



**OFFICE OF THE CHIEF MEDICAL OFFICER**  
**CHIEF MEDICAL OFFICER**

1097 Budapest, Gyáli út 2-6. 1437 Budapest, Pf.: 839

**CONTRACT NOTICE AND DOCUMENTATION**

Immunochemical reagent  
and other accessories used for faecal occult blood testing

**Budapest, February 2011**

<b>OFFICE OF THE CHIEF MEDICAL OFFICER.....</b>	<b>1</b>
ADDITIONAL ADDRESSES AND CONTACT POINTS.....	16
1. GUIDELINES FOR PREPARING, SUBMITTING AND EVALUATING TENDERS .	18
1.1. Preparation and costs of tenders.....	18
1.2. Documentation and supplementary information.....	19
1.3. Documents forming part of the tender .....	19
1.4. Form of the tender .....	21
1.5. Submission, closure and marking of tenders.....	21
1.6. Prices and payment terms.....	22
1.7. Selection criteria and scoring .....	23
1.8. Evaluation criteria .....	24
1. Antecedents .....	34
ANNEXES .....	38

**Application for the publication of a European Union contract notice (Article 23)**

**(3)** The application shall include the following::

b) the application initiates a **rectification procedure** in the Official Journal of the European Union;

c) the provision of the Public Procurement Act (Article, Paragraph, Point) based on which the contracting authority falls within its scope [including cases of voluntary application as per Article 2 (4) of the Public Procurement Act];

**Article 22 (1) (b)**

d) the procedure set out in the Public Procurement Act (specifying the Part or Chapter) that the contracting authority is using [an express declaration stating that the notice must be published in the Public Procurement Bulletin in the cases specified under Articles 21 (3) and 161 (5) of the Public Procurement Act; an express declaration stating that the notice must be published in the Official Journal of the European Union in case of publication as per Article 98 (3) of the Public Procurement Act, pursuant to Article 250 (4)];

**Part II Chapter IV**

e) the estimated value of the public procurement (procurement) [reference to Article 40 (3) or Article 179 (4) of the Public Procurement Act, as necessary];

**HUF 38 000 000, also referring to Article 40 (3) of the Public Procurement Act**

f) if the applicant requests the publication of a notice in the Official Journal of the European Union that is not compulsory pursuant to the Public Procurement Act, this circumstance shall also be noted;

**It is compulsory**

g) to include the date of submission of the application and the notice to the Editorial Board.

**11 February 2011**

**Article 5 (6)** Publication of the notice shall be initiated by the person or organisation authorised by the tenderer; such person or organisation shall make a statement about their power of representation in the notice. In the absence of a statement on power of representation, the Editorial Board shall issue a call for a rectification procedure, sent to the tenderer.

Power of representation [ ]

Other notices:

Tax number: 12329530-2-43 Coverage does not include any EU funding. Please verify the notice to ensure that the contracting authority is not entitled to exemption or any discount.



EUROPEAN UNION

Publication of Supplement to the Official Journal of the European Union  
2, rue Mercier, L-2985 Luxembourg Fax: (352) 29 29 42 670

E-mail: [mp-ojs@opoce.cec.eu.int](mailto:mp-ojs@opoce.cec.eu.int) Info & on-line forms: <http://simap.eu.int>

**CONTRACT NOTICE**

## SECTION I: CONTRACTING AUTHORITY

### I.1) NAME, ADDRESSES AND CONTACT POINT(S)

<b>Official name:</b> Office of the Chief Medical Officer		
<b>Postal address:</b> Gyáli út 2-6.		
<b>Town</b> Budapest	<b>Postal code:</b> 1097	<b>Country:</b> HU
<b>Contact points(s):</b>  <b>To the attention of:</b> Dr. Judit Paller MB, Chief Medical Officer		<b>Telephone:</b> +36 1 215-53-39
<b>E-mail:</b> kovats.peter@oth.antsz.hu; gazdig@oth.antsz.hu		<b>Fax:</b> +36 1 215-33-65
<b>Internet address(es) (if applicable)</b> General address of the contracting authority (URL): www.antsz.hu Address of the buyer profile (URL):		

Further information can be obtained at: <input type="checkbox"/> As in abovementioned contact point(s) <input checked="" type="checkbox"/> Other: <i>please complete Annex A.I</i>
Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained at: <input type="checkbox"/> As in abovementioned contact point(s) <input checked="" type="checkbox"/> Other: <i>please complete Annex A.II</i>
Tenders or requests to participate must be sent to: <input type="checkbox"/> As in abovementioned contact point(s) <input checked="" type="checkbox"/> Other: <i>please complete Annex A.III</i>

### I.2) TYPE OF THE CONTRACTING AUTHORITY AND MAIN ACTIVITY OR ACTIVITIES

<input type="checkbox"/> Ministry or any other national or federal authority, including their regional or local sub-divisions <input checked="" type="checkbox"/> National or federal agency/office <input type="checkbox"/> Regional or local authority <input type="checkbox"/> Regional or local agency/office <input type="checkbox"/> Body governed by public law <input type="checkbox"/> European institution/agency or international organisation <input type="checkbox"/> Other ( <i>please specify</i> ):	<input type="checkbox"/> General public services <input type="checkbox"/> Defence <input type="checkbox"/> Public order and safety <input type="checkbox"/> Environment <input type="checkbox"/> Economic and financial affairs <input checked="" type="checkbox"/> Health <input type="checkbox"/> Housing and community amenities <input type="checkbox"/> Social protection <input type="checkbox"/> Recreation, culture and religion <input type="checkbox"/> Education <input type="checkbox"/> Other ( <i>please specify</i> ):
The contracting authority is purchasing on behalf of other contracting authorities <b>yes</b> <input type="checkbox"/> <b>no</b> <input checked="" type="checkbox"/>	

## SECTION II: OBJECT OF THE CONTRACT

### II.1) DESCRIPTION

<b>II.1.1 ) Title attributed to the contract by the contracting authority</b>  Immunochemical reagent and accessories for faecal occult blood testing		
<b>II.1.2) Type of contract and location of works, place of delivery or of performance</b> <i>(Choose only one category – works, supplies or services – that best corresponds to the specific object of your contract or purchase(s))</i>		
<b>a) Works <input type="checkbox"/></b>	<b>b) Supplies <input checked="" type="checkbox"/></b>	<b>c) Services <input type="checkbox"/></b>
Execution <input type="checkbox"/>  Design and execution <input type="checkbox"/>  Realisation, by whatever means of work, corresponding to the requirements specified by the contracting authorities <input type="checkbox"/>	Purchase <input checked="" type="checkbox"/>  Lease <input type="checkbox"/>  Rental <input type="checkbox"/>  Hire purchase <input type="checkbox"/>  A combination of these <input type="checkbox"/>	Service category   <i>(For service categories 1–27, please see Annex II to Directive 2004/18/EC)</i>
Main site or location of works  NUTS code	Main place of delivery  1097 Budapest Vágóhíd u. 39.	Main place of performance  NUTS code

NUTS code HU101	
<b>II.1.3) The notice involves</b> A public contract [x] The setting up of a dynamic purchasing system (DPS) [ ] The establishment of a framework agreement [ ]	
<b>II.1.4) Information on framework agreement (if applicable)</b>	
Framework agreement with several operators [ ] Number <i>OR, if applicable</i> , maximum number of participants to the framework agreement envisaged	Framework agreement with a single operator [ ]
<b>Duration of the framework agreement:</b> Duration in year(s): or month(s): Justification for a framework agreement the duration of which exceeds four years:	
<b>Estimated total value of purchases for the entire duration of the framework agreement (if applicable; give figures only):</b> Estimated value excluding VAT: Currency: <i>OR</i> range between: and Currency: Frequency and value of the contracts to be awarded (if known):	
<b>II.1.5) Short description of the contract or purchase(s)</b> Supply contract for immunochemical reagents and accessories for faecal occult blood testing	
<b>II.1.6) Common procurement vocabulary (CPV)</b> <div style="display: flex; justify-content: space-between;"> <span><b>Main vocabulary</b></span> <span><b>Supplementary vocabulary (if applicable)</b></span> </div> <b>Main object</b> 33141625-7	
<b>II.1.7) Contract covered by the General Procurement Agreement (GPA) yes [x] no [ ]</b>	

**II.1.8) Division into lots** (for information about lots, use Annex B as many times as there are lots) **yes** [ ] **no** [x]

If yes, tenders should be submitted for (tick one box only):

one lot only [ ]

one or more lots [ ]

all lots [ ]

**II.1.9) Variants will be accepted** **yes** [ ] **no** [x]

## II. 2) QUANTITY OR SCOPE OF THE CONTRACT

**II.2.1) Total quantity or scope** (including all lots and options if applicable)

40,000 immunochemical reagents for faecal occult blood testing and 40,000 sampling devices, for use in automated processes and sufficient for screening 20,000 persons + an additional 100% at most

If applicable, estimated value excluding VAT (give figures only): Currency:

OR: range: between and Currency:

**II.2.2) Options** (if applicable) **yes** [ ] **no** [x]

If yes, description of these options:

If known, provisional timetable for recourse to these options:

in months: or days: (from the award of the contract)

Number of possible renewals (if any): or Range: between and

If known, in the case of renewable supplies or service contracts, estimated time-frame for subsequent contracts:

in months: or days: (from the award of the contract)

## II.3) DURATION OF THE CONTRACT OR TIME-LIMIT FOR COMPLETION

Duration in months: 6 or days: (from the award of the contract)

OR: starting (dd/mm/yyyy)

completion (dd/mm/yyyy)

## SECTION III: LEGAL, ECONOMIC, FINANCIAL AND TECHNICAL INFORMATION

### III.1) CONDITIONS RELATING TO THE CONTRACT

#### III.1.1) Deposits and guarantees required (if applicable)

Penalty for defective performance, default and cancellation, as defined in the documentation.

#### III.1.2) Main financing conditions and payment arrangements and/or reference to the relevant provisions regulating them

Compensation for performance complying with the method and contents defined in the contract shall be settled by the contracting authority within 15 days of receipt of the invoice (currency: HUF) issued following certified performance by wire transfer, with regard to Article 305 of the Public Procurement Act and Article 36/A of the Act on the Rules of Taxation, in line with the rules of treasury payment.

#### III.1.3) Legal form to be taken by the grouping of economic operators to whom the contract is to be awarded (if applicable)

#### III.1.4) Other particular conditions to which performance of the contract is subject to yes [ ] no [x] (if applicable)

If yes, description of the particular conditions

### III.2) CONDITIONS FOR PARTICIPATION

#### III.2.1) Personal situation of the economic operators, including requirements to enrolment on professional or trade registers

Information and formalities necessary for evaluating if requirements are met:

Parties:

- against which there are excluding factors as per Article 60 (1) (a)-(i) of the Public Procurement Act,
- against which there are excluding factors as per Article 61 (1) (d) of the Public Procurement Act may not act as tenderer, subcontractor or organisation providing resources.

Parties:

- against which there are excluding factors as per Article 61 (1) (a)-(c) of the Public Procurement Act,
  - against which there are excluding factors as per Article 62 (1) (a)-(b) of the Public Procurement Act may not act as tenderer, subcontractor in excess of 10% of the contract value or organisation providing resources.
- Pursuant to Article 63 (2)-(9) of the Public Procurement Act, the tenderer, the subcontractor in excess of 10% of the contract value or the organisation providing resources shall certify in the tender that it does not fall within the scope of excluding factors as per Article 60 (1) (a)-(i) or Article 61 (1) (a)-(d) of the Public Procurement Act

The tenderer shall include a declaration in its tender regarding the subcontractors to be employed for less than ten percent of the contract value pursuant to Article 63 (3) of the Public Procurement Act stating that it shall not employ subcontractors falling within the scope of excluding factors for the performance of the contract.



<b>III.2.2) Economic and financial capacity</b>	
<p>Information and formalities necessary for evaluating if requirements are met:</p> <p>Statements no more than 30 days old (in simple copy form) issued by all credit institutions managing the accounts of the tenderer or subcontractor employed in excess of ten percent the contract value indicating</p> <ul style="list-style-type: none"> <li>- the date since the credit institution has been managing the tenderer's current account,</li> <li>- whether it meets its payment obligations on time,</li> <li>- whether any prompt collection orders were rejected due to insufficient funds in the course of the two preceding years .</li> </ul> <p>The tenderer or subcontractor employed in excess of ten percent of the contract value shall issue a declaration stating that it does not have any other accounts besides those managed by the credit institutions issuing the submitted statements.</p>	<p>Minimum level(s) of standards possible required (if applicable):</p> <p>The tenderer or subcontractor employed in excess of ten percent of the contract value shall not be suitable for performing the contract if any of the statements made by its credit institutions reveals that it does not meet its payment obligations on time or a prompt collection order has been rejected due to insufficient funds on its account in the course of the two preceding years.</p>

<b>III.2.3) Technical capacity</b>	
<p>Information and formalities necessary for evaluating if requirements are met:</p> <p>Main delivery references performed in 2008, 2009 and 2010 (at least one), indicating at least:</p> <ul style="list-style-type: none"> <li>- the type of product</li> <li>- quantity (units)</li> <li>- time of delivery</li> <li>- the name of the other contracting party</li> <li>- the amount of consideration or any other data referring to the delivered quantity.</li> </ul> <p>Please certify the references as per Section 68 (1) of the Public Procurement Act.</p>	<p>Minimum level(s) of standards possible required (if applicable):</p> <p>The tenderer or subcontractor employed in excess of ten percent of the contract value shall not be suitable if it does not have references at least for the following deliveries for 2008, 2009 and 2010 combined:</p> <p>At least one delivery of the product forming the object of the procurement during the three years specified, which may not be under 10,000 units, with a value of at least HUF 8,000,000</p>
<b>III.2.4) Reserved contracts (if applicable) yes [ ] no [x]</b>	

The contract is restricted to sheltered workshops[ ]

The execution of the contract is restricted to the framework of sheltered employment programmes [ ]

### III. 3) CONDITIONS SPECIFIC TO SERVICES CONTRACTS

**III.3.1) Execution of the service is reserved to a particular profession**

yes [ ] no [ ]

If yes, reference to the relevant law, regulation or administrative provision:

**III.3.2) Legal persons should indicate the names and professional qualifications of the staff responsible for the execution of the service** yes [ ] no [ ]

## SECTION IV: PROCEDURE

### IV.1) TYPE OF PROCEDURE

**IV.1.1) Type of procedure**

**Open** [x]

**Restricted** [ ]

**Accelerated restricted** [ ]

Justification for the choice of accelerated procedure:

**Negotiated** [ ]

Candidates have already been selected **yes** [ ] **no** [ ]

If yes, provide names and addresses of operators already selected under Section VI.3), Additional Information

**Accelerated negotiated**[ ]

Justification for the choice of accelerated procedure:

**Competitive dialogue** [ ]

**IV.1.2) Limitations on the number of operators who will be invited to tender or to participate**  
(restricted and negotiated procedures, competitive dialogue)

Envisaged number of operators

OR: envisaged minimum number and, if applicable, maximum number

Objective criteria for choosing the limited number of candidates:

**IV.1.3) Reduction of the number of candidates during the negotiation or dialogue** (negotiated procedure, competitive dialogue)

Recourse to staged procedure to gradually reduce the number of solutions to be discussed or tenders to be negotiated  
yes ☐ no ☐

**IV. 2) AWARD CRITERIA**

**IV.2.1) Award criteria** (please tick the relevant box(es))

**Lowest price** ☐

or

**the most economically advantageous tender in terms of** ☒

☒ the criteria stated below (the award criteria should be given with their weighting or in descending order of importance where weighting is not possible for demonstrable reasons)

☐ the criteria stated in the specifications, in the invitation to tender or to negotiate or in the descriptive document

Criteria	Weighting
1. Total gross tender price	100
2. Calibration stability	15
3. Sample stability	15
4. Reagent stability after opening	15
5. Range of measurement	7
6. Proportion of non-negative (test-positive) findings	15
7. Sensitivity	15

8. Specificity	15
9. Positive predictive value	15
10. Speed of analysis	8

  

<b>IV.2.2) An electronic auction will be used yes [ ] no [x]</b>
<b>If yes,</b> additional information about electronic auction ( <i>if appropriate</i> )

#### IV.3) ADMINISTRATIVE INFORMATION

<b>IV.3.1) File reference number attributed by the contracting authority (<i>if applicable</i>)</b>
---

  

<b>IV.3.2) Previous publication(s) concerning the same contract yes [ ] no [x]</b>  <b>If yes,</b> Prior information notice [ ] Notice number in OJ: /S - ( <i>dd/mm/yyyy</i> ) Notice on a buyer profile [ ] Notice number in OJ: /S - ( <i>dd/mm/yyyy</i> ) Other previous publications ( <i>if applicable</i> ) [ ] Notice number in OJ: /S - ( <i>dd/mm/yyyy</i> )
--

  

<b>IV.3.3) Conditions for obtaining specifications and additional documents (<i>except for a DPS</i>) or descriptive documents (<i>in the case of a competitive dialogue</i>)</b>
Time-limit for receipt of requests and for accessing documentation Date: 18/04/2011 ( <i>dd/mm/yyyy</i> ) Time: 10:00

<p>Payable documents <b>yes</b> [ ] <b>no</b> [x]</p> <p><b>If yes, price (give figures only):</b> Currency:</p> <p>Terms and method of payment:</p>
<p><b>IV.3.4) Time-limit for receipt of tenders and requests to participate</b>  Date: 18/04/2011 (dd/mm/yyyy) Time: 10:00</p>
<p><b>IV.3.5) Date of dispatch of invitations to tender or to participate to selected candidates (if known)</b>  <i>(in the case of restricted and negotiated procedures, and competitive dialogue)</i>  Date: (dd/mm/yyyy)</p>
<p><b>IV.3.6) Language(s) in which tenders or requests to participate may be drawn up</b></p> <p>HU</p> <p>Other: Technical specifications of the product, data and publications pertaining to screening outcomes and the original user's manual for the product will also be accepted in English</p>
<p><b>IV.3.7) Minimum time frame during which the tenderer must maintain the tender (open procedure)</b></p> <p>Until (dd/mm/yyyy)  Or duration in month(s): 30 (from the date stated for receipt of tender)</p>
<p><b>IV.3.8) Conditions for opening tenders</b></p> <p>Date: 18/04/2011 (dd/mm/yyyy) Time: 10:00</p> <p>Place (if applicable): 1097 Budapest, Gyáli út 2-6. building C , meeting room III</p> <p>Persons authorised to be present at the opening of tenders (if applicable) <b>yes</b> [x] <b>no</b> [ ]</p> <p>The persons specified under Article 80 (2) of the Public Procurement Act</p>

## SECTION VI: COMPLEMENTARY INFORMATION

**VI.1) THIS IS A RECURRENT PROCUREMENT (if applicable) yes [ ] no [x]**

If yes, estimated timing for further notices to be published:

**VI.2) CONTRACT RELATED TO A PROJECT AND/OR PROGRAMME FINANCED BY COMMUNITY FUNDS**

yes [ ] no [x]

If yes, reference to project(s) and/or programmes:

**VI.3) ADDITIONAL INFORMATION (if applicable)**

Planned date of announcement of the results: 27.04.2011

Planned date of contract conclusion: 09.05.2011

Documentation can be collected in person (workdays between 10:00 am and 12:00 pm, and submitted between 8:00 am and 10:00 am on the expiry date of the submission deadline) at Pátiaconsult Zrt. 1034 Budapest, Seregély u. 13.

Documentation may also be posted by the contracting authority upon request, and is also available on its website. The contracting authority does not assume any responsibility for postal delivery.

For the evaluation of the substantive elements of the tender criteria allowing the selection of the overall most advantageous tender, the lower and upper thresholds for the score awardable for each criteria are 1 and 100, respectively.

The method applied by the contracting authority for awarding the scores ranging between the above two extreme values by which to select the overall most advantageous tender is as follows: The maximum score is awarded to the tenderer with the most advantageous offer, while the other tenderers are awarded scores determined proportionally compared to the best offer. The scores awarded for each criterion are then multiplied by their respective weighting and then added up for all the award criteria. The total scores thus determined for each tender are then compared.

The criteria set out in III.2.2) and III.2.3), and the means of certification thereof, are stricter than the qualification criteria defined as the condition for entry of qualified tenderers in the official register.

Tenderer shall accurately indicate the data prescribed under Article 71 (1) of the Public Procurement Act in its tender.

Tenderer shall issue a declaration as specified under Article 63 (3) of the Public Procurement Act.

Tenders shall include the tender and the document certifying the power of representation of the person signing the tender on behalf of the tenderer (specimen signature, incorporation certificate dated no more than 60 days prior to the submission deadline). The original or copy of the authorisation certified by a notary, as necessary.

All other data pertaining to the tendering procedure are included in the documentation. Collection of the documentation is a precondition to participation in the procedure. The documentation may not be transferred to a third party.

Tender may request supplementary (explanatory) information on the contract notice in writing for the sake of submitting an adequate tender, which it can submit to the address specified under Point I.1 ten days prior to the expiry of the submission deadline at the latest. The contracting authority shall issue written replies to the inquiries thus received, which shall be sent to every tenderer six days prior to the expiry of the submission deadline at the latest, in keeping with Article 56 of the Public Procurement Act. In keeping with Article 56 (4) of the Public Procurement Act, the contracting authority shall allow tenderers access to supplementary information at the place specified under Point I.1 between 10:00 am and 12:00 pm on workdays, and between 8:00 am and 10:00 pm on the expiry date of the submission deadline.

Tenderer shall bear the costs of application.

Tenderer shall draw up and submit its tender in compliance with the formal and substantive requirements set out in the contract notice and the documentation. Tenders shall be submitted by the submission deadline in writing, in a sealed envelope directly at the address specified in the contract notice or by post. In case of direct submission, tenders shall be submitted at the contracting authority's seat (at the address specified under Point I.1) between 10:00 am and 12:00 pm on workdays, and between 8:00 am and 10:00 am on the expiry date of the submission deadline.

The tenderer shall declare its form as per Act XXXIV of 2004 (micro, small or medium-sized enterprise).

In case of joint tenders, the cooperation agreement concluded between the tenderers (declaration on joint and severable liability, the rules of mutual liability and the specification of roles and competences), duly signed by each of the joint tenderers.

#### **VI.4) PROCEDURES FOR APPEAL**

##### **VI.4.1) Body responsible for appeal procedures**

**Official name:**

Public Procurement Arbitration Board

**Postal address:**

Margit krt. 85.

**Town**

Budapest

**Postal code:**

1024

**Country:**

HU

**E-mail:**

**Telephone:**

336-7776

**Internet address(URL):**

**Fax:**

336-7778

Body responsible for mediation procedures *(if applicable)*

**Official name:**

**Postal address:**

**Town:**

**Postal code:**

**Country:**

**E-mail:**

**Telephone:**

**Internet address(URL): -**

**Fax:**

##### **VI.4.2) Lodging of appeals** *(please fill heading VI.4.2 OR if need be, heading VI.4.3)*

Precise information on deadline(s) for lodging appeals:

##### **VI.4.3) Service from which information about the lodging of appeals may be obtained**

<b>Official name:</b> Public Procurement Arbitration Board		
<b>Postal address:</b> Margit krt. 85.		
<b>Town</b> Budapest	<b>Postal code:</b> 1024	<b>Country:</b> HU
<b>E-mail:</b>		<b>Telephone:</b> 336-7776
<b>Internet address (URL):</b>		<b>Fax:</b> 336-7778
<b>VI.5) DATE OF DISPATCH OF THIS NOTICE:</b> (dd/mm/yyyy)		

#### ANNEX A

### ADDITIONAL ADDRESSES AND CONTACT POINTS

#### I) ADDRESSES AND CONTACT POINTS FROM WHICH FURTHER INFORMATION CAN BE OBTAINED

<b>Official name:</b> Office of the Chief Medical Officer		
<b>Postal address:</b> Gyáli út 2-6.D épület I. emelet C részleg		
<b>Town</b> Budapest	<b>Postal code:</b> 1097	<b>Country:</b> HU
<b>Contact point(s):</b> dr. András Budai <b>For the attention of:</b> dr. András Budai		<b>Telephone:</b> 476 1100
<b>E-mail:</b> budai.andras@oth.antsz.hu		<b>Fax:</b> +36 1 476-6437
<b>Internet address (URL):</b>		

#### II) ADDRESSES AND CONTACT POINTS FROM WHICH SPECIFICATIONS AND ADDITIONAL DOCUMENTS (INCLUDING DOCUMENTS FOR COMPETITIVE DIALOGUE AS WELL AS A DYNAMIC PURCHASING SYSTEM) CAN BE OBTAINED

<b>Official name:</b> Pátia Consult Zrt.
<b>Postal address:</b> Seregély u. 13.



<b>Town</b> Budapest	<b>Postal code:</b> 1034	<b>Country:</b> HU
<b>Contact point(s):</b> Szabó Zsolt <b>For the attention of:</b> Szabó Zsolt		<b>Telephone:</b> +36 1 368-7221
<b>E-mail:</b> kozbeszerzes@patriaconsult.hu		<b>Fax:</b> +36 1 388-6963
<b>Internet address (URL):</b>		

### III) ADDRESSES AND CONTACT POINTS TO WHICH TENDERS/REQUESTS TO PARTICIPATE MUST BE SENT

<b>Official name:</b> Office of the Chief Medical Officer		
<b>Postal address:</b> Gyáli út 2-6.D épület I. emelet C részleg		
<b>Town:</b> Budapest	<b>Postal code:</b> 1097	<b>Country:</b> HU
<b>Contact point(s):</b> dr. András Budai <b>For the attention of:</b> dr. András Budai		<b>Telephone:</b> 476 1100
<b>E-mail:</b> budai.andras@oth.antsz.hu		<b>Fax:</b> +36 1 476-6437
<b>Internet address (URL):</b>		

## ANNEX B

### INFORMATION ABOUT LOTS

#### LOT NO. / TITLE

1) SHORT DESCRIPTION
2) COMMON PROCUREMENT VOCABULARY (CPV)

<p><b>3) QUANTITY OR SCOPE</b></p> <p><i>If known, estimated cost excluding VAT (give figures only): Currency:</i></p> <p><i>OR range: between and Currency:</i></p>
<p><b>4) INDICATION ABOUT DIFFERENT DATE FOR DURATION OF CONTRACT OR STARTING/COMPLETION (if applicable)</b></p> <p>Duration in months: <i>or days: (from the award of the contract)</i></p> <p><i>Or starting (dd/mm/yyyy)</i></p> <p><i>completion (dd/mm/yyyy)</i></p>
<p><b>5) ADDITIONAL INFORMATION ABOUT LOTS</b></p>

----- (Use this Annex as many times as there are lots) -----

#

## 1. GUIDELINES FOR PREPARING, SUBMITTING AND EVALUATING TENDERS

### 1.1. Preparation and costs of tenders

The public procurement procedure shall be carried out pursuant to the rules set out in Act CXXIX of 2003 on Public Procurement (hereinafter referred to as “Public Procurement Act”). In the course of this public procurement procedure, the rules governing European Community procedures defined in the Public Procurement Act shall apply.

This documentation forms the entirety of written information available to those wishing to partake in public procurements, based on which tenders can be prepared in a comparable and assessable form.

Tenders shall be written in Hungarian. All correspondence and other material related to the tender shall also be in Hungarian. If documents in languages other than Hungarian are attached, their Hungarian translation shall also be included, except in the cases specified in the contract notice.

All costs arising from the preparation, submission and receipt of documentation shall be borne by the tenderer. No consideration shall be claimed for the tender elaborated by the tenderer.

Tenderer has until the submission deadline to amend its tender. Tenders submitted after expiry of the submission deadline cannot be amended, even with the contracting authority's authorisation.

## **1.2. Documentation and supplementary information**

The public procurement procedure will be carried out by the Office of the Chief Medical Officer (hereinafter referred to as "CMO"), as contracting authority. All written material or requests for supplementary information shall be submitted to the CMO's Financial Directorate, located at 1097 Budapest, Gyáli út 2-6., A épület fszt. 6.

Tenderers requesting information (via fax, mail or email sent to the address provided in the contract notice) may request additional information from the contracting authority up to ten days prior to the expiry of the submission deadline, which shall provide such information via fax up to the sixth day preceding the expiry of the submission deadline at the latest<sup>1</sup>. The contracting authority shall provide a written response to all questions concerning the contract notice and the documentation, simultaneously notifying all tenderers having purchased the tender documentation.

## **1.3. Documents forming part of the tender**

The following documents, certificates and statements shall be appended to the tenders, in the following order:

Number	Name
1.	Fiche <sup>2</sup> as per Annex "A"

---

<sup>2</sup> To be appended following the table of contents.

2.	Tenderer's statement as per Annex "B", stating the tenderer's intention to submit a tender in the context of the procedure. <sup>3</sup>
3.	Statements dated no more than 60 days prior to the submission deadline and issued by all credit institutions managing the accounts of the tenderer, each indicating the date since the given credit institution has been managing the tenderer's current account, whether it meets its payment obligations on time, and whether any prompt collection orders were rejected due to insufficient funds during 2009 or 2010.
4.	Tenderer's declaration that it holds no other accounts besides those indicated in the tender, certified by the necessary documents.
5.	Tenderer's declaration pertaining to Article 71 (1) (a)-(b) of the Public Procurement Act <sup>4</sup> , as per Annex "C". If the tenderer does not wish to employ a subcontractor for performing the contract, its declaration stating such lack of intention, as per Annex "C".
6.	The certificates as per Article 63 of the Public Procurement Act <sup>5</sup> certifying that the tenderer and the subcontractor employed in excess of 10% of the contract value do not give grounds for exclusion pursuant to Article 60 (1) (a)-(i) of the Public Procurement Act.
7.	The declaration required as per Article 63 (7) of the Public Procurement Act if the tenderer wishes to employ any of the organisations specified under Article 66 (2) or 67 (4) of the Public Procurement Act for the performance of the contract.
8.	Declaration required as per Article 63 (3) of the Public Procurement Act, as defined in Annex "D".
9.	Certification of references for deliveries made in 2008, 2009 and 2010 (indicating at least the type of product, quantity (units) and time of delivery, the name of the other contracting party, the amount of consideration or any other data referring to the delivered quantity) pursuant to Article 68 (1) of the Public Procurement Act.
10.	Copies of the documents certifying the power of representation of the person signing the tender on behalf of the tenderer (specimen signature, incorporation certificate no older than 60 days prior to the submission deadline). The original or copy of the authorisation certified by a notary, as necessary.
11.	Tenderer's declaration on its form (micro, small or medium-sized enterprise) as per Act XXXIV of 2004.
12.	In case of joint tenders, the cooperation agreement concluded between the tenderers (declaration on joint and severable liability, the rules of mutual liability and the specification of roles and competences), duly signed by each of the joint tenderers.

## Supplying missing information

<sup>3</sup> Declaration required as per Article 70 (1) of the Public Procurement Act.

<sup>4</sup> Tenderer shall indicate the part of the procurement for which it will conclude a contract with a third party, without defining such organisation (person) [Article 71 (1) (a) of the Public Procurement Act], and also indicate subcontractors to be employed for over 10% of the contract value in performing the contract [Article 71 (1) (b) of the Public Procurement Act].

<sup>5</sup> For the certification methods referenced in Article 63 of the Public Procurement Act, the notice published in Issue 23, Year XIII of the Public Procurement Council's Public Procurement Bulletin for tenderers established in Hungary, and in Issue 68, Year XII of the Public Procurement Council's Public Procurement Bulletin for tenderers established abroad shall govern.

The contracting authority shall fully allow all tenderers to supply missing information with the same conditions. Supplying missing information may not affect or alter the substantive elements of the tender serving as the basis of evaluation.. (Article 83 of the Public Procurement Act)

#### **1.4. Form of the tender**

The tender shall be prepared and submitted in three copies (one original and two duplicates), page numbered and initialled, duly signed where necessary — or signed by the person(s) authorised to render the contract binding for the tenderer — in a single, sealed envelope, with a table of contents indicating page numbers, bound or stitched, the object of the tender marked as: “*Testing reagent*”.

Please note that Article 70/A of the Public Procurement Act contains the formal requirements in detail. The covers of each copy shall be marked accordingly as “original” or “duplicate”.

The duplicates shall be fully identical to the original; if there is nevertheless a discrepancy between the duplicates and the original, the original copy shall prevail.

Nothing may be inserted, deleted or reformulated in the tender, except corrections made by the tenderer. The person(s) signing the tender shall attach their signature next to such corrections.

#### **1.5. Submission, closure and marking of tenders**

Tenderers shall place and seal the original and all copies of the tender in one envelope (package).

The following must be indicated on the envelope (package):

a) the following address: *Office of the Chief Medical Officer,  
Financial Directorate, H-1097 Budapest,  
Gyáli út 2-6., A épület fsz. 6.*

b) the following text:

*“TENDER”*

*“Screening reagent”*

*“Do not open before the tendering deadline”*

c) the tenderer's data: *name and seat*

The contracting authority bears no liability for redirecting inadequately addressed tenders or prematurely opening such tenders.

Tenders may be submitted in person or by post.

The contracting authority shall consider tenders as having been submitted within the defined deadline if the tenders are received by the expiry of the deadline at the submission address indicated in the contract notice (Point 1.5). All risks arising from the incorrect delivery or loss of mail shall be borne by the tenderer. It is the tenderer's responsibility to ensure the tender is submitted in adequate packaging and form, at the time and place defined in the contract notice. The contracting authority is only able to assess tenders submitted by the deadline and at the place specified in the contract notice. All Tenderers should note that tenders are to be submitted in an institution accessible through a security and reception service, therefore entry may take some time. Tenders received after the submission deadline will be kept by the contracting authority in a sealed state.

## **1.6. Prices and payment terms**

Tenderers shall submit their quote in Hungarian forints, exclusive of value added tax, by completing and duly signing the fiche included in the documentation. The tender price is fixed during the term of the contract, and may not be modified under any circumstances (including exchange rate fluctuations). The price shall include all fees and expenses incurred in the course of performance, in particular customs, packaging and delivery costs.

Terms and method of payment: The Contracting Authority shall transfer the fee for each award criterion based on the certificate of performance and the invoice issued no later than 15 days after performance, in keeping with the rules of treasury payment and with regard to Article 305 of the Public Procurement Act and Article 36/A of Act XCII of 2003.

The contracting authority shall not make any advance payments.

The contracting authority shall define a penalty for default, cancellation and defective performance.

The contracting authority shall be entitled to charge a cancellation penalty if performance is cancelled, whether in full or in part. The amount of the penalty shall be 35% of the cancelled task or part of the task.

The contracting authority shall consider and defective performance all negative deviations in the screening performance of the product in excess of the margin of error defined in the tender. In the event of defective performance, the penalty shall be 15% of the gross value.

## **1.7. Selection criteria and scoring**

*The tender selection criteria shall be the overall lowest price, pursuant to Article 57 (2) (b) of the Public Procurement Act.*

For the selection criteria determining the overall lowest price, the lowest awardable score used for evaluating the substantive elements of the award criteria is one, while the highest awardable score is one hundred.

The contracting authority shall determine the score between the two extreme values using the proportionality method, with the tender offering the lowest price corresponding to the maximum score of one hundred and the rest of the tenders corresponding to proportionally lower figures.

The scores awarded for each award criterion are then multiplied by their respective weighting and then added up for all award criteria. The total scores thus determined for each tender are then compared.

### **Calculation error**

If there is an apparent calculation error in the tender, the contracting authority shall correct such error by calculating the total value or other piece of data based on the values (basic data) defined for each element of the public procurement's object. If each tender has such a calculation error, the contracting authority shall directly notify all tenderers about the correction of the error at the same time in writing.

### **Rounding rules**

If the final score based on the award criteria is not a whole number, the contracting authority shall round the final figure to the second decimal place based on the general rules of rounding.

In the event that all tender elements contain a measure of 0, the contracting authority shall calculate using 0.1.

## 1.8. Evaluation criteria

<i>Award criterion for evaluation</i>	<i>Weighting</i>
<b>1. Gross total tender price</b>	<b>100</b>

For the award criterion of the gross tender price, the contracting authority shall evaluate the offered product tender price by awarding the maximum score of 100 (one hundred) points to the tender offering the lowest gross amount, and a proportionally lower score to the other tenderers based on the following formula:

$$P_{price} = \frac{P_{min}}{P_{act}} * 100$$

where:

$P_{price}$ : score calculated for the tender price offered by the tenderer.

$P_{min}$ : lowest tender price offered by the tenderers.

$P_{act}$ : tender price offered by the tenderer.

<i>Award criterion for evaluation</i>	<i>Weighting</i>
<b>2. Calibration stability</b>	<b>15</b>

The calibration stability criterion reflects the duration of the product's calibration stability. Calibration stability shall be determined in whole calendar days.

Calibration stability of under one day shall not be accepted.

The contracting authority shall only accept manufacturer's data.

Longer calibration stability is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_{Cs} = \frac{C_{S_{act}}}{C_{S_{max}}} * 100$$

where:



- $P_{cs}$ : score calculated for the calibration stability offered by the tenderer.
- $CS_{max}$ : longest calibration stability offered by the tenderers.
- $CS_{act}$ : calibration stability offered by the tenderer.

### ***Award criterion for evaluation***

### ***Weighting***

#### **3. Sample stability**

**15**

The sample stability criteria reflects the duration of the product's sample stability. Sample stability shall be determined in whole calendar days. Sample stability of under seven days shall not be accepted. The contracting authority shall only accept manufacturer's data.

Longer sample stability is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score to the other tenderers based on the following formula:*

$$P_{ss} = \frac{Ss_{act}}{Ss_{max}} * 100$$

where:

- $P_{Ms}$ : score calculated for the sample stability offered by the tenderer.
- $Ss_{max}$ : longest sample stability offered by the tenderers.
- $Ss_{act}$ : sample stability offered by the tenderer.

### ***Award criteria of evaluation***

### ***Weighting***

#### **4. Reagent stability — after opening**

**15**

The “reagent stability — after opening” criteria reflects the duration of the product's stability after opening. Stability after opening shall be determined in whole calendar days. Stability of under seven days shall not be accepted. The contracting authority shall only accept manufacturer's data.

Longer stability after opening is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a*

*proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_{Os} = \frac{O_{s_{act}}}{O_{s_{max}}} * 100$$

where:

$P_{Bs}$ : score calculated for the stability after opening offered by the tenderer.

$O_{s_{max}}$ : longest stability after opening offered by the tenderers.

$O_{s_{akt}}$ : stability after opening offered by the tenderer.

<i><b>Award criterion for evaluation</b></i>	<i><b>Weighting</b></i>
<b>5. Range of measurement</b>	<b>7</b>

The range of measurement criteria reflects the range in which a reliable outcome can be obtained, and the extreme values between which the reagent can be used. The upper and lower extreme values shall be given in ng/ml.

The contracting authority shall only accept manufacturer's data.

A wider measurement range for the product is more advantageous for the contracting authority, therefore *the tenderer offering the highest range shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_R = \frac{R_{avt}}{R_{max}} * 100$$

where:

$P_R$ : score calculated for the product's measurement range.

$R_{max}$ : widest measurement range offered.

$R_{act}$ : measurement range offered by the tenderer.

<i><b>Award criterion for evaluation</b></i>	<i><b>Weighting</b></i>
<b>6. Proportion of non-negative (test-positive) findings</b>	<b>15</b>

The "proportion of non-negative (test-positive) findings" reflects that percentage of samples classified as non-negative (test-positive) in the

context of mass (public health) usage, signalling the need for further, more in-depth colonoscopy examination. The proportion shall be given as a percentage, with the numerator being the number of non-negative tests and the denominator being the total number of persons tested.

Figures above 10% shall not be accepted.

The contracting authority shall accept specialised journals with evaluation and requirement systems characterised by their impact factor as sources of the requested data. The data quantified by the award criterion shall be contained in a scientific journal with an impact factor of at least 1.000 (one). As a further criterion, the journal shall also specifically name the offered product(s) and contain the data to be quantified by the award criterion. With regard to the above, the Tenderer shall specify the author(s) of the relevant publication(s), the full title thereof, the name of the journal, the year of publication, the volume, the page number and the journal's impact factor.

A *lower* proportion of non-negative (test-positive) findings is more advantageous for the contracting authority, therefore the tenderer offering the lowest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:

$$P_{Nn} = \frac{Nn_{min}}{Nn_{act}} * 100$$

where:

$P_{Nn}$ : score calculated for the proportion of non-negative findings

$Nn_{min}$ : lowest proportion of non-negative findings offered.

$Nn_{act}$ : proportion of non-negative findings offered by the tenderer.

<b>Award criterion of evaluation</b>	<b>Weighting</b>
<b>7. Sensitivity</b>	<b>15</b>

Sensitivity reflects the certainty with which the product can detect the target condition in the context of mass (public health) usage, that is the percentage of cases discovered to be cancer for which the test yielded a non-negative (positive) outcome. Sensitivity shall be given as a

percentage, with the numerator being the number of cancer cases discovered with the test (true positive) and the denominator being the total number of tested persons affected by cancer, including both revealed cases (true positive) and not revealed (false negative).

With respect to cancer cases, figures below 60 % shall not be accepted.

The contracting authority shall accept specialised journals with evaluation and requirement systems characterised by their impact factor as sources of the requested data. The data quantified by the award criterion shall be contained in a scientific journal with an impact factor of at least 1.000 (one). As a further criterion, the journal shall also specifically name the offered product(s) and contain the data to be quantified by the award criterion. With regard to the above, the Tenderer shall specify the author(s) of the relevant publication(s), the full title thereof, the name of the journal, the year of publication, the volume, the page number and the journal's impact factor.

Higher “sensitivity” is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_s = \frac{S_{act}}{S_{max}} * 100$$

where:

$P_s$ : score calculated for product sensitivity.

$S_{max}$ : highest sensitivity offered.

$S_{act}$ : sensitivity of the product under assessment.

<b>Award criterion of evaluation</b>	<b>Weighting</b>
<b>8. Specificity</b>	<b>15</b>

Specificity reflects the certainty with which the product can exclude the presence of cancer in the cancer-free cases tested in the context of mass (public health) usage, that is the percentage of cancer-free cases for which the test yielded a negative test outcome. Specificity shall be given as a percentage, with the numerator being the number of true negative cases

and the denominator being the total number of tested persons not affected by cancer, including both true negative and false positive (that is cancer-free) cases.

Figures below 90% shall not be accepted.

The contracting authority shall accept specialised journals with evaluation and requirement systems characterised by their impact factor as sources of the requested data. The data quantified by the award criterion shall be contained in a scientific journal with an impact factor of at least 1.000 (one). As a further criterion, the journal shall also specifically name the offered product(s) and contain the data to be quantified by the award criterion. With regard to the above, the Tenderer shall specify the author(s) of the relevant publication(s), the full title thereof, the name of the journal, the year of publication, the volume, the page number and the journal's impact factor.

Higher “specificity” is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_F = \frac{F_{act}}{F_{max}} * 100$$

where:

$P_F$ : score to be calculated for product specificity.  
 $F_{max}$ : highest specificity offered.  
 $F_{act}$ : specificity of the product under assessment.

<b>Award criterion of evaluation</b>	<b>Weighting</b>
<b>9. Positive predictive value</b>	<b>15</b>

The positive predictive value reflects the percentage of cancer cases revealed by the product among cancer cases subsequently confirmed by histopathology in the context of public health screening, that is whether it revealed non-negative (positive) test results. The proportion shall be given as a percentage, with the numerator being the number of cancer cases corroborated by histopathology (true positive) and the denominator being

the number of cancer cases confirmed by histopathology (true positive and false positive).

Figures below 60% shall not be accepted.

The contracting authority shall accept specialised journals with evaluation and requirement systems characterised by their impact factor as sources of the requested data. The data quantified by the award criterion shall be contained in a scientific journal with an impact factor of at least 1.000 (one). As a further criterion, the journal shall also specifically name the offered product(s) and contain the data to be quantified by the award criterion. With regard to the above, the Tenderer shall specify the author(s) of the relevant publication(s), the full title thereof, the name of the journal, the year of publication, the volume, the page number and the journal's impact factor.

A higher “positive predictive value” (approaching 100%) is more advantageous for the contracting authority, therefore *the tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and the other tenderers awarded a proportionally lower score based on the following formula:*

$$P_{PPV} = \frac{PPV_{act}}{PPV_{max}} * 100$$

where:

$P_{PPV}$ : score to be calculated for the product's positive predictive value.

$PPV_{max}$ : highest positive predictive value offered.

$PPV_{act}$ : positive predictive value offered by the tenderer.

<b>Award criterion of evaluation</b>	<b>Weighting</b>
<b>10. Speed of analysis</b>	<b>8</b>

The speed of analysis reflects the number of samples screened by the product offered by the Tenderer in one hour.

Devices unable to screen at least 199 samples per hour shall not be accepted.

Speed of analysis shall be given in sample screening / hour / installed device, with the assessment covering the screened number above the minimum requirement.

Hourly screening quantity of 200 or above is more advantageous for the Contracting Authority, therefore *the Tenderer offering the highest value shall be awarded the maximum score of 100 (one hundred) points, and a proportionally lower score awarded to the other tenderers based on the following formula:*

$$P_{PPV} = \frac{AS_{act}}{AS_{max}} * 100$$

where:

$P_{As}$ : score calculated for the device's speed of analysis.

$AS_{max}$ : highest speed of analysis offered.

$AS_{act}$ : speed of analysis offered by the tenderer.

#### 4.5 Summary

The contracting authority shall add up the scores calculated for each constituent element and multiplied by their respective weighting (rounded as necessary) for each tenderer. The winning tenderer shall be the one with the highest score determined in the above manner.

## Technical specification

The tasks to be fulfilled by the Supplier in the context of performing the contract and its obligations required for contractual performance defined in detail are set



out in the contract terms and conditions defined in Section 4 of this documentation.

### **Objective**

Laboratory diagnostic procedure financed by the Ministry of National Resources (NEFMI) — in the context of the National Public Health Programme — as a model programme for public health population-based screening aimed at *identifying faecal occult blood, yielding a human haemoglobin-specific* outcome using a fully *automated immunochemical* method, confirmed by sound scientific evidence of high quality, with good diagnostic performance in public health application in the screening population.

The objective of this public procurement is the purchase of sampling tools and reagents for attaining the abovementioned goal, and the deployment of at least one automatic measurement device complete with its online linkup.

### **Volume:**

Volume of examinations to be carried out over the course of 12 months in the context of the model programme:

*20,000 persons, 2 samples per person*

### **Specification:**

Requirements for the sampling device (40,000 units):

- allows the collection of at least two samples/patient,
- user-friendly for patients,
- user's manual for patients available in Hungarian,
- suitable for mailing.
- the sampling device's expiry date shall be at least one year.
- the device shall have a CE mark.

Analytical requirements for the test and the screening device:

- lower faecal occult blood detection threshold: 50 ng/ml or lower.
- speed of analysis: at least 199 tests/hour/installed device.
- internal and external laboratory quality assurance procedures must be feasible.
- the reagent's expiry date (in function of the annual screening volume) must be at least 14 months.
- the test must signal the prozone phenomenon



- the test must comply with the effective European IVD directives, and have a CE mark.
- the automatic device performing measurement must be suitable for showing quantitative results
- the process must be fully automatic.

**The tender shall include the following:**

1. The analytical and other performance indicators, indicating the sources;
2. Indicators reflecting the test's diagnostic performance (e.g. sensitivity, specificity, predictive value, diagnostic cut-off value, positivity ratio, ROC curve) in the screening population, listing the scientific evidence confirming the data;
3. Costs broken down per patient, including the cost of the screening reagent and other consumables, and the calibration and control measurements required for maintaining continuous measurement quality.
4. Terms and conditions for insurance on measurement devices, and their warranty-based service and maintenance.
5. Declaration on full compliance with the requirements set out in the specification.

**SUPPLY CONTRACT  
(Draft)**

entered into  
by and between

- The **Office of the Chief Medical Officer**, 1097 Budapest, Gyáli út 2–6., represented by: Mrs. Sándor Bánóczy, dr., Chief Medical Officer, as Client) hereinafter referred to as: Client),

on the one part and

• ..... (address: .... represented by: ... as Supplier (hereinafter referred to as: Supplier) — *in case of joint tenders, all tenderers have joint and severable liability* —  
— hereinafter jointly referred to as Parties — as of the day first below written, with the following terms and conditions.

## **1. Antecedents**

- 1.1 By publishing the contract notice (hereinafter referred to as: “Notice”) pursuant to Act CXXIX of 2003 on Public Procurement, Client has launched a public procurement procedure for the procurement of **immunochemical reagent and other accessories used for faecal occult blood testing**.
- 1.2 Contracting authority has awarded — based on the evaluation method set out in the Notice — this contract for the supply of reagents as per the object of this contract to the Supplier.
- 1.3 The Notice launching the public procurement procedure, the tender documentation (hereinafter referred to as: “Documentation”) and the winning tender submitted by the winning tenderer (Supplier) (hereinafter referred to as: “Tender”) shall form an integral part of this contract.
- 1.4 The winning business entities submitted a joint tender in the public procurement procedure, they therefore **hold joint and several** rights arising from this contract, and shall also fulfil the obligations arising therefrom. Parties hereby declare that statements made by the Client to any of the winning business entities shall be considered as having been made to all of them — (in case of joint tenders).

## **2. Object of the contract**

- 2.1 Supply of immunochemical reagents and accessories for faecal occult blood testing (hereinafter referred to as: “Reagent”), detailed below, by the Supplier, in line with the specifications defined in section ... of the technical description included in the Documentation (quantity, quality, usage requirements), as per the terms and conditions set out in this contract.

Name of reagent:

Total quantity: 40,000 tests required for screening 20,000 persons and 40,000 sampler devices (Quantity ordered by the contracting authority + an allowed divergence of at most 35%.)

Packaging: Manufacturer’s packaging (not necessarily sterile)

Usability: reagents shall be usable for 14 months from the date of delivery.

Delivery deadline(s):

### **2.2 Object of the contract:**

- 2.2.1 Delivery and storage of the offered reagents at the location and by the deadline specified in Sections 4.1 and 4.2 of this contract.

It is the tenderer’s obligation to fulfil the obligations set out by the customs administration procedure required for the import of the Reagent to Hungary — as per the stipulations of Act CXXVI of 2003 on the Implementation of Community Customs Law —, and it is the Supplier’s obligation to obtain all authorisations necessary for the distribution in Hungary of the Reagent based on the currently effective legislation.

### **3. Terms of delivery**

#### **3.1 Cooperation obligation:**

- 3.1.2 Supplier shall cooperate with the Agent commissioned by and acting on behalf of the Client, in particular in the delivery and the qualitative and quantitative verification of the goods.

#### **3.2 Time and scheduling of delivery:**

- 3.2.1 Delivery shall be scheduled as prescribed under Section 2.1, carried out on the delivery dates and in the quantities defined therein for the Reagent.
- 3.2.2 Client shall be entitled to deviate from the quantities defined in the Documentation, but up to the extent set out therein (+ 35 %) when performing this contract.
- 3.2.3 Client shall furthermore be entitled to deviate from the delivery dates and quantities defined herein. Client shall in such cases notify the Supplier directly (or through the appointed contact person) about the changes in writing (via fax or mail) at least one month prior to the original delivery date. Supplier shall issue a written confirmation of receipt of such notice (via fax or mail). Client may amend the quantity of the reagent to be delivered, taking into account the percentage of deviation defined under Section 3.3.1 herein.
- 3.2.4 Supplier shall perform delivery without a separate notice from the Client.
- 3.2.5 Supplier shall notify the Distributor of the arrival of the goods at least three days prior to performance.

#### **3.3 Supplementary orders:**

- 3.3.1 Client shall be entitled to deviate from the quantities defined in the Documentation for the reagent up to the extent set out in the Documentation (+ 35 %).
- 3.3.2 Client shall be entitled to submit supplementary orders one month prior to the date of planned delivery at the latest.
- 3.3.3 Client shall submit supplementary orders to the Supplier or its appointed contact person in writing (fax or mail). Supplier shall confirm supplementary orders without delay. Parties shall cooperate in the course of supplementary orders, taking into account their mutual interests and other circumstances. Client shall thus directly notify Supplier about any foreseeable supplementary orders and the expected quantities thereof. Supplier shall immediately confirm any supplementary orders submitted following direct notification thereof.

### **4. Place of performance**

- 4.1. The place of delivery is defined as the Client's warehouse. The warehouse is located at: **1097 Budapest, Vágóhíd út 39.**
- 4.2. In the event of any changes in the place of delivery, Client shall notify the Supplier or its appointed contact person in writing two weeks prior to the due delivery at the latest.

### **5. Order of quantitative and qualitative controls**

#### **5.1 Quantitative control**

- 5.1.1 The quantitative control and receipt of the reagent takes place upon arrival of the reagent at the place of performance.

- 5.1.2 The documents on the quantity delivered — a bill of delivery and a bill of freight — shall be attached to the delivered goods.
- 5.1.3 The party appointed by the Client shall verify the condition and quantity of the delivered parcels. Delivery shall be concluded by handing over the delivery documents certifying the adequate condition and quantity of goods, and by signing the bill of delivery.
- 5.1.4 The Supplier and the Agent shall prepare a protocol on any parcels damaged during delivery or in the course of handover by the Supplier, specifying the data needed for identifying the damaged parcel, the extent of the damage, the quantity of material no longer fit for use, the presumed cause of the damage and the provisions applying to the further use of the damaged goods.
- 5.1.5 Client or its Agent shall notify the Supplier on the further use of the damaged goods defined under Section 5.1.4.

## **5.2 Qualitative control**

- 5.2.1 The effective usage instructions defined by the Supplier shall apply to the composition, quality, storage, handling and use of the delivered reagent.
- 5.2.2 Reagent quality shall be verified at the premises located at 1097 Budapest, Gyáli u. 2-6.
- 5.2.3 The qualitative control of the reagent shall be conducted in line with the EU requirements.
- 5.2.4 Reagents pronounced suitable by the Client, having all necessary documentation shall be considered as compliant with the qualitative requirements set out in the contract.
- 5.2.5 Delivery of production items considered as unsuitable shall qualify as defective performance, of which the Office of the Chief Medical Officer shall immediately notify the Supplier.
- 5.2.6 In case of Reagents deemed inadequate or damaged as per Sections 5.1.4 and 5.1.5, the Supplier shall ensure removal and return delivery of the defective reagent from the place of storage, and of the proper elimination thereof at its own expense.
- 5.2.7 If the name and/or packaging of the Reagent does not comply with those set out in the contract, or the expiry period is shorter than the required period, Client shall be entitled to consider performance as defective and request replacement of the shipment without further qualitative examinations.

## **6. Delivery fee**

- 6.1. The value of the reagent forming the object of this contract (hereinafter referred to as: “unit price” is:

price of one unit of reagent: HUF ..... +VAT, that is a gross amount of ..... forint.

- 6.2. Supplier hereby undertakes the obligation to regard the delivery fee (unit price x number of units) as fixed, and shall not increase on any grounds.
- 6.3. The delivery fee includes expenses incurred in the course of the contractual and lawful performance of all tasks defined in this contract. The contracting Parties agree that the Supplier shall not be entitled to charge any expenses besides the delivery fee, which

shall include all expenses incurred in the course of contractual performance (production, packaging, delivery, receipt, etc.).

## **7. Terms of compensation**

- 7.1. Compensation for performance complying with the method and contents defined in the contract shall be settled within 15 days of receipt of the invoice (currency: HUF) issued following certified performance by wire transfer, in line with the rules of treasury payment.
- 7.2. Supplier shall be entitled to issue an invoice following certified delivery of the reagent quantity defined under Section 2.1.
- 7.3. The bill of delivery, the certificate or protocol of receipt shall be appended to the invoice.  
In the event of default on payment, a default interest rate corresponding to the central bank base rate effective at the time of default may be charged to the Client.

## **8. Ancillary obligations ensuring the contract**

- 8.1. Supplier shall pay a penalty in the event of late delivery due to any reason for which it is responsible or occurring on its own part. The value of the goods delivered late plus VAT shall form the basis of the penalty, and the rate shall be 0.5 (that is half a percentage point) per calendar day.
  - 8.1.1. The date of expiry of the defined delivery deadline shall be the starting date of default.
- 8.2.2 In the event of defective performance as per Sections 5.1.4, 5.1.5, and 5.2.6, the starting date of the Supplier's penalty payment obligation shall be the expiry of the delivery deadline as per Sections 3.2 and 3.3.
- 8.2.3 In the event of defective performance, the starting date of the Supplier's penalty payment obligation shall be the date of dispatch of the notice on defective performance (Section 5.2.5).
- 8.3 Client shall be entitled to include the penalty calculated in the above manner in the invoice due issued to the Supplier.
- 8.4 If performance of the contract is cancelled or becomes unfeasible for any reason for which the Supplier is responsible, it shall pay a lump-sum cancellation penalty. The amount of the cancellation penalty shall be 25% of the cancelled delivery.

## **9. Termination of the contract**

- 9.1 The Client shall be entitled to terminate the contract with extraordinary notice in the event of repeated late or defective performance by the Supplier.

## **10. Miscellaneous provisions**

- 10.1 Parties hereby acknowledge that pursuant to Government Decision 2190/2002 (VI. 21.) on the controlling of the use of budgetary funds, the State Audit Office of Hungary and the Government Control Office shall both be entitled to control the contractual usage of the budgetary funds allocated to them, furthermore, that they may not deny any information on the contents of the contract pursuant to Article 19 of Act LXIII of 1992 on the protection of personal data and the disclosure of data of public interest and Article 81 of Act IV of 1959 on the Civil Code of the Republic of Hungary.

10.2 Parties hereby declare that they shall consider immediate consultations between their representatives as the primary means of settling any dispute arising out of or in connection with this contract, which shall take place at the Client's seat in every instance.

This contract has been executed in six (6) identical counterparts, all of which shall evidence the same agreement. IN WITNESS WHEREOF, the parties have caused this contract to be executed — as the same being the full expression of their respective will and the terms negotiated in the course of the public procurement procedure —, on the day and date written below.

Budapest, February 2011

.....  
Client

.....  
Supplier

**Financial countersignatory:**

.....

<b>ANNEXES</b>
----------------

Annex “A” (fiche)

Annex “B” (tenderer model declaration)

Annex “C” (model declaration for Article 71 (1) (a) and (b) of the Public Procurement Act)

Annex “D” (model declaration for Article 71 (3) of the Public Procurement Act)

Annex “A”

## FICHE

### Tenderer:

<b>Name:</b>	
<b>Seat:</b>	

### Contact person:

<b>Name:</b>	
<b>Position:</b>	
<b>Address:</b>	
<b>Telephone:</b>	
<b>Fax:</b>	

<b>E-mail:</b>	
----------------	--

Data bearing significance in the selection procedure:

<b>Award criterion for evaluation</b>	<b>Offered value</b>
Total gross tender price	HUF
Calibration stability	day
Sample stability	day
Reagent stability after opening	day
Range of measurement	ng/ml
Proportion of non-negative (test-positive) findings	%
Sensitivity	%
Specificity	%
Positive predictive value	%
Speed of analysis	unit/hour/device

Date:

.....  
(authorised signature)



## TENDERER'S DECLARATION

*We hereby declare on behalf of the undersigned (company name) that (company name) wishes to participate in the public procurement procedure announced for*

***"Immunochemical reagent and other accessories required for faecal occult blood testing".***

*tárgyban meghirdetett közbeszerzési eljáráson a (cégnév) részt kíván venni.*

*We have compiled our tender in line with the contract notice and the documentation, and accept the terms and conditions set out therein. We hereby certify that the information contained in the documents called for in the contract notice and submitted by the applicant (company name) is true.*

*We hereby declare on behalf of the tenderer that in the event of the acceptance of our tender, we accept without reserve or restriction the entire content of the tender and shall perform our tasks in keeping with the contract, while also acknowledging the stipulations of Articles 305 and 306/A of the Public Procurement Act.*

*We accept the contracting authority's decision whereby it shall select the tenderer offering the lowest cost.*

*We hereby declare that if the contract authority accepts our tender, we shall be present in order to sign the contract at the date specified in the contract notice. We hereby acknowledge that the contractual relationship between us shall not be established until both parties have signed the contract. We shall maintain the net prices specified in our tender over the entire performance period.*

*Pursuant to Act XXXIV of 2004 on SMEs and subsidising SME development, tenderer is*

- *a micro-enterprise.*
- *a small enterprise.*
- *a medium-sized enterprise.*
- *Tenderer does not fall within the scope Act XXXIV of 2004. \**

Date: ....., 2011. .... day.....month ..... year

.....  
(authorised signature(s))

Annex "C"

---

\* underline the appropriate form

**DECLARATION  
FOR THE POINTS OF ARTICLE 71 (1) OF THE PUBLIC PROCUREMENT ACT**

**The following partners are participating in performance as joint tenderers:**

Name of organisation participating in performance	Seat	Contact details (tel, e-mail, fax)

**Part(s) of the public procurement for which a contract will be concluded in the event of a winning tender (in order to perform the concluded contract) with a person (or organisation), or amended:**

Name of task or activity, and proportion in performance (in % or as a value)	Status of subcontractors to be employed (subcontractors exceeding or falling below 10% of contract value)

**We wish to employ the following subcontractors exceeding 10% of contract value in the performance of the contract:**

Name of subcontractor to be employed, exceeding 10% of contract value	Seat	Contact details (tel, e-mail, fax)

**The following organisation(s) will provide resources for performing the contract (external resources):**

Name and seat of the organisation providing resources	Suitability	Relationship with the tenderer

Date: ....., 2011. .... day.....month ..... year

.....  
(authorised signature(s))

Remark:

- Tables shall be duly completed, with each line expandable/deletable as necessary.
- If the tenderer does not employ a partner, please note “We do not wish to employ a partner”.

DECLARATION

I, the undersigned ..... , as the representative of the tenderer ..... in the public procurement procedure launched by the Officer of the Chief Medical Officer for the procurement of **“Immunochemical reagent and other accessories used for faecal occult blood testing”** hereby declare that the tenderer shall not employ any subcontractors giving grounds for exclusion in excess of 10% of the contract value for the performance of the contract.

Date: ....., 2011. .... day.....month ..... year

.....  
(authorised signature)