

DOCUMENTATION RELATED TO THE PUBLIC PROCUREMENT PROCEDURE

SUBJECT OF THE PUBLIC PROCUREMENT: SERVICE

GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY- STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL

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Invitation number: 461-112(809013)/2025-3

Date: November 27, 2025

A) INVITATION TO SUBMIT A TENDER

We invite you to submit a tender for the public procurement concerning:

GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY- STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL

The tender must be prepared in accordance with the instructions provided in this procurement documentation.

Tender:

**GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS
REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-
STAGE BREAST CANCER FOR PREMENOPAUSAL
PATIENTS AND PATIENTS ELIGIBLE FOR
THE ADAPT PROTOCOL**

**B) INSTRUCTIONS TO TENDERERS
FOR PREPARING A TENDER**

I GENERAL

1.1 Basic Information about the Procurement

Subject of the procurement:	<p>GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL.</p> <p>The subject of the public procurement is described in more detail in the Specification of the contracting authority's requirements with the proforma estimate and in Section 2.11 of these instructions.</p>
Type of procedure:	<p>The contracting authority will award this public procurement via an open procedure in accordance with Article 40 of the Public Procurement Act (Official Gazette of RS, Nos. 91/15, 14/18, 121/21, 10/22, 74/22 – Constitutional Court decision, 100/22 – ZNUZSZS, 28/23, and 88/23 – ZOPNN-F; hereinafter: ZJN-3), with the aim of concluding a framework agreement under Article 48 of ZJN-3.</p>
Duration of the contract:	<p>For a period of two years from the date of the final decision on the award of the public contract.</p>
Deadline for submission of bids:	<p>Bidders must submit their bids via the e-JN information system at https://ejn.gov.si by December 30, 2025 at 12:00 noon (see Section 2.4 of these instructions).</p>
Public opening of bids:	<p>The opening of bids will take place automatically in the e-JN information system on December 30, 2025, starting at 15:00 at https://ejn.gov.si (See Section 2.5 of these instructions).</p>

Bidders may submit bids for individual tests.

The contracting authority will conclude a framework agreement with the most favorable bidder for each individual test.

In the event that the contracting authority receives a bid that exceeds the available funds, it reserves the right not to award the public contract in its entirety.

The documentation relating to the award of the public contract is written in Slovenian and translated into English. In the event of differences in the meaning (interpretation) of individual provisions, the Slovenian language shall be considered the relevant language, i.e. the documentation relating to the public contract in Slovenian.

1.2 Participation

Any legal or natural person registered for the activity that is the subject of this public procurement, and who holds all required authorizations to carry out this public procurement, may participate as a bidder.

1.2.1 Foreign bidders

For bidders based abroad, the contracting authority will assess capability in the same manner as for bidders based in Slovenia. Foreign bidders must submit evidence as listed in Section 2.10 of these instructions.

1.2.2 Joint bids

Groups of economic entities may submit a joint bid.

In a joint bid, legal entities must list all participants in the ESPD form. One entity may be designated as the contact point for communication with the contracting authority until the award decision. Otherwise, the contracting authority will address all documents to all participants in the joint bid.

For each participant in a joint bid, the contracting authority will individually verify competence according to Section 2.10, including:

- no grounds for exclusion,
- professional competence,
- other criteria.

Each participant in a joint bid must submit a separate **ESPD form**.

If any participant in a joint bid has grounds for exclusion under Section 2.10.1, the contracting authority shall act in accordance with paragraphs 9, 10, and 11 of Article 75 of ZJN-3.

The "Specification of the contracting authority's requirements with the cost estimate" form must be submitted collectively by all participants in the joint bid (one form signed by at least one participant).

If a joint bid is selected, the contracting authority may request a formal joint implementation agreement (e.g., collaboration agreement) detailing the responsibilities of each participant. Participants remain jointly and severally liable to the contracting authority.

1.2.3 Subcontractors

The bidder may execute the contract entirely themselves or with subcontractors. In case of subcontracting, the bidder must specify:

- all subcontractors (name, full address, registration number, tax number, account) and the part of the contract to be subcontracted (type of work, value) (OBR-4);
- completed ESPD forms for these subcontractors in accordance with Article 79 of ZJN-3;
- request and consent for direct payment if required by the subcontractor (OBR-4).

During the performance of the agreement, the contracting party must notify the contracting authority of any changes to the information referred to in the previous paragraph and send

information on new subcontractors that it intends to subsequently include in the service, no later than five days after the change. In the event of the inclusion of new subcontractors, the party to the agreement must also submit the information and documents referred to in the second and third indents of the previous paragraph together with the notification.

When the bidder intends to execute a public contract with a subcontractor, the contracting authority will individually assess the capacity of each subcontractor according to Section 2.10 of these instructions, specifically:

- no grounds for exclusion may be present,
- capacity to perform professional activity,
- other conditions.

If any of the subcontractors present grounds for exclusion under point 1 of Section 2.10.1 of these instructions, the contracting authority will act in accordance with the provisions of paragraphs 9, 10, and 11 of Article 75 of the Public Procurement Act (ZJN-3).

The contracting authority may also reject a proposal to replace a subcontractor or include a new subcontractor if this could affect the uninterrupted performance of the service, or if the new subcontractor does not meet the conditions set by the contracting authority in the procurement documentation. The contracting authority will notify the party to the agreement of any potential rejection of a new subcontractor no later than ten days after receiving the proposal.

If a subcontractor requests direct payment in accordance with and as specified in paragraphs two and three of Article 94 of the ZJN-3, direct payment to the subcontractor is considered mandatory under the law, and the obligation binds both the contracting authority and the party to the agreement. When the bidder intends to execute the public contract with a subcontractor that requests direct payment under this provision, the following must occur:

- the party to the agreement must authorize the contracting authority to pay the subcontractor directly based on an invoice approved by the party to the agreement. The authorization is an integral part of the framework agreement;
- the subcontractor shall submit a consent form (OBR-4), on the basis of which the contracting authority shall settle the subcontractor's claim against the tenderer instead of the tenderer;
- the party to the agreement shall attach the subcontractor's invoice, which it has previously approved, to its invoice.

If direct payment to the subcontractor is not mandatory, the contracting authority shall require the selected tenderer to send it, within 60 days of payment of the invoice at the latest, its written statement and the subcontractor's written statement that the subcontractor has received payment for the service performed directly related to the subject of the public contract.

The selected tenderer shall be fully responsible to the contracting authority for the performance of the contract.

1.3 Clarifications regarding the documentation related to the public procurement

Clarifications regarding the content of the documentation related to the public procurement may only be requested via the public procurement portal. Clarifications will be provided via the public procurement portal.

If any tenderer requests any additional clarification regarding the documentation relating to the award of the public contract or the preparation of the tender, they must request it **in due time and no later than December 15, 2025 by 12:00 noon**. The contracting authority will provide additional clarification no later than six days before the deadline for submitting bids, provided that the request was submitted in a timely manner.

1.4 Supplements and amendments to the documentation relating to the award of the public contract

The contracting authority reserves the right to amend or supplement the documentation relating to the award of the public contract. If the contracting authority amends or supplements the documentation relating to the award of the public contract within the deadline for the submission of tenders, it shall publish this on its website (<http://www.ukc-mb.si>) and on the public procurement portal.

After the deadline for receipt of tenders, the contracting authority will not amend or supplement the documentation relating to the award of the public contract.

If the contracting authority changes or supplements the documentation relating to the award of the public contract 6 or fewer days before the deadline for the submission of tenders, it shall, depending on the scope and content of the changes, extend the deadline for the submission of tenders accordingly.

By moving the deadline for the receipt of tenders, the rights and obligations of the contracting authority and the tenderer shall be bound by the new deadlines resulting from the extended deadline for the submission of tenders.

II TENDER

2.1 Language

The tender should be drawn up in the Slovenian language, except for catalogues, information material, technical documentation, etc., which may be submitted in English.

2.2 Admissibility of the Tender

An admissible tender is a tender submitted by a tenderer for whom there are no grounds for exclusion and who meets the conditions to participate. Their tender must meet the needs and requirements of the client set out in the technical specifications and in the documentation related to the award of the contract, which was submitted on time and there was no evidence of collusion or corruption; the Contracting Authority did not assess it as unusually low, and the price did not exceed the contracting authority's guaranteed funds.

2.3 Submission of Tender

The Tenderer must submit the completed:

1. Tenderer Information Form (OBR-1);
2. Framework Agreement Sample (OBR-2);
3. Completed form Specification of the client's requirements with a preliminary estimate (OBR-3);
4. information about the subcontractor, the request and the subcontractor's consent for direct payment (OBR-4) – applies if the tenderer participates with a subcontractor;

5. a completed Statement regarding Restrictive Measures (OBR-5) in accordance with Section 2.10.3 of these instructions – applies to all economic operators except those subcontractors, suppliers, or entities on whose capacities the tenderer relies, whose participation does not exceed 10% of the contract value;
6. a completed ESPD form for all economic operators included in the tender.

The forms in Sections 1, 2, 3, 4, 5, and 6 are an integral part of this documentation relating to the award of the public contract. All forms must be completed, signed, and stamped (with a uniform seal). The documents shall be completed and signed by the legal representative or a person authorized by the legal representative. If the forms are not signed, a legally binding document shall be deemed to have been submitted, which shall have the same validity as a signed document.

Signed and stamped documents must be scanned into a PDF file, except for the ESPD form (although this is desirable).

The tenderer shall upload the entire tender in electronic form to the e-JN information system in the "Other attachments" section.

The bidder must upload the completed form "Specification of the contracting authority's requirements with a preliminary estimate (OBR-3)" in PDF format to the "Preliminary estimate" section of the e-JN information system, which will be accessible at the public opening of bids.

When preparing the bid and completing the forms, the bidder must follow the instructions provided on each form, including the instructions on the ESPD form. The content of the forms may not be changed.

If the tenderer submits a joint tender for the execution of the contract, it must submit the following additional documents for each partner in the joint tender:

- a completed tender form (OBR-1);
- a completed statement regarding restrictive measures (OBR-5);
- ESPD for all economic operators in the bid.

If bidders submit criminal record certificates in their bids, these must not be older than 4 months from the deadline for submission of bids for all economic operators in the bid..

The age of the documents may not exceed the deadline specified in the individual provisions of this documentation relating to the award of the public contract. In cases where the age of the documents is not specified, they must reflect the legally relevant status of the economic operator on the date specified for the submission of bids.

ESPD form

The ESPD form is an official statement by the economic operator that there are no grounds for its exclusion and that it meets the conditions for participation, while also providing the relevant information required by the contracting authority. The ESPD form also includes a formal declaration that the economic operator will be able to provide, upon request and without delay, evidence proving that there are no grounds for exclusion or that it meets the conditions for participation.

By submitting the ESPD form, the tenderer also confirms that it meets all other requirements of the contract.

The information provided in the ESPD and/or the evidence submitted by the economic operator must be valid.

The economic operator shall import the contracting authority's ESPD form (XML file) at the following web link <https://ejn.gov.si/espd> and enter the required information directly into it.

The completed and signed ESPD must be included in the tender for all economic operators who are involved in the tender in any capacity (tenderer, participating tenderers in the case of a joint tender, economic operators whose capacities are relied upon by the tenderer, and subcontractors).

A tenderer submitting a tender in the e-JN system shall upload their ESPD in the "Documents" section, under "ESPD – tenderer", and the ESPDs of other participants shall be uploaded in the "Participants" section, under "ESPD – other participants". A tenderer submitting a tender in the e-JN system shall upload an electronically signed ESPD in XML format or an unsigned ESPD in XML format. In the latter case, in accordance with the General Terms and Conditions of Use of the e-JN system, it is considered that a legally binding document has been submitted, which has the same validity as a signed document.

For other participants, the tenderer shall attach a hand-signed ESPD in the PDF format or an electronically signed XML.

2.4 Method and deadline for submitting bids

Bidders must submit their bids via the e-JN information system at <https://ejn.gov.si>, in accordance with the Instructions for using the information system for the electronic submission of bids via e-JN: BIDDERS (hereinafter: Instructions for using e-JN), published at <https://ejn.gov.si/aktualno/vec-informacij-ponudniki.html>. Before submitting a bid, the bidder must register at <https://ejn.gov.si> in accordance with the Instructions for using e-JN. If the bidder is already registered in the e-JN information system, they log into the application at the same address.

The user of the bidder who is authorized to submit bids in the e-JN information system submits the bid by clicking on the "Submit" button. When bids are submitted, the e-JN information system records the identity of the user and the time of submission. By submitting a bid, the user demonstrates and declares their willingness to submit a binding bid on behalf of the provider (Article 18 of the Obligations Code). Once submitted, the bid is binding for the period specified in the bid, unless the user withdraws or changes it before the deadline for submitting bids.

The bid shall be considered submitted on time if the contracting authority receives it via the e-JN system <https://ejn.gov.si> **no later than December 30, 2025 by 12:00 noon**. A bid shall be considered submitted if it is marked with the status "SUBMITTED" in the e-JN information system.

The bidder may withdraw or change their bid until the deadline for submission of bids. If the bidder withdraws their bid in the e-JN information system, the bid shall be deemed not to have been submitted and the contracting authority will not see it in the e-JN system. If the bidder changes their bid in the e-JN information system, the last submitted bid will be open to the contracting authority in this system.

After the deadline for submitting bids, it will no longer be possible to submit bids.

2.5 Time and place of opening of tenders

The opening of tenders will take place automatically in the e-JN information system on **December 30, 2025** and will begin **at 3 p.m.** at the web address <https://ejn.gov.si>.

The opening will take place in such a way that the e-JN information system will automatically display information about the tenderer and the variants, if requested or permitted, at the time specified for the public opening of tenders, and will provide access to the .pdf document uploaded by the tenderer to the e-JN system under the tab "Preliminary estimate". Bidders who have submitted bids can find this information in the e-JN information system, under the "Minutes of bid opening" section.

2.6 Correcting errors

Corrected errors must be marked with the initials of the person or persons signing the bid.

2.7 Permissible changes and additions to the tender

If the information or documentation to be submitted by economic operators is incomplete or incorrect, or if individual documents are missing, the contracting authority shall proceed in accordance with the provisions of the paragraphs 5, 6, and 7 of Article 89 of ZJN-3.

2.8 Providing misleading information

Whenever the contracting authority has reasonable grounds for believing that an individual economic entity has submitted an untrue statement or a forged or amended document as authentic in the public procurement procedure, the contracting authority shall submit a proposal to the National Audit Commission for the revision of public procurement procedures referred to in Section 5 of paragraph 1 or Section 1 of paragraph 2 of Article 112 of the ZJN-3.

2.9 Costs associated to the preparation of a tender

Bidders shall bear all costs associated with the preparation and submission of bids.

2.10 Verification of suitability

When submitting a tender, instead of certificates issued by public authorities or third parties, the contracting authority shall accept, in accordance with Article 79 of ZJN-3, an ESPD, which is a self-declaration, as preliminary evidence in relation to Sections 2.10.1 and 2.10.2.1 of these instructions.

The contracting authority will assess the suitability of economic operators as follows:

2.10.1 Grounds for Exclusion

The contracting authority shall exclude an economic operator from participation in the public procurement procedure:

1. if, during the verification in accordance with Articles 77, 79, and 80 of ZJN-3, it establishes or otherwise becomes aware that the economic operator or a person who is a member of the administrative, management or supervisory body of that economic operator or who has powers of representation, decision-making or control therein, has been convicted of a criminal offense under the Criminal Code (Official Gazette of

the Republic of Slovenia, No. 50/12 – official consolidated text, 6/16 – corr., 54/15, 38/16, 27/17, 23/20, 91/20, 95/21, 186/21, and 105/22 – ZZNSPP, 16/23; hereinafter: KZ-1) or for comparable criminal offenses handed down by foreign courts.

- terrorism (Article 108 of the Criminal Code-1),
- financing of terrorism (Article 109 of the Criminal Code-1),
- incitement and public glorification of terrorist acts (Article 110 of the Criminal Code-1),
- recruitment and training for terrorism (Article 111 of the Criminal Code-1),
- enslavement (Article 112 of the Criminal Code),
- human trafficking (Article 113 of the Criminal Code),
- accepting bribes in elections (Article 157 of the Criminal Code),
- violation of fundamental rights of workers (Article 196 of the Criminal Code),
- fraud (Article 211 of the Criminal Code),
- unlawful restriction of competition (Article 225 of the Criminal Code),
- causing bankruptcy through fraud or dishonest business practices (Article 226 of the Criminal Code),
- harming creditors (Article 227 of the Criminal Code),- poslovna goljufija (228. člen KZ-1),
- fraud against the European Union (Article 229 of the Criminal Code),
- deception in obtaining and using loans or benefits (Article 230 of the Criminal Code),
- deception in securities trading (Article 231 of the Criminal Code),
- deception of customers (Article 232 of the Criminal Code),
- unauthorized use of a foreign mark or model (Article 233 of the Criminal Code),
- unauthorized use of a foreign invention or topography (Article 234 of the Criminal Code),
- forgery or destruction of business documents (Article 235 of the Criminal Code),
- disclosure and unauthorized acquisition of business secrets (Article 236 of the Criminal Code),
- misuse of information systems (Article 237 of the Criminal Code),
- misuse of inside information (Article 238 of the Criminal Code),
- abuse of the financial instruments market (Article 239 of the Criminal Code),
- abuse of position or trust in economic activity (Article 240 of the Criminal Code),
- money laundering (Article 245 of the Criminal Code),
- misuse of non-cash means of payment (Article 246 of the Criminal Code),
- use of counterfeit non-cash means of payment (Article 247 of the Criminal Code),
- manufacture, acquisition, and disposal of counterfeiting devices (Article 248 of the Criminal Code),
- tax evasion (Article 249 of the Criminal Code),
- smuggling (Article 250 of the Criminal Code),
- abuse of official position or official rights (Article 257 of the Criminal Code-1),
- damage to public funds (Article 257.a of the Criminal Code-1),
- disclosure of confidential information (Article 260 of the Criminal Code-1),
- accepting bribes (Article 261 of the Criminal Code-1),
- giving bribes (Article 262 of the Criminal Code),
- accepting benefits for illegal mediation (Article 263 of the Criminal Code),
- giving gifts for illegal mediation (Article 264 of the Criminal Code),
- criminal association (Article 294 of the Criminal Code).

Evidence: ESPD for all economic operators in the tender

Note:

As evidence of compliance with the above condition, the economic operator may also submit certificates from the criminal record itself, provided that they reflect the latest

status and are not older than four months from the deadline for submission of tenders, namely for all economic operators in the tender and for all persons who are members of the administrative, management, or supervisory body of the economic operator or who have powers of representation, decision-making, or control therein.

2. if, during the verification in accordance with Articles 77, 79, and 80 of ZJN-3, it is established that the economic operator does not fulfill its mandatory contributions and other monetary non-tax obligations in accordance with the law governing financial administration, which are collected by the tax authority in accordance with the regulations of the country in which it is established or the regulations of the contracting authority's country. An economic operator shall also be deemed not to have fulfilled the obligations referred to in the previous sentence if it has not submitted all tax withholding statements for income from employment for the last five years by the deadline for submission of tenders. The economic operator shall not be excluded if, by the deadline for submission of tenders, it settles any outstanding liabilities amounting to EUR 50 or more and submits all tax withholding statements for income from employment for the last five years up to the deadline for submission of tenders.

Evidence: ESPD for all economic operators in the tender

3. if, on the date of expiry of the deadline for submission of tenders, it is excluded from public procurement procedures due to its inclusion in the register of economic operators subject to secondary sanctions of exclusion from public procurement procedures.

Evidence: ESPD for all economic operators in the tender

4. if, in the last three years prior to the deadline for submission of tenders, the competent authority of the Republic of Slovenia or another Member State or a third country has found at least two infringements relating to payment for work, working time, rest periods, the performance of work on the basis of civil law contracts despite the existence of elements of an employment relationship, or in relation to undeclared work, for which it has been fined by a final decision or several final decisions.

Evidence: ESPD for all economic operators in the tender

Corrective mechanism for Sections 1 and 4:

An economic operator who is in one of the situations referred to in points 1 and 4 of Chapter 2.10. 1. Reasons for exclusion, may submit evidence to the contracting authority by the deadline for submission of tenders at the latest, that it has taken sufficient measures to demonstrate its reliability despite the existence of reasons for exclusion under those points.

An economic operator who has been excluded from participation in public procurement procedures on the basis of a final judgment or decision on an offence that has an effect in the Republic of Slovenia is not entitled to use the option referred to in the previous paragraph during the period of exclusion.

Sufficient measures shall be deemed to include payment or an undertaking to pay compensation for all damage caused by the criminal act or infringement, active cooperation with the investigating authorities to clarify the facts and circumstances fully, and the adoption of concrete technical, organisational, and personnel measures

appropriate to prevent further criminal offences or infringements. When assessing the measures taken by the economic operator, the contracting authority shall take into account the seriousness and specific circumstances of the criminal offence or violation. If the contracting authority considers that the evidence provided by the economic operator is sufficient, it shall not exclude the economic operator from the public procurement procedure, notwithstanding Sections 1 and 4 of Chapter 2.10.1 Grounds for exclusion.

If the economic operator is in one of the situations referred to in Sections 1 or 4 of Chapter 2.10.1 Grounds for exclusion and invokes the corrective mechanism, it must submit a self-declaration indicating the violations and self-cleaning measures, and provide evidence that it has taken sufficient measures to demonstrate its reliability despite the existence of grounds for exclusion under points 1 and 4 of Chapter 2.10.1 of these instructions.

2.10.2 Conditions for participation

2.10.2.1 Suitability to pursue the professional activity:

The economic operator must be registered with the competent court or other authority.

Evidence: ESPD for all economic operators in the tender.

Note:

In the first field, tenderers must enter their registration number with the competent court or other authority. When asked: "Is this information available free of charge to the authorities from the databases of EU Member States?", answer YES and enter the link to AJPES in the first line, enter the number you entered under Registration number again under "Reference/Code", enter AJPES in the "Issuer" field (applies to bidders based in the Republic of Slovenia);

2.10.3 Other conditions

In accordance with the provisions of paragraph 1 of Article 5k of COUNCIL REGULATION (EU) 2022/ 576 of 8 April 2022 amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine, it is prohibited to award or continue to implement any public procurement or concession contracts:

- a) Russian nationals or natural or legal persons, entities or bodies domiciled in Russia;
- b) legal persons, entities or bodies more than 50% of which are owned, directly or indirectly, by an entity referred to in point (a) of this paragraph; or
- c) natural or legal persons, entities or bodies acting on behalf of or at the direction of an entity referred to in point (a) or (b) of this paragraph.

The same applies to a subcontractor or an entity whose capacity is relied on by the tenderer if it represents more than 10% of the contract value.

To prove that the relevant grounds for exclusion do not exist, all economic operators must enclose with their tender a completed Declaration regarding restrictive measures (OBR-5), except for those subcontractors, suppliers, or entities whose capacities are referred to by the tenderer and which do not represent more than 10% of the contract value.

Evidence: Completed Declaration regarding restrictive measures (OBR-5).

2.11 Additional requirements of the contracting authority

Additional requirements of the contracting authority are specified in the Technical Requirements attached to this documentation relating to the award of the public contract.

2.12 Tender value

Prices must be quoted in euros (EUR).

The price includes all costs (investigation costs, data preparation costs, and any other costs), all discounts and rebates.

The final bid value must also be stated, which is obtained by multiplying the prices by the quantities and summing the resulting values. The offer value must include all costs.

Value added tax shall not be charged in accordance with the provisions of Section 1 of paragraph 1 of Article 42 of the Value Added Tax Act (Official Gazette of the Republic of Slovenia, No. 13/11 – official consolidated text, 18/11, 78/11, 38/12, 83/12, 86/14, 90/15, 77/18, 59/19, 72/19, 3/22, 29/22 – ZUOPDCE, 40/23 – ZdavPR-B, 122/23 and 104/24).

Prices are fixed until all obligations under the framework agreement have been fulfilled, except for value adjustments permitted by the Rules on the methods of valorization of monetary obligations agreed in multi-year contracts by legal entities in the public sector (Official Gazette of the Republic of Slovenia, No. 1/04; hereinafter: the Rules). The contracting parties agree that the valorization of monetary obligations shall be carried out in the event of both an increase and a decrease in monetary obligations, whereby in the event of a reduction in monetary obligations, the provisions of the Rules shall apply *mutatis mutandis*. The consumer price index shall be used as the basis for revaluation. The price change may not exceed 80% of the change (increase or decrease) in the consumer price index calculated from the date of conclusion of the framework agreement.

The contracting parties shall make price changes only upon prior written notification from the other party.

The changed prices shall apply only in advance on the basis of an annex to the framework agreement.

In the event of a change to the Rules or the adoption of another regulation that newly or differently regulates the issue of revaluation during the implementation of the framework agreement, the contracting parties shall be obliged to conclude a new annex to the framework agreement.

2.13 Criterion

The criterion to be used in selecting the most favorable bidder:

- the lowest final value of each individual examination.

Note:

If several bidders offer the same price, excluding VAT, for the same examination, the contracting authority will conduct a draw for that examination. Those bidders who have offered the same prices may be present at the draw. The contracting authority will notify these bidders in writing of the date, time, and place of the draw. The contracting authority will conduct the draw. The contract will be awarded to the bidder who is drawn first.

2.14 Selection of tenderer

The provider will be selected who:

- submits an acceptable offer and
- offers the lowest final price for each examination

In accordance with Paragraph 6 of Article 14 of the Integrity and Prevention of Corruption Act (Official Gazette of the Republic of Slovenia, No. 69/11 – official consolidated text, 158/20, 3/22 – ZDeb and 16/23 - ZZPri), the selected tenderer is obliged, at the request of the contracting authority, before signing the framework agreement, submit a statement or information on the participation of natural and legal persons in the ownership of the selected tenderer, and on economic entities which, in accordance with the provisions of the law governing companies, are considered to be affiliated companies of the selected tenderer. If the tenderer submits a false statement or provides false information on the above facts, this will result in the framework agreement being declared null and void.

2.15 Validity of the bid

The bid must be valid for six months from the date of the public opening of bids.

In exceptional circumstances, the contracting authority may request that bidders extend the validity of their bids for a specified additional period. The request and the tenderers' responses must be made in writing. The tenderer may reject the request. A tenderer who agrees to the request shall not be required or permitted to modify the tender in any way other than to extend its validity.

2.16 Variant bids

Variant bids are not permitted.

III CONCLUSION OF THE FRAMEWORK AGREEMENT

3.1 Conclusion of the framework agreement

The contracting authority and the selected tenderer shall conclude a framework agreement for the provision of services in accordance with the provisions of the model framework agreement (OBR-2) referred to in Section 2.3 of these instructions for a period of two years from the date of the final decision on the award of the public contract.

The tenderer is obliged to sign the framework agreement within seven (7) days of receiving the contracting authority's request to sign the framework agreement; otherwise, the contracting authority will consider that the tenderer does not wish to conclude the contract with the contracting authority.

IV FINAL PROVISIONS

In addition to the provisions of these instructions, the provisions of the framework agreement and all documentation relating to the award of the public contract shall also apply. In case of doubt, individual provisions shall be assessed in accordance with the articles of the Public Procurement Act (ZJN-3) and the Obligations Code (Official Gazette of the Republic of Slovenia, No. 97/07, 64/16 – decision of the Constitutional Court, and 20/18 – OROZ631).

V LEGAL PROTECTION

Legal protection for bidders in public procurement procedures is provided in accordance with the provisions of the Public Procurement Legal Protection Act (Official Gazette of the Republic of Slovenia, No. 43/11, 60/11 - ZTP-D, 63/13, 90/14 - ZDU-11 60/17 and 72/19), in accordance with the procedure and manner prescribed by law.

A request for legal protection in public procurement procedures may be filed against any action of the contracting authority in the public procurement procedure, unless the law governing public procurement or the ZPVPJN provides otherwise. A request for legal protection may be filed by a person with active legal standing as defined in Article 14 of the ZPVPJN.

The request for review must contain:

1. the name and address of the applicant (hereinafter: the applicant) and the contact person,
2. the name of the contracting authority,
3. the reference number of the public contract or the decision on the award of the public contract or the recognition of suitability
4. the subject matter of the public contract,
5. the power of attorney for representation in the pre-review and review proceedings, if the applicant is represented by an authorized representative,
6. receipt for the payment.

The applicant must state in the request for review the alleged violations and the facts and evidence supporting them.

The fee is EUR 4,000.00. The fee must be paid into a sub-account opened with the Bank of Slovenia for the purpose of paying fees for the pre-audit and audit procedures, number 01100-1000358802 – execution of the budget of the Republic of Slovenia. The applicant must enter the following information in the pre-field and reference field for the approval number on the payment order: 11 16110-7111290- XXXXXXLL (the letter X stands for the public procurement notice number, and the letter L stands for the year. If the public procurement publication number is shorter than six characters, enter 0 in the missing places at the beginning).

The request for review is submitted via the eRevizija portal.

A request for review relating to the content of the publication, invitation to tender, or tender documentation shall be submitted within ten working days of the date of publication of the contract notice or receipt of the invitation to tender. Where the contracting authority changes or supplements the information in the publication, invitation to tender or tender documentation, a request for review relating to the changed, supplemented or clarified content of the publication, invitation or tender documentation, or to a statement in the original publication, invitation to tender or tender documentation directly related thereto, shall be submitted within ten working days of the date of publication of the additional information, information on the invitation to tender or tender documentation.

If the contracting authority finds that the procedural conditions set out in the first, third, fourth, or fifth indent of Paragraph 1 of Article 26 of the ZPVPJN are not met, the request for review shall be rejected by decision within three working days of receipt at the latest.

TENDER

Method of tender submission:

 Joint tender: (indicate: yes/no).¹

1. Description of the subject of the public procurement:	
GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-STAGE BREAST CANCER, FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL	
2.1 Tender value in EUR excluding VAT:	
3. Tenderer information:	
3.1 Company name:	
3.2 Address:	
3.3 Legal representative:	
3.4 VAT identification number:	
3.5 Company registration number:	
3.6 Bank account number:	
3.7 Telephone number:	
3.8 Personal identification number of the legal representative*:	
3.9 E-mail:	
3.10 Contact person:	
3.11 Person responsible for signing the framework agreement:	

Note*

- For other members of the management, executive, or supervisory body, or for any person who has authorization for representation, decision-making, or supervision within it (if applicable), the tenderer must provide their personal identification numbers either on their own forms or list them in the ESPD.

Date:

Stamp and signature of the tenderer:

.....

¹ In the case of a joint tender, each partner in the joint tender must complete the specified form.

SAMPLE FRAMEWORK AGREEMENT

concluded between:

UNIVERSITY MEDICAL CENTER MARIBOR, Ljubljanska ulica 5, 2000 Maribor, represented by the Director General of the University Medical Center, Prof. Vojko Flis, MD, PhD (hereinafter: the Contracting Authority), VAT identification number: SI56644817, contracting authority registration number: 5054150000

and the economic operator:

represented by the director _____ (hereinafter: the Contracting Party), VAT identification number of the party to the agreement: _____, registration number of the party to the agreement: _____.

I GENERAL PROVISIONS

Article 1

The contracting authority and the party to the agreement acknowledge that the contracting authority has conducted a public procurement procedure for "**GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL**," by open procedure in accordance with Article 40 of the Public Procurement Act (Official Gazette of the Republic of Slovenia, Nos. 91/15, 14/18, 121/21, 10/22, 74/22-decision of CC, 100/22-ZNUZSZS, 28/23 and 88/23–ZOPNN-F; hereinafter ZJN-3) with the aim of concluding a framework agreement in accordance with Article 48 of ZJN-3, published on the public procurement portal, publication number JN00..... / 2025-EUe16/01, publication date __ __ 2025.

Article 2

With this framework agreement (hereinafter: agreement), the contracting authority and the party to the agreement agree on the general and specific terms and conditions for the implementation of this agreement.

II SUBJECT OF THE AGREEMENT

Article 3

The subject of this agreement is the provision of the following service: genomic testing to support treatment decisions regarding chemotherapy in patients with early-stage breast cancer for premenopausal patients and patients eligible for the ADAPT protocol, (hereinafter: examination), as defined in the bid submitted by the party to the agreement in the public procurement procedure referred to in Article 1 of this agreement (hereinafter: bid) and in the documentation relating to the public procurement procedure.

The tender and the documentation relating to the public procurement procedure are annexed to and form an integral part of this agreement.

The subject matter of this agreement is the performance of examinations, which includes the following work or services to be provided by the party to the agreement:

- to provide examination reports within 10 days of receipt of the sample by the laboratory, provided that the sample is suitable.

In performing the services, the party to the agreement shall:

- collect samples from the Oncology Department in accordance with the agreement with the courier/transport service provided by the party to the agreement,
- provide an electronic link that enables the ordering of examinations (at least via secure e-mail in accordance with the GDPR),
- the party to the agreement shall ensure the possibility of direct ordering if the contracting authority enables this on their part,
- provide an electronic link to service requesters (doctors) for reviewing the results of analyses (at least via secure e-mail in accordance with the GDPR).

The contracting authority shall provide appropriately completed accompanying documentation for the order and a properly prepared breast cancer tissue sample.

The subject of this agreement also includes any additional test quantities that will be required by the contracting authority. The contracting authority shall perform the aforementioned examinations at the prices agreed upon in this agreement (point 1 of paragraph 1 of Article 95 of ZJN-3).

If new tests are required, the contracting authority reserves the right to supplement the list of examinations specified in the tender. In this case, the contracting authority shall invite the contracting party to submit a tender for these new tests at any time during the term of this agreement.

III SUBCONTRACTORS

Article 4

The provisions of this article shall apply in cases where a party to the agreement acts with subcontractors.

The party to the agreement shall engage a subcontractor in the performance of this agreement:

- (state the name, full address, registration number, VAT identification number, and bank account),
and the said subcontractor shall perform (state the type and value of the service).

The payment deadline for the subcontractor is the same as that specified for the payment of the contracting authority's obligations to the party in this agreement.

The party to the agreement authorizes the contracting authority to pay the subcontractor directly based on an invoice approved by the party to the agreement.

The subcontractor's consent, based on which the contracting authority settles the subcontractor's claim against the party to the agreement instead of the party to the agreement, is an integral part of and an annex to this agreement.

The party to the agreement shall attach to its invoice the subcontractor's invoice, which it has previously approved (this applies if the subcontractor requests direct payment).

The party to the agreement undertakes to send the contracting authority, no later than 60 days after payment of the invoice, its written statement and the subcontractor's written statement that the subcontractor has received payment for the service provided, directly related to the subject of the procurement (applies in cases where the subcontractor does not request direct payment).

The party to the agreement undertakes to notify the contracting authority during the implementation of the agreement of any changes to the information on already nominated subcontractors and to send information on new subcontractors it intends to subsequently include in the implementation of the public contract, no later than five days after the change. In the event of the inclusion of new subcontractors, the party to the agreement must also submit the following information and documents together with the notification:

- contact details and legal representatives of the proposed subcontractors;
- completed ESPD forms for these subcontractors in accordance with Article 79 of ZJN-3;
- attach the subcontractor's request for direct payment, if the subcontractor so requests (OBR-4).

The contracting authority reserves the right to reject a proposal to replace a subcontractor or include a new subcontractor if this could affect the uninterrupted performance of the service and if the new subcontractor does not meet the criteria set by the contracting authority in the documentation relating to the award of the public contract. The contracting authority shall notify the party to the agreement of any rejection of a new subcontractor within ten days of receiving the proposal.

Article 5

The contracting party and the contracting authority agree that, during the period covered by this agreement, the contracting party will only perform those types of services specified in Article 3 of this agreement that the contracting authority will require during that period.

The quantities specified in the tender are approximate. The client does not undertake to order a specific number of services.

The contracting party shall perform the services subject to this agreement for the contracting authority upon prior order, which the contracting authority shall send to the party in writing by post, courier, or e-mail.

IV PRICES

Article 6

The contracting authority shall order the services covered by this agreement at the prices

The price includes all costs (examination costs, data preparation costs, and other possible costs), all discounts, and rebates.

Prices are fixed until all obligations under this agreement have been fulfilled, except for value adjustments permitted by the Rules on the methods of valorization of monetary obligations agreed in multi-year contracts by legal entities in the public sector (Official Gazette of the Republic of Slovenia, No. 1/04; hereinafter: the Rules). The contracting parties agree that the valorization of monetary obligations shall be carried out in the event of both an increase and a decrease in monetary obligations, whereby in the event of a decrease in monetary obligations, the provisions of the Rules shall apply *mutatis mutandis*. The consumer price index shall be used as the basis for revaluation. The price change may not exceed 80% of the change (increase or decrease) in the consumer price index calculated from the date of conclusion of this agreement.

The contracting parties shall make price changes only upon prior written notification from the other party.

The changed prices shall only apply in advance on the basis of an annex to this agreement.

In the event that, during the term of the framework agreement, the Rules are amended, or another regulation is adopted that newly or differently regulates the valorisation of monetary obligations, the latest valid regulation replacing the currently valid Rules shall apply.

Value added tax shall be applied in accordance with the provisions of point 1 of paragraph 1 of Article 42 of the Value Added Tax Act (Official Gazette of the Republic of Slovenia, No. 13/11 – official consolidated text, 18/11, 78/11, 38/12, 83/12, 86/14, 90/15, 77/18, 59/19, 72/19, 3/22, 29/22 – ZUOPDCE, 40/23 – ZdavPR-B, 122/23 and 104/24), value added tax shall not be charged.

V QUALITY OF SERVICES

Article 7

The party to the agreement undertakes to provide professional and high-quality services with due skill, care and diligence.

The party to the agreement shall compensate the client for any actual damage or costs incurred through its fault.

VI PAYMENT TERMS

Article 8

The party to the agreement shall issue an e-invoice once a month for the services provided in the previous month. The e-invoice must include an attachment – a breakdown of the costs charged by departments.

The invoice must include the number of the framework agreement.

The contracting authority shall pay the total value of the services provided within 30 days

or within a period that complies with the legislation in force during the term of the agreement from the date of receipt of a correctly issued e-invoice to the transaction account specified on the e-invoice.

The party to the agreement shall send all invoices to the contracting authority exclusively in electronic form (e-invoice), in accordance with the Act on the Provision of Payment Services for Budget Users Act (Official Gazette of the Republic of Slovenia, Nos. 77/16 and 47/19).

In the event of a delay in payment, the contracting authority shall pay the contractor statutory default interest.

VII AGREEMENT ADMINISTRATOR

Article 9

The authorized representative for the contracting authority:

The agreement administrator for the contracting authority:

The agreement administrator for the contracting party: .

VIII CONCLUSION, DURATION OF THE AGREEMENT, AND WITHDRAWAL FROM THE AGREEMENT

Article 10

This agreement is concluded for a period of two years from the date of the final decision on the award of the public contract. It is concluded on the date of signature by the contracting authority and the contracting party.

In accordance with point 1 of paragraph 1 of Article 95 of ZJN-3, the parties to this agreement may mutually extend the duration of this agreement by concluding an annex to the agreement, provided that the new public procurement procedure, which must commence no later than three (3) months before the expiry of this agreement, is not completed in time. The extension may be carried out exclusively for the period until the completion of the public procurement procedure or until the conclusion of a new framework agreement, but for a maximum period of six (6) months. In the event of an extension of the term of this agreement, the service provider shall perform the services at the prices and under the other conditions agreed in this agreement.

If several consecutive amendments to the agreement are made due to an additional number of examinations, possible new types of examinations, and the extension of the agreement's validity, the increase in value may not exceed 30 per cent of the total value for which the agreement was concluded with the party to the agreement.

This agreement is concluded under a resolute condition, which shall be fulfilled in the event of one of the following circumstances:

- if the contracting authority becomes aware that a court has found, by a final decision, that the party to the agreement or a subcontractor has violated obligations under labor, environmental, or social legislation, or
- if the contracting authority becomes aware that the competent state authority has found at least two violations in relation to the party to the agreement or subcontractor during the performance of the agreement in relation to:

- payment for work,
- working hours,
- rest periods,
- performance of work on the basis of civil law contracts despite the existence of elements of an employment relationship or in connection with undeclared work, and for which it has been fined for an offense by one or more final decisions.

If the contracting authority becomes aware of a breach of the circumstances referred to in the previous paragraph, it shall proceed in accordance with the third indent of paragraph 4 of Article 67 of ZJN-3.

The resolutive condition shall be fulfilled provided that at least six months remain between the contracting authority becoming aware of the breach and the expiry of the agreement.

If the resolutive condition referred to in this article is fulfilled, the agreement shall be deemed terminated on the date of conclusion of a new framework agreement on the execution of the public contract for the public contract in question.

If the contracting authority does not initiate a new public procurement procedure within 60 days of becoming aware of the breach, the agreement shall be deemed to have been terminated on the sixtieth day after becoming aware of the breach.

Article 11

The contracting authority shall communicate all comments regarding the execution of this agreement to the contracting party in writing. If the contracting party fails to take into account the client's justified comments in the next performance of the service, the contracting authority may withdraw from this agreement without prior notice. The client shall notify the other party to the agreement in writing of its withdrawal from the agreement.

Under the terms set out in the previous paragraph, the contracting authority may withdraw from this agreement without notice, in particular if the contracting party:

- unjustifiably rejects a service,
- is late in executing a service,
- executes a service in a substandard manner,
- in the event of other breaches of this agreement.

Each party to the agreement may withdraw from this agreement without cause with a 3-month notice period. During the notice period, the party to the agreement must ensure the type and quantity of examinations that are the subject of this agreement at the prices specified in the offer.

The parties to the agreement may agree on a shorter notice period upon mutual agreement.

IX ANTI-CORRUPTION CLAUSE

Article 12

If it is established that, in the performance of the public contract on the basis of which this agreement was signed or in the implementation of this agreement, anyone acting on

behalf of or at the expense of the other party to the agreement a representative or intermediary of the contracting authority or other public sector body or organization has promised, offered, or given any undue advantage to obtain this contract or to conclude this contract on more favorable terms, or to omit the required supervision of the performance of contractual obligations, or for any other act or omission, which causes damage to a public sector body or organization or enables the representative of a public sector body, intermediary of a public sector body or organization, other contracting party or its representative, agent, intermediary to obtain an unauthorized benefit, this agreement shall be null and void.

X FINAL PROVISIONS

Article 13

The terms of this agreement are valid for the duration of the agreement.

The Agreement may be amended or supplemented in writing by a written annex to be accepted and signed by both parties to the Agreement. In the event that any of the provisions of this Agreement become invalid, such invalidity shall not prejudice any other provision of this agreement. Any invalid provision shall be replaced by a valid one, which achieves to the extent possible the original purpose and goal of the void provision.

Article 14

Both contracting parties undertake to process personal data and sensitive personal data to which they have access to in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council as of April 27, 2016 on the protection of individuals 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), and in accordance with the applicable legislation governing data protection).

The contracting party undertakes to protect any data and documentation obtained from the contracting authority related to the provision of services as defined in this Agreement as a business secret and to comply with the provisions of the law governing the protection of personal data.

Should the contracting parties learn of personal data during the performance of this agreement, the contracting parties agree not to use personal data obtained by their employees in accordance with the legislation governing personal data protection. Each contracting party shall process personal data only in the manner that is vital to the performance of this agreement. This provision shall apply for the duration of the agreement and indefinitely after the expiry of the Term.

The parties to the agreement agree not to use personal data obtained by the client's employees and the party to the agreement during the implementation of the agreement in contravention of the provisions of the law governing the protection of personal data. Personal data shall not be used for any purpose other than those specified in this agreement. This provision shall apply for the duration of the agreement and for the entire period after its expiry.

The parties to the agreement shall endeavor to ensure the conditions and measures for the protection of personal data and to prevent possible abuse, within the meaning of the provisions of the aforementioned law referred to in the previous paragraph.

Article 15

Any disputes arising from this agreement that cannot be resolved amicably by the parties to the agreement shall be settled by the competent court in Maribor.

Article 16

The agreement is drawn up in two identical copies, one of which shall be received by each party to the agreement.

	No.
Place , Date	Maribor, (date)
Contracting Party:	Contracting Authority: University Medical Centre Maribor:
Director:	Director General: Prof. Vojko Flis, MD, PhD

UNIVERSITY MEDICAL CENTRE MARIBOR

Ljubljanska street 5, 2000 Maribor

OBR-3

SPECIFICATION OF THE CLIENT'S REQUIREMENTS WITH A PRELIMINARY ESTIMATE

Date: _____

Quotation number:

THE SUBJECT OF THE PUBLIC PROCUREMENT

GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL

	Unit price per test, excluding tax	Estimated 2- year quantity	Amount
Name of the test	A	B	C=A*B
Genomic testing to support treatment decisions regarding chemotherapy in patients with early-stage breast cancer for premenopausal patients and patients eligible for the ADAPT protocol		50	
Total value:			

Stamp and signature:

SUBCONTRACTOR INFORMATION, REQUEST, AND CONSENT OF THE SUBCONTRACTOR FOR DIRECT PAYMENT

As the tenderer, we declare that for the execution of the public procurement “**GENOMIC TESTING TO SUPPORT TREATMENT DECISIONS REGARDING CHEMOTHERAPY IN PATIENTS WITH EARLY-STAGE BREAST CANCER FOR PREMENOPAUSAL PATIENTS AND PATIENTS ELIGIBLE FOR THE ADAPT PROTOCOL**”, we will include the following subcontractor:

1. Subcontractor information:

Name:	
Address:	
Tax identification number:	
Company registration number:	
Legal representative:	
Personal identification number of the legal representative*:	
Contact information (person, phone, e-mail):	
Bank account (number and bank name):	

***Note:**

- For other members of the management, executive, or supervisory body, or for any person with authorization for representation, decision-making, or supervision (if applicable), the tenderer must provide their personal identification numbers either on their own forms or list them in the ESPD.

2. Type and value of subcontracted work:

Type of subcontracted work:	
Value of subcontracted work (EUR excluding VAT):	

Date: _____

Stamp and signature of the tenderer's responsible person

3. Subcontractor consent

Request (4th indent of the second paragraph of Article 94 of the Public Procurement Act – ZJN-3) and consent of the subcontractor for direct payment (2nd indent of the fifth paragraph of the same article) *(to be completed by the subcontractor if requesting direct payment)*:

The undersigned legal representative or authorized person of the subcontractor

DECLARES,

that we request direct payment and in this regard consent that the contracting authority may pay our claim directly instead of paying it to the tenderer/main contractor.

Name and surname of the
legal representative of the subcontractor:

Signature and stamp of the legal
representative of the subcontractor:

Date: _____

INSTRUCTIONS:

- This form is completed only if subcontractors are involved (otherwise, this form does not need to be submitted).
- In the case of multiple subcontractors, a separate form must be submitted for each subcontractor.
- If a subcontractor requests direct payment, the tenderer must complete Section 3 of this form. If the tenderer does not submit the request along with the subcontractor's signed consent explicitly requesting direct payment, the contracting authority will consider that the subcontractor's consent for direct payment has not been given.

Name of the economic entity:

Registered office (address) of the economic entity:

STATEMENT REGARDING RESTRICTIVE MEASURES

We declare, under our material and criminal liability, that we are not in any of the situations listed below, as defined in the first paragraph of **Article 5k of COUNCIL REGULATION (EU) 2022/576 of 8 April 2022** amending Regulation (EU) No 833/2014 concerning restrictive measures in view of Russia's actions destabilizing the situation in Ukraine:

- a) a Russian citizen or a natural or legal person, entity, or body established in Russia;
- b) a legal person, entity, or body more than 50% of whose share is directly or indirectly owned by an entity referred to in point (a) of this paragraph; or
- c) a natural or legal person, entity, or body acting on behalf of or under the instructions of an entity referred to in point (a) or (b) of this paragraph.

This form is an integral part of the tender we submit for the public procurement **“Genomic testing to support treatment decisions regarding chemotherapy in patients with early-stage breast cancer for premenopausal patients and patients eligible for the ADAPT protocol.”**

Place:

Name and surname of the responsible
person of the economic entity:

Date:

Stamp:

Signature of the responsible person

PROFESSIONAL AND TECHNICAL REQUIREMENTS

1. The genomic test must be developed for the purpose of an individualized approach to the treatment of early invasive breast cancer. The test must have proven clinical utility in predicting breast cancer recurrence (original English term: *“breast cancer recurrence test”*), which must be confirmed in a prospective clinical study.
2. The test or the set of genomic tests must allow for easy and, as much as possible, reliable identification of patients who can safely avoid adjuvant chemotherapy.
3. The test or set of genomic tests should help predict the benefit of adjuvant chemotherapy.
4. The test must be applicable for early breast cancer: invasive, estrogen receptor-positive (ER+) and human epidermal growth factor receptor 2-negative (HER2-) breast cancer, stage I-II, tumor size ≤ 5.0 cm, with clinically high risk of recurrence, including patients eligible for the preoperative hormone sensitivity testing protocol (ADAPT protocol).
5. The test must also be applicable to premenopausal women.
6. The test must be based on protein expression microarray technology and NGS (RNA), or alternatively on qRT-PCR (RNA) technology.
7. The test must be included in internationally recognized breast cancer treatment guidelines: European Society of Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO), and the National Comprehensive Cancer Network (NCCN version 4.2024 – *“NCCN Category of Evidence and Consensus”*).
8. Test results or the set of test results must be available to the oncologist no later than 10 days from the receipt of the sample in the manufacturer’s laboratory, provided that the tissue sample has been properly collected and sent together with a correctly and fully completed test request form, which is a prerequisite for initiating laboratory analysis.
9. The tenderer of the test or set of tests, as well as the manufacturer, must guarantee that the service(s) are provided in compliance with the GDPR and the Personal Data Protection Act (ZVOP-1) regulations, ensuring the anonymity of the patients.