







Konstantynów Łódzki, 11.04.2022

MABION S.A. 60 gen. Mariana Langiewicza St. 95-050 Konstantynów Łódzki

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REQUEST FOR TENDER no. 01/04/2022/IMM

Project name: "Development of an analytical methods panel for the characterization of immunogenicity in a clinical trial aimed at patients suffering from rheumatoid arthritis using rituximab as a drug substance".

The procedure to select the best tender is conducted in observance of the rules of fair competition, openness, and transparency.

The provisions of the Act of 29 January 2004 Public Procurement Law do not apply to this procedure.

I. PARTICULARS OF CONTRACTING ENTITY

MABION S.A. with its registered office in Konstantynów Łódzki [95-050] at 60 gen. M. Langiewicza St., entered in the Business Register kept by the District Court for Łódź-Śródmieście in Łódź, 20th Commercial Division of the National Court Register, under KRS number: 0000340462, NIP: 7752561383, REGON: 100343056, with a share capital of 1.616.182,60 PLN [in words: one million six hundred and sixteen thousand one hundred eight two zloty 60/100], fully paid up.









II. SUBJECT OF THE CONTRACT

1. Description of the subject of the contract

- a. The subject of the contract is the supply of reagents and consumables materials. The list of consumables materials/reagents has been divided into four groups and presented in the table below.
- b. The reagents in the first group are intended for the ADCC assay, which is used to assess the neutralizing activity of the antibodies (NAb).
- c. The reagents included in the second group are intended for cell culture and assessment of biological activity of anti-CD20 antibodies.
- d. The reagents in the third group are intended to label antibodies used in immunoenzymatic assays.
- e. The materials and reagents included in the fourth group are intended for the bioanalytical system, for the performance of immunoenzymatic assays of clinical trial samples, in the nanolitre scale in an automated microfluid system.

No.	-Name-of product	total number of pieces/sets	
1	ADCC assay kit (Antibody Dependent Cell Cytotoxicity) (for 5 tests –	20 sets	
	ten 96-well plates), containing:		
	Effector cells, an immortalized line of human T lymphocytes,		
	Jurkat line, designed to assessment the biological activity of		
	anti-CD20 antibodies in an antibody dependent cell		
	cytotoxicity (ADCC) assay.		
	Cells must be express FcyRIIIa receptors on their surface		
	with valine at position 158 (V158).		
	Cells must be express firefly luciferase under the NFAT		
	promoter, enabling a readout of the luminescence signal		
	(linear to the concentration of the tested sample).		
	Thaw -and- use cells that do not require culture		
	propagation.		
	RMPI 1640 cell medium		









	RMPI 1640 cell medium	
	 Fetal Bovine Serum (FBS) with low IgG level 	
	Reagent for detecting expression of firefly luciferase	
	reporter gene in ADCC bioassay; The reagent must be enable	
	the readout of the luminescence signal on the luminescence	
	reader.	
	The expiry date of all components – minimum 22 months from the	
	date of delivery.	
2.	Reagent for detection of the expression of firefly luciferase reporter	10 x 100 mL
	gene in an ADCC bioassay.	
	The reagent must be enable the readout of the luminescence signal	
	on the luminescence reader.	
	Compatible with the Effector cells presented in point 1.	
	The reagent must be resistant to components of the culture	
	medium, including phenol red.	
	The reagent in a lyophilized form that enables storage at -20 °C for	
	more than 20 months from the date of delivery.	
	Possibility to re-freeze the reconstituted reagent and store it at -20	
	°C for more than 4 weeks.	

No.	Name of product	total number of pieces/sets
	RPMI 1640 medium with stable L-glutamine	
	The medium must be in liquid form, sterile filtered (free from fungi,	
1.	mold, aerobic and anaerobic bacteria).	20 x 500 mL
	The reagent must be stable for more than 20 months stored at 2-8 °C.	
	The pH of the medium must be 7.3 ± 0.3.	
2.	1M HEPES buffer	1 x 100 mL









	The buffer must be in liquid form, sterile filtered (free from fungi, mold,	
	The bullet must be in liquid form, sterile littered (free from fullg), mold,	
	aerobic and anaerobic bacteria).	
	The reagent must be stable for more than 35 months stored at 2-8 °C.	
	The pH of the buffer must be 7.3 ± 0.3.	
	96-well plates with the following features:	
	White, for cellular testing with luminescence-based reading (with	
	minimum autoluminescence and maximum reflection),	
	Flat-bottom (F - bottom) for optimal optical properties,	
3.	sterile,	150 pcs
	with lid,	
	individually packed,	
	raised edges of the wells to reduce contamination,	
	Working volume: minimum 200 μL per well	

No.	Name of product	total number of pieces/sets
1.	Monoclonal antibodies biotinylation reagent with	1 set (10 x
	N- Hydroxysulfosuccinimide (NHS) ester reactive group. Reagent must	1mg)
	be demonstrate the following features:	
	- Chemical formula: C ₂₀ H ₂₉ O ₉ N ₄ S ₂ Na	
	- Molecular weight: 556.59Da	
	- Alkyl spacer: 22.4 angstroms length	
	- Water soluble	
	- Reactivity: primary amines (-NH ₂) in alkaline conditions	
	- No-Weigh format (1mg per alliquot)	
2.	Alexa Fluor™ 647 fluorochrome monoclonal antibodies labelling kit.	3 sets
	Kit should provide for preparation of 3 labelling reactions of 1mg of	
	antibody (per each reaction). Kit must be composed of following	
	elements about characteristics as stated:	









- Labeling reagent (aliquoted for three reactions), stable at pH range from 4 to 10,
- Sodium bicarbonate (NaHCO₃),
- Spin columns allowing to remove unbound labeling reagent,
- Reagent that allows to modulate DOL (Degree of Labeling)
 parameter i.e., enables to lower the number of fluorochrome
 molecules coupled to one molecule of the antibody

No.	Name of product	total number of pieces/sets
1.	Buffer of pH 11 designed to cleaning of automated microfluidic system.	10 sets / 10
	Portioned into single (10g) aliquots, no-weigh format.	pcs per set (10 x 10g)
	Buffer must be contain:	(======0)
	Disodium metasilicate,	
	Tetrasodium pyrophosphate,	* 1
	Pentasodium triphosphate,	
	Sodium disilicate,	
	Troclosene sodium, dihydrate	= -
2.	Compact disc (CD) consisting of 96 microfluidic structures featuring	130 pieces
	streptavidin beads packed columns that are designed to quantitative	
	(by immunoenzymatic reaction) measurement of the analyte amount.	
	Compact disc must be consist of mixing chamber that allows to	
	incorporate into Anti-Drug antibodies (ADA) analysis setup an acid	_
	dissociation step. Volume of analyte in the reaction – 200 μ L.	
	Compact disc must be transparent to enable laser excited fluorescence	
	detection method.	
	The expiry date – minimum 12 months from the date of delivery.	
3.	Buffer used for samples dilution (>1:2 ratio), compatible with compact	9 x 25mL
	discs used for automated microfluidic system. Buffer must be contain	
	detergent and enables to perform an analysis in acidic conditions.	









Buffer must be packed in a plastic bottle that protects against light.

The expiry date – minimum 12 months from the date of delivery.

The indicated provisions do not impose on the bidder the obligation to use the indicated solutions, they only inform about the minimum parameters and standards. Indications in relation to the expected technical parameters and indications concerning specific types and producer names are of general nature, referring only to sample indications of equivalent products and do not constitute the only accepted solution. On this basis, the customer accepts equivalent solutions.

- f. The reagents delivery will take place after every partial order by Purchaser. Total number of reagents will be divided on regular order parts according to current need of Purchaser, but Purchaser is not determining minimum or maximum number of orders.
- g. Package of reagents should guarantee its safe delivery and storage without damage and ensure its sterility.
- 2. Common Procurement Vocabulary (CPV): 3800000000 -5 laboratory, optical and precision equipment (except glass); 33696500 0 Laboratory reagents
- 3. The offer validity period 90 days with the possibility of extension with the consent of the Tenderer for another 60 days.
- 4. The date of conclusion of the agreement: during the validity period of the tender
- 5. Delivery time up to 45 calendar from the day of order.
- 6. Validity of the contract from the date of conclusion by 30.06.2023
- 7. Validity of Place of realization of order: 17 Fabryczna street 90-344 Łódź

III. FORMAL REQUIREMENTS FOR TENDERS

- 1. Tenderer must submit only one tender.
- 2. Tenderer must submit an offer using the template attached as Annex 1, The form of range and prices in Annex 2 and substantive provisions of the agreement in Annex 5 to the present Request for Tender. The offer should be accompanied by a statement on the lack of personal or capital links, constituting an Annex 3 and a declaration on the fulfillment of the formal conditions of participation in the procedure constituting Appendix 4 to this Offer Request. The contractor forbids any modification of the contents of the documents, except for places to fill the content of the offer or statements.









Contracting Entity forbids any document content modifications, except gaps to be filled.

3. The Contracting Entity can call Tenderers, which did not submit required statements or submitted the statements and documents containing errors or incomplete documents, to submit or to justify the lack of document or its parts. Tenderers are required to provide documents or justification on the date specified by the Contracting Entity by the means of submission/justification described in section VII.1 If the Tenderer does not provide missing documents/ justification, the offer is rejected and does not take part in tender process. The Contracting Entity does not have to call Tenderers for re-submission if the rest of submitted documentation results in rejection of a tender, or the tender process is cancelled.

4. The offer must contain:

- b. Full name of the Tenderer or Tenderers if they submit the tender jointly.
- c. Tenderer's address or registered office, NIP number [or equivalent tax identification number].
- d. Name, phone number and e-mail of the contact person who handles the tender.
- e. The overall price for the tender proposed by Tenderer demands for the subject matter of the contract for particular groups, given in PLN or EUR, filled in using digits and words [net and gross price should be presented, gross price should include value-added tax, VAT, unless the tender is submitted by a foreign entity which is not required to pay VAT in Poland on the basis of separate provisions]. Tenders submitted by such Tenderers should state the price net of VAT. In case of any discrepancies between the price written with digits and words, the price written in words is recognized as valid.
- f. The unit prices for individual materials given in PLN or EUR, filled in using digits [the price should be stated inclusive of the tax on goods and services (VAT) unless the tender is submitted by a foreign entity which is not required to pay VAT in Poland on the basis of separate provisions. Tenders submitted by such Tenderers should state the price net of VAT]. In the event that the tender contains an ambiguity in relation to the tender sum, the amount in words shall prevail
- g. Time of payment; minimum 30 days from the date of delivery to the Contracting Entity issued invoice. The Contracting Entity do not accept prepayment.
- 5. All pages of the tender and all attachments should be signed by Tenderer's authorized representative. All corrections/alterations of the offer need to be signed by the authorized representative.
- 6. The tender and all attached documents should be written in Polish or English.









- 7. The costs related to the preparation of the offer are borne by the Tenderer.
- 8. The Contracting Entity does not allow variant bids or price variants
- Contracting Entity accepts to submit bids for the selected group. Offers shall contain all the
 items of a given item group indicated in the chart/table. It is not allowed to submit partial offers
 for single items of a given item group.
- 10. Tender that not satisfy the requirements referred to in the points 1 and 8 shall be subject to rejection, in the points 2, 4-6, 9 shall be subject to complement.

IV. FORMAL REQUIREMENTS FOR PARTICIPATION IN THE PROCEDURE

- 1. The tender may be submitted by any entity that:
 - a. Has the appropriate knowledge and experience, enabling the subject of the contract to be performed to the highest standard.
 - b. Is in an economic situation guaranteeing execution of the entire order.

In order to confirm fulfilment of formal conditions, the Tenderer is obliged to provide with the offer a statement constituting **Appendix 4** to this inquiry. The Tenderer who does not meet any of the above mentioned conditions will be excluded from the procedure.

V. EXCLUSIONS

- 1. To avoid a conflict of interest, public contracts may not be awarded to any entities that have personal or capital links with the Contracting Entity. Capital or personal links are understood as mutual ties between the Contracting Entity or persons authorized to bind the Contracting Entity or persons who act on behalf of the Contracting Entity in connection with preparing and conducting the procedure for selection of a contractor, and the contractor, which are in particular the following:
 - a. participation in a partnership as a partner of a civil law partnership or general partnership;









- a. holding a least 10% of shares or stocks, unless the lower threshold results from legal regulations in force or has not been defined by the EU Funds and Grants Managing Authority responsible for the Operational Program legal basis for this Request for Tender;
- b. serving as a member of a supervisory body or a managing body, acting as a registered representative or an attorney;
- c. being a spouse, a relative by lineal consanguinity or affinity, by collateral consanguinity to the 2nd degree or affinity to the 2nd degree, or a person linked by way of adoption, custody, or legal guardianship.
- 2. Tenderer is required to submit, along with its tender, a statement attached as **Appendix 3** to this Request for Tender.

VI. EVALUATION CRITERIA FOR SELECTION OF TENDER

When selecting the best tender, Contracting Entity will take into account the following criteria:

No.	Name	Maximum point number	Weight of criterion [%]	Maximum point score for criterion
1.	Net price per group	100	80%	80
2.	Delivery time	100	20%	20
1		TOTAL		100 pts

For Tenderers who have met the conditions for participation in the procedure, offers will be evaluated based on following criteria:

1. Net Price (,,C'') – 100 pts (weight of criterion 80%)

The Contracting Entity will take into account the net price in PLN within the group mentioned in the object of the contract for each group in PLN currency. Tenders submitted in foreign currency will be converted to PLN with average exchange rate of PLN indicated by NBP on the day of the opening of tenders.

Offer with the lowest price will receive 100 points multiplied by the weight of criterion and will be adopted as the basis for the study of other offers. Scoring for the following offers will be hold according to the following formula:









Criterion "C" = $\frac{\text{The lowest price (net price per group)}}{\text{Price of evaluated of fer (net price per group)}} * 100 \text{ pts} * 80\% \text{ (weight of the criterion)}$

2. The delivery time ("T") – 100 points (weight of criterion 20%) max 45 calendar from the day of order

Offer with the shortest time of completion (expressed as calendar days from the date of delivery of antigens by the Contracting Entity to receiving by the Contracting Entity from the Contractor a draft of the final report) will receive 100 pts multiplied by the weight of criterion and will be adopted as the basis for the study of other offers. Scoring for the following offers will be hold according to the following formula:

The shortest time of completion
$$Criterion T = \frac{(calendar\ days)}{Time\ of\ completion\ of\ evaluated\ offer}*100\ pts*20\% \ (weight\ of\ the\ criterion)$$

$$(calendar\ days)$$

The total score will be calculated based on above presented data with the following formula:

- 1. The Contracting Entity will select the most advantageous Tender, which achieves the highest number of total points.
- 2. If two or more Tenders obtain the same number of points, the Contracting Entity will call Tenderers to submit additional Tenders. If after the submission of additional Tenders, it is not possible to select the Tenderer, due to the fact that one or more Tender will receive the same number of points, the Contracting Entity will close the proceedings without resolution.
- 3. During the examination and evaluation of Tenders, the Contracting Entity reserves the right to request additional information from Tenders, which it deems necessary for a reliable evaluation of the submitted Tenders.
- 4. The Contracting Entity reserves the right to close this proceeding without resolution in terms of selecting a Tender.









5. Contracting Entity reserves right to change conditions and requirements of request for tenders, or cancellation of tender process. The Contracting Entity reserves the right to change the announcement or the conditions of the request for a quotation or annul or cancel the proceeding at its sole discretion and without giving a reason.

VII. PLACE, MANNER AND DEADLINE FOR SUBMITTING TENDERS

- 1. The tender should be delivered in writing by mail, courier service or personally at the address of Contracting Entity given in Section I of this Request for Tender or sent via e-mail: przetargi@mabion.eu by 11.05.2022. It is also possible to submit an offer through the Competitiveness Database https://bazakonkurencyjnosci.funduszeeuropejskie.gov.pl/.
- If the offer is submitted in writing by mail, courier service or personally, it should be placed in non-transparent and sealed envelope which must bear the following address details of Tenderer, its name, and the following phrase: "Tender regarding Request for Tender no. 01/04/2022/IMM do not open 12.05.2022 at 9:00"

If the offer is sent via e-mail, the above sentence should be entered as topic of an e-mail.

- 3. The offers will be opened by the Contracting Entity in 12.05.2022 at 9:00 at its facility.
- 4. Offers submitted after the deadline will not be considered.
- 5. The Contracting Entity informs that in accordance with the guidelines on the eligibility of expenditures under the European Regional Development Fund, European Social Fund and the Cohesion Fund for the period 2014-2020, the Contracting Entity at the request of the Tenderer who submitted the tender is obligated to make available to the Tenderer protocol of tender proceedings, with the exception of parts of tenders which constitutes the company's secret within the meaning of the provisions of the Act of 16 1993 April on Combating Unfair Competition (Dz. U. of 2003 No. 169, item 1503, with amendments).
- 6. The Contracting Entity recommends to submit the proprietary information which constitutes the company's secret in a separate inner envelope marked "company's secret" or to bound it (staple) separately from the other public documents. The lack of a clear indication that the information constitutes a company's secret means that all the statements made in the course of the present proceedings are open to the public without any reservation. Request for confidentiality of the information which are not company's secrets within the meaning of the Act on Combating Unfair Competition, will be treated as ineffective and will result its declassification.









- 7. The Tenderer may change, complete or withdraw its Tender before the Tenders submission deadline. In the event of a changing, completion or withdrawal of the Tender, aforementioned paragraph shall apply accordingly, however, an envelope should be marked with the following note: CHANGE / COMPLETION/ WITHDRAWAL OF THE TENDER.
- 8. The resolution of the Tenders comparison is ultimate, i.e. no appeal may be lodged against the results of this proceeding carried out by the Contracting.

VIII. WEBSITE WITH NOTICE OF THE REQUEST FOR TENDER

https://mabion.eu/pl/2/o-mabion/zapytania-ofertowe/

https://www.mabion.eu/en/2/about-mabion/request-proposal/

https://bazakonkurencyjnosci.gov.pl/

IX. ADDITIONAL INFORMATION

Additional information on behalf of the Contracting Authority will be provided by

Eliza Kęsy – Siwik

e-mail: przetargi@mabion.eu

X. DETERMINATION OF CONDITIONS FOR CHANGING THE CONTRACT

The Contracting Entity determines the following circumstances that may result in the necessity of the content of the concluded contract amendments in comparison to the content of the submitted Offer, unless it does not constitute an amendment to the nature of the contract, i.e.

- 1. The occurrence of circumstances independent from Contractor or the Contracting Entity, which will have an impact to the date of the contract in such a way that they will prevent the completion of the research service within the time limit specified in the contract the extension of the contract will be extended by the period corresponding to the period necessary to remove the circumstances. The period for which the extension of the contract period has become necessary will be justified by the person named in the contract in writing.
- 2. The term of the term of the Agreement resulting from, among others from extending project implementation;
- 3. The term of the contract performance for reasons beyond the Tenderer's attempt;
- 4. The remuneration specified in the contract may change in case of the VAT rate changes;









- 5. A change in applicable law and regulations to the extent that affects for the execution of the contract subject;
- 6. The necessity of amendments to the contract is caused by circumstances that the Contracting Entity, acting with due diligence, could not foresee, and the value of the amendments to the contract does not exceed 50% of the value of the contract originally specified in the contract;
- 7. The change does not lead to an amendment to the nature of the contract and the total amendments to the value of the contract is less than the amounts stipulated in the provisions issued on the basis of art. 11 paragraph 8 Public Procurement Law, according to which the submission of notices to the Publications Office of the European Union is required, and simultaneously constitutes less than 10% of a value of the contract originally specified in the contract in the case of service or supply contracts or, in the case of building contracts, is less than 15% of the a value of the contract originally specified in the contract;
- 8. The modifications relate process of additional supplies, services or the construction works contract from the contractor being the party of the Contract, not covered by the basic contract, if they have become necessary and the following conditions have been cumulatively met:
 - the contractor cannot be replaced for economic or technical reasons, in particular regarding the interchangeability or interoperability of the equipment, services or installations ordered under the basic contract,
 - a replacement of contractor would cause significant inconvenience or a significant increase in costs for the Contracting Party,
 - the value of each subsequent change does not exceed 50% of the contract value originally specified in the contract.
- 9. The occurrence of obvious typing and calculation errors in the content of the contract.

The Contracting Party shall immediately inform other party of contract regarding the impact of the circumstances related to the occurrence of COVID-19 affecting the proper performance of the contract if such influence has occurred or may occur. The parties to the contract confirm this impact by adding to the information referred to in the first sentence, statements or documents that may relate in particular to:









- 1) the absence of employees or persons performing the duties for remuneration based on other legal grounds than an employment relationship, that participate or may participate in the performance of the contract;
- 2) decisions issued by the Chief Sanitary Inspector or the voivodship sanitary inspector acting on the authority of the latter, in connection with counteracting COVID-19, imposing on the contractor the obligation to take specific preventive or control activities;
- 3) orders issued by any Voivod/ Governor (PL: "wojewoda") or decisions issued by the Prime Minister related to counteracting COVID-19, referred to in art. 11 paragraph 1 and 2 of Public Procurement Law:
- 4) withholding the supply of products, product components or materials, difficulties in accessing equipment or difficulties in providing transport services;
- 5) the circumstances referred in points 1-4 hereinabove in an extent that they relate to a subcontractor or a further subcontractor.

XI. INFORMATION CLAUSE WITH ARTICLE 13 GDPR

According to art. 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ EU L 119 from 04.05.2016, p. 1), hereinafter "GDPR", Mabion S.A. informs that:

- The controller of personal data is Mabion S.A. with its registered office in Konstantynów Łódzki at 60 gen M. Langiewicza St., 95-050 Konstantynów Łódzki;
- Personal data will be processed in the course of the conduct of the competition, in order to:
 - > To allow you to participate in the proceedings article 6 (1b) "GDPR";
 - Archiving (Evidencing) being of the legitimate interest of the controller, such as redress and defending the rights of the Administrator article 6 (1f) "GDPR".
- 3. Personal data will be stored for a period of 10 years + 1 from the end of the proceedings. In the case of EU co-financing proceedings, the retention period may be longer, as determined in accordance with art. 140 Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural









Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006;

- 4. With regard to personal data, decisions shall not be taken in an automated manner, the application to article 22 GDPR;
- 5. The controller does not transmit data outside the European Economic Area;
- 6. The recipients of your personal data will be the only entities authorized to obtain personal data under the laws;
- 7. Each Tenderer shall have the right to have access to personal data, to receive copies thereof and subject to the laws of rectification, transfer, erasure or restriction of processing;
- 8. The right to lodge a complaint with the President of the Office for Personal Data protection where the natural person considers that the processing of personal data relating to him violates the GDPR;
- 9. Providing personal data is voluntary but is necessary to fulfill the purposes for which it was collected, failure to provide personal data will prevent you from attending the proceedings.

XII. APPENDICES

Form of Tender [Appendix 1];

The form of range and prices [Appendix 2];

Statement on the absence of personal or capital connections [Appendix 3];

Statement of fulfilling the formal requirements for participation in the procedure [Appendix 4]; Substantive provisions of the agreement [Appendix 5].

signature of Contracting Entity









APPENDIX 1 – to Request for Tender no. 01/04/2022/IMM dated 11.04.2022 FORM OF TENDER

XIII.	Name and address of Tenderer and its registration details, including NIP (tax ID):
XIV.	Name, phone number and e-mail of the contact person:
•••••	
XV.	Price
-	nted price within a given group must result from the calculation of the unit price (given in 2 to the inquiry) multiplied by the number of set/pieces requested by the Purchaser in the
Group 1	: price:]
•	
	s price:
Group 2	
	orice:[in words:]
	[in words
Gross	s price:[in words:]
Group 3	4
Net p	price:]
]
Gross	s price: [in words:]
Group 4	:
Net p	rice:]
Gross	s price: [in words:]









XVI. Execution time

Order processing time counted from the date of placing the order by the Contracting Entity i
calendar days (maximum 45 calendar days).
XVII. Payments
days from the date of delivery of the invoice to the Purchaser (min 30 days)
XVIII. Tenderer's declaration regarding the company secret (if applicable):
I/we certify that:
1) the following information is a business secret:
(documents containing a business secret need to be indicated)2) Explanation of the request for confidentiality of the aforementioned information is enclosed to the tender.
XIX. Other statements by the Tenderer:
I declare, that:
- I am bound by this offer for a period of 90 days from the deadline of submission of offers
Place and date:
Signature of Tenderer or Tenderer's authorized representative
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APPENDIX 2 - To Request for Tender no. 01/04/2022/IMM dated 11.04.2022

THE FORM OF RANGE AND PRICES

The unit prices listed below for a given item multiplied by the number of set/pieces requested by the Purchaser in the request for proposal must be consistent with the net and gross prices listed for the given group in Appendix 1 - Offer Form.

No	Name of product	Criteria fulfilment [YES]/NO]	Net price for the given line item
1	ADCC assay kit (Antibody Dependent Cell	[YES_/NO_]	
	Cytotoxicity) (for 5 tests – ten 96-well plates),		
	containing:		
	• Effector cells, an immortalized line of		
	human T lymphocytes, Jurkat line,		
	designed to assessment the biological		
	activity of anti-CD20 antibodies in an		
	antibody dependent cell cytotoxicity		
	(ADCC) assay.		
	Cells must be express FcyRIIIa receptors		
	on their surface with valine at position		
	158 (V158).		
	Cells must be express firefly luciferase		
	under the NFAT promoter, enabling a		
	readout of the luminescence signal	*	
	(linear to the concentration of the		
	tested sample).		
	Thaw -and- use cells that do not require		
	culture propagation.		









	RMPI 1640 cell medium		
×	 Medium komórkowe RMPI 1640 		
	• Fetal Bovine Serum (FBS) with low IgG		
	level		
	• Reagent for detecting expression of		
	firefly luciferase reporter gene in ADCC		
	bioassay; The reagent must be enable		
	the readout of the luminescence signal		
	on the luminescence reader.	=	
	The expiry date of all components – minimum		
	22 months from the date of delivery.		
		[VEC /NO]	
2.	Reagent for detection of the expression of	[YES]/NO]	
	firefly luciferase reporter gene in an ADCC		
	bioassay.		
	The reagent must be enable the readout of the		
	luminescence signal on the luminescence		
	reader.		
	Compatible with the Effector cells presented in		
	point 1.		
	The reagent must be resistant to components of		
	the culture medium, including phenol red.		
	The reagent in a lyophilized form that enables		
	storage at -20 °C for more than 20 months from		
	the date of delivery.		
	Possibility to re-freeze the reconstituted		
	reagent and store it at -20 °C for more than 4		
	weeks.		

Prod	uct	no	1:
------	-----	----	----

Manufacturer:	•••	• • •	•••	• • •	•••	••	• •		• •	
Catalog no :										









Product no 2:

Manufacturer:	
Catalog no.:	
GROUP 2	

		Cuitouio	
		Criteria	Net price for the
No	Name of product	fulfilment	given line item
		[YES]/NO]	
	RPMI 1640 medium with stable L-glutamine	[YES_/NO_]	
	The medium must be in liquid form, sterile		
	filtered (free from fungi, mold, aerobic and		
1.	anaerobic bacteria).		
	The reagent must be stable for more than 20		
	months stored at 2-8 °C.		
	The pH of the medium must be 7.3 ± 0.3 .		
	1M HEPES buffer	[YES_/NO_]	
	The buffer must be in liquid form, sterile		
	filtered (free from fungi, mold, aerobic and		
2.	anaerobic bacteria).		
	The reagent must be stable for more than 35		
	months stored at 2-8 °C.		
	The pH of the buffer must be 7.3 ± 0.3 .		
-	96-well plates with the following features:	[YES]/NO]]	
	White, for cellular testing with luminescence-		
	based reading (with minimum		
	autoluminescence and maximum reflection),		
	Flat-bottom (F - bottom) for optimal optical		
3.	properties, sterile, with lid, individually		
	packed,		
	raised edges of the wells to reduce		
	contamination,		
	Working volume: minimum 200 μL per well		









Prod	luct	no	1:
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Manufacturer:
Catalog no.::
Product no 2:
Manufacturer:
Catalog no.:
Product no 3:
Manufacturer:
Catalog no.:

No.	Name of product	Criteria fulfilment [YES] /NO]	Net price for the given line item
1.	Monoclonal antibodies biotinylation reagent with N- Hydroxysulfosuccinimide (NHS) ester reactive group. Reagent must be demonstrate the following features: - Chemical formula: C ₂₀ H ₂₉ O ₉ N ₄ S ₂ Na - Molecular weight: 556.59Da - Alkyl spacer: 22.4 angstroms length - Water soluble - Reactivity: primary amines (-NH ₂) in alkaline conditions No-Weigh format (1mg per alliquot)	[YES]/NO]]	
2.	Alexa Fluor™ 647 fluorochrome monoclonal antibodies labelling kit. Kit must be provide for preparation of 3 labelling reactions of 1mg of antibody (per each reaction). Kit must be composed of following elements about characteristics as stated: - Labeling reagent (aliquoted for three reactions), stable at pH range from 4 to 10,	[YES]/NO]	









- Sodium bicarbonate (NaHCO₃),		
- Spin columns allowing to remove unbound		
labeling reagent,	:	
Reagent that allows to modulate DOL (Degree of		5,
Labeling) parameter i.e., enables to lower the number		
of fluorochrome molecules coupled to one molecule of		
the antibody		

Product no 1:	
Manufacturer:	
Catalog no.:	
Product no 2:	
Manufacturer:	
Catalog no.:	

No	Name of product	Criteria fulfilment [YES]/NO]	Net price for the given line item
1.	Buffer of pH 11 designed to cleaning of automated microfluidic system. Portioned into single (10g) aliquots, no-weigh format. Buffer must be contain: Disodium metasilicate, Tetrasodium pyrophosphate, Pentasodium triphosphate, Sodium disilicate,	[YES]/NO]	
2.	Troclosene sodium, dihydrate Compact disc (CD) consisting of 96 microfluidic structures featuring streptavidin beads packed columns that are designed to	[YES]/NO]	







	quantitative (by immunoenzymatic reaction)		
	measurement of the analyte amount.		
	Compact disc must be consist of mixing		
	chamber that allows to incorporate into Anti-		
	Drug antibodies (ADA) analysis setup an acid		
	dissociation step. Volume of analyte in the		
	reaction – 200 μL.		
	Compact disc must be transparent to enable		
	laser excited fluorescence detection method.		
	The expiry date – minimum 12 months from		
	the date of delivery.		
	Buffer used for samples dilution (>1:2 ratio),	[YES_/NO_]	
	compatible with compact discs used for		
	automated microfluidic system. Buffer must be		
	contain detergent and enables to perform an		
3.	analysis in acidic conditions.		
	Buffer must be packed in a plastic bottle that		
	protects against light.		ž.
	The expiry date – minimum 12 months from		
	the date of delivery.		
	· · · · · · · · · · · · · · · · · · ·		

Product no 1:
Manufacturer:
Catalog no.::
Product no 2:
Manufacturer:
Catalog no.:
Product no 3:
Manufacturer:
Catalog no.:









Explanations (if applicable):						
••••••	•••••••••••••••••					
Place and date:						
Signat	ure of Tenderer or Tenderer's authorized representative					









APPENDIX 3 – to Request for Tender no. 01/04/2022/IMM dated 11.04.2022

STATEMENT ON THE ABSENCE OF PERSONAL OR CAPITAL CONNECTIONS

I, the undersigned,						
[name and surname of Tenderer or its authorised representative], declare that						
Capital or personal links are understood as mutual ties between Contracting Entity or persons						
authorised to bind Contracting Entity or persons who act on behalf of Contracting Entity in						
connection with preparing and conducting the procedure for selection of a contractor, and the						
contractor, which are in particular the following:						
• participation in a partnership as a partner of a civil law partnership or general partnership,						
holding at least 10% of shares or actions, supposing that lower limit is not required by other						
laws and regulation,						
serving as a member of a supervisory body or a managing body, acting as a registered						
representative or an attorney,						
being a spouse, a relative by lineal consanguinity or affinity, by collateral consanguinity to the						
2 nd degree or affinity to the 2 nd degree, or a person linked by way of adoption, custody, or lega						
guardianship.						
Place and date:						
Signature of Tenderer or Tenderer's authorized representative						









APPENDIX 4 – to Request for Tender no. 01/04/2022/IMM dated 11.04.2022

STATEMENT ON FULFILLING THE FORMAL REQUIREMENTS FOR PARTICIPATION IN THE PROCEDURE

I, the u	inders	igned	•••••			• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	,
[name	and	surname	of	Tenderer	or	its	authorized	representative],	declare	that
	•••••	[[nam	e of Tende	erer]					
• ha	ve/ ha	s the appro	opria	ite knowle	dge a	and e	experience to	perform the cont	ract to th	e
hi	ghest s	tandards								
• ha	ve/ ha	s a financia	al sit	uation that	gua	rant	ees the perfo	ormance of the en	tire contra	act
Place a	ind da	te:	•••••		•••••	•••••				
			••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • •	•••••				
			Sign	nature of Tender	rer or 1	Tender	er's authorized repr	resentative		









ANNEX 5 – to Request for Tender no 01/04/2022/IMM dated 11.04.2022

SUBSTANTATIVE PROVISIONS OF THE AGREEMENT

- Consumable materials provided for in the contract shall be supplied by the Contractor
 to the Contracting Entity in the amount and range established in the orders submitted
 by the Ordering Party.
- 2. The Ordering Party is entitled to submit orders with any frequency and concerning any range of products.
- 3. Consumable materials shall be delivered to the Ordering Party at the cost of the Contractor and on his responsibility.
- 4. Chemical reagents/consumable materials delivered to the Ordering Party shall be protected by the packaging which provides safe delivery and storing conditions and no risk of damage. Sterile materials shall be packed in single sterile packages. Each series of a given chemical reagent/ consumable material shall have a quality certificate of the Manufacturer.
- 5. Payment for delivered materials shall be settled after delivery of materials to the registered office of the Contracting Party, in compliance with the order submitted by the Contracting Party, upon a correct VAT invoice issued by the Contractor within min 30 days from its receipt date. The invoice date shall not be prior to the date of delivery and shall concern a transfer to a bank account indicated the Contractor.

Place and date::							

	Signature of Tenderer or Tenderer's authorized representative						