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**Specification for the tender for the procurement Drug Rapid Tests (Tender DRT-2026-PHC)**

International Charitable Foundation "Alliance for Public Health" (hereinafter referred to as the Alliance) is a leading professional organization that, in cooperation with key non-governmental organizations, the Ministry of Health, and other government bodies, combats a number of epidemics, including HIV/AIDS and TB in Ukraine, manages prevention programs, and provides high-quality technical support and financial resources to organizations on the ground. The Alliance's mission is to reduce the spread of infections and mortality and minimize the negative impact of epidemics by supporting the public response to them in Ukraine, as well as by disseminating effective approaches to prevention and treatment in Eastern Europe and Central Asia.

As an independent legal entity registered in Ukraine since 2003 and having gained managerial autonomy since January 2009, the Alliance shares the values and remains a member of the global partnership of the Alliance for Public Health (an international charitable organization uniting 30 organizations from different countries, with a Secretariat in Hove, Great Britain).

The main programs currently implemented by the Alliance are financed by the Global Fund to Fight AIDS, Tuberculosis and Malaria (hereinafter referred to as the Global Fund).

This procurement is carried out within the framework of the Program: "Sustainable response to the HIV and TB epidemics in the context of war and recovery of Ukraine for 2024-2026" in accordance with Grant Agreement No. 3644 dated "19" December 2023 (grant name UKR-C-AUA) between the International Charitable Foundation "Alliance for Public Health" and the Global Fund to Fight AIDS, Tuberculosis and Malaria.

**Payment is made without Value Added Tax on the basis of paragraph 26 of subsection 2 of section XX of the Tax Code of Ukraine**.

1. **Goods to be procured.**

|  |  |
| --- | --- |
| **Lot** | **Product Name** |
| 1 | 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Methadone (urine) |
| 2 | 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Buprenorphine (urine) |

**Intended use**

The Multi-Drug Rapid Test Panel is a rapid chromatographic immunoassay for the qualitative one step detection of multiple drugs (6 types) and drugs metabolites in human urine specimen. It is intended for in vitro diagnostic use only

1. **Quantity of Goods to be Procured. Terms of Delivery and Payment.**
   1. **Goods to be Procured**.

|  |  |  |
| --- | --- | --- |
| **Lot** | **Product Name** | **Quantity of Goods to be Procured, pcs.\*** |
| 1 | 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Methadone (urine) | 33 600 |
| 2 | 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Buprenorphine (urine) | 3 675 |

* The quantity of tests may be adjusted according to the packaging increment.
* The Alliance reserves the right to increase or decrease the quantity of the procured goods while remaining within +/- 20% of the total value of the goods.
* A winner will be selected for each lot separately.
  1. Prices must be provided in accordance with INCOTERMS 2010 under the following terms:
     + DP (Delivered Duty Paid) Alliance warehouse. Address: 07300, Kyiv region, Vyshhorod district, Vyshhorod, Sholudenka street, 18

All taxes and duties must be included, but without VAT in Ukraine.

* + - Non-resident Participants may submit a proposal under CIP (Carriage Paid To) delivery terms to a port or airport in countries bordering Ukraine. In this case, the non-resident participant must necessarily provide additional information in Annex 3 (Price Proposal) regarding the logistical parameters of the cargo:

2.3.1. Size and quantity of boxes.

2.3.2. Size and quantity of pallets.

2.3.3. Gross weight.

**When evaluating such a proposal, the calculated cost of logistics services for delivering the goods to the Alliance's warehouse will be added to the total amount of the proposal.**

**Attention!** Exemption from VAT payment in Ukraine is carried out in accordance with the Resolution of the Cabinet of Ministers of Ukraine dated 17.04.2013 No. 284 "Some issues of import into the customs territory of Ukraine and supply in the customs territory of Ukraine of goods and provision of services paid for by grants (subgrants) of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine";

In accordance with paragraph 26 of subsection 2 of section XX of the Tax Code of Ukraine, temporarily, for the period of implementation of the Global Fund to Fight AIDS, Tuberculosis and Malaria programs in Ukraine carried out in accordance with the law, **operations for the supply of goods (except excisable goods) in the customs territory of Ukraine and the provision of services are exempted from Value Added Tax** if such goods/services are paid for by grants (subgrants) provided in accordance with the Global Fund programs.

In case of carrying out operations exempted according to this paragraph, the provisions of paragraph 198.5 of Article 198 of this Code and the provisions of Article 199 of this Code shall not apply.

* 1. The Supply Contract will be concluded and payment for the delivered products will be made in:
* US Dollars (USD) for non-resident companies of Ukraine;
* Ukrainian Hryvnia (UAH) for residents of Ukraine (the contract price is fixed at the amount of the Applicant's price proposal, converted at the NBU exchange rate on the contract signing date. Payment of the US Dollar equivalent is made converted into Ukrainian Hryvnia at the NBU exchange rate on the date of issuance of each individual invoice).
  1. **Terms of Payment**:
* Advance payment of 50% of the cost of each separate batch. The final payment of 50% of the cost of each separate delivered batch is due within 20 calendar days after the completion of its delivery..
  1. The desired time of arrival of the Goods to the destination for the full scope of the order is: April 2026, Each participant must provide their forecast for the arrival of the Goods to the destination (see Annex No. 3 to the specification).
  2. The supply of tests must be carried out in compliance with the necessary transportation and storage conditions, which must be confirmed by the data from a temperature logger (data logger), recorded during the acceptance of the Goods.

Details regarding the data logger (serial number/code, etc.) shall be provided at the time the goods are shipped by the manufacturer to allow for verification of the data upon acceptance of the goods by an authorized representative of the Alliance in Ukraine. The installation of this equipment and the reading of the results shall be performed at the Supplier's expense..

1. Quantity of Product Batches**.**

Desired delivery is one or the smallest possible number of product batches

1. **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.

1. **Primary packaging and marking.**

The packaging must comply with Ukraine’s applicable regulatory requirements. It must ensure the quality, safety and stability of the products shipped. All packaging containers must be properly sealed and protected against damage occurring in transit or due to poor handling.

The rapid test kits must be individually packaged in compact and heavy-duty containers capable of withstanding adverse field conditions, if required, and must contain all the set of components required to conduct testing.

The primary package must indicate the following details: name and address of manufacturer, month and year of production, conditions of storage, information about state registration in Ukraine.

In the course of delivering tests, the awarded company (supplier) must make sure that each individual testing kit comes complete with directions for use in Ukrainian.

Marking of test systems should comply with the provisions of the Technical Regulations on medical products (approved by the CMU Resolution No. 753/754 dated November 2, 2013).

1. **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 наркозалежності та ЗПТ 0 800-507-727” to the group carton box 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.

1. **Medical and technical requirements to the products.** 
   1. 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Methadone (urine)

6 Panel rapid test is a rapid, one step, immunochromatographic assay designed for qualitative detection Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Methadone and/or their metabolites in human urine specimen.

It is intended for in vitro diagnostic use only.

Duration of assay is up to 10 min.

A procedural control is included in the test. A line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Temperature requirements to tests storage: at 2-30°C. The test is stable through the expiration date.

Remaining shelf life upon delivery must be at least 75% of the total shelf life.

* 1. 6 panel rapid test to detect: Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Buprenorphine (urine)

6 Panel rapid test is a rapid, one step, immunochromatographic assay designed for qualitative detection Opiate, Barbiturates, Amphetamines, Methamphetamines, Benzodiazepines, Buprenorphine and/or their metabolites in human urine specimen.

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Temperature requirements to tests storage: at 2-30°C. The test is stable through the expiration date.

Remaining shelf life upon delivery must be at least 75% of the total shelf life.

* 1. **Cutoffs of the analytes**

|  |  |
| --- | --- |
| **Initial test analyte** | **Cutoff concentration (ng/mL)** |
| Amphetamine (AMP) | 500 |
| Methamphetamine (METH) | 500 |
| Morphine (MOR) | 300 |
| Barbiturates (BAR) | 300 |
| Benzodiazepines (BZD) | 300 |
| Methadone (MTD) | 300 |
| Buprenorphine (BUP) | 10 |

**8. Content of tender proposals**

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

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

8.2. 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.

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

8.4. 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.

8.5. 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!

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

8.7. Other documents as per requirements of para. 8.1. of the Specification.

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

**9. 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.

**10. 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 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.

**11. Special requirements.**

11.1. In submitting a tender bid, the Bidder confirms its awareness of the principles and requirements applied by the Global Fund with respect to potential and actual suppliers of the goods (works, services) and grantees, as well as their representatives, as set forth in the Code of Conduct for Suppliers, freely accessible on the Buyer’s website (http://www.aph.org.ua/policies-procedures-ua/), and the website of the Global Fund at (<https://www.theglobalfund.org/media/3275/corporate_codeofconductforsuppliers_policy_en.pdf>), and agrees to be bound by the terms hereof.

**11.2. Exemption from VAT of transactions to supply goods and services on the customs territory of Ukraine within the grants provided in accordance with the programs of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine.**

As per p. 26 subsection 2 section XX of the Tax Code of Ukraine, temporarily, for the period of implementation of the programs of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine, which are implemented according to the law, transactions with supply on the customs territory of Ukraine of goods (apart from excise goods) and delivery of services shall be exempt from the value added tax, if such goods/services are paid for within the grants (sub-grants) provided in accordance with the programs of the Global Fund.

The procedure of such transactions is defined by the Resolution of the Cabinet of Ministers of Ukraine dated 17.04.2013 N 284.

In case of performance of the transactions exempt in accordance with this paragraph, provisions of paragraph 198.5 article 198 of the Tax Code and provisions of article 199 of the Code shall not be applied.

**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 are to be stated in US dollars in compliance with the above terms of delivery including all applicable taxes and fees, but excluding VAT (in accordance with the requirements of p.13. of the Specification).
3. Please pay attention to the terms of payment stated in p.3.4. of the Specification.

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, Country of origin** | **Content of kit to be supplied** | | **Quantity of tests per kit** | **Total Shelf Life** | **Shelf Life Remaining upon Delivery** | **Price per 1 unit of goods in US dollars** | **Estimated Delivery Time (Alliance warehouse)**\* |
| Лот 1 |  | Amphetamine (AMP) |  |  |  |  |  |  |
| Methamphetamie (METH) |  |
| Morphine (MOR) |  |
| Barbiturates (BAR) |  |
| Benzodiazepines (BZD) |  |
| Methadone (MTD) |  |
| Лот 2 |  | Amphetamine (AMP) |  |  |  |  |  |  |
| Methamphetamie (METH) |  |
| Morphine (MOR) |  |
| Barbiturates (BAR) |  |
| Benzodiazepines (BZD) |  |
| Buprenorphine (BUP) |  |

**FOR NON-RESIDENTS:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Lot** | **Trade name, catalogue number, country of origin** | **Quantity to be procured, pcs.** | **Box size** | **Number of boxes** | **Pallet size** | **Number of pallets** | **Gross weight** | **Port of delivery** |
| **Lot** 1 |  | 33 600 |  |  |  |  |  |  |
| **Lot** 2 |  | 3 675 |  |  |  |  |  |  |

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

БЛАГОДІЙНА ДОПОМОГА

**Продаж заборонено**

**Національна гаряча лінія з питань**

**наркозалежності та ЗПТ**

**0 800-507-727**

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

*[signature] [acting as]*

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

**Annex 5 to the 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*