary, that can be used must be specified. On the device.	
	3.6 It should be specified whether the device will allow continuous loading of samples.	
	3.7 It should be specified whether the proposed device reads barcodes for samples, controls and reagents. 3.8 It	
	should be specified the types of stands for controls and reagents available in the device. 3.9 It should	
	be specified the sampling method of the device (use of disposable tips or probe). 3.10 It should be specified whether the device	
	includes a sampling control system (for example, Clot detection or .)liquid level/foam/bubble detection	

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

	3.11 It must be specified whether the proposed system has the option of connecting to the water and sewage systems. The main ones in the laboratory.	
	3.12 It must be specified whether the device meets the requirements of accepted international and Israeli standards, Including safety standards, electricity, etc. 3.13	
	The relevant values attributed to the proposed device during operation at maximum power must be specified: • Electromagnetic radiation intensity • Laser radiation • Noise level The intensity of the heat emitted	
	Ongoing operation of the system:	**4**
	4.1 The manufacturer's maintenance requirements (daily, weekly, monthly, annual) for each component must be specified. The system. The time on hands required for maintenance by the team must be specified. The laboratory.	
	4.2 The maintenance operations performed by a technician and the length of time required to perform the maintenance operations must be specified, including the time the device is shut down during routine maintenance operations by a technician. 4.3 The method	
	of management, notification and documentation of the maintenance operations (Maintenance log) must be specified. **5**	
	Quality control	
	5.1 The types and values of controls for each analyte must be specified. The manufacturer must specify the validity of the controls and specify the method	
	of their preparation. 5.2 The method of identifying the controls by the device must be specified (whether by barcode, unique test, etc.).	
	5.3 The method of monitoring quality control in the device must be specified. 5.4 The	
	method of displaying data on the screen and in printout must be specified, as well as displaying them graphically. .)Levey-Jennings)	
	5.5 It should be specified whether the software allows comparing results against predefined limits. And against measured boundaries.	
	5.6 It should be specified whether the software will allow analysis of results based on various metrics such as time ranges, Calibrations or reagent batches.	
	5.7 The length of time for storing QC results on the device must be specified.	
	5.8 External quality control: Specify which specific programs and tests the system The proposed participant and send sample reports	___
	Calibrations	**6**
	6.1 The method of identifying the calibrators by the instrument must be specified. 6.2	
	The required calibration frequency and the method of notification of the need for calibration must be specified. 6.3	
	The indicators for receiving the calibration must be specified.	
	6.4 The duration of the storage of calibration data in the instrument must be specified. **7** 7.1	
	Reagents	
	The reagents required must be specified, whether they require preparation. MSDS must be attached for all reagents.	
	7.2 The duration of the on-board stability of the reagents for the tests must be specified. The proposed.	
	7.3 The system's ability to warn about:	

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

	Reagents that remain on board beyond the allowed time. Expired reagents. Reagents whose calibration has expired.	
	7.4 It should be specified whether the manufacturer is able to provide reagents with a validity of approximately six months. at least.	
	7.5 Is the manufacturer able to supply the same batch of reagents for at least 3 months?	

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

	Software and computing	**8**
	8.1 The operating system on the device must be specified (full name, including version and SP if applicable). (relevant). It must be specified whether the operating system is supported by the manufacturer.	
	8.2 The name and version of the software that will be supplied with the device must be specified. It is clarified that the software is an integral part of the device and the cost of the device and its maintenance also includes the software. 8.3 It must be	
	specified whether there is a possibility for direct and proper two-way communication with the LIS. Lab Information System (including): Receiving work lists, reporting test results, and reporting controller results. A system should be proposed that can be run in batch without work lists.	
	8.4 It must be specified whether there is a driver for communication with existing PGP and SCC LIS. In the laboratory. Additional LIS systems that have drivers should be listed and all types of supported communication interfaces such as CSV, XML, HL7, ASTM should be listed.	
	8.5 All computing requirements, hardware and software, for operating the device and system, calculating the results and reporting them will be provided by the supplier, at his own responsibility and expense. Clarification: If the solution includes software, the computers and associated equipment on which the software will be installed must also be provided.	
	8.6 The architecture of the solution proposed by him must be fully and clearly detailed (detailing software and hardware aspects that accompany the proposed solution in order to meet the maximum output of the devices and the solution as a whole) as well as infrastructural requirements from Maccabi for the implementation of the solution (if such exist). A drawing of the architecture must be attached with a detailed description of the connections between the solution components, what the role of each component is and how it connects to the other components and to the Maccabi network, if any.	
	8.7 The computing configuration provided with the system must be specified: servers, endpoints, processor, memory, storage, basic software versions and operating systems. The infrastructure preparations required for the installation of the equipment must be specified (including bandwidth and latency requirements to the extent required). Communications, if servers are provided as part of the solution - Maccabi will allow the installation of servers in the "U" ("Pizza") standard only and at the supplier's responsibility and expense. It must be specified whether the server can be installed remotely from the device (in the facility's server room)	
	7.8 It must be specified whether the device software or the software accompanying the device requires the use of the cloud/ internet. If the cloud/ internet is used – it is required that the information be backed up on the local site (Maccabi site). The information retention/backup policy must be specified, including storage requirements. 8.9 It must be specified whether there is a limit to the amount of	
	data that can be stored over time in the cloud. and/or on the computers and/or server offered. The solution for storing the relevant information (runtime files, analysis files, etc.) for future use of the information must be specified (the information must be stored for a period of one generation). The supplier will specify all types of information necessary for storage, the method of storage, and if storage space is required at Maccabi, the supplier will specify the storage volumes required for the benefit of the The subject.	

	8.10 The method of linking all system components to the server must be specified. 8.11	
	Whether there is a limit on the number of workstations/devices/computers must be specified. Who can connect to the server and work at the same time.	
	8.12 It should be specified whether there is a limit on the maximum number of devices that can connect. For each companion computer.	
	8.13 It should be specified whether there is a limit on the number of computers/devices capable of working in it. temporarily.	
	8.14 Maintenance work and software/hardware updates for servers and computers must be detailed, including: Reference to the frequency and time of system downtime. The configuration of software version updates must be specified (frequency of updates, nature of the update, responsibility for performing the update, evaluation of the update, etc.). Reference must be made to the manner in which results from previous runs are affected by the update. 8.15 It must be specified	
	whether periodic or ongoing maintenance operations are required to maintain The information of the system and the device and the method of execution (and whether there is a requirement to connect remotely for this purpose). The frequency and duration of system downtime during these operations must be specified. 8.16 If	
	the software has a client to install/run - the specifications of the positions must be described. The work (computer configuration, processor, memory, storage, including OS type and version, basic software, and monitor size) required to work with the client. 8.17 It should be specified	
	whether the software will allow retrieval of results based on various metrics such as numbers sample, test type, or execution time. 8.18 Specify	
	whether the software has the ability to record the identification numbers of the reagents in Tests were performed on each sample or controller, and the ability to retrieve this information quickly and easily.	
	8.19 The method of managing and tracking reagent, consumable, and waste inventory must be specified. 8.20	
	The software must be specified whether the software will allow sending controller results to the LIS system. 8.21 The option of	
	exporting results to another software (Excel) must be specified. **If the communication protocol with**	
	the LIS system is based on a communication network, specify: 9	
	9.1 Mutual identification mechanism (to prevent device impersonation) before creating connectivity with Maccabi systems – implementing a mutual identification mechanism that includes a password will be an advantage. 9.2 How the	
	software enables sending information while ensuring the confidentiality of patient information During the transfer process.	
	9.3 A mechanism for verifying the integrity and reliability of the software information.	
	10 User/Operator Interface, Detail:	
	10.1 What is the identification mechanism that exists in the system? At a minimum, a username and password are required. To prevent access by an unauthorized party. 10.2 What	
	is the ability to define password policies in the user interface (such as password length)? and password complexity, password validity).	
	10.3 Is there a mechanism for closing a user's session based on a pre-planned time component in a manner adapted to the device's operating environment? 10.4 Is there and what is the	
	mechanism for defining permissions for work groups while creating a compartmentalization of Users according to their work requirements.	
	10.5 Whether measures were used to maintain the confidentiality of medical information, and what they were.	

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

	10.6 What is the indication mechanism (logs) that exists in the software for the actions performed in it? What is detailed These instructions and whether the instructions will specify, among other things, the name of the agent, the time of the action, the nature of the action, and on whom the action was performed.	
	10.7 Will the notifications saved in the system be available for viewing by Maccabi and how will this be possible? Watch them.	
	individual:, **Implementation, maintenance and updates**	**11**
	11.1 The computing infrastructure will be based on licensed operating systems, which can be updated and maintained, and are actually updated according to the manufacturer's instructions based on verified updates and patches for operating systems, or for the medical device software, according to needs.	
	11.2 The supplier will present relevant information proving that the software and medical devices are free of codes malicious when implemented.	
	11.3 As a general rule, system maintenance will only be possible at the Maccabi site, with prior coordination by authorized supplier representatives only.	
	11.4 Information is required to be presented regarding mechanisms that enable verification of codes (Code Authenticated) (For software or firmware updates) - Implementation of code authentication mechanisms in the solution will be an advantage. **Application -**	
	Required to specify:	**12**
	12.1 Will the software and medical equipment support changing default passwords? Default passwords will be changed during implementation. 12.2 The supplier will present	
	satisfactory results of a code review and a Penetration Test (for the version of the software offered by him). 12.3 Please provide	
	information on the implementation of mutual identification in the link between the equipment and the management software. His – implementing a mutual identification mechanism that includes a password would be an	
	advantage. **13 Printer**	
	13.1 A Maccabi-approved printer model: W6400L-HL Brother and toner must be attached to the system. original	
	Information security requirements:	**14**
	For the medical device 2MDS 14.1 Fill out a questionnaire MDS2.XLSX	

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

שירותי הבריאות הטובים בישראל

(According to 2024 data) # **Appendix A – Test Panel and Quantities (for both laboratories together)**

Average number of tests per year	Test group test	
174,000	Anti tissue transglutaminase (TTG), IgA	A
1,700	Anti Deamidated gliadin peptide (DGP), IgG	Celiac
6,900	Anti myeloperoxidase (MPO) Ab, IgG	on
6,100	Anti Proteinase 3 (PR3) Ab, IgG	ANCA antibodies

The tests will be performed in two laboratories with a general distribution of 60% in one laboratory and 40% in a second laboratory. #

Appendix B – Analytical characteristics: measurement range, repeatability, analytical and functional sensitivity

Lot to lot % variation	sensitivity Analytical	sensitivity Functional	The apartments* %CV	domain measurement	Standard according to which The test is calibrated.	examination

The maximum CV will be according to the manufacturer's declaration in most measurement ranges. *

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

מכבי
שירותי הבריאות הטובים בישראל

3. Application form:

3.1 The offering corporation: _____

3.2 Manufacturer's name: _____

3.3 System name: _____

3.4 System model: _____

3.5. Dimensions of the proposed system:_____

3.6. Country of manufacture:_____

3.7. Technology's seniority in Israel/worldwide: _____

3.8 Existing standards for the proposed system: _____

.3.9 Additional relevant information: _____

3.10 Estimated delivery time: _____

3.11. Key customers:

phone	Contact person	The seniority of the subject of the request with the client	country	client

3.12. Price assessment

currency	Price estimate For a reported inspection	Estimated testing per year	Item name
		According to Table 1	**Each test in Table 1 above**
		above 170,000	Anti tissue transglutaminase (TTG), IgA
		1,700	Anti Deamidated gliadin peptide (DGP), IgG
		6,700	Anti myeloperoxidase (MPO) Ab, IgG
		5,900	Anti Proteinase 3 (PR3) Ab, IgG

A complete list (including a price estimate) of everything required to perform the tests on the proposed device must be attached, including accompanying equipment, reagents and controls.

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

Definition of Reported Test: A final reportable result of a test performed on a biological sample. It is clarified that tests

Repeats of the same sample and quality control and calibration tests will not be included in the number of tests reported.

The price estimate for a reported test will include the cost of the system, all reagents required to perform the tests, and the cost of

System service after the warranty expires.

Note: This is a five-year deal.

3.13 The following details must be attached to the application:

3.13.1 The proposed system

3.13.2 The accompanying equipment required for the proposed system (if necessary)

3.13.3 List of reagents required to perform the tests, including consumables,

Controls and calibrators and their cost

List of consumables required to operate the device and their cost

currency	Device price /Consumable	Estimated quantity for testing Lonely	Device name /Consumable

Estimated costs for direct procurement:

3.13.4 Device cost: **3.13.5**

3.13.6 Number of instruments required: 3.13.6.1 Cost of reagents in direct purchase:

מכבי שירותי בריאות
רכש ציוד וחומרים
רחוב המרד 27, תל אביב 6812509

שירותי הבריאות הטובים בישראל

Storage conditions and temp.	currency	price	estimate Quantity per year	Quantity in package	name

Spare parts price list:

Annual service and warranty cost:

.3.14 Notes:

• The estimate is an estimate only. Maccabi is not obligated to the estimated quantity or any quantity. • Prices do not include VAT. • Do not bid with more than 2 digits after the point. • Bids can be made in NIS$/US/Euro/Japanese Yen/ Swiss Franc/British Pound/Canadian Dollar/Australian Dollar. For all Other currency requires prior approval.

3.15 Documents that must be attached to the application:

• Quality standards.

• Prospects .

• Any other relevant information