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**Procurement specification**

**for rapid immunochromatographic 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 made within the scope of Programs:

“Investing for impact against Tuberculosis and HIV” according to Grant Agreement #613 dd. 23/02/2015 (Grant UKR-C-AUA) concluded between Alliance for Public Health and the Global Fund to Fight AIDS, Tuberculosis and Malaria;

1. **Goods description**

Lot 1. Rapid tests to detect antibodies to HIV ½.

Lot 2. Rapid tests for the diagnosis of viral hepatitis C.

Lot 3. Rapid tests for the diagnosis of viral hepatitis B HBsAg.

Lot 4. Rapid tests to detect syphilis.

1. **Intended use.**

Using rapid tests in field settings within the activities of HIV/AIDS prevention projects.

Lot No.1. Rapid tests for visual, one-stage, quality detection of antibodies to HIV types 1 and 2 (HIV ½) in whole blood samples (for testing capillary fingertip blood)..

Lot No.2. Rapid tests for viral hepatitis C diagnostics intended for qualitative detection of antibodies to HCV by immunochromatographшс method in whole blood samples.

Lot No.3. Rapid tests for viral hepatitis B diagnostics intended for qualitative detection of HepB surface antigen (HBsAg) by immunochromatographic method in whole blood samples.

Lot No. 4. Rapid tests for the detection of syphilis intended for qualitative detection of Treponema Pallidum antibodies by immunochromatographic method in whole blood samples.

1. **Quantity of Goods Required. Terms and Conditions of Payment and Delivery.**
   1. Quantity of goods required.

|  |  |  |
| --- | --- | --- |
| **Lot** | **Name of goods** | **Quantity\* of goods to be supplied** |
| 1. | Rapid tests to detect antibodies to HIV ½. | 10 600 |
| 2. | Rapid tests for the diagnosis of viral hepatitis C. | 31 290 |
| 3. | Rapid tests for the diagnosis of viral hepatitis B HBsAg. | 2 820 |
| 4. | Rapid tests to detect syphilis. | 8 250 |

* + 1. The quantity of tests can be adjusted according to the multiplicity of packaging.
    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.
  1. A mandatory condition of payment and delivery of the above-mentioned quantity of HIV and HCV test kits is verification of each separate produced batch for its compliance with the requirements stated in p. 9 of the Specification.

Important:

* Verification procedure is applicable only to HIV and HCV tests.
* At the discretion of Alliance, verification will be conducted by an independent laboratory based in Ukraine. The expected time required to conduct the laboratory verification: 1-2 weeks.
* Alliance will pay for the services of such laboratory.
* For the purposes of verification, the Supplier shall organize delivery of at least 100 additional tests of each batch included into every lot to be delivered to the address of the independent laboratory selected by Alliance. The cost of such batch of tests will be paid by Alliance.
* Attention! The number of tests required to conduct verification is not included to the quantity set for in p. 3.1 hereof. Alliance will cover the cost of such additional tests to the Supplier.
  1. All prices are to be in U.S. dollars, **DAP Kyiv region**, Irpin town (warehouse) in accordance with INCOTERMS 2010, including all applicable taxes and fees, but excluding VAT in Ukraine.

Attention! The goods are exempt from VAT as required under the terms of Resolution of the Cabinet of Ministers of Ukraine dated April 17, 2013 [no. 284] "Particular Issues Concerning Importing Goods into the Customs Territory of Ukraine and Supply of Goods and Provision of Services Within the Customs Territory of Ukraine Paid for Using Grants (Sub-Grants) of the Global Fund to Fight AIDS, Tuberculosis and Malaria in Ukraine” for procurement under Global Fund Program;

* + 1. 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).

3.4 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. 3.2.
* Balance payment of 50% of the cost of each individual shipment made – within 20 calendar days after completion of delivery.

3.4.1. If the Supplier is a non-resident of Ukraine provided that the scheduled delivery date extends beyond 50 calendar days after advance payment of the Alliance (p. 3.5 hereof), payment for the goods shall be effected in the following manner: by means of 100% irrevocable letter of credit payable at sight.

* 1. Consignment terms: DAP (for non-residents of Ukraine) or DDP (for residents of Ukraine) Irpin, Kyiv oblast, Ukraine.

The goods shall be delivered in no more than 2 consignments.

* 1. It is desirable to have the fastest arrival time of the ordered Goods at place of destination. Each bidder should make a forecast as for the time of Goods delivery to the place of destination (Annex 3 hereto).
  2. 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 the data should be captured at the expense of the Supplier.

1. **Batch number.**

To the extent feasible, when making a delivery, the Supplier must keep the number of product batches to a minimum.

1. **Registration.**

5.1. Products should be allowed for use in Ukraine according to the laws currently in force (should be accompanied with a valid registration certificate and/or pass a procedure to assess compliance with the requirements of technical regulations) as of the date of delivery to the place of destination.

5.2. 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.

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.

5.3. By participating in this bidding, the winning bidder shall guarantee extension of the term of Goods registration in Ukraine as per the laws currently in force up to the end of shelf life of the Goods delivered within this procurement.

5.4. Requirements for registration apply to all components of the test system, including consumables, if they are offered together with the main kit or separately before delivery.

WARNING! Pay particular attention to the fact that the registration of test systems should cover the possibility of using scarifiers. Scarifiers (lancets), as a medical device (class II-a), must undergo a procedure for assessing the functioning of an integrated quality management system in accordance with the CMU Resolution No. 753 of 02.10.2013 "On Approval of the Technical Regulations Regarding Medical Products".

1. **Primary packaging**

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.

**7. Marking.**

7.1. Marking of test systems should comply with the provisions of the Technical Regulations on medical products (approved by the CMU Decree No. 753 of 02.11.2013).

7.2. 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 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 individual packaging must be attached to the application.

1. **Kitting requirements**

Pay attention! The requirements for the set of test kits contain both desirable and mandatory parameters.

Compliance with the requirements of clause 8.5 of the specification is mandatory, while the parameters of the desired kitting may be achieved by the additional supply of materials that are lacking in the original (primary) kits.

The packaging in which the product is delivered must be compact and sufficiently durable to protect the goods against the possible adverse factors in the field.

* 1. The desired package content of each test kit should include:

8.1.1. test cassette;

8.1.2. buffer solution;

8.1.3. sterile automatic lancet;

8.1.4. pipette/capillary tube with a mark;

8.1.5. sterile alcohol wipe (1 pc);

8.1.6. sterile dry wipes (2 pc);

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

* 1. Bidder’s ability to ensure the delivery of a full package of test kits as per the requirement of p. 8.1. hereof will be an advantage all other conditions being equal.
  2. If the Bidder is not able to deliver a full package of test kits as per p. 8.1. hereof, the cost of its bid will be assessed by the bid organizer adding a) the cost of additional components which are not offered (at average market prices) and b) the cost of kits packaging.
  3. The delivery of individual buffer solutions is desirable, i.e. the number of such buffer solutions should be in line with the number of test cassettes delivered.

If the test kits packaging does not stipulate individual buffer solutions (including considering the requirements of p. 8.5 hereof), the bidder should stipulate the delivery of additional buffer solutions to ensure the delivery of at least 1 buffer solution per 5 test cassettes. In such case, the cost of delivery of additional buffer solutions should be provided together with the quote for test kits (price per unit; see Annex 3 hereto).

* 1. In any case, the kit you offer should not conflict with the requirements for product compliance with one of the criteria:

8.5.1. WHO Prequalification (Important: the only allowed option for HIV tests!);

8.5.2. authorization for use by one of the Regulatory Authorities of the Founding Members of GHTF (US, EU, Canada, Japan, Australia);

8.5.3. determined by the Global Fund to be acceptable for procurement following advice from the Expert Review Panel.

Important! In any case for HIV tests the compliance with the requirements of clause 8.5.1 or 8.5.3. of the Specification is strictly required. For all other tests, all 3 options can be used.

See details by the link:

https://www.theglobalfund.org/media/5885/psm\_qadiagnostics\_policy\_en.pdf

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

The manufacturer, supplier and tests offered under this bidding, need to fully comply with the requirements set in the Global Fund to Fight AIDS, Tuberculosis and Malaria Quality Assurance policy (see more here with relevant downloads:

<http://www.theglobalfund.org/en/sourcing/policies/>

<http://www.theglobalfund.org/en/sourcing/qa/> )

https://www.theglobalfund.org/media/5885/psm\_qadiagnostics\_policy\_en.pdf

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| --- | --- | --- |
| **Requirements** | **Mandatory requirement/desired characteristic** | **Document to be provided by the Supplier** |
| **1.Operational characteristics** |  |  |
| 1.1.Sensitivity | HIV ≥ 99%  HepC ≥ 98%  HepB =100%  Syphilis ≥ 87% | Directions for use, registration dossier materials, public WHO prequalification report |
| 1.2.Specificity | HIV ≥ 98%  HepC ≥ 97%  HepB ≥ 98%  Syphilis ≥ 99.5% |
| **2.Quality standards** |  |  |
| 2.1.Supplier: ISO 9001 | desired | Copy of certificate |
| 2.2.Producer: ISO 9001 | mandatory | Copy of certificate |
| 2.3.Producer: ISO 13485 | mandatory | Copy of certificate |
| **3.Registration** |  |  |
| Registration of Goods in Ukraine as per the requirements of the laws currently in force before expiration of the Goods delivered | mandatory | Certificate of compliance with technical regulations or warranty letter (see p. 5 hereof). |
| Compliance with one of the below criteria:   * criterion 1: recommended for use in HIV or malaria programs by WHO based   on a technical review of quality and  performance indicators (important! Criterion 1 or 3 are mandatory for HIV tests);  OR   * Criterion 2- authorized for use by a regulatory   authority member of Global  Harmonization Task Force (US, EU, Canada, Japan, Australia)  OR   * Criterion 3- determined by the Global Fund to be acceptable for procurement following advice from the Expert Review Panel. | mandatory | Supporting documents (see https://www.theglobalfund.org/media/5878/psm\_productshiv-who\_list\_en.pdf) |
| Authorized distributor’s status | mandatory | Letter from producer |
| State registration of the Supplier | mandatory | Copies of the documents to confirm state registration of the Supplier. |
| **4.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 | ≤ 30 μl |  |
| Remaining shelf life as of the date of Goods delivery. | 75% of the total remaining shelf life | Letter from the Supplier with confirmation. |
| Total shelf life | indicate | Directions for use |
| **5. Packaging of the Goods** |  |  |
| Buffer solution | Declare the possibility to supply additional buffer solutions. Specify the number of buffer solutions supplied in the package. | Indicate in the pricing proposal (See Annex 3) |
| Automatic lancet | Must have sharp, fine metal cutting edge/needle to ensure a painless finger prick procedure (little effort to break skin); non-toxic, pyrogen-free, sterile, complying with the established medical criteria/indicators for the control over sterility of healthcare products. Ensures **high** blood flow to collect the required volume of finger prick blood sample.  Technical characteristics – needle gauge 18G (1.25 mm), prick depth – 2.0 - 2.4 mm. | Directions for use,  Certificate of state registration/certificate of analysis issued in Ukraine, certificate of the Sanitary and Epidemiological Service. |
| Pipette/capillary tube with a mark | Ensures quality finger prick blood sampling required to run the assay. Has a mark to define the required sample volume. | Directions for use. |
| Wet wipe | Sterile, disposable for external use (for skin preparation before the injection).  Content: a wipe made of non-woven fabric (polypropylene), approximate size – 30х65 mm, soaked with antiseptic solution.  Shelf life should correspond to the shelf life of the test.  Packaging: sterile individual paper/foil-laminated package. | Compliance declaration |
| Dry wipe | Sterile dry wipe for external use (for skin treatment after the injection). Approximate size – 30-50х30-65 mm. Packaging: sterile individual paper/foil-laminated package. | Compliance declaration |
| Directions for use in Ukrainian for each test | mandatory |  |
| **Additional requirements** |  |  |
| Possibility to provide training to medical staff to use the rapid tests | mandatory | Confirmatory letter |

* 1. The winning bidder must ensure training of the testing specialists in the use of test kids for rapid testing. The number and the schedule of such trainings will be agreed at the stage of contract negotiation.

1. **Contents of tender proposals**

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

* 1. Copies of documents that evidence state registration of the Bidder.

10.2. 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.

10.3. Duly completed and signed Annexes 1-4 to the Specification.

10.4. 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.

10.5. Copies of 5 certificates of conformity/quality for different batches of the goods manufactured previously (during the year preceding the date of the Bidder’s proposal) similar to the products offered for supply within the framework of this tendering process. In its official letter, the Bidder must make sure to advise if the goods have not been manufactured previously, or if the product has been launched only recently; in this case, the Bidder’s failure to provide copies of the documents required under this paragraph, deemed as an evaluation criterion, shall not be grounds for disqualification. However, the Bidder’s experience in manufacturing or supplying the goods offered is an advantage.

10.6. Copies of documents that evidence the manufacturer’s compliance with ISO13485 and 9001 with regard to the test systems offered.

10.7. Copies of documents to confirm that the bidder complies with the quality management system requirements ISO 9001 (DSTU ISO 9001:2009 “Quality Management System”), if available.

10.8. At least 3 (three) sample tests in the packaging to be delivered by the Bidder (p. 8 of the Specification). The Goods planned for delivery in future should be identical to such sample!

10.9. The supplier must provide directions for use in Ukrainian for each test.

10.10. Other documents in accordance with the requirements stated in p. 9.1. of the Specification.

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

1. **Key criteria for bid evaluation.**

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

* compliance of the bid with the medical and technical requirements of the Specification;
* product price;
* completeness of product packaging;
* terms of delivery.

1. **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.

1. **Miscellaneous.** 
   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 ([http://www.theglobalfund.org/documents/business/ CodeOfConduct.pdf](http://www.theglobalfund.org/documents/business/%20CodeOfConduct.pdf)), and agrees to be bound by the terms hereof.
   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 Bid.

If our Bid 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 Bid 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 Bid for the Bid 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....

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.
4. 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.

DAP Kyiv region, Irpin town/delivery to the warehouse located in Irpin.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Lot | Goods | Brand name | Country of origin | Total shelf life | Number of pieces in one inner box (middle packaging) | Number of pieces in one outer box (external packaging) | Price of 1 unit in US dollars | Estimated time of delivery  (Kyiv)\* |
| Lot 1 | Rapid tests to detect antibodies to HIV ½.. | The kit/set is comprised of:  1) test cassette, buffer solution – \_\_\_pcs.  2) Lancet – \_\_\_ pcs.  3) Alcohol wipe – \_\_\_ pcs.  4) Dry wipe - \_\_\_ pcs.  5) Pipette – \_\_\_ pcs.  6) Directions for use – \_\_\_ pcs. |  |  |  |  |  |  |
| Additional buffer |  |  |  |  |  |  |  |
| Lot 2 | Rapid tests for the diagnosis of viral hepatitis C. | The kit/set is comprised of:  1) test cassette, buffer solution – \_\_\_pcs.  2) Lancet – \_\_\_ pcs.  3) Alcohol wipe – \_\_\_ pcs.  4) Dry wipe - \_\_\_ pcs.  5) Pipette – \_\_\_ pcs.  6) Directions for use – \_\_\_ pcs. |  |  |  |  |  |  |
| Additional buffer |  |  |  |  |  |  |  |
| Lot 3 | Rapid tests for the diagnosis of viral hepatitis B HBsAg | The kit/set is comprised of:  1) test cassette, buffer solution – \_\_\_pcs.  2) Lancet – \_\_\_ pcs.  3) Alcohol wipe – \_\_\_ pcs.  4) Dry wipe - \_\_\_ pcs.  5) Pipette – \_\_\_ pcs.  6) Directions for use – \_\_\_ pcs. |  |  |  |  |  |  |
| Additional buffer |  |  |  |  |  |  |  |
| Lot 4 | Rapid tests to detect syphilis | The kit/set is comprised of:  1) test cassette, buffer solution – \_\_\_pcs.  2) Lancet – \_\_\_ pcs.  3) Alcohol wipe – \_\_\_ pcs.  4) Dry wipe - \_\_\_ pcs.  5) Pipette – \_\_\_ pcs.  6) Directions for use – \_\_\_ pcs. |  |  |  |  |  |  |
| Additional buffer |  |  |  |  |  |  |  |

\*If it is planned to make a delivery in two consignments, please specify separately for each consignment (also see p. 3.5. of the Specification)

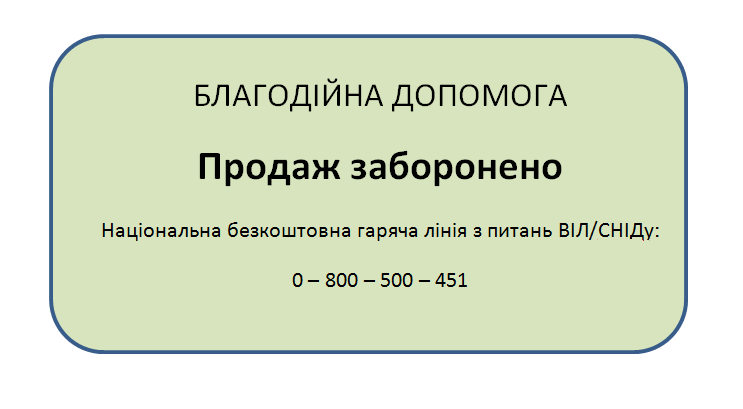
Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 20....

*[signature] [acting as]*

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

**Annex 4 to the Procurement Specification**

Marking Design



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

*[signature] [acting as]*

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