

## **LOW-VALUE PROCUREMENT**

### **PROCESS DOCUMENTS**

#### **SUBJECT-MATTER OF THE PROCUREMENT SERVICE PROVISION OF**

### **GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE BREAST CANCER**

#### Contents:

- A) Invitation to tender
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No.: 460-E-DS-79/22  
Date: February 23, 2022

## **A) INVITATION TO TENDER**

Hereby we would like to invite tenderers to submit a low-value tender to deliver the following:

### **GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE BREAST CANCER**

The tender must be produced in accordance with the instructions provided in this documentation regarding the low-value award of contract.

Public Contract:

**GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE  
BREAST CANCER**

**B) INSTRUCTIONS FOR TENDERERS  
TO COMPILE THE TENDER**

February, 2022

## GENERAL

### 1.1 Basic Contracting Data

Subject of the Contract:	<p><b>GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE BREAST CANCER</b></p> <p>The subject of the public contract is further specified in the document Specification of Requirements by the Contracting Authority and Quote/Pro Forma Invoice for the Group 1 and 2 in Section 2.11 of these Guidelines and Requirements by the Contracting Authority for the Group # 1 and group # 2.</p> <p>The tenderer is required to offer 100% of types and quantities of services tendered in a group or groups (applies for both tendered groups).</p>
Type of procedure:	The Contracting Authority shall award this public contract in accordance with the small value procurement procedure in line with Article 47 of the Public Procurement Act (Official Gazette of the Republic of Slovenia, No. 91/15 and 14/18, hereinafter referred to as ZJN-3) to enter into a Framework Agreement in accordance with Article 48 of ZJN-3.
Duration:	From May 14, 2022, to May 13, 2023
Submission Deadline:	Tenderers must submit tenders within the e-JN system at <a href="https://ejn.gov.si/eJN2">https://ejn.gov.si/eJN2</a> by <b>March 15, 2022 until 12:00</b> (See Section 2.5).
Public tender-opening session:	The opening of tenders shall take place automatically within the e-JN information system on <b>March 15 and shall begin at 14:00</b> at <a href="https://ejn.gov.si/eJN2">https://ejn.gov.si/eJN2</a> (See Section 2.6).

The low-value contract was divided into two categories/groups by the Contracting Authority.

Group # 1: Genomic testing to Define Treatment for Early-Stage Breast Cancer I;

Group # 2: Genomic testing to Define Treatment for Early-Stage Breast Cancer II.

A tenderer may submit a tender for a specific group or both groups.

The Contracting Authority will conclude a framework agreement for a specific group with the most economically advantageous tender.

In the event that the contracting authority receives a tender Tenders exceeding the base price, it reserves the right to:

- not award a small value contract in full,
- not to award a public contract for the part (individual group) where the tender exceeds the provided funds
- reduce the number of examinations.

The documentation related to public procurement is written in the Slovene and English language. In the event of differences in the meaning (interpretation) of individual provisions, the Slovene language shall be taken into account, i.e. the documentation related to public procurement in the Slovene language.

## **1.2 Who may submit a tender**

Participation in this call for tenders is open on equal terms to all natural and legal persons registered for an activity as the subject of this public procurement and can provide all the required permits to take part in this public procurement.

### **1.2.1 Foreign Tenderers**

For the tenderers from foreign countries, the contracting authority will equally check the capacity as for tenderers/legal persons established in the Republic of Slovenia.

### **1.2.2 Joint Tenders**

A joint tender may be submitted by a group of economic operators.

In the event of a tender submitted by a group of economic operators and selected to perform the contract, the contracting authority may require the tenderer to submit a written contract for the purposes of the public contract, that contains at least the following elements:

- to indicate/authorize the Group Leader to perform the public procurement,
- the type of contractual obligations to be performed by each partner and his responsibilities
- a statement saying they are aware of the payment terms set out in the documentation relating to the award of the small value contract and an indication that all Group members shall be jointly and severally liable towards the Contracting Authority for the performance of the contract
- the Group members grant to the Group leader all the necessary powers to act on their behalf in the submission of the tender and the conclusion of the contract

In the event that a Group members submit a joint tender, the contracting authority will individually identify the capacity referred to in Section 2.11 of these Guidelines for each tenderer in the group, as follows:

- Verification of non-exclusion of tenderers,
- It has the capacity to pursue the professional activity.

If the reasons for exclusion referred to in Section 2.10.1 of these Guidelines are given to any of the Group Members, the contracting authority will act in line with the provisions of the ninth, tenth and eleventh paragraphs of Article 75 of the ZJN-3.

### **1.3 Clarification to tender of low-value procurement**

Clarifications in regard to the procurement documents shall be provided by the contracting authority in response to written queries only at Public Procurement Portal.<sup>1</sup> Clarifications will be submitted at the Public Procurement Portal.

If any tenderer requests any additional explanation in regard to the documents related to the award of a low-value contract or creating a tender, they should file in a request in due time and no later than March 3, 2022 by 12:00 (noon).

### **1.4 Clarification and amendments to tender of low-value procurement**

The contracting authority reserves the right to amend or supplement the documentation related to low value procurement. In the event that the contracting authority changes or supplements the documentation related to the award of a small value contract within the deadline for submission of tenders, the amendments or/and supplements will be published at the Public Procurement Portal.

After the closing date for receipt of tenders, the Contracting Authority will no longer amend or supplement the tender documentation.

In the event that the contracting authority amends or supplements the documentation related to the award of the contract three or less days prior to the deadline for submission of tenders, it will extend the deadline for submission of tenders accordingly and depending on the scope and content of the amendments.

By moving the deadline for submission of tenders, the rights and obligations of the Contracting Authority and the Tenderer are subject to new deadlines arising from the extended deadline for submission of tenders.

## **II TENDERS**

### **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 Tender**

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. Eligibility Declaration (OBR-3);

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<sup>1</sup> <http://www.enarocanje.si>

4. Specification of Requirements by the Contracting Authority Form and Quote/Pro Forma Invoice for Group # 1 (OBR-4); valid only in the event, if the tenderer submits a tender for Group # 1;
5. Specification of Requirements by the Contracting Authority Form and Quote/Pro Forma Invoice for Group # 2 (OBR-5); valid only in the event, if the tenderer submits a tender for Group # 2;
6. CE IVD Certificate for test provided; valid for Group # 1 and Group # 2;
7. Certificate proving that the laboratory meets the accreditation standards. valid for Group # 1 and Group # 2.

Forms in Section 1, 2, 3, 4 and 5 are an integral part of this contract documentation. All forms must be completed, signed, and stamped (with a single stamp). The documents shall be completed and signed by the legal representative or a person authorized by him. If the forms are not signed, it is considered that a legally binding document has been submitted having the same validity as the signed one in accordance with the General Terms and Conditions of Use of the e-JN Information System.

**All documents must be signed and stamped and submitted in a pdf readable format.**

**The tenderer should upload and submit the tender in the e-JN system in the Section "Other Attachments".**

**The tenderer should upload and submit the completed form "SPECIFICATION OF THE CONTRACTING AUTHORITY'S REQUIREMENTS WITH A PROFORMA INVOICE FOR GROUP # 1" and/or "SPECIFICATION OF THE CONTRACTING AUTHORITY'S REQUIREMENTS WITH A PROFORMA INVOICE FOR GROUP # 2" in the "Proforma Invoice" Section in a PDF readable format to be available for public tender opening session.**

## **2.4 Performance of Tender**

When preparing the tender and filling in the forms, the tenderer must follow the instructions/guidelines provided on the relevant form.

In the event that the tenderer provides a different packaging from the advertised one, the quoted price must be converted with the regard to the advertised packaging.

## **2.5 How and when to submit the tender**

**Tenderers must submit their tenders to the e-JN information system at <https://ejn.gov.si/eJN2> in accordance with point 3 of the Instructions for using the e-JN system for use of the functionalities of electronic submission of tenders in the e-JN system: TENDERERS (hereinafter referred to as: e-Jn Instructions), which is a part of this procurement documentation and published here: <https://ejn.gov.si/eJN2>.**

**Prior to the submission, tenderer needs to register at <https://ejn.gov.si/eJN2> in accordance with the e-Jn Instructions. If you (tenderer) are already registered with the e-JN system, log in to the application at**

**The user authorized to submit tenders in the e-JN information system, submits the tender by clicking on the "Submit" button. When the tender is submitted, the e-JN information system records the user's identity and the time of tender submission. By the act of submitting a tender, the user demonstrates and declares his will to**

**submit a binding offer on behalf of the tenderer (Article 18 of the Code of Obligations<sup>2</sup>). By submitting a tender, it is binding on the time indicated in the tender, unless the user withdraws or changes it prior to the deadline expiration for the submission of tenders.**

Tenders shall be deemed to have been submitted on time if the contracting authority receives them via the e-JN system <https://ejn.gov.si/eJN2> **by March 15, 2022 until 12:00 (noon)**. A tender is regarded as having been submitted if it is designated as "SUBMITTED" in the e-JN information system.

A tenderer may withdraw or revise its tender up until the deadline for the submission of tenders. If a tenderer withdraws its tender from the e-JN information system, the tender shall be regarded as having not been submitted and the contracting entity shall not be able to see it in the e-JN system. If a tenderer revises its tender in the e-JN information system, the last submitted tender is available to the contracting entity in the system.

Tenders may no longer be submitted after the deadline for submission has passed.

## **2.6 When and where will the tenders be opened**

The opening of tenders shall take place automatically within the e-JN information system on **March 15, 2022 and shall begin at 14:00 at** <https://ejn.gov.si/eJN2>.

The opening process shall take place with the e-JN information system displaying the tenderer's details and the variants (if required or permitted) automatically at the time set for the public opening of tenders and enabling access to the pdf document that the tenderer uploads to the e-JN system under the "Pro-Forma Invoice/Quote" section. Tenderers that have submitted tenders shall have these details available to them in the "Records on the opening of tenders" Section within the e-JN information system.

## **2.7 Rectification of Errors**

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

## **2.8 Revisions and allowed supplementation of tender**

If the information or documentation to be submitted by economic operators is or seems incomplete or incorrect, or if individual documents are missing, the contracting authority will act in accordance with the provisions of the fifth, sixth and seventh paragraphs of Article 89 of ZJN-3.

## **2.9 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 point 5 of the first paragraph or point 1 of the second paragraph of Article 112 of the ZJN-3.

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<sup>2</sup> [Code of Obligations](#) (Official Gazette of the Republic of Slovenia, No. 97/07 - official consolidated text US and 20/18 – OROZ631)



## 2.10 Costs associated to the preparation of a tender

The contracting authority is not liable for the costs of preparing the tender.

## 2.11 Qualitative selection

The Contracting Authority will determine the ability of economic operators as follows:

### 2.11.1 Grounds for Exclusion

1. The contracting authority shall exclude an economic operator from the public procurement procedure if, during the verification in accordance with Articles 77, 79 and 80 of this Act, it finds or is otherwise informed that final judgment containing elements of the following criminal offences defined in the Criminal Code (Official Gazette of the RS, No. 50/12 - officially consolidated text and 6/16 – corr., 54/15, 54/15, 38/16, 27/17, 23/20, 91/20 and 95/21 hereinafter referred to as KZ-1) have been imposed on the economic operator or a person who is a member of the administrative, management or the supervisory body of this economic entity or which has the authority to represent or decide or supervise within: KZ-1):
  - Terrorism (Article 108 of the Criminal Code - KZ-1),
  - Financing of terrorist activities (Article 109 of the Criminal Code - KZ-1),
  - Incitement and public glorification of terrorist activities (Article 110 of the Criminal Code - KZ-1)
  - Conscripting and training for terrorist activities (Article 111 of the Criminal Code - KZ-1),
  - Enslavement (Article 112 of the Criminal Code - KZ-1),
  - Trafficking in human beings (Article 113 of the Criminal Code - KZ-1),
  - Acceptance of bribe during the election or ballot (Article 157 of the Criminal Code - KZ-1),
  - Violation of fundamental rights of employees (Article 196 of the Criminal Code - KZ-1),
  - Fraud (Article 211 of the Criminal Code - KZ-1),
  - Unlawful restriction of competition (Article 225 of the Criminal Code - KZ-1),
  - Causing bankruptcy by fraud or careless operations (Article 226 of the Criminal Code - KZ-1),
  - Defrauding creditors (Article 227 of the Criminal Code - KZ-1),
  - Business fraud (Article 228 of the Criminal Code - KZ-1),
  - Fraud to the detriment of the European Union (Article 229 of the Criminal Code - KZ-1),
  - Loan and benefit fraud (Article 230 of the Criminal Code - KZ-1),
  - Fraud in securities trading (Article 231 of the Criminal Code - KZ-1),
  - Deception of purchasers (Article 232 of the Criminal Code - KZ-1)
  - Unauthorized use of another's mark or model (Article 233 of the Criminal Code - KZ-1),
  - Unauthorized use of another's patent or topography (Article 234 of the Criminal Code - KZ-1),
  - Forgery or destruction of business documents (Article 235 of the Criminal Code - KZ-1),
  - Disclosure and unauthorized acquisition of trade secrets (Article 236 of the Criminal Code - KZ-1),
  - Information system abuse (Article 237 of the Criminal Code - KZ-1),
  - Abuse of insider information (Article 238 of the Criminal Code - Z-1),
  - Abuse of financial instruments market (Article 239 of the Criminal Code - KZ-1),

- Abuse of position or trust in business activity (Article 240 of the Criminal Code - KZ-1)
- Unauthorized acceptance of gifts (Article 241 of the Criminal Code - KZ-1),
- Unauthorized giving of gifts (Article 242 of the Criminal Code - KZ-1),
- Counterfeiting money (Article 243 of the Criminal Code - KZ-1),
- Fabrication and use of counterfeit stamps of value or securities (Article 244 of the Criminal Code - KZ-1),
- Money laundering (Article 245 of the Criminal Code - KZ-1),
- Abuse of non-cash means of payment (Article 246 of the Criminal Code - KZ-1),
- Use of a counterfeit non-cash means of payment (Article 247 of the Criminal Code - KZ-1),
- Fabrication, acquisition, and disposal of instruments of forgery (Article 248 of the Criminal Code - KZ-1),
- Tax evasion (Article 249 of the Criminal Code - KZ-1),
- Smuggling (Article 250 of the Criminal Code - KZ-1),
- Abuse of office or official duties (Article 257 of the Criminal Code - KZ-1),
- Causing damage to public funds (Article 257.a of the Criminal Code - KZ-1),
- Disclosure of classified information (Article 260 of the Criminal Code - KZ-1),
- Acceptance of bribes (Article 261 of the Criminal Code - KZ-1),
- Giving bribe (Article 262 of the Criminal Code - KZ-1),
- Accepting benefits for illegal intermediation (Article 263 of the Criminal Code - KZ-1),
- Giving of gifts for illegal intervention (Article 264 of the Criminal Code - KZ-1),
- Criminal association (Article 294 of the Criminal Code - KZ-1);

**Proof:** Eligibility Declaration (OBR-3)

2. The contracting authority shall exclude an economic operator from the public procurement procedure if, during the verification in accordance with Articles 77, 79 and 80 of this Act, it finds that the economic operator does not meet mandatory duties and other monetary non-tax liabilities in accordance with the law governing financial administration collected by the tax authority in accordance with the regulations of the country of establishment or those of the contracting authority country, if the value of these unpaid due obligations on the day of submission of the tender or application equals EUR 50 or more. An economic operator is deemed not to have fulfilled the obligations of the preceding sentence, if on the date of the submission of the tender or request, all withholding tax returns for employment earnings for the period of five years to the date of the submission of the tender or request have not been submitted.

**Proof:** Eligibility Declaration (OBR-3)

3. The contracting authority will also exclude the economic operator from the public procurement procedure if it is excluded from public procurement procedures on the day when the deadline for submission of tenders expires due to inclusion in the register of economic operators with imposed sanctions of exclusion from public procurement procedures.

**Proof:** Eligibility Declaration (OBR-3)

4. The contracting authority shall exclude an economic operator from the public procurement procedure if during the last three years prior to the deadline expiry of the submission of tenders the competent authority of the Republic of Slovenia or another Member State or a third country has identified at least two breaches of

remuneration for work, working hours, rest periods, performance of contract-based work despite the existence of elements of an employment relationship, or regarding undeclared employment, for which a fine was issued for a misdemeanor by a final decision or several final decisions.

**Proof:** Eligibility Declaration (OBR-3)

5. The contracting authority shall exclude an economic operator from the public procurement procedure if insolvency or winding-up proceedings have been initiated against it under the law governing insolvency and compulsory winding-up proceedings, or liquidation proceedings under the law governing companies, if its assets or the operations are managed by a liquidator or by court, or if its business activities are suspended, or if proceedings have been instituted against it in accordance with the regulations of another country, or an analogous situation having the same legal effect has arisen.

**Proof:** Eligibility Declaration (OBR-3)

## **2.11.2 Terms and Conditions for the Participation**

### **2.11.2.1 Capacity to pursue professional activity**

1. Any economic operator must be registered to pursue an activity with a competent court or other authority.

**Proof:** Eligibility Declaration (OBR-3)

## **2.12 Additional Requests by the Contracting Authority**

Additional requirements by the contracting authority are set out in Technical Specifications as part of this documentation related to the award of a small value contract.

## **2.13 Contract Value**

Prices must be expressed in EUR.

Prices include all costs associated with the production of data and other unforeseen expenses, discounts, and rebates.

In accordance with the provision of Point 1 of the first paragraph of Article 42 of the Value Added Tax Act (Official Gazette of the Republic of Slovenia No. 117/06, 52/07, 33/09, 85/09, 85/10, 18), value added tax / 11, 78/11, 38/12, 40/12 - ZUJF, 83/12, 14/13, 46/13 - ZIPRS1314-A, 101/13 - ZIPRS1415, 86/14, 90/15, 77/18, 59/19, 72/19, 49/20 - ZIUZEOP) is not applicable.

The final value of the tender, obtained by multiplying the prices by the quantities and adding up the values obtained, must also be stated. The tender value must include all costs.

Prices per unit must be fixed for the duration of the contract.

## **2.13 Criteria**

The criterion to be applied to select the most economically advantageous tenderer:

- **the lowest final value of an individual group, VAT excluded.**

**Note:**

In the event that several tenderers submit a tender with the same minimum final value for an individual group excluding VAT, the contracting authority shall select the tender that is delivered first to the information system.

## **2.15 Tenderer Selection**

Selected will be the tenderer who will:

- submit the admissible tender and
- offering the lowest final value of an individual group, VAT excluded.

In accordance with Point 6 of Article 14 of the Integrity and Prevention of Corruption Act (Official Gazette of the Republic of Slovenia, No. 45/10, 26/11, 43/11 and 158/20), the selected tenderer is required to within eight days of receiving such a request from the contracting authority:

- information about its founders, partners, silent partners, shareholders, or other owners, and information about their respective participating interest;
- information about economic operators that are considered to be its affiliates according to the law governing companies.

## **2.16 Validity of Tender**

Tenders must be valid until September 15, 2022.

In exceptional cases, the contracting authority may require tenderers to extend the validity of tenders for a specific additional period. The request and answers provided by the bidders must be submitted in writing or sent by fax. The tenderer may reject the request. A tenderer who agrees to the request will not be required or permitted to modify the tender in any way other than extending the validity of the tender.

## **2.17 Variant Bids/Tenders**

Variant bids are not allowed.

# **III FRAME AGREEMENT CONCLUSION**

## **3.1 Frame Agreement Conclusion**

The Contracting Authority and the selected tenderer will enter into a framework agreement for the provision of services in accordance with the provisions of the framework agreement sample (OBR-2) referred to in point 2.3 of these guidelines for a period from May 14, 2022, to May 13, 2023.

The tenderer is obliged to sign the framework agreement within 10 days after receiving the Contracting Authority's invitation to sign the framework agreement, otherwise the Contracting Authority will consider that the tenderer does not want to conclude this transaction.

# **IV FINAL PROVISIONS**

In addition to these provisions, the provisions of the framework agreement and the complete documentation relating to the award of the low value contract also apply. In case of doubt, assessment of individual provisions is necessary in accordance with the

statutory articles of the ZJN-3 and the Code of Obligations (Official Gazette of the Republic of Slovenia, No. 97/07).

## V LEGAL PROTECTION

The Legal Protection in Public Procurement Procedures 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) provides legal protection of tenderers in the public procurement procedure in accordance with the procedure and in the manner prescribed by law.

A legal protection request in public procurement procedures may be filed against any conduct of the contracting authority in the public procurement procedure, unless the law governing public procurement or the ZPVPJN states otherwise. A legal protection request may be filed by an actively legitimized person, as defined in Article 14 of the ZPVPJN.

The request for revision must include the following:

1. the name and address of the request applicant (hereinafter referred to as: applicant) and the contact person,
2. the name of the contracting authority,
3. an indication of the public contract or the decision to award a public contract or on the recognition of qualifications,
4. the subject of the procurement,
5. authorization to act in the pre-review and review procedure, if a representative is acting on behalf of the applicant,
6. confirmation of payment of the fee.

The request for review must contain the alleged breaches and the facts and evidence that prove a breach to have occurred.

The fee is €2,000 and shall be paid into a sub-account at the Bank of Slovenia for the purpose of payment of pre-audit and audit procedure charges, on the account number 01100-1000358802 - budgetary authority of the Republic of Slovenia. The applicant is required to submit the following information on the payment order and the approval number in the reference box: 11 16110-7111290- XXXXXXLL (X being the publication number of the tender notice, while L stands for the year; in the event, that there are less than six characters of the publication number, insert the number 0 in the missing spaces).

The request for revision must be submitted at the eRevizija portal.

The deadline for filing a request for review in relation to the content of the contract notice, the invitation to tender or the procurement documents, should be filed within ten business days of procurement documents or the receipt of a notice. When the contracting authority modifies or supplements the statements in the publication, invitation to tender or in the tender documentation, the request for revision, which refers to the change or supplement or clarification of the amendment, invitation or tender dossier or a directly related indication in the initial publication, invitation or dossier, shall be made within ten working days from the date of additional information publication, information on the pending procedure or correction, if this notice affects changes or supplements the requirements or criteria for selection of the most favorable tenderer.

If the contracting authority establishes that the procedural conditions referred to in the first, third, fourth or fifth indent of the first paragraph of Article 26 of ZPVPJN-B are not met, the request for review shall be rejected by a decision no later than three working days after receipt.

# TENDERER INFORMATION

## Submitting bids procedure:

Joint tender: (Please indicate: yes/no).<sup>1</sup>

<b>1. Description of the subject-matter of the public contract/tender:</b>	
<b>GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE BREAST CANCER</b>	
<b>2.1 Tender value in EUR for group # 1, VAT excluded</b>	
<b>2.2 Tender value in EUR for group # 2, VAT excluded:</b>	
<b>3. Tenderer Information:</b>	
3.1 Company Name:	
3.2 Address:	
3.3 Statutory Representative:	
3.4 VAT Identification Number:	
3.5 Company Reg. Number	
3.6 Bank Account Number:	
3.7 Phone Number:	
3.8 Email:	
3.9 Contact:	
3.10 Person responsible to sign the framework contract:	

Date:

Stamp and signature:

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<sup>1</sup> If a joint tender has been submitted, each joint tender partner needs to complete the form.

## FRAMEWORK AGREEMENT SAMPLE

Signed by:

UNIVERSITY MEDICAL CENTER MARIBOR, Ljubljanska ulica 5, 2000 Maribor (hereinafter referred to as: UKC Maribor), represented by the CEO of UKC, Prof. Anton Crnjac, MD, PhD, Senior Adviser (hereinafter referred to as: Contracting Authority), VAT ID: SI56644817, Contracting Authority Registration Number: 5054150

and economic operator:

, represented by (hereinafter referred to as: Agreement Party, VAT ID: Agreement Party Registration Number: .

### I PRELIMINARY OBSERVATIONS

#### Article #1

The contracting parties hereby establish that the Contracting Authority conducted the low-value procurement procedure to deliver Genomic testing to Define Treatment for Early-Stage Breast Cancer in accordance with Article 47 of the Public Procurement Act (Official Gazette RS no. 91/15, 14/18 and 121/21, hereinafter referred to as: ZJN-3) to enter into a framework agreement in accordance with Article 48 of ZJN-3.

#### Article #2

The contracting authority and the contracting party agree on the general and specific conditions for the implementation of the agreement based on this framework agreement (hereinafter referred to as: the Agreement).

### II SUBJECT

#### Article #3

The subject of the contract is service provision of: Genomic testing to Define Treatment for Early-Stage Breast Cancer (hereinafter referred to as: Service), as defined in the tender/offer provided by the Contracting Party.

The procurement documents referring to the small value contract award and the contractor's tender constitute integral parts of this contract.

The subject of the contract is the provision of services including the following services to be provided and ensured by the selected contracting party:

- genomic testing to predict the recurrence probability of Early-Stage Breast Cancer,
- written results delivered to the client/user (physician), unless otherwise agreed with the client/user;

- test results provided within 10 days of sample/specimen receipt in the laboratory, if the sample/specimen is relevant.

When providing the services, the contracting party is obliged to:

- collect samples at the Department of Gynecologic and Breast Oncology in line with the courier/transport service agreement ensured by the provider or test manufacturer,
- provide an electronic connectivity with the ability to order tests (min. secure email in accordance with GDPR, the provider should ensure the option for direct ordering, if allowed by UKC),
- provide an electronic link or connectivity to the test clients/users (physicians) to review the analysis results of (min. secure e-mail in accordance with GDPR),
- the provider ensures the option of direct procurement, if allowed by UKC.

The contracting authority must provide a duly completed supporting documentation for the contract.

The contracting authority must provide a relevant breast cancer tissue sample.

The procurement documents referring to the public contract award and the contractor's tender constitute integral parts of this contract.

#### **Article #4**

The contracting party and the contracting authority agree that throughout the period for which this agreement is in force, the contracting party will deliver to the contracting authority only those types of services referred to in Article 3 of this Agreement the contracting authority will require during that period.

The services covered by this Agreement will be provided by the contracting party for the contracting authority following by prior order, which will be provided to the contracting party by the contracting authority in writing by post or per courier service or by e-mail.

The contracting party will deliver the services within the deadlines specified in the rules.

### **III PRICING**

#### **Article #5**

The prices incorporated in the contract/tender are fixed for the entire duration of this agreement.

Prices include all costs associated with the production of data and other unforeseen expenses, discounts, and rebates.

In accordance with the provision of point 1 of the first paragraph of Article 42 of the Value Added Tax Act (Official Gazette of the Republic of Slovenia 117/06, 52/07, 33/09, 85/09, 85/10, 18/11, 78/11, 38/12, 40/12 - ZUJF, 83/12, 14/13, 46/13 - ZIPRS1314-A, 101/13 - ZIPRS1415, 86/14, 90/15, 77/18, 59/19, 72/19, 49/20 - ZIUZEOP) the value added tax **shall not be chargeable**.



## IV QUALITY OF SERVICES PROVIDED

### Article #6

The Contracting Party undertakes to deliver high-quality services in a professional manner and with due skill, care, and diligence.

The Contracting Party will compensate the Contracting Party for the actual damage or costs incurred as a result of his fault.

## V PAYMENT TERMS

### Article #7

The Contracting Party shall issue the invoice for the provided services within eight days following the delivery of services.

The Contracting Authority will settle the invoice no later than 60 days from the date of the correctly issued invoice on the bank account .

In line with the Provision of Payment Services to Budget Users Act (Official Gazette of the Republic of Slovenia, No. 77/16 and 47/19), the contracting party must submit all invoices to the Contracting Authority electronically (e-invoice).

The contracting parties agree that, in the case of a late payment, the Contracting Party is required to pay the default interest.

## VI CONTRACT ADMINISTRATOR

### Article #8

The contract administrator on behalf of the contracting authority is: .....  
The contract administrator on behalf of the contracting party is: .

## VII DURATION AND WITHDRAW FROM THE AGREEMENT

### Article #9

This agreement is concluded for a period from May 14, 2022, to May 13, 2023 enters into force when signed by the contracting authority and the contracting party.

This Agreement is concluded under a resolutive condition, which shall take effect if one of the following circumstances is met:

- if the contracting authority learns that a court found by virtue of a final decision a breach of obligations arising from environmental, social, or labor law on the part of either the contractor (Contracting Party) or its subcontractor or
- if the contracting authority learns that a fine has been imposed on the contractor (Contracting Party) or its subcontractor twice or more during the performance of the agreement
  - by virtue of one or more final decisions rendered by a competent state authority for a misdemeanor in connection with remuneration for work,
  - working hours,
  - rest periods,

- or the performance of contract-based work despite the existence of elements of an employment relationship, or in connection with undeclared work,

and provided there are at least six months from the time of becoming apprised of the breach to the expiry of validity of the Agreement, and in the event of participation with subcontractors also if after the identification of a breach by a subcontractor that subcontractor is not substituted or replaced within 30 days of the contractor's becoming apprised of the breach as set out in Article 94 of the ZJN-3 and the provisions of this Agreement.

In the event of the fulfillment of the resolutive condition referred to in the previous paragraph, the Agreement shall be deemed null and void on the day of the concluding of a new agreement on the delivery of the public contract. The contracting authority will inform the contracting party of the date of conclusion of the new agreement.

If the contracting authority fails to initiate a new public contract award procedure within 30 days after becoming apprised of the breach, the Agreement shall be deemed null and void on the thirtieth day after it is becoming apprised of the breach.

### **Article #10**

The Contracting Authority shall notify the Contracting Party in writing of any comments regarding the delivery or implementation of this agreement. If the contracting party does not consider or follow the justified comments made by Contracting Authority when delivering or completing the subsequent service, the Contracting Authority may withdraw from this Agreement. The Contracting Authority shall notify the Contracting Party in writing of the withdrawal from the agreement.

The Contracting Authority may withdraw from this Agreement if the Contracting Party:

- dismisses the contractual obligations as unfounded,
- fails to perform the contractual obligations in a timely fashion,
- fails to perform the contractual obligations at the requisite quality.

## **VIII ANTI-CORRUPTION CLAUSE**

### **Article #11**

If it is found that, during this public tender, on the basis of which this agreement has been concluded, or during the execution of this contract, anyone acting in the name of – or on the account of – the Contracting Party, has promised, offered or given any undue advantage to the contracting authority, or those employees that had a decisive influence on the choice of the Contracting Party, in order to win this public contract, to conclude this contract under more favorable conditions, to omit due diligence in the supervision of the contract implementation, to carry out any other act or omission causing damage to the Contracting Party or allowing the Contracting Party or its employees to obtain an undue advantage, this contract will be void.

## **IX FINAL PROVISIONS**

### **Article #12**

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 #13**

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 contracting parties shall aim to provide conditions and measures to ensure the protection of personal data and to prevent possible misuse pursuant to the provisions of the preceding paragraph of the said Act.

### **Article #14**

In the event that the contracting parties cannot settle a dispute by common consent, they shall abide by the decision of the competent court in Maribor.

### **Article #15**

The contract is drawn up in two identical copies, each contracting party receiving one copy.

No.: .....

In , date

In Maribor, date .....

Contracting Party:

Contracting Authority:

UKC Maribor:

CEO

CEO of UKC:

Prof. Anton Crnjac, MD, PhD, Senior Adviser

TENDERER

## ELIGIBILITY STATEMENT

Subject of the low-value contract: GENOMIC TESTING TO DEFINE TREATMENT FOR EARLY-STAGE BREAST CANCER

The tenderer / contracting party hereby declares under criminal and material liability that:

1. We (an economic operator or a person who is a member of the administrative, management or supervisory body of that economic operator or who has the authority to represent or decide on or supervise it) has not been the subject of a final judgment having the elements of the following offenses defined in the Criminal Code (Official Gazette of the RS, No. 50/12 - officially consolidated text and 54/15, hereinafter referred to as KZ-1): KZ-1):
  - Terrorism (Article 108 of the Criminal Code - KZ-1),
  - Financing of terrorist activities (Article 109 of the Criminal Code - KZ-1),
  - Incitement and public glorification of terrorist activities (Article 110 of the Criminal Code - KZ-1)
  - Conscripting and training for terrorist activities (Article 111 of the Criminal Code - KZ-1),
  - Enslavement (Article 112 of the Criminal Code - KZ-1),
  - Trafficking in human beings (Article 113 of the Criminal Code - KZ-1),
  - Acceptance of bribe during the election or ballot (Article 157 of the Criminal Code - KZ-1),
  - Violation of fundamental rights of employees (Article 196 of the Criminal Code - KZ-1),
  - Fraud (Article 211 of the Criminal Code - KZ-1),
  - Unlawful restriction of competition (Article 225 of the Criminal Code - KZ-1),
  - Causing bankruptcy by fraud or careless operations (Article 226 of the Criminal Code - KZ-1),
  - Defrauding creditors (Article 227 of the Criminal Code - KZ-1),
  - Business fraud (Article 228 of the Criminal Code - KZ-1),
  - Fraud to the detriment of the European Union (Article 229 of the Criminal Code - KZ-1),
  - Loan and benefit fraud (Article 230 of the Criminal Code - KZ-1),
  - Fraud in securities trading (Article 231 of the Criminal Code - KZ-1),
  - Deception of purchasers (Article 232 of the Criminal Code - KZ-1)
  - Unauthorised use of another's mark or model (Article 233 of the Criminal Code - KZ-1),
  - Unauthorised use of another's patent or topography (Article 234 of the Criminal Code - KZ-1),
  - Forgery or destruction of business documents (Article 235 of the Criminal Code - KZ-1),
  - Disclosure and unauthorized acquisition of trade secrets (Article 236 of the Criminal Code - KZ-1),
  - Information system abuse (Article 237 of the Criminal Code - KZ-1),
  - Abuse of insider information (Article 238 of the Criminal Code - Z-1),
  - Abuse of financial instruments market (Article 239 of the Criminal Code - KZ-1),
  - Abuse of position or trust in business activity (Article 240 of the Criminal Code - KZ-1)
  - Unauthorised acceptance of gifts (Article 241 of the Criminal Code - KZ-1),
  - Unauthorised giving of gifts (Article 242 of the Criminal Code - KZ-1),
  - Counterfeiting money (Article 243 of the Criminal Code - KZ-1),

- Fabrication and use of counterfeit stamps of value or securities (Article 244 of the Criminal Code - KZ-1),
  - Money laundering (Article 245 of the Criminal Code - KZ-1),
  - Abuse of non-cash means of payment (Article 246 of the Criminal Code - KZ-1),
  - Use of a counterfeit non-cash means of payment (Article 247 of the Criminal Code - KZ-1),
  - Fabrication, acquisition, and disposal of instruments of forgery (Article 248 of the Criminal Code - KZ-1),
  - Tax evasion (Article 249 of the Criminal Code - KZ-1),
  - Smuggling (Article 250 of the Criminal Code - KZ-1),
  - Abuse of office or official duties (Article 257 of the Criminal Code - KZ-1),
  - Causing damage to public funds (Article 257.a of the Criminal Code - KZ-1),
  - Disclosure of classified information (Article 260 of the Criminal Code - KZ-1),
  - Acceptance of bribes (Article 261 of the Criminal Code - KZ-1),
  - Giving bribe (Article 262 of the Criminal Code - KZ-1),
  - Accepting benefits for illegal intermediation (Article 263 of the Criminal Code - KZ-1),
  - Giving of gifts for illegal intervention (Article 264 of the Criminal Code - KZ-1),
  - Criminal association (Article 294 of the Criminal Code - KZ-1);
2. we comply with mandatory duties and other monetary non-tax liabilities in accordance with the law governing the financial administration 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 to the value of any outstanding due the application amounts to less than EUR 50 and that on the day of submission of the tender we have submitted all withholding tax returns for employment income for the period of the last five years until the date of submission of the tender or application;
  3. on the day when the deadline for submission of tenders expired, we were not excluded from public procurement procedures due to the inclusion into the register of economic operators with imposed supplementary sanctions of exclusion from public procurement procedures;
  4. during the last three years prior to the deadline expiry of the submission of tenders the competent authority of the Republic of Slovenia or another Member State or a third country has not identified at least two breaches of remuneration for work, working hours, rest periods, performance of contract-based work despite the existence of elements of an employment relationship, or regarding undeclared employment, for which a fine was not issued for a misdemeanor by a final decision or several final decisions;
  5. no insolvency or winding-up proceedings have been initiated against the contracting party under the law governing insolvency and compulsory winding-up proceedings, or liquidation proceedings under the law governing companies, if its assets or the operations are managed by a liquidator or by court, in addition our business activities are not suspended, and no proceedings have been instituted against us in accordance with the regulations of another country, neither an analogous situation having the same legal effect has arisen;
  6. the economic operator is registered to pursue an activity with the competent court or other authority;

This statement is an integral part of the service tender to apply for the low-value contract to supply the following: Genomic Testing to Define Treatment for Early-Stage Breast Cancer.

Date:

Stamp and signature:

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**University Medical Center Maribor as Contracting Authority**

Ljubljanska ulica 5, SI-2000 Maribor

**Specification of Requirements by the Contracting Authority and Pro Forma Invoice for group # 1**

OBR-4

Date:

No. of Tender:

**SUBJECT-MATTER OF THE PROCUREMENT** Genomic Testing to Define Treatment for Early-Stage Breast Cancer

	Unit Price Excl. VAT	Indicative Annual Quantity	Value
	A	B	C=A*B
<b>EXAMINATION</b>			
Genomic testing to Define Treatment for Early-Stage Breast Cancer I		40	
<b>TOTAL VALUE OVER ONE YEAR</b>			

**Stamp and signature:**

**University Medical Center Maribor as Contracting Authority**

Ljubljanska ulica 5, SI-2000 Maribor

**Specification of Requirements by the Contracting Authority and Pro Forma Invoice for grouš # 2**

OBR-5

Date:

No. of Tender:

**SUBJECT-MATTER OF THE PROCUREMENT** Genomic Testing to Define Treatment for Early-Stage Breast Cancer

	Unit Price Excl. VAT	Indicative Annual Quantity	Value
	A	B	C=A*B
<b>EXAMINATION</b>			
Genomic testing to Define Treatment for Early-Stage Breast Cancer II		20	
<b>TOTAL VALUE OVER ONE YEAR</b>			

**Stamp and signature:**

## Technical/Medical Tender Requirements to Purchase Genomic Tests for Breast Cancer Treatment for group # 1

1. A genomic test should be developed to individually treat early invasive breast cancer. The test must demonstrate clinical utility in terms of breast cancer recurrence testing and medically proven prognostic and predictive value.
2. The test can be based on protein expression network (microarray) and next-generation sequencing (RNA) or qRT-PCR (RNA) technology.
3. The test or the set of genetic tests must allow for the quick and reliable identification of patients who require or do not require adjuvant chemotherapy in the treatment process without any impact on the long-term treatment outcome.
4. The test should be at least included in the following breast cancer treatment guidelines: European Society of Medical Oncology (ESMO), European Group for Tumor Markers (EGTM), St. Gallen International Breast Cancer Consensus.
5. The test must be validated with an internationally accepted validation set out in the guidelines for the treatment of patients of all ages and:
  - for invasive, estrogen-positive (ER+) breast cancer, stage I-II, with a size of  $\leq 5.0$  cm and a clinically high risk of recurrence,
  - to apply to as many other cancer types as possible (ER+/- and HER2+/-), and
  - for positive axillary lymph nodes (LN+) patients.The test set should provide oncologists with additional information to enable them determine the most appropriate neoadjuvant or adjuvant treatment, as well as the potential de-escalation of hormonal therapy, in addition to deciding on the use of chemotherapy.
6. If the tissue sample was properly obtained and sent including a duly completed test order form, the findings of the test(s) must be delivered to the oncologist no later than 10 days after the sample has arrived at the manufacturer's laboratory.
7. In order to protect patient anonymity, the test provider and the manufacturer guarantee that the service(s) are provided in conformity with the requirements of the GDPR and the Personal Data Protection Act of the Republic of Slovenia.
8. The test provider must also present the following evidence:
  - CE IVD Certificate for the tests provided.
  - Certificate proving that the laboratory meets the accreditation standards.



## Technical/Medical Tender Requirements to Purchase Genomic Tests for Breast Cancer Treatment for group # 2

1. A genomic test should be developed to individually treat early invasive breast cancer. The test must demonstrate clinical utility in terms of breast cancer recurrence testing and medically proven prognostic and predictive value.
2. The test can be based on protein expression network (microarray) and next-generation sequencing (RNA) or qRT-PCR (RNA) technology.
3. The test or the set of genetic tests must allow for the quick and reliable identification of patients who require or do not require adjuvant chemotherapy in the treatment process without any impact on the long-term treatment outcome.
4. The test should be at least included in the following breast cancer treatment guidelines: European Society of Medical Oncology (ESMO), National comprehensive cancer network (NCCN), St. Gallen International Breast Cancer Consensus.
5. The test must be validated with a validation according to the international guidelines for the treatment of patients of all ages and:
  - for the invasive, estrogen receptor positive (ER+) breast cancer, stage I-II, size  $\leq 5.0$  cm, and up to 3 positive axillary lymph nodes, regardless of the clinically identified risk of disease recurrence.
6. If the tissue sample was properly obtained and sent including a duly completed test order form, the findings of the test(s) must be delivered to the oncologist no later than 10 days after the sample has arrived at the manufacturer's laboratory.
7. In order to protect patient anonymity, the test provider and the manufacturer guarantee that the service(s) are provided in conformity with the requirements of the GDPR and the Personal Data Protection Act of the Republic of Slovenia.
8. The test provider must also present the following evidence:
  - CE IVD Certificate for the tests provided.
  - Certificate proving that the laboratory meets the accreditation standards.