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**Procurement specification**

**for rapid 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).

The main programs currently carried out by the Alliance are supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria (hereinafter – the Global Fund).

This procurement is carried out within: “Improving HIV Treatment Cascade for Key Populations through Differentiated Case Detection and Linkage to Care and Increased Capacity at Center for Public Health and Strategic Information in Ukraine” with the financial support of the Centers for Disease Control and Prevention (CDC). (Project (program) Registration Card # № 4349-07 dd 17.05.2024).

**1. Procured goods.**

Lot 1. Rapid tests for the diagnosis of viral hepatitis C.

**2. Quantity of Goods Required. Terms and Conditions of Payment and Delivery.**

2.1. Quantity of goods required .

|  |  |  |
| --- | --- | --- |
| **Lot** | **Name of the goods** | **Number of the Goods to be supplied** |
|  | Rapid tests for the diagnosis of viral hepatitis C. | 61 920 |

2.1.1. The quantity of tests can be adjusted according to the multiplicity of packaging.

2.1.2. The Alliance reserves the right to revise the quantities of supplies to be purchased upward or downward whilst keeping the requirement figures within +/- 20% of the total volume of the goods.

2.3. All prices are to be in U.S. dollars in accordance with INCOTERMS 2010:

**For non-residents:**

DAP, St. Sholudenka, 18, Vyshhorod district, Vyshhorod city, 07300, Kyiv region, Ukraine (warehouse)**.**

**For residents:**

DDP (for residents of Ukraine) St. Sholudenka, 18, Vyshhorod district, Vyshhorod city, 07300, Kyiv region, Ukraine (warehouse). All taxes and fees must be included, but excluding VAT in Ukraine.

**Attention!** According to Article 1 (a) of the Agreement between the Government of Ukraine and the Government of the United States of America on humanitarian and technical and economic cooperation dated 05.07.1992, this purchase is exempt from payment of value added tax.

2.4. The currency of the supply contract and payment for the goods to be delivered under contract shall be:

* U.S. dollars for companies who are non-residents of Ukraine;
* Ukrainian hryvnias (UAH) for companies who are residents of Ukraine (the price of the contract shall be established in accordance with the Bidder’s price proposal, and re-calculated at the exchange rate of the National Bank of Ukraine in effect as of the date of the contract. Payments will be made in UAH according to the official rate of the National Bank of Ukraine on day invoicing).

2.5. Payment for the Goods :

* Advance payment of 50% of the cost of each individual shipment. Periods of payment: within 20 calendar days after Alliance confirms satisfactory results of the verification as per p. 2.2.
* Balance payment of 50% of the cost of each individual shipment made – within 20 calendar days after completion of delivery.

2.6. Consignment terms:

**For non-residents:**

DAP, St. Sholudenka, 18, Vyshhorod district, Vyshhorod city, 07300, Kyiv region, Ukraine (warehouse)**.**

**For residents:**

DDP (for residents of Ukraine) St. Sholudenka, 18, Vyshhorod district, Vyshhorod city, 07300, Kyiv region, Ukraine (warehouse). All taxes and fees must be included, but excluding VAT in Ukraine.

The goods shall be delivered in one consignment.

2.7. Delivery time: not later than Sept, 29 2024. Participants should indicate their forecast for arrival to the final destination (see Annex 3 to the Specification).

Faster delivery time will be an advantage.

2.8. The tests shall be delivered in compliance with the required terms of transportation and storage, which should be confirmed by the data of temperature data logger, which will be recorded when accepting the Goods.

The details of data logger (series/number, etc.) shall be provided at the moment of Goods dispatch by the producer to enable data verification when an authorized representative of Alliance accepts the Goods in Ukraine. Such equipment shall be installed and data capturing should be ensured at the expense of the Supplier.

**3. Number of the batches of the Goods.**

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

**4. Registration.**

4.1 The products must be registered in Ukraine in accordance with current legislation at the time of delivery.

The product may be unregistered in Ukraine at the time of proposal submission. In this case, the participant must provide a **written guarantee of the registration of the products with obtaining permits for the right to use such products on the territory of Ukraine**. In this case, if the participant is elected as a bidding winner, it shall receive such registration no later than the time of receipt of the first batch of products on the territory of Ukraine. Written warranty must contain a schedule for obtaining this permission. Moreover, the letter should state that all costs associated with the registration procedure in Ukraine will be borne by the Applicant. The Alliance will be able, if necessary, to provide technical assistance related to the registration procedure.

In any case, at the time of receipt of the goods into the territory of Ukraine for its customs clearance, the goods must necessarily be registered for use in Ukraine. In case of the absence of registration at the time of arrival of the Goods for customs clearance, the supplier shall compensate all possible expenses, including related to storage costs of the unregistered Goods at the customs warehouse.

The permission 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. Primary packaging and marking.**

The packaging and marking must comply with the WHO pre-qualification registration dossier or CE mark registration dossier.

**6. Special marking requirements.**

The Supplier must make sure to attach a sticker containing special information including “Благодійна допомога. Продаж заборонено. Національна безкоштовна гаряча лінія з питань ВІЛ/СНІДу: 0-800-500-451” to the individual package of each testing kit and to the carton in accordance with Annex 4 to the Specification. The design of the sticker must be coordinated with and pre-approved by the Buyer.

The layout of the sticker positioning on packaging must be attached to the application.

**7. Kitting requirements.**

7.1. The complete set of test systems must comply with the WHO pre-qualification registration dossier or CE mark registration dossier.

7.2. The requirements of paragraph 7.1. are obligatory. The price offers for different sets will be compared by calculating the cost of a complete set, which consists of the following.

. test cassette;

. buffer solution;

. sterile automatic lancet;

. pipette/capillary tube with a mark;

. sterile alcohol wipe (1 pc);

. sterile dry wipes (2 pc);

. directions for use (package insert instructions) in Ukrainian.

**8. Medical and technical requirements to the products.**

8.1. General requirements.

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Requirements** | **Document to be provided by the Supplier** |
| **1.Operational characteristics** |  |  |
| 1.1.Sensitivity | HepC ≥ 98% | Directions for use, registration dossier materials, public WHO prequalification report |
| 1.2.Specificity | HepC ≥ 97% |
| **2.Registration** |  |  |
| Registration of Goods in Ukraine as per the requirements of the laws currently in force before expiration of the Goods delivered | obligatory | Declaration of compliance to technical regulation or warranty letter (see para. 5 of the Specification) |
| Compliance to one of the below criteria:   * Criterion 1: Availability of the current WHO prequalification dossier   OR   * Criterion 2- registered with the respective regulatory body and authorized for use in a founding country of the Global   Harmonization Task Force (US, EU, Canada, Japan, Australia) | obligatory | Confirmatory documents |
| Authorized distributor status | obligatory | Letter from the producer |
| State registration of the supplier | obligatory | Copies of the documents confirming the state registration of the Bidder |
| **3.Operational characteristics** |  |  |
| Temperature requirements to tests storage | 2-30°С | Directions for use |
| Operating temperature range | 15-30°С |
| Duration of assay | ≤20 minutes |
| Volume of capillary blood needed for the assay | desirable ≤ 35 mcl  (for assisted (self) testing the lowest indicator of the necessary volume is considered the best) |  |
| Remaining shelf life as of the date of Goods delivery. | ≥ 75% of the total shelf life | Confirmatory letter from the supplier. |
| Total shelf life | indicate | Instruction for use |
| **4.Products kitting for procurement** |  |  |
| Compliance to the WHO pre-qualification registration dossier or CE mark registration dossier. | See cl.7.1-7.2 of the spec. | Directions for use, registration dossier materials, public WHO prequalification report or CE mark registration dossier. |
| **Additional requirements** |  |  |
| Possibility to provide training to medical staff to use the rapid tests | obligatory | Confirmation letter |

\*The winning bidder must must be ready, if necessary, to provide the training of the testing specialists in the use of test kids for rapid testing procedure. The number and the schedule of such trainings will be agreed at the stage of contract negotiation.

**9. Content of tender proposals**

The following documents must be attached to the Bidder’s tender proposal:

9.1. Copies of documents that evidence state registration of the Bidder.

9.2. Copies of the Bidder’s documents regarding state registration of the products offered in compliance with the laws and regulations of Ukraine. The Bidder must submit a copy of the product registration certificate under the official corporate seal of the supplier and/or a certificate of compliance with technical regulations. In case if at the date of bid submission the Goods are in the process of registration – an official letter should be provided to confirm obligations of such bidder to provide all the necessary approvals to the Alliance before the supply of the first batch.

9.3. Duly completed and signed Annexes 1-5 to the Specification .

9.4. If the Bidder is an intermediary entity (i.e. not the manufacturer but the supplier of products manufactured by another company), the Bidder must present a copy of the original document issued by the manufacturer to support its status as a distributor of the product.

9.5. **It is obligatory** to provide photos of test systems offered by the bidder for supply. The photos should demonstrate:

• complete set,

• marking of all components of the set.

The products in further supplies must be identical to the provided photos!

9.6. The supplier must provide directions for use in Ukrainian (if available).

9.7. Other documents as per requirements of para. 8. of the Specification.

9.8. Any other information that can be helpful in terms of evaluating product and supplier performance.

**10. Key criteria for proposal evaluation**

. The tender proposal (together with all annexes hereto) shall be evaluated based on the following criteria:

* Compliance of the products to the medical and technical requirements of tender specifications;
* cost of the goods;
* completeness of kitting;
* terms of supply.

**11. Proposal Preparation Requirements:**

A translated copy of any document described above must be provided if the original document is done in a language other than English, Russian, or Ukrainian.

Please note that separate sections of the tender bid must be preceded with title pages. For example, the copy of the registration documents must be preceded by a title page “Copy of the State Registration Documents of the Participant.”

All copies of the documents must bear the Bidder’s official corporate seal and signature.

**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 Procurement Specification.

Please fill in the table below.

Before you start, please pay attention to the requirements of this Specification, in particular to the following aspects:

1. Applied terms of delivery: see p. 3. of the Specification.
2. **The Prices must be indicated in US dollars according to the above delivery conditions, must include all necessary taxes and fees, certification costs (including CE mark), excluding VAT (see clause 2.3. Specifications). Please pay attention to the terms of payment stated in p.3.4. of the Specification.**
3. The “estimated time of delivery” means the maximum period of time needed to produce the Goods and deliver them to Kyiv. The period should start from signing the contract and end on the date when the Goods are ready for customs clearance in Kyiv.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Lot** | **Brand name, catalogue number** | **Content of kit to be supplied** | **Country of origin** | **Overall storage time** | **Number of goods in 1 internal carton (intermediary packaging)** | **Number of goods in 1 external carton (external packaging)** | **Price per unit in dollars** | **Terms of deliveryerms of delivery**  **(Incoterms 2010)** | **Estimated time of delivery** |
| Lot 1 |  | Original kit/set is comprised of:   1. Test cassette \_\_\_pcs. 2. Buffer solution – \_\_\_pcs. 3. Lancet – \_\_\_ pcs. 4. Alcohol wipe – \_\_\_ pcs. 5. Dry wipe - \_\_\_ pcs. 6. Pipette – \_\_\_ pcs. 7. Directions for use – \_\_\_ pcs. |  |  |  |  |  |  |  |

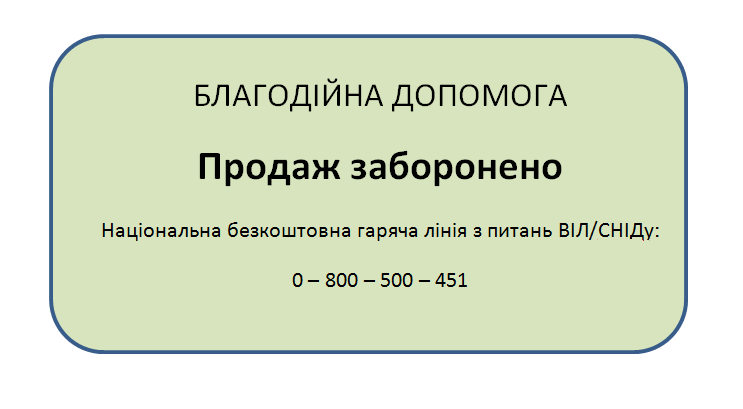
Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20....

*[signature] [acting as]*

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

**Annex 4 to the Specification**

Marking layout



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

*[signature] [acting as]*

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

**Annex 5 to Specification**

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*