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**Specification**

**for the purchase of quick (express) combined tests.**

ICF "Alliance for Public Health" (hereinafter - Alliance) is a leading professional organization which in cooperation with the key civil society organizations, Ministry of Health and other governmental bodies is fighting a number of epidemics, including HIV/AIDS and TB, in Ukraine, managing prevention programs and providing high-quality support and financial resources to the local organizations. Alliance’s mission is to reduce the morbidity and mortality levels, as well as alleviate the negative impact of epidemics through supporting community action against the epidemics in Ukraine and disseminating effective approaches to HIV prevention and care throughout Eastern Europe and Central Asia.

As an independent legal entity registered in Ukraine since 2003, and upon establishment of its own governing bodies since January 2009, Alliance shares the values and remains a member of the global partnership of the International HIV/AIDS Alliance – an international charitable foundation uniting 30 organizations from different countries, with its secretariat in Hove (UK).

This procurement is carried out within the framework of the program "Innovative solutions in the field of HIV and harm reduction for the unreached segments of key groups and bridge groups in Ukraine". In particular, for the needs of the " Help 24" project.

The project is aimed at tertiary social prevention using a strategy of harm reduction for persons with risky behavior, prevention of HIV/AIDS transmission, Heatitus S. Target groups of the project : users of injection drugs, sex workers, men who have sex with men and trans - personalities.

The project has three areas of activity :

- Rating medical institutions

- Providing free medical , psychological and legal consultations to customers target audience ,

- Formation the package handouts materials and mailing to customers key groups HelpBox

Within the framework of the third direction activities - mailings individual preventive sets , the Help24 team purchases materials for assistance to customers to prevent HIV/AIDS infection and transmission ; Also from these materials are formed individual HelpBox with filling that \_ meets the needs of customers .

1. **Procured goods..**

Lot 1. Rapid tests for determining multi -infections: HIV 1/2, hepatitis B/C, syphilis .

1. **Purpose of the Product.**

Application of rapid tests for assisted testing by representatives of vulnerable population groups within the framework of HIV/AIDS prevention projects.

Lot No. 1 . Quick tests for visual, one-step , qualitative:

* detection of antibodies to HIV type 1 and 2 (HIV ½)
* determination of antibodies to the hepatitis C virus
* determination of hepatitis B surface antigen ( HBsAg )
* Treponema antibodies Pallidum

in whole blood samples (when conducting a study of capillary blood from a finger).

1. **Quantity of Goods to be purchased. Terms of delivery and payment.**
   1. Quantity of goods to be purchased.

|  |  |  |
| --- | --- | --- |
| **Lot** | **Product name** | **Quantity\* of goods to be delivered** |
| 1 . | Rapid tests for determining multi -infections : HIV 1/2, hepatitis B and C, syphilis | 8,000 |

* + 1. The number of tests can be adjusted according to the multiplicity of the package.
    2. The Alliance reserves the right to increase or decrease the quantity of goods purchased, while remaining within +/- 20% of the total cost of the goods.
  1. Prices must be provided in accordance with INCOTERMS 2010 on the terms of **DDP Kyiv region Vyshhorod city** (warehouse) in US dollars, including all taxes and fees, including VAT in Ukraine.
     1. The supply contract will be concluded and payment for the delivered products will be made in:
        + US dollars for non-resident companies of Ukraine;
        + hryvnias of Ukraine for residents of Ukraine (the price of the contract is fixed in the amount of the Applicant's price offer converted at the NBU exchange rate on the date of conclusion of the contract. Payment of the equivalent in US dollars is made in Ukrainian hryvnias at the NBU exchange rate on the date of issue of each separate invoice).
  2. Payment for the goods:
* Advance payment of 50% of the cost of each individual lot. Payment terms: 20 calendar days after signing the Agreement.
* Final payment of 50% of the cost of each individual delivered batch - within 20 calendar days after completion of its delivery.
  1. Delivery terms: DDP with. Vyshhorod city, Kyiv region, Ukraine.
  2. It is desirable that the ordered Goods arrive at their destination as soon as possible.
  3. Delivery of tests must be carried out in compliance with the necessary conditions of transportation and storage.
  4. Delivery time: January 2025, The earliest possible delivery is desired. Participants can offer their delivery times. A faster deadline will be preferred, other things being equal.

1. **Number of series of the Product.**

Delivery must be made within the framework of the smallest possible number of product series.

1. **Registration.** 
   1. The product must be approved for use in Ukraine in accordance with current legislation (availability of a declaration of compliance with the requirements of technical regulations) at the time of delivery to the destination.
   2. At the time of submitting the offer, the product may not be registered in Ukraine. In such a case, the participant must provide **a written guarantee of registration of products with the receipt of permit documentation for the right to use such products on the territory of Ukraine.** At the same time, in the event that he is selected as the winner, such a participant must obtain such registration no later than the time of arrival of the first batch of products on the territory of Ukraine. The written guarantee must necessarily contain a schedule for obtaining this permission. The letter should also state that all costs related to the registration procedure in Ukraine will be borne by the Applicant. If necessary, the Alliance will be able to provide technical assistance related to the registration procedure.

In any case, at the time of arrival of products on the territory of Ukraine for customs clearance, it must be registered for its use in Ukraine.

Permissive documentation for the right to use products on the territory of Ukraine includes: a certificate of compliance with technical regulations, certified by the seal of the supplier company.

5.3. By participating in this tender, the winner of the tender undertakes to guarantee the extension of the term of registration of this product in Ukraine in accordance with the current legislation until the end of the shelf life of the products supplied under the terms of this procurement.

1. **Primary packaging.**

The packaging must comply with the legislation of Ukraine. It must maintain the quality, safety and stability of the product it contains. All packaging must be properly sealed and protected from damage during shipping and improper use.

The test package should be individual, compact, sufficiently resistant to the effects of possible adverse factors in field conditions and contain the entire set of tools necessary for conducting the test (if possible).

The primary packaging must contain the following information: name and address of the manufacturer, month and year of production, storage conditions, information on state registration in Ukraine.

During the delivery of the tests, the winning company (supplier) must provide instructions for using the tests in Ukrainian with each individual test.

1. **Marking.**

7.1. The marking of test systems must be carried out in accordance with the terms of the Technical Regulation on medical devices (approved by Resolution of the CMU of November 2, 2013 No. 753 /754 ).

1. **Completion of products before purchase.**

The packaging in which the products are delivered must be compact and sufficiently resistant to the effects of possible adverse factors in field conditions.

* 1. Mandatory equipment **from the manufacturer** of each individual test set includes all necessary consumables for testing:

8.1.1. test cassette;

8.1.2. buffer;

8.1.3. 2 sterile automatic scarifiers;

8.1.4. pipette/capillary tube;

8.1.5. 2 alcohol wipes;

This requirement is justified by the fact that the purchased combined tests will be used to form preventive HelpBox kits , which will be sent by courier service to the program's clients. Therefore, the key requirement is that all materials necessary for testing must be packed in a sachet package from the manufacturer.

8.2. Instructions for use in Ukrainian

1. **Medical and technical requirements for products.**
   1. General requirements.

|  |  |  |
| --- | --- | --- |
| **Requirements** | **Mandatory requirement \_ \_ / desirable characteristic** | **A document to be provided by the supplier** |
| **1. Operating characteristics** |  |  |
| 1.1. Sensitivity | HIV ≥ 99%  Hepatitis C ≥ 98%  Hepatitis B =100%  Syphilis ≥ 87% | Instructions for use or materials |
| 1.2. Specificity | HIV ≥ 98%  Hepatitis C ≥ 97%  Hepatitis B ≥ 98%  Syphilis ≥ 99.5% |
| **2. Quality standards** |  |  |
| Manufacturer: ISO 13485 | necessarily | A copy of the certificate |
| **3. Registration** |  |  |
| Registration of products in Ukraine in accordance with the requirements of current legislation during the shelf life of the delivered products | necessarily | Declaration of compliance with technical regulations or warranty letter (see clause 5 of the specification) |
| Authorized distributor status | necessarily | Letter from the manufacturer |
| State registration of the supplier | necessarily | Copies of documents testifying to the state registration of the tendering company. |
| **4. Operational characteristics** |  |  |
| Test storage temperature regime | 2-30°C | Instructions for use |
| Operating temperature range | 15-30°C |
| The duration of the analysis | ≤20 minutes |
| Expiry date at the time of product delivery. | ≥ 75% of the total storage period | Letter from the supplier with confirmation. |
| General expiration date | to indicate | Instructions for use |
| **5. Assembly of products before purchase** |  |  |
| Buffer | Declare the possibility of supplying additional buffers. Specify the number of buffers supplied in the kit. | Specify in the price offer (see Appendix 3) |
| Automatic scarifier/lancet | must have a sharp, thin metal blade/needle that provides a painless puncture of the finger (low puncture force); non-toxic, non-pyrogenic , sterile, meets established medical criteria/indicators for controlling the sterility of medical products. Provides **a high** blood flow to take the required volume of blood sample from the finger for testing.  Technical characteristics: needle gauge – 18 G -21 G ( 1.25-0.8 mm), puncture depth – 2.0-2.4 mm. | Instructions for use,  certificate of conformity issued in Ukraine, conclusion of the SES (if available). |
| A pipette or capillary tube with a label | Ensures high-quality blood sampling from the finger, necessary for performing the test.  It is desirable: the presence of a label to determine the required volume of the sample . | Instructions for use. |
| Wet napkin | Disposable napkin, for external use (for skin treatment before injection).  Composition: a napkin made of non-woven material (polypropylene), approximate size - 30x65 mm, impregnated with an antiseptic solution.  Term of sterility : during the shelf life of the test system supplied with napkins.  Type of packaging: sterile individual paper-foil bag. | Declaration of conformity |
| Instructions for use in Ukrainian for each individual test. | necessarily | Provide instructions in Ukrainian |
| **Additional requirements** |  |  |
| Ability to train medical personnel who will use the rapid tests | necessarily | Confirmation letter |

* 1. If the participant is selected as the winner of this tender, he must provide training for testing specialists on the use of the test system for the rapid testing procedure. The number and schedule of trainings will be agreed at the stage of discussion of the supply contract.

1. **Content of tender applications**

Participants must include the following information in the Tender Applications:

* 1. Copies of documents testifying to the state registration of the tender participant.

10.2. A copy of the Applicant's documents on the state registration of products in accordance with the legislation of Ukraine. The supplier must provide: a copy of the declaration of compliance with technical regulations. If the product is still in the process of registration at the time of submitting the tender offer, provide an official letter confirming the obligation of such a participant to provide the Alliance with all the necessary permit documentation before the delivery of the first batch of goods.

10.3. Completed and signed Annexes Nos. 1-4 to the specification.

10.4. If the participant is an intermediary (does not produce goods, but offers products of another legal entity), a copy of a valid document issued by the manufacturer confirming the participant's status as a distributor of such products.

10.5. A copy of the documents confirming compliance of the production of test systems with ISO13485 standards.

10. 6 . The supplier must provide instructions for using the tests in Ukrainian.

10. 7 . NECESSARILY! the supplier must provide a photo of the complete set from the manufacturer of one individual test kit.

10. 8 . Other documents in accordance with the requirements of clause 9.1. specifications.

10.9. Any other information that may help evaluate the product and supplier.

1. **Key criteria for evaluating tender applications**

The application/proposal (together with its attachments) will be evaluated according to the following criteria:

* compliance of the products with the medical and technical requirements of the tender specification, and the requirements for completeness;
* cost of goods ;
* delivery terms.

1. **Requirements for the preparation of tender applications:**

An English/Ukrainian translation of each of the above-mentioned documents must be provided, if the original of such a document is not written in one of the specified languages.

**Annex 1 to the Procurement Specification**

Please complete and sign this form to confirm that you agree with the following terms.

***To: ICF “Alliance for Public Health”***

Ladies and/or Gentlemen,

Having revised the bidding documents, the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply and deliver the goods in conformity with the said bidding documents at the prices contained in the attached document, which forms an integral part of this proposal.

If our proposal is accepted, we undertake to deliver the goods according to the terms indicated in the draft contract (which forms an integral part of the Bidding Documents).

If our proposal is accepted, we undertake to provide performance guarantees in the form, in the amounts, and within the times specified in the Bidding Documents.

We agree to abide by this proposal for the Proposal Validity Period specified in the Bidding announcement and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

Until a formal contract is prepared and executed, this Bid, together with your written acceptance thereof and your notification of award, shall constitute a binding contract between us.

We understand that your organization is not bound to accept the lowest or any bid you may receive.

We certify/confirm that we have the legal capacity to enter into the contract.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20... р.

*[signature] [acting as]*

# Duly authorized to sign this Bid on behalf and upon assignment of… Annex 2 to the Procurement Specification

# General Information

Please fill in the table below

|  |  |  |
| --- | --- | --- |
| 1. | Full name of the company |  |
| 2. | Legal address of the company |  |
| 3. | Business address of the company |  |
| 4. | Director of the company: job title, full name |  |
| 5. | Director’s phone number |  |
| 6. | Contact person on matters concerning bid submission |  |
| 7. | Phone number for the contact person |  |
| 8. | E-mail address for the contact person |  |

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20....

*[signature] [acting as]*

Who has the authority to sign the Bid for and on behalf of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Annex 3 to the Specification.

Please complete the table below.

, be sure to pay attention to the requirements of this specification, including on the following aspects:

1. applicable terms of delivery: see clause 3. specifications.
2. Prices must be quoted in US dollars at the above terms of delivery, inclusive of all applicable taxes and fees, inclusive of VAT.
3. carefully familiarize yourself with the terms of payment given in clause 3.4. specifications.
4. "estimated delivery time " means the maximum period of time required for the production of the batch and delivery to the Alliance warehouse. The period begins with the signing of the contract and ends with the date of shipment to the Alliance warehouse.

D D P Kyiv region, c . Vyshgorod / delivery to a warehouse located in c . Vyshgorod.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Lot | Product, brand name, catalog number | Composition of the set for delivery | Country of origin | Total storage period | The price of 1 product unit  **in US dollars , including VAT** | Estimated delivery time, calendar days |
| Lot 1 |  | The kit/set consists of:  1) Test card, buffer - \_\_unit.  2) Scarifier - \_\_\_unit.  3) Wet napkin - \_\_\_ units.  4) Dry napkin - \_\_\_ units.  5) Pipette - \_\_\_ units.  6) Instruction - \_\_\_ units. |  |  |  |  |

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20... r.

*[signature] [acting as*

That has the proper authority to sign the Application on behalf of and on behalf of

**Annex 4 to Specifications**

**SWORN DECLARATION**

**BY CANDIDATES/BIDDERS INVOLVED IN THE IMPLEMENTATION OF A GRANT FINANCED BY EXPERTISE FRANCE**

*To be attached to the [application/bid/contract]*1

Object of the service/supply/works purchase contract: **procurement** **of rapid diagnostic (express) combo tests**

In the context of the Grant contract covering: # 23-SB0638 від 02.03.2023

1. We acknowledge and accept that, in the aforementioned circumstances, Expertise France shall be entitled to exclude our company from the tender procedure for services/supplies/works in the context of the implementation of a Grant financed by Expertise France and, should the contract be awarded to our company, any such situation may lead to termination of the contract, in accordance with the terms of the latter.
2. We hereby declare that neither we, nor any member of our consortium, nor any supplier, service provider, consultant or subcontractor (including the directors, employees and agents of said entities) nor any person holding the power of representation, decision-making or control over said persons, is in any of the following situations:
   1. Bankruptcy or proceedings relating to bankruptcy, liquidation, safeguarding or cessation of operations, or any similar situation resulting from proceedings of the same nature;
   2. Or has been the subject of:
      1. A ruling dated from within the past five years with the force of res judicata in the country of implementation of the contract for fraud, corruption or any offence committed in the context of an award or performance of a tender or contract; in the event of any such ruling, we reserve the right to append additional information to this Integrity Undertaking specifying that said ruling is not relevant to the contract;
      2. An administrative sanction dated from within the past five years by the European Union or by the competent authorities of the country in which we are established for fraud, corruption or any offence committed in the context of an award or performance of a tender or contract; in the event of any such sanction, we reserve the right to append additional information to this Integrity Undertaking specifying that said sanction is not relevant to the contract;
      3. A ruling dated from within the past five years with the force of res judicata for fraud, corruption or any offence committed in the context of an award or performance of a contract financed by the AFD;

1 This document must be appended to the application/bid of the applicant/bidder for all competitive tenders. This document must be appended to the contract for all non-competitive procedures.

* 1. Feature on any sanctions list adopted by the United Nations, European Union or France, notably in respect of anti-money laundering, counter-financing of terrorism and the undermining of international peace and security.
  2. Any termination issued solely due to failings on our part within the past five years as a result of us having committed any serious or persistent breach of our contractual obligations during the performance of a previous tender or contract, subject to said sanction not currently being contested by us or which has led to a court ruling dismissing said termination solely due to failings on our part;
  3. Any breach of our obligations to pay taxes in accordance with the legal provisions of the country in which we are established or those of the country of the contracting authority;
  4. Any exclusion decision issued by the World Bank or to feature in this regard on the list published at <http://www.worldbank.org/debarr>; in the event of any such exclusion decision, we reserve the right to append additional information to this Integrity Undertaking specifying that said exclusion decision is not relevant to the contract;
  5. Or has produced false documents or been found guilty of false declarations when providing documents demanded by the contracting authority in the context of this contract award process.

1. We hereby declare that neither we nor any member of our consortium or our suppliers, contractors, consultants or service providers is confronted by any of the following conflicts of interest:
   1. Being a shareholder controlling the contracting authority or a subsidiary controlled by the contracting authority, unless the resultant conflict has been notified to Expertise France and been resolved to its satisfaction;
   2. Having a business or family relationship with any member of the contracting authority's departments who is involved in the contract award or supervision process, unless the resultant conflict has been notified to Expertise France and been resolved to its satisfaction;
   3. Controlling or being controlled by another bidder or consultant, being under the control of the same company as another bidder or consultant, receiving from another bidder or consultant or awarding a grant to another bidder or consultant, whether directly or indirectly, having the same legal representative as another bidder or consultant, directly or indirectly maintaining contacts with another bidder or consultant enabling us to have access and provide access to information contained in our respective bids or proposals, or of influencing such bids or proposals or the decisions of the bidder or consultant;
   4. Having been engaged to provide intellectual services, the nature of which runs the risk of being incompatible with our assignments carried out on behalf of the bidder or consultant.
   5. In the case of a procedure covering the award if a works, supplies or equipment contract:
      1. We have ourselves prepared or have been supported by a consultant who has prepared the specifications, plans, calculations and other documents used in the context of the contract award procedure;
      2. We have ourselves, or one of the firms with which we are affiliated, been recruited, or will be recruited, by the contracting authority to supervise or audit the works under the contract.
2. If we are a public institution or public company, in order to be able to participate in a competitive tender we hereby certify that we enjoy legal and financial autonomy and that we are governed by the rules of company law.
3. We undertake to notify the contracting authority without undue delay, which will in turn notify Expertise France, of any change of situation with regard to points 2 to 4 above.
4. In the context of contract award and execution:
   1. We have not committed and will not commit any unfair practices (action or omission) designed, with regard to any third party, to deliberately deceive, intentionally conceal information, inveigle or vitiate consent, circumvent legislative or regulatory obligations or violate internal rules in order to obtain an illegitimate benefit.
   2. We have not committed and will not commit any unfair practices (action or omission) contrary to our legislative or regulatory obligations and/or internal rules in order to obtain an illegitimate benefit.
   3. We have not promised, offered or granted, nor will do so in the future, whether directly or indirectly, to (i) any person holding a legislative, executive, administrative or judicial office within the country of the contracting authority, whether such person is appointed or elected, permanently or otherwise, remunerated or otherwise and regardless of their hierarchical level, (ii) any other person exercising a public function, including for a public body or public company, or which provides a public service, or (iii) any other person defined as a public official in the country of the contracting authority, any undue advantage of any kind, to the person directly or for any other person or entity, to incite said person to take action or omit to take action during the exercise of their official public functions.
   4. We have not promised, offered or granted, nor will do so in the future, whether directly or indirectly, to any person managing a private-sector entity or working for any such entity in any capacity whatsoever, any undue benefit of any kind, to the person directly or for any other person or entity, to incite said person to take action or omit to take action in breach of their legal, contractual or professional obligations.
   5. We have not committed, nor will do so in the future, any act likely to influence the contract award process to the detriment of the contracting authority, notably no anti- competitive practices having the purpose and effect of preventing, restricting or distorting fair competition, notably by limiting access to the contract or the free exercise of competition by other companies.
   6. We hereby certify that neither we ourselves nor any member of our consortium or any of our subcontractors will acquire or supply goods or take action in sectors subject to embargo implemented by the United Nations, the European Union or France.
   7. We undertake to comply with, and shall obtain a similar undertaking from all our subcontractors, the environmental and social standards recognised by the international community, including the fundamental conventions of the International Labour Organisation (ILO), conventions of freedom of association and collective bargaining, on the elimination of forced labour, on the elimination of discrimination in employment, on the elimination of child labour and international agreements on environmental protection, in compliance with the laws and regulations applicable in the country of contract implementation. Furthermore, we undertake to implement mitigation measures

against environmental and social risk where stated in the environmental and social management plan provided by the contracting authority.

We acknowledge and accept that, should any of the aforementioned situations be identified to apply to us, the Beneficiary of the Grant would be obliged to forward such information to Expertise France, or to the Donor of the financing or any other entity of the Agence Française de Développement group, and that said parties may integrate such information within a rapid detection and exclusion system, including publication on their website.

With regard to this declaration, we undertake to notify Expertise France without delay of any change to our situation during the tender process and, as applicable, during contract execution.

Name: Function:

Duly authorised to sign on behalf of:1

Date: Signature:

**Annex 5 to the Specification for procurement** **of rapid diagnostic (express) combo tests**

by signing this form, we confirm the following assurances, which are important for the conclusion of the contract with the ICF "Alliance for Public Health":

1. The Company (the legal entity that submits this and other documents for participation in the tender is specified below), any of its directors (members of the board of directors), members of the Company, its ultimate beneficial owner/owners, its officials or employees of the Company , or any agent, affiliate or other person acting on behalf of the Company, is not currently subject to US sanctions administered by the Office of Foreign Assets Control of the US Department of the Treasury or the US Department of State, the United Nations Security Council Nations, the European Union, Her Majesty's Treasury of the United Kingdom or other authorized sanctioning body.
2. The Company, and/or a member of the Company, and/or the ultimate beneficial owner of the Company are not included in the sanctions list of the National Security and Defense Council of Ukraine (in accordance with Article 5 of the Law of Ukraine "On Sanctions").
3. Personal special economic and other restrictive measures (sanctions) have not been applied to the Company's goods, services and/or works in accordance with Article 5 of the Law of Ukraine "On Sanctions".

**Composition of the final beneficiaries of the participant**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of the organization/ person's full name** | **Registration code/passport data** | **Registration address** | **Citizenship** | **Is the organization/ person included in the sanctions lists of the USA, the European Union, and Ukraine.** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# *signature] [position]*

Authorized to sign a commercial proposal for and on behalf of:

*[the company name] Company seal*