



Supplement to the Official Journal of the European Union

Info and online forms: <http://simap.ted.europa.eu>

Voluntary ex ante transparency notice

This notice is related to following:

- Directive 2014/23/EU
- Directive 2014/24/EU
- Directive 2014/25/EU
- Directive 2009/81/EC

This notice aims at providing voluntary prior transparency as referred to in Article 2d(4) of Directives 89/665/EEC and 92/13/EEC on remedies, and Article 60(4) of Directive 2009/81/EC.

Section I: Contracting authority/entity

I.1) Name and addresses

Official name: Health Service Executive HSE		National registration number: ²	
Postal address: Oak House, Millennium Park Naas Co. Kildare			
Town: Kildare	NUTS code: IE	Postal code:	Country: Ireland
Contact person:		Telephone:	
E-mail: ellen.white2@hse.ie		Fax:	
Internet address(es)			
Main address: (URL) https://hse.ie			
Address of the buyer profile: (URL) https://hse.ie			

I.4) Type of the contracting authority (in the case of a notice published by a contracting authority)

<input type="radio"/> Ministry or any other national or federal authority, including their regional or local subdivisions	<input type="radio"/> Regional or local agency/office
<input type="radio"/> National or federal agency/office	<input checked="" type="radio"/> Body governed by public law
<input type="radio"/> Regional or local authority	<input type="radio"/> European institution/agency or international organisation
	<input type="radio"/> Other type:

I.5) Main activity (in the case of a notice published by a contracting authority)

<input type="radio"/> General public services	<input type="radio"/> Housing and community amenities
<input type="radio"/> Defence	<input type="radio"/> Social protection
<input type="radio"/> Public order and safety	<input type="radio"/> Recreation, culture and religion
<input type="radio"/> Environment	<input type="radio"/> Education
<input type="radio"/> Economic and financial affairs	<input type="radio"/> Other activity:
<input checked="" type="radio"/> Health	

I.6) Main activity (in the case of a notice published by a contracting entity)

<input type="radio"/> Production, transport and distribution of gas and heat	<input type="radio"/> Railway services
<input type="radio"/> Electricity	<input type="radio"/> Urban railway, tramway, trolleybus or bus services
<input type="radio"/> Extraction of gas and oil	<input type="radio"/> Port-related activities
<input type="radio"/> Exploration and extraction of coal and other solid fuels	<input type="radio"/> Airport-related activities
<input type="radio"/> Water	<input type="radio"/> Other activity:
<input type="radio"/> Postal services	

Section II: Object

II.1) Scope of the procurement

II.1.1) Title: Oncotype DX Gene Expression Profiling Test	Reference number: ² HSE 21223
II.1.2) Main CPV code: 71900000	Supplementary VOC code: ^{1,2}
II.1.3) Type of contract <input type="radio"/> Works <input type="radio"/> Supplies <input checked="" type="radio"/> Services	
II.1.4) Short description: This is a VEAT notice to indicate that the HSE intends utilize EU public procurement directive Art 32.2(b) (iii) negotiated procedure without prior publication in the following case. (B) Where works, supplies or services can be supplied only by a particular economic operator for any of the following reasons: (iii) competition is absent for technical reasons. This notice is to indicate that the HSE intends to contract with Exact Sciences Ireland for the continued provision of the Gene Expression Profiling Test (GEP); Oncotype Dx.	
II.1.6) Information about lots This contract is divided into lots <input type="radio"/> yes <input checked="" type="radio"/> no	
II.1.7) Total value of the procurement (excluding VAT) Value: [10000000.00] (Please give the total value of the procurement. For information about individual contracts, please use section V) or Lowest offer: [] / Highest offer: [] taken into consideration Currency: EUR (for framework agreements – total maximum value for their entire duration) (for contracts based on framework agreements, if required – value of contract(s) not included in previous contract award notices)	

II.2) Description ¹ (1)

II.2.1) Title: ²	Lot No: ²
II.2.2) Additional CPV code(s): ²	
II.2.3) Place of performance NUTS code: ¹ [IE] Main site or place of performance:	
II.2.4) Description of the procurement: This is a VEAT notice to indicate that the HSE intends utilize EU public procurement directive Art 32.2(b) (iii) negotiated procedure without prior publication in the following case. (B) Where works, supplies or services can be supplied only by a particular economic operator for any of the following reasons: (iii) competition is absent for technical reasons. This notice is to indicate that the HSE intends to contract with Exact Sciences Ireland for the continued provision of the Gene Expression Profiling Test (GEP); Oncotype Dx. Gene Expression Profiling (GEP) tests are intended to provide information on disease prognosis and some may also be able to identify the patients who are most likely to benefit from chemotherapy. In this way they support clinical decision-making regarding a patient's need for adjuvant chemotherapy. This test is used to inform decision-making in relation to the management of early-stage invasive breast cancer. The Oncotype Dx has been contracted for use in Ireland since 2011. In February 2023, HIQA published an updated health technology assessment (further details available on their website), reviewing the current market for GEP tests. Their advice and recommendation is for the continued used of Oncotype Dx for certain patient cohorts. This view is supported by clinicians within the health service. The HSE intends to award this contract to Exact Sciences Ireland for the provision of the Oncotype Dx test. However, if future advice were to change this position, a competition may be conducted at a later date. (nature and quantity of works, supplies or services)	
II.2.5) Award criteria: ⁸ (Directive 2014/24/EU / Directive 2014/25/EU) <input type="checkbox"/> Quality criterion ^{1,2,20} <input checked="" type="checkbox"/> Cost criterion ^{1,20} Name Weighting Ultimate Cost 100 <input type="radio"/> Price ²¹ - Weighting:	
II.2.11) Information about options Options <input type="radio"/> yes <input checked="" type="radio"/> no Description of options:	
II.2.13) Information about European Union funds The procurement is related to a project and/or programme financed by European Union funds <input type="radio"/> yes <input checked="" type="radio"/> no Identification of the project:	
II.2.14) Additional information:	

Section IV: Procedure

IV.1) Description

IV.1.1) Type of procedure *(please complete Annex D)*

- Negotiated procedure without prior publication *(in accordance with Article 32 of Directive 2014/24/EU)*
- Negotiated procedure without prior call for competition *(in accordance with Article 50 of Directive 2014/25/EU)*
- Negotiated procedure without publication of a contract notice *(in accordance with Article 28 of Directive 2009/81/EC)*
- Award of a concession without prior publication of a concession notice *(in accordance with Article 31(4) and (5) of Directive 2014/23/EU)*
- Award of a contract without prior publication of a call for competition in the Official Journal of the European Union in the cases listed below *(please complete point 2 of the Annex D)*

IV.1.3) Information on framework agreement

- The procurement involves the establishment of a framework agreement

IV.1.8) Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement yes no

IV.2) Administrative information

IV.2.1) Previous publication concerning this procedure ²

Notice number in the OJ S:

Section V: Award of contract/concession ¹Contract No: Lot No: ² Title:**V.2) Award of contract/concession**

V.2.1) Date of conclusion of the contract: (dd/mm/yyyy) 29/05/2023			
V.2.2) Information about tenders			
The contract has been awarded to a group of economic operators: <input type="radio"/> yes <input checked="" type="radio"/> no			
V.2.3) Name and address of the contractor/concessionaire ¹ (Agree to publish? <input type="radio"/> yes <input type="radio"/> no)			
Official name: Exact Sciences Ireland		National registration number: ²	
Postal address:			
Town: Dublin	NUTS code: IE	Postal code:	Country: Ireland
E-mail: Europeansupport@exactsciences.com		Telephone:	
Internet address: (URL) https://exactsciences.com		Fax:	
The contractor/concessionaire will be an SME: <input type="radio"/> yes <input checked="" type="radio"/> no (SME – as defined in Commission Recommendation 2003/361/EC)			
V.2.4) Information on value of the contract/lot/concession (excluding VAT)			
Initial estimated total value of the contract/lot/concession: ² []			
Total value of the contract/lot/concession: [10000000.00]			
or			
Lowest offer: [] / Highest offer: [] taken into consideration			
Currency: EUR			
for framework agreements – total maximum value for this lot			
for contracts based on framework agreements, if required – value of contract(s) for this lot not included in previous contract award notices			
V.2.5) Information about subcontracting ⁸			
<input type="checkbox"/> The contract/lot/concession is likely to be subcontracted			
Value or proportion likely to be subcontracted to third parties ⁴			
Value excluding VAT: [] Currency:			
Proportion: [] %			
Short description of the part of the contract to be subcontracted:			

Section VI: Complementary information

VI.3) Additional information ²

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VI.4) Procedures for review

VI.4.1) Review body		
Official name: The High Court		
Postal address:		
Town: Dublin	Postal code:	Country: Ireland
E-mail:		Telephone:
Internet address: (URL)		Fax:
VI.4.2) Body responsible for mediation procedures ²		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: (URL)		Fax:
VI.4.3) Review procedure		
Precise information on deadline(s) for review procedures:		
VI.4.4) Service from which information about the review procedure may be obtained ²		
Official name:		
Postal address:		
Town:	Postal code:	Country:
E-mail:		Telephone:
Internet address: (URL)		Fax:

VI.5) Date of dispatch of this notice: (dd/mm/yyyy) [29/05/2023](#)

It is the contracting authority's/contracting entity's responsibility to ensure compliance with European Union law and any applicable laws.

¹ please repeat as many times as needed

² if applicable

⁴ if this information is known

⁸ optional information

²⁰ importance may be given instead of weighting

²¹ importance may be given instead of weighting; if price is the only award criterion, weighting is not used

Annex D1 – General procurement

Justification for the award of the contract without prior publication of a call for competition in the Official Journal of the European Union

Directive 2014/24/EU

(please select the relevant option and provide an explanation)

- 1. Justification for the choice of the negotiated procedure without prior publication of a call for competition in accordance with Article 32 of Directive 2014/24/EU**
- No tenders or no suitable tenders/requests to participate in response to
- open procedure
 - restricted procedure
- The products involved are manufactured purely for the purpose of research, experiment, study or development under the conditions stated in the directive (*for supplies only*)
- The works, supplies or services can be provided only by a particular economic operator for the following reason
- absence of competition for technical reasons
 - procurement aiming at the creation or acquisition of a unique work of art or artistic performance
 - protection of exclusive rights, including intellectual property rights
- Extreme urgency brought about by events unforeseeable for the contracting authority and in accordance with the strict conditions stated in the directive
- Additional deliveries by the original supplier ordered under the strict conditions stated in the directive
- New works/services, constituting a repetition of existing works/services and ordered in accordance with the strict conditions stated in the directive
- Service contract to be awarded to the winner or one of winners under the rules of a design contest
- Procurement of supplies quoted and purchased on a commodity market
- Purchase of supplies or services on particularly advantageous terms
- from a supplier which is definitively winding up its business activities
 - from the liquidator in an insolvency procedure, an arrangement with creditors or a similar procedure under national laws and regulations
- 2. Other justification for the award of the contract without prior publication of a call for competition in the Official Journal of the European Union**
- The procurement falls outside the scope of application of the directive

3. Explanation

Please explain in a clear and comprehensive manner why the award of the contract without prior publication in the Official Journal of the European Union is lawful, by stating the relevant facts and, as appropriate, the conclusions of law in accordance with the directive: (500 words maximum)

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This notice is to indicate that the HSE intends to contract with Exact Sciences Ireland for the continued provision of the Gene Expression Profiling Test (GEP); Oncotype Dx.

The value is an estimate based on maximum contract value and may not be accurate.

Gene Expression Profiling (GEP) tests are intended to provide information on disease prognosis and some may also be able to identify the patients who are most likely to benefit from chemotherapy. In this way they support clinical decision-making regarding a patient's need for adjuvant chemotherapy. This test is used to inform decision-making in relation to the management of early-stage invasive breast cancer. The Oncotype Dx has been contracted for use in Ireland since 2011.

In February 2023, HIQA published an updated health technology assessment (further details available on their website), reviewing the current market for GEP tests. Their advice and recommendation is for the continued used of Oncotype Dx for certain patient cohorts. This view is supported by clinicians within the health service.

The HSE intends to award this contract to Exact Sciences Ireland for the provision of the Oncotype Dx test. However, if future advice were to change this position, a competition may be conducted at a later date.