**Section III: Returnable Bidding Forms**

**Note to Bidders:** **Instructions to complete each Form are highlighted in blue in each Form. Please complete the Returnable Bidding Forms as instructed** **and return them as part of your quotation.**

The following returnable forms are part of this RFQ and must be completed and returned by bidders as part of their Quotation.

**Form A: Quotation submission form**

Bidders are requested to complete this form, sign it and return it as part of their bid submission. The bidder shall fill in this form in accordance with the instructions indicated. No alterations to its format shall be permitted and no substitutions shall be accepted.

Date: [Insert submission date]

**Subject: Request for Quotations (RFQ) for the Procurement of Quality Control Testing Services of Locally Manufactured Anti Malarial Drugs in Nigeria. RFQ Ref No. RFQ/2023/47865**

*We, the undersigned, declare that:*

* 1. *We offer to supply in conformity with the bidding documents, including the UNOPS General Conditions of Contract;*
  2. *Our quotation shall be valid for the period of time of 60 days from the date fixed for the submission deadline as set out in the RFQ, and it shall remain binding upon us and may be accepted at any time before the expiration of that period;*
  3. *We have no conflict of interest in any activity that would put it, if selected for this assignment, in a conflict of interest with UNOPS. [If you have any actual or potential conflict of interest as defined in Article 3 of Section II: Instructions to Bidders, please disclose it here];*
  4. *Our firm confirms that the offeror and sub-contractors have not been associated, or had been involved in any way, directly or indirectly, with the preparation of the design, terms of references and/or other documents used as a part of this solicitation;*
  5. *Our firm, its affiliates or subsidiaries—including any subcontractors or suppliers for any part of the Contract—has not been declared ineligible by UNOPS, nor is included in the suspended/ineligibility list of the UN/PD, other UN Agencies, the UN Security Council, and the World Bank, in accordance with Instructions to Bidders Article 3, Eligibility;*
  6. *We embrace the UN Supplier Code of Conduct and adhere to the principles of the UN Global Compact;*
  7. *We have not declared bankruptcy, are not involved in bankruptcy or receivership proceedings, and there is no judgment or pending legal action against them that could impair their operations in the foreseeable future;*
  8. *We have not offered and will not offer fees, gifts and/or favours of kind in exchange for this RFQ and will not engage in any such activity during the performance of any Contract awarded.*

I, the undersigned, certify that I am duly authorized by…… [***insert full name of bidder (QC Laboratory name)***] to sign this quotation and bind …………..[***insert full name of bidder (QC Laboratory name)***] should UNOPS accept this quotation:

Name: [complete]

Title: [complete]

Date: [complete]

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Provide the name and contact information for the primary contact from your company for this quotation:

Name: [complete]

Title: [complete]

Email address: [complete]

Telephone: [complete]

# Form B: Price Schedule Form

Bidders shall fill in this Price Schedule Form in accordance with the instructions indicated.

RFQ reference no:

Name of Bidder: [insert name of Bidder (QC Laboratory Name)]

| **Currency** | United States Dollar (USD) |
| --- | --- |

**Price for QC Testing Services**

| **Lot #** | **Item#** | **Drug Name** | **Strength** | **Dosage Form** | **Pack Size** | **Unit Price\* Per Sample (USD)** |
| --- | --- | --- | --- | --- | --- | --- |
| **1** | **QC Testing for Artemether/Lumefantrine** | | | | | |
| I) | Artemether/Lumefantrine- (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 20/120mg | Dispersible Tablet | Blister of 6Tabs (1X6) | ***Insert fixed price*** |
| II) | Artemether/Lumefantrine (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 20/120mg | Dispersible Tablet | Blister of 12Tabs (1X12) | ***Insert fixed price*** |
| III) | Artemether/Lumefantrine (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 20/120mg | Non-Dispersible Tablet | Blister of 18Tabs (1X18) | ***Insert fixed price*** |
| IV) | Artemether/Lumefantrine (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 20/120mg | Non-Dispersible Tablet | Blister of 24Tabs (1X24) | ***Insert fixed price*** |
| **Sub Total-(1)** | | | | |  |
| **2** | **QC Testing for Artesunate/Amodiaquine** | | | | | |
|  | I) | Artesunate/Amodiaquine  (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 100/270mg | Non-Dispersible Tablet | Blister of 3Tabs (1X3) | ***Insert fixed price*** |
|  | II) | Artesunate/Amodiaquine  (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph -* International Pharmacopoeia 10th edition | 100/270mg | Non-Dispersible Tablet | Blister of 6Tabs (1X6) | ***Insert fixed price*** |
|  | **Sub Total-(2)** | | | | |  |
| **3** | **QC Testing for Sulphadoxine/Pyrimethamine** | |  |  |  |  |
|  | I) | Sulphadoxine/Pyrimethamine  (*See Testing Parameters in Section 5.4 of the ToR)*  *reference Pharmacopoeia/Monograph-* USP 43rd Edition | 500/25mg | Non-Dispersible Tablet | Blister of 3Tabs (1X3) | ***Insert fixed price*** |
|  | **Sub Total- (3)** | | | | |  |
|  | **Grand Total Lots (1+2+3)** | | | | |  |

**Remark:**

**\*** *Unit Price quoted must include all costs to be incurred by the bidder for performing the required QC testing services, including costs for customs clearance of the imported sample, courier charge for sending reports to UNOPS, and costs of materials, standards, reference, etc.*

*(ii) Price shall be fixed during the contract period.*

*(iii) Evaluation will be done lot by lot*

**Payment terms:** within 30 days - accepted: ☐ Yes

I, the undersigned, certify that I am duly authorized by ……[***insert full name of Bidder (QC Laboratory Name)*** to sign this quotation and bind [***insert full name of Bidder (QC Laboratory Name)***] should UNOPS accept this quotation:

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[*Stamp form of bid with official stamp of the bidder*]

# Form C: Technical Quotation Form

RFQ reference no:

Name of Bidder: [insert name of Bidder (QC Laboratory Name)]

Bidders are required to complete the **Comparative Data Tables** included in Section II: Schedule of Requirements to demonstrate compliance with UNOPS requirements and insert them below. Bidders are NOT allowed to make any change in the “UNOPS requirements” columns of the Comparative Data Tables. Such changes might disqualify your quotation.

| **Terms of Reference** | **Is quotation compliant?**  Bidder to complete | **Bidder to Insert Details of offered services if applicable** |
| --- | --- | --- |
| **(1) Type of Drugs for QC Testing**  The following Locally Manufactured Anti Malarials in Nigeria will be tested   | **Drug Name** | **Strength** | **Dosage Form** | **Pack Size** | **Reference pharmacopoeia monograph** | | --- | --- | --- | --- | --- | | Artemether/Lumefantrine | 20/120mg | Dispersible Tablet | Blister of 6Tabs (1X6) | International pharmacopoeia 10th edition | | Artemether/Lumefantrine | 20/120mg | Dispersible Tablet | Blister of 12Tabs (1X12) | International pharmacopoeia 10th edition | | Artemether/Lumefantrine | 20/120mg | Non-Dispersible Tablet | Blister of 18Tabs (1X18 | International pharmacopoeia 10th edition | | Artesunate/Amodiaquine | 100/270mg | Non-Dispersible Tablet | Blister of 3Tabs (1X3) | International pharmacopoeia 10th edition | | Artesunate/Amodiaquine | 100/270mg | Non-Dispersible Tablet | Blister of 6Tabs (1X6) | International pharmacopoeia 10th edition | | Sulphadoxine/Pyrimethamine | 500/25mg | Non-Dispersible Tablet | Blister of 3Tabs (1X3) | USP 43rd Edition | | ☐ Yes ☐ No |  |
| **(2) Parameters for QC testing**  In general, the following tests/parameters should be performed and reported.   * 1. Appearance   2. Identification   3. Related Substances   4. Water Content   5. Active Pharmaceutical Ingredient (API) Assay   6. Dissolution tests   7. Microbial limit test   h) Uniformity of weight /Uniformity of Dosage Unit | ☐ Yes ☐ No |  |
| **(3) Methods for QC testing**  The specifications/methods for analysis shall be in accordance with the referenced Pharmacopoeia/monogram (International Pharmacopoeia - IP, British Pharmacopoeia - BP, and United State Pharmacopoeia - USP, otherwise, the manufacturer’s specifications and validated methods shall be used after obtaining UNOPS email approval. | ☐ Yes ☐ No |  |
| **(4) The Contracted QC laboratory must meet the following criteria in full**:  a) Must be a WHO prequalified for the required QC testing.  b) Be listed in the latest version of WHO List of Prequalified Quality Control Laboratories.  c) Have the technical capability to adopt the in-house specifications for testing as provided by the manufacturer for non-compendia products.  d) Should be in a position to perform the method transfer process to validate the in-house method provided by the manufacturer.  e) Should be adequately equipped with appropriate equipment and should have the technical capabilities including well-qualified and trained staff to undertake the quality control on products required for testing.  f) Should be capable of communicating with the manufacturer (where required/permitted by UNOPS) in case samples are found to be out-of-specifications, to take decision to declare the products as non-compliant and advice on actions to be taken | ☐ Yes ☐ No |  |
| **(5) Analysis Report**   * Reports shall be in a format acceptable to UNOPS and shall be sent in electronic version to only UNOPS Nigeria Office. Reports to be provided to UNOPS are as follows:  1. Individual Report 2. Consolidated report  * When the tested products are found acceptable (compliant with the Specifications), the analysis report shall be sent to UNOPS Nigeria. The report should include a standardized management summary as per section 6.0 of the ToR * When the tested products are found not acceptable or Out Of Specifications (OoS), the QC laboratory shall investigate the OoS following its internal procedures, and where required/permitted by the UNOPS - communicate with the manufacturer/supplier of the drugs in order to clarify/verify the severity of the issue. A specific alert has to be sent without delay to UNOPS. * The alert shall include the following:   + - 1. Manufacturing and batch data: Product, manufacturing and packing site and batch number       2. A description of the extent of the issue (area and severity of the diversion from accepted standards)       3. A brief description of the possible implications for the patient with regards to safety and efficacy       4. Description of actions already taken       5. A set of recommended actions and corrective measures       6. The ordinary reporting has to follow the alert.       7. Prior to any further action, the QC laboratory has to obtain a clearance from UNOPS. | ☐ Yes ☐ No |  |
| **(6) Sample Size and sampling**  Bidder is required to provide the sample size required for testing each batch of sample. Batches of FPPs for quality control testing will be sampled in accordance with the laboratory standard procedure/process for sample withdrawal/collection. | **Sample Size Required for Each Sample Per Batch**  ☐ Yes ☐ No  Lot 1- (1.1) \_\_\_\_ Tablets  Lot 1 - (1.2)\_\_\_\_\_Tablets  Lot 1 - (1.3)\_\_\_\_\_Tablets  Lot 1 - (1.4)\_\_\_\_\_Tablets  Lot 2 - (2.I) \_\_\_\_\_\_Tablets  Lot 2 - (2.2)\_\_\_\_\_\_Tablets  Lot 3 - (3.1)\_\_\_\_\_Tablets |  |
| **(7) Customs Clearance and and Sample Reception**  The contractor QC laboratory shall be responsible for conducting customs clearance of samples dispatched to the laboratory for QC through courier and meeting all expenditures related to the clearance; therefore these costs should be incorporated into the financial/price offer made.  Upon receipt of sample(s), the contracted Laboratory shall share a confirmation of receipt of the sample by email with UNOPS, including sample photos with clear documentation of the batch number of all samples. | ☐ Yes ☐ No |  |
| **(8) Materials Required for QC Testing**  Bidder is responsible for providing all materials (except Samples), standards, reference, and equipment to be used for performance of the service required and meeting other expenditure necessary to perform this service, including courier fee for sending reports. | ☐ Yes ☐ No |  |
| **(9) Required Document**  Bidder is required to provide the following documents with the quotation submitted.   * Valid prequalification letter/certificate issued by WHO for QC Laboratory * Latest laboratory quality management audit report. | ☐ Provided  ☐ Not Provided |  |
| **(10) Turn Around Time ( time frame)**  Bidder is required to advise on the turn-around time at which testing results and reports will be issued to UNOPS relative to the workflow and timeline proposed by UNOPS below  1- Sample collection/Sampling - 1 days  2 - Sample Dispatch/Transportation to QC Testing laboratory - 5 days  3- Sample Custom Clearance at Destination - 2 days  4- Sample Receipt, Documentation and feedback - 1 day  5- Quality Control Testing and Analysis - 7 days  6- Reporting, Report Approval and submission - 2 day  7-Review / Feedback on submitted report - 2 day   * **Total Number of Days/Turnaround Time = 20 days** | 1-Sample collection/Sampling \_\_ days  2-Sample Dispatch/Transportation to QC Testing laboratory \_\_ days  3-Sample Custom Clearance at Destination\_\_ days  4-Sample Receipt, Documentation and feedback\_\_ day  5-Quality Control Testing and Analysis - \_\_ days  6-Reporting, Report Approval and submission \_\_ day  7-Review / Feedback on submitted report \_\_ day  -**Total Number of Days/Turnaround Time = \_\_\_ days** |  |
| **(11) Records Management**  The contracted Laboratory is responsible to provide any reports when required by UNOPS and shall be responsible to keep analysed samples for a minimum 1-month. | ☐ Yes - Agreed  ☐ No - Not Agreed |  |
| (12) Required Accreditation and Certification for QC/Testing Laboratory The Contracted QC laboratory must meet the following criteria in full:   1. Must be a WHO prequalified for the required QC testing. 2. Be listed in the latest version of WHO List of Prequalified Quality Control Laboratories. 3. Have the technical capability to adopt the in-house specifications for testing as provided by the manufacturer for non-compendia products. 4. Should be in a position to perform the method transfer process to validate the in-house method provided by the manufacturer. 5. Should be adequately equipped with appropriate equipment and should have the technical capabilities including well-qualified and trained staff to undertake the quality control on products required for testing. 6. Should be capable of communicating with the manufacturer (where required/permitted by UNOPS) in case samples are found to be out-of-specifications, to take decision to declare the products as non-compliant and advice on actions to be taken | ☐ Yes ☐ No |  |
| **(13) Sustainability Requirement**  Bidder shall provide a statement that demonstrates their commitment to support gender mainstreaming through their operations. | Statement:.......... |  |

ANY DEVIATION MUST BE LISTED BELOW:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[*Stamp form of bid with official stamp of the bidder*]

# Form D: Previous Experience Form

RFQ reference no:

Name of Bidder: [insert name of Bidder (QC Laboratory Name)]

Bidder is required to provide experience in supplying specific/ similar services during the last 3 (three) years.

| **Description of services** | **Country** | **Total amount of Contract** | **Contract Identification and Title and**  **Contact details of Client**  **(Name, Address, telephone, email, fax)** | **Year project was undertaken** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[*Stamp form of bid with official stamp of the bidder*]