January 4, 2020

Request for Proposals

RFP Number:	GHSC-PSM-TO2-2021-0001
Issuance Date:	January 4, 2021
Deadline for Offers:	February 15, 2021 no later than 5:00 pm local EST time
Description:	Laboratory Testing Services
For:	USAID Global Health Supply Chain (GHSC) - Procurement and Supply Management (PSM) Project
Funded By:	United States Agency for International Development (USAID), Contract No.: AID-OAA-I-15-00004 Task Order No.: AID-OAA-TO-15-00009
Implemented By:	Chemonics International Inc.
Point of Contact:	Alexis Moore, PSMTO2QARFP@ghsc-psm.org
Submission of offers:	PSMTO2QARFP@ghsc-psm.org

Attachments:

Annex 1 - Cover Letter Template
Annex 2 - Required Certifications
Annex 3 - Cost Proposal Template
Annex 4 - Technical Proposal Template
Annex 5 - Completed Method Transfer Template
Annex 6 - PSM Draft Subcontract Template
Annex 7 - DUNS and SAM Registration Template

Dear Sir or Madam,

Chemonics International Inc. (hereinafter referred to as "Chemonics"), under the United States Agency for International Development, USAID Contract No.: AID-OAA-1-15-00004 Task Order No.: AID-OAA-TO-15-00009, is issuing a Request for Proposals (RFP) for Lab Testing Services. The attached RFP contains all the necessary information for interested Offerors.

Global Health Supply Chain - Procurement Supply Management (GHSC-PSM) is an official project of the United States Agency for International Development (USAID) implemented by Chemonics International and its consortium members. The purpose of GHSC-PSM is to ensure uninterrupted supplies of health commodities in support of USG-funded public health initiatives around the world. The project provides direct procurement and supply chain management support to the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and Population and Reproductive Health (PRH). GHSC-PSM supports health programs through the supply of a wide range of health commodities, including contraceptives and condoms, essential drugs; and select commodities for HIV/AIDS, malaria, maternal and child health, and infectious diseases.

Questions regarding the technical or administrative requirements of this RFP may be submitted no later than 17:00 EST on January 15, 2021 by email to PSMTO2QARFP@ghsc-psm.org. Companies or organizations should indicate their interest by submitting a proposal for the anticipated IDIQ Subcontract to PSMTO2QARFP@ghsc-psm.org by 5:00 pm Eastern Standard Time on February 15, 2021.

This RFP does not obligate Chemonics to execute a subcontract nor does it commit Chemonics to pay any costs incurred in the preparation and submission of the proposals. Furthermore, Chemonics reserves the right to reject any and all offers, if such action is considered to be in the best interest of Chemonics.

Sincerely,

Alexis Moore
Global Health Supply Chain - PSM

******* ETHICAL AND BUSINESS CONDUCT REQUIREMENTS *******

Chemonics is committed to integrity in procurement, and only selects suppliers based on objective business criteria such as price and technical merit. Chemonics expects suppliers to comply with our Standards of Business Conduct, available at http://www.chemonics.com/Ourstory/OurMissionAndValues/Pages/default.aspx.

The GHSC-PSM Project does not tolerate fraud, collusion among offerors, falsified proposals/bids, bribery, or kickbacks. Any firm or individual violating these standards will be disqualified from this procurement, barred from future procurement opportunities, and may be reported to both USAID and the Office of the Inspector General.

Employees and agents of Chemonics are strictly prohibited from asking for or accepting any money, fee, commission credit, gift, gratuity, object of value or compensation from current or potential vendors or suppliers in exchange for or as a reward for business. Employees and agents engaging in this conduct are subject to termination and will be reported to USAID and the Office of the Inspector General. In addition, Chemonics will inform USAID and the Office of the Inspector General of any supplier offers of money, fee, commission, credit, gift, gratuity, object of value or compensation to obtain business.

We acknowledge here for the information of all offerors that Chemonics/GHSCO-PSM has subcontractor personnel employed on the project from partner companies that are also potential offerors for this solicitation. Such potential conflicts are addressed through comprehensive and transparent mitigation measures including certification statements from evaluation panelists attesting to no conflicts, required recusal of relevant partner staff for any solicitations in which the parent company is a potential offeror, and fire walling of relevant partner staff from proposal files and discussions. Any identified COI issues or concerns are addressed promptly and documented

Offerors responding to this RFP must include the following as part of the proposal submission:

- Disclose any close, familial, or financial relationships with Chemonics or project staff. For example, if an offeror's cousin is employed by the project, the offeror must state this.
- Disclose any family or financial relationship with other offerors submitting proposals. For example, if the offeror's father owns a company that is submitting another proposal, the offeror must state this.
- Certify that the prices in the offer have been arrived at independently, without any consultation, communication, or agreement with any other offeror or competitor for the purpose of restricting competition.
- Certify that all information in the proposal and all supporting documentation are authentic and accurate.
- Certify understanding and agreement to Chemonics' prohibitions against fraud, bribery and kickbacks.

Please contact Mirela Smole, Lead Risk Manager, at PSMRiskManagement@ghsc-psm.org with any questions or concerns regarding the above information or to report any potential violations. Potential violations may also be reported directly to Chemonics" Washington office through the contact information listed on the website found at the hyperlink above.

RFP Table of Contents

List of Acronyms

CFR	Code of Federal Regulations
CO	USAID Contracting Officer
COP	Chief of Party
COR	USAID Contracting Officer's Representative
CV	Curriculum Vitae
FAR	Federal Acquisition Regulations
GHSC	Global Health Supply Chain
ISO	International Organization for Standardization
M&E	Monitoring and Evaluation
NICRA	Negotiated Indirect Cost Rate Agreement
NGO	Nongovernmental Organization
PSM	Procurement Supply Management
RFP	Request for Proposals
SAF	Strategic Activities Fund
U.S.	United States
USAID	U.S. Agency for International Development
USG	U.S. Government
VAT	Value Added Tax
WHO	World Health Organization

Section I. Instructions to Offerors

I.1. Introduction

Chemonics, the Buyer, acting on behalf of the U.S. Agency for International Development (USAID) and the President's Malaria Initiative (PMI), under contract number AID-OAA-1-15-00004 is soliciting offers from companies and organizations to submit proposals to participate with Global Health Supply Chain - Procurement Supply Management (GHSC-PSM) to carry out Lab Testing Services.

Global Health Supply Chain - Procurement Supply Management (GHSC-PSM) is an official project of the United States Agency for International Development (USAID) implemented by Chemonics International and its consortium members. The purpose of GHSC-PSM is to ensure uninterrupted supplies of health commodities in support of USG-funded public health initiatives around the world. The project provides direct procurement and supply chain management support to the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and Population and Reproductive Health (PRH). GHSC-PSM supports health programs through the supply of a wide range of health commodities, including contraceptives and condoms, essential drugs; and select commodities for HIV/AIDS, malaria, maternal and child health, and infectious diseases.

Chemonics shall issue an IDIQ Subcontract to one or more companies or organizations. Individual Sub-Task Orders shall then be issued against the IDIQ Subcontract. The successful Offeror/Offerors shall be required to adhere to the scope of work and terms and conditions of the IDIQ Subcontract & Individual Sub-Task Orders.

The Period of Performance for this IDIQ contract shall be for a one-year period with 1 option year. The subcontractor shall deliver the deliverables set forth in each sub-task order in accordance with the sub-task order schedule.

Offerors are invited to submit proposals in response to this RFP in accordance with **Section I Instructions to Offerors,** which will not be part of the subcontract. The instructions are intended to assist interested Offerors in the preparation of their offer. Any resulting subcontract will be guided by Sections II and III.

This RFP does not obligate Chemonics to execute a subcontract nor does it commit Chemonics to pay any costs incurred in the preparation and submission of the proposals. Furthermore, Chemonics reserves the right to reject any and all offers, if such action is considered to be in the best interest of Chemonics.

Unless otherwise stated, the periods named in the RFP shall be consecutive calendar days.

I.2. Offer Deadline

Offerors shall submit their offers electronically.

Emailed offers must be received no later than 5:00 pm local EST on February 15, 2021 at the following email address:

PSMTO2QARFP@ghsc-psm.org

Offerors are responsible for ensuring that their offers are received in accordance with the instructions stated herein. Late offers may be considered at the discretion of Chemonics. Chemonics cannot guarantee that late offers will be considered.

I.3. Submission of Offers

Proposals must be submitted electronically.

A. Instructions for the Submission of Electronic Copies

Separate technical and cost proposals must be submitted by email no later than the time and date specified in I.2. The proposals must be submitted to the point of contact designated in I.2.

The Offeror must submit the proposal electronically. Emails must not contain more than 150 MB data. All attachments shall be compatible with MS Word, MS Excel readable format or Adobe Portable Document (PDF) format in a Microsoft XP environment. Offerors must not submit zipped files. Those pages requiring original manual signatures should be scanned and sent in PDF format as an email attachment.

The technical proposal and cost proposal must be kept separate from each other. Technical proposals must not make reference to pricing data in an effort to be sure that the technical evaluation may be performed strictly on the basis of technical merit.

I.4. Requirements

To be determined responsive, an offer must include all documents and sections included in I.4.A and I.4.B.

A. General Requirements

Chemonics anticipates issuing a subcontract to companies from a combination of countries provided each company is legally registered; recognized under the laws of the country where it is registered; and in compliance with all applicable civil, fiscal, and other regulations. Such a company or organization could include a private firm, non-profit, civil society organization, or university.

Companies and organizations that submit proposals in response to this RFP must meet the following requirements:

(i) Companies or organizations, whether for-profit or non-profit, must be legally registered under the laws of the country that it is registered in upon award of thesubcontract.
(ii) Firms operated as commercial companies or other organizations or enterprises (including nonprofit organizations) in which foreign governments or their agents or agencies have a controlling interest are not eligible as suppliers of commodities and services.
(iii)Companies or organizations, whether for-profit or non-profit, shall be requested to provide a DUNS number if selected to receive a sub award valued at USD $30,000 or more, unless exempted in accordance with information certified in the Evidence of Responsibility form included in the required certifications in Annex 2.

Offerors may present their proposals as a member of a partnership with other companies or organizations. In such cases, the subcontract will be awarded to the lead company in the partnership. The leading company shall be responsible for compliance with all subcontract terms and conditions and making all partnership arrangements, including but not limited to division of labor, invoicing, etc., with the other company(ies). A legally registered partnership is not necessary for these purposes; however, the different organizations must be committed to work together in the fulfillment of the subcontract terms.

B. Required Proposal Documents

1. Technical Proposal

The technical proposal shall comprise of the following parts:

- Part 1: Cover Letter. Offerors shall complete Annex 1 (Cover Letter Template) and attach it here. Other required documents required in Part 1 include:
    - Copy of registration or incorporation in the public registry, or equivalent document from the government office where the offeror is registered.
    - Copy of company tax registration, or equivalent document.
    - Copy of trade license, or equivalent document.
    - Applicable documents listed in I.4.A.

- Part 2: Overview. This part must include a description of the company and organization with appropriate reference/s to any parent companies and/or subsidiaries. Additionally, offerors must include an overview detailing the company's relevant experience testing the commodities stated in this solicitation document as well as experience providing these services to a similar project(s). Offerors shall submit proof of two (2) projects of similar work (under contracts or subcontracts) previously implemented as well as contact information for the companies for which such work was completed.

- Part 3: Detailed Work Plan. This part shall be between 2 & 10 pages long but may not exceed 10 pages.

- Part 4: Management and Staffing Plan. This part shall be between 2 & 5 pages long but may not exceed 5 pages. CVs for key personnel shall not count against the 5-page limit.

- Part 5: Corporate Capabilities and Past Performance. This part shall be between 2 and 7 pages long but may not exceed 7 pages.

- Part 6: Annex 4 (Technical Proposal Template) shall be completed and attached as Part 6 of your Technical Proposal Package.

- Part 7: Annex 5 (Completed Method Transfer List) shall be completed and attached as Part 7 of your Technical Proposal Package *if bidding for Malaria Pharmaceutical Testing Services.*

- Part 8: Annex 2 (Required Certifications)

- Part 9: Offeror shall provide a copy of the commercial license in the country of legal domicile as a **quality testing entity.** Offeror shall also provide a copy of all certificates stating that their testing is conducted according to the appropriate standards (International Organization for Standardization (ISO-including applicable standard number), World Health Organization, etc.). Non-compliance to either standard will result in disqualification from this RFP. Offeror must also provide information about their monthly production capacity, estimated production and delivery lead time.

Chemonics reserves the right to check additional references not provided by an offeror.

The sections of the technical proposal stated above must respond to the detailed information set out in Section II of this RFP, which provides the background, states the scope of work, describes the deliverables, and provides a deliverables schedule.

2. Cost Proposal

- Annex 3 (Cost Proposal Template) shall be completed and attached as part of your cost proposal. Please email PSMTO2QARFP@ghsc-psm.org with your request to receive Annex 3 for Malaria Pharmaceuticals, LLINs, or both.

The cost proposal is used to determine which proposals represent the best value and serves as a basis of negotiation before award of a subcontract.

The price of the subcontract to be awarded will be an all-inclusive indefinite delivery indefinite quantity subcontract. No profit, fees, taxes, or additional costs can be added after award. Offers must show unit prices and lead times. All cost information must be expressed in USD Currency. See Annex 3 for a sample cost structure.

Because GHSC-PSM is a USAID funded project and is implemented under a bilateral agreement between each country and the U.S. Government, offerors must not include VAT and customs duties in their cost proposal.

Under no circumstances may cost information be included in the technical proposal. No cost information or any prices, whether for deliverables or line items, may be included in the technical proposal. Cost information must only be shown in the cost proposal.

I.5. Source of Funding, Authorized Geographic Code, and Source and Origin

Any subcontract resulting from this RFP will be financed by USAID funding and will be subject to U.S. Government and USAID regulations.

All goods and services offered in response to this RFP or supplied under any resulting award must meet USAID Geographic Code 935 in accordance with the United States Code of Federal Regulations (CFR), 22 CFR §228, available at: http://www. gpo.gov/fdsys/pkg/C·R-2012- title22-vol 1/pdf/CFR-2012-title22-voll -pa.tt 2 28.pdf.

The cooperating country for this RFP is the United States.

Offerors may not offer or supply any products, commodities or related services that are manufactured or assembled in, shipped from, transported through, or otherwise involving any of the following countries: Burma (Myanmar), Cuba, Iran, North Korea, (North) Sudan, Syria. Related services include incidental services pertaining to any/all aspects of this work to be performed under a resulting contract (including transportation, fuel, lodging, meals, and communications expenses).

I.6. Chronological List of Proposal Events

The following calendar summarizes important dates in the solicitation process. Offerors must strictly follow these deadlines.

RFP published	January 4, 2021
Deadline for written questions	January 15, 2021
Answers provided to questions/clarifications	January 30, 2021
Proposal due date	February 15, 2021
Subcontract award (estimated)	April 1, 2021

The dates above may be modified at the sole discretion of Chemonics. Any changes will be published in an amendment to this RFP.

Written Questions and Clarifications. All questions or clarifications regarding this RFP must be in writing and submitted via email to PSMTO2QARFP@ghsc-psm.org no later than January 15, 2021. Questions and requests for clarification, and the responses thereto, will be circulated to all RFP recipients who have indicated an interest in this RFP.

Only written answers from Chemonics will be considered official and carry weight in the RFP process and subsequent evaluation. Any answers received outside the official channel, whether received verbally or in writing, from employees or representatives of Chemonics International,

the GHSC-PSM project, or any other party, will not be considered official responses regarding this RFP.

Proposal Submission Date. All proposals must be received by February 15, 2021. Late offers will be considered at the discretion of Chemonics.

Subcontract Award (estimated). Chemonics will select the proposal that offers the best value based upon the evaluation criteria stated in this RFP.

I.7. Validity Period

Offerors' proposals must remain valid for 90 calendar days after the proposal deadline.

I.8. Evaluation and Basis for Award

GHSC-PSM anticipates the award of a sub-contractual agreement with the offerors who best meet the criteria established in this RFP and are determined to be responsible, eligible suppliers for the specified items.

All evaluations of offerors' proposals submitted in response to this solicitation will use the Assurance Quality Service Cost Innovation Regulatory "AQSCIR" Model for determining an award of business based on the best value for money. The model takes into account the following categories:

Category	Relevant Section from offeror's proposal
Assurance of Supply/Regulatory	Licensing (Technical Proposal)
	Experience (Technical Proposal)
	Management and Staffing Plan (Technical Proposal)
	Independence from pharmaceutical and/or WHOPES approved LLINs manufacturers (Technical Proposal)
Quality	Years' experience (Technical Proposal)
	Accreditation (Technical Proposal)
	Technical Approach (Technical Proposal)
Service	*Capacity (Technical Proposal)* *
	Corporate Capabilities (Technical Proposal)
	Completed Method Transfers (Technical Proposal, Pharma) *
	Lead Time (Cost Template) *
	Product/Testing Parameter Coverage (Technical Proposal) *
Cost	*Cost Template (Annex 3)* *
Innovation	*N/A*

*Denoted categories will be evaluated in a weighted fashion.

After a primary examination of the completion of the offers (formal and technical criteria), proposals will be evaluated by the following relevant criteria in order of importance:

Pharmaceuticals	**LLINs**
Lead Time	Lead Time
Cost	Cost
Completed Method Transfers	Capacity
Product/Testing Parameter Coverage	Product/Testing Parameter Coverage
Capacity	

- Formal criteria
  All the offers will be checked for compliance with the formal conditions stated in this solicitation document such as:
  a) Offer has been properly signed by an authorized representative of the offeror
  b) Eligibility of the company
  c) Provision of the required documentation requested

- Technical criteria
  Technical criteria consist of the testing criteria and methodologies described in the SOW.

  Supplier technical criteria
  a) Business license. Offeror must provide a copy of a current commercial license in the country of legal domicile as a quality testing entity
  b) Testing certifications. Offeror must provide copy of all certificates stating that the testing is conducted according to the appropriate standards (International Organization for Standardization (ISO-including applicable standard number), World Health Organization, etc.)
  c) Offeror must provide an overview detailing the company's experience testing the commodities stated in this solicitation document as well as experience providing these services to a similar project

  Product technical and qualification
  a) Technical and quality compliance as requested in Annex 3: Technical Proposal
  b) Production capacity/ability to perform. Offeror must provide information about monthly production capacity, estimated production, completed method transfers, and delivery lead times

- Financial criteria
  Price is an important factor in the evaluation of the offers, but it is not the only determining factor.

It is anticipated that an award will be made solely based on proposals. However, Chemonics reserves the right to conduct negotiations with and/or request clarifications from any offeror prior to award.

If there are significant deficiencies regarding responsiveness to the requirements of this RFP, an offer may be deemed "non-responsive" and thereby disqualified from consideration. Chemonics reserves the right to waive immaterial deficiencies at its discretion.

In submitting a response to this RFP, the offerors understand that USAID is not a party to this solicitation and the offerors agree that any questions or concerns hereunder must be presented in writing with full explanations and in accordance with the guidance set forth above; to Chemonics for consideration. Chemonics reserves the right to cancel this RFP at any time.

In regard to the above evaluation criteria, the Chemonics anticipates awarding several Sub-Task Orders. Primary laboratories will be selected that will conduct the majority of the testing on an alternating basis by order. Where applicable, a pool of secondary suppliers will also be selected to use in emergency or unique "one-off' situations, in the event that a primary service provider cannot satisfy a particular requirement or is not fulfilling contractual obligations.

I.9. Negotiations

Best offer proposals are requested. It is anticipated that a subcontract will be awarded solely on the basis of the original offers received. However, Chemonics reserves the right to conduct discussions, negotiations and/or request clarifications prior to awarding a subcontract. Furthermore, Chemonics reserves the right to conduct a competitive range and to limit the number of offerors in the competitive range to permit an efficient evaluation environment among the most highly-rated proposals. Highest-rated offerors as determined by the technical evaluation committee, may be asked to submit their best prices or technical responses during a competitive range. At the sole discretion of Chemonics, offerors may be requested to conduct oral presentations. If deemed an appropriate, Chemonics reserves the right to make separate awards per component or to make no award at all.

I.10. Terms of Subcontract

This is a request for proposals only and in no way obligates Chemonics to award a subcontract. In the event of subcontract negotiations, any resulting subcontract will be subject to and governed by the terms and clauses detailed in Annex 6: PSM Draft Subcontract Template. Chemonics will use the template shown as Annex 6 to finalize the subcontract. Terms and clauses are not subject to negotiation. By submitting a proposal, offerors certify that they understand and agree to all of the terms and clauses contained in Annex 6.

Chemonics reserves the right to suspend this IDIQ for bad performance at Chemonics' discretion. Financial penalties shall be assessed for late submission of results.

I.11. Privity

By submitting a response to this request for proposals, offerors understand that USAID is NOT a party to this solicitation.

Section II Background, Scope of Work, Deliverables, and Deliverables Schedule

II.2 Background

The Global Health Supply Chain - Procurement and Supply Management (GHSC-PSM) is an official project of the United States Agency for International Development (USAID) implemented by Chemonics International and its consortium members. The purpose of GHSC-PSM is to ensure uninterrupted supplies of health commodities in support of USG-funded public health initiatives around the world.

The project provides direct procurement and supply chain management support to the President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), and Population and Reproductive Health (PRH). GHSC-PSM supports health programs through the supply of a wide range of health commodities, including contraceptives and condoms, essential drugs; and select commodities for HIV/AIDS, malaria, maternal and child heath, and infectious diseases.

The President's Malaria Initiative (PMI) is a core component of the Global Health Initiative (GHI), along with HIV/AIDS, and tuberculosis. The PMI was launched in June 2005 as a 5-year, $1.2 billion initiative to rapidly scale up malaria prevention and treatment interventions and reduce malaria-related mortality by 50% in 15 high-burden countries in sub-Saharan Africa. PMI now works in 19 African focused countries and the Greater Mekong sub-region. The PMI is a joint initiative operationally led by the U.S. Agency for International Development (USAID) and Centers for Disease Control and Prevention (CDC).

While taking into account the achievements from 2001-2013, the PMI strategy for 2015-2020 is to further decrease malaria mortality by 33 percent and malaria morbidity by 40 percent by focusing on five key areas: 1. Achieving and sustaining scale of proven interventions; 2. Adapting to changing epidemiology and incorporating new tools: 3. Improving countries' capacity to collect and use information; 4. Mitigating risk against the current malaria control gains; 5. Building capacity and health systems. Therefore, the need for quality pharmaceutical products is pivotal for proper treatment.

As part of program activities, the GHSC-PSM Project requires services to provide Quality Assurance Laboratory Testing Services of Pharmaceuticals and Long Lasting Insecticide Treated Bed Nets (WHOPES-approved LLINs) purchased under the Chemonics International Inc. GHSC-PSM Project Contract #AID-OAA-I-15-00004 PMI Task Order 2 #AID-OAA-TO-15-00009.

II.2 Scope of Work

The Period of Performance for this IDIQ contract shall be for a one-year period with 1 option year. The subcontractor shall deliver the deliverables set forth in each sub-task order in accordance with the sub-task order schedule.

GHSC-PSM requires testing services from laboratories to perform quality assurance analysis of antimalarials and related pharmaceuticals and long-lasting insecticide treated nets (WHOPES-approved LLINs) procured under GHSC-PSM Task Order 2 (President's Malaria Initiative - PMI). Product testing shall ensure products procured conform to their corresponding quality standards and specifications. Samples shall be collected throughout different points of the supply chain and be delivered to the testing laboratory by PSM or its designated courier.

To reach the objective of this RFP, offerors shall perform the following tasks:

Perform quality control analysis of **malaria pharmaceuticals**

and/or

Perform quality control analysis of **long-lasting insecticide treated nets (WHOPES-approved LLINs)**

For pharmaceuticals, offerors shall perform both physical tests and chemical analyses and/or microbiological tests when appropriate.

Offerors can submit proposals for testing both WHOPES-approved LLINs and pharmaceuticals or only one.

Offerors must demonstrate compliance with the criteria and requirements defined below.

Offerors will be awarded as a primary or a secondary provider (if applicable) of these services. Primary providers will provide these services regularly to PSM, while secondary providers will do this work as a backup to or in support of primary providers. Each time there is an order ready to be tested, the PSM QA/QC team will solicit the selected laboratory for the testing lead time by providing the product and number of batches. The laboratory will then provide the estimated lead time for testing, which will be used as an indicator to measure the performance deliverables two (2) and three (3) set forth in section II.3.

If the laboratory subcontracts the testing, the offering laboratory must provide a list of the subcontracted laboratories and provide the corresponding documentation demonstrating compliance with all of the criteria mentioned below.

To guide offerors, a list of the pharmaceuticals and WHOPES-approved LLINs that will be tested are as follows (note: this list should be used as guidance. It is not an all-encompassing list. PSM reserves the right to request testing services of products that are not included in this list):

Malaria Pharmaceuticals	
Artesunate (Single Ingredient product)	30mg vial 60mg vial 120mg vial 50mg Suppository 100mg Suppository 200mg Suppository
Artemether (Single Ingredient product)	20mg/ml 1ml/ampoule 40mg/ml 1ml/ampoule 80mg/ml 1ml/ampoule
Amodiaquine (Single Ingredient product)	75mg Tablet 76.5mg Tablet 150mg Tablet 153mg Tablet
Artesunate/ Mefloquine (Fixed dose combination)	100/200mg Tablet
Artesunate / Amodiaquine (Fixed dose combination)	25mg/67.5 mg Tablet 50mg/135 mg Tablet 100mg/270 mg Tablet
Artemether / Lumefantrine (Fixed dose combination)	20mg/120 mg Tablet 40mg/240mg Tablet 60mg/360mg Tablet 80mg/480 mg Tablet
	20 mg / 120 mg Dispersible tab
Sulfadoxine /Pyrimethamine (Fixed dose combination)	250mg/12.5mg Tablet 500mg/25mg Tablet
Chloroquine (Single Ingredient product)	250mg Tablet
Dihydroartemisinin-Piperaquine (Fixed dose combination)	20mg/160mg Tablet 30mg/240mg Tablet 40mg/320mg Tablet 60mg/480mg Tablet 80mg/640mg Tablet
Primaquine (Single Ingredient product)	7.5mg Tablet 15mg Tablet
Atovaquone and Proguanil hydrochloride (Fixed dose combination)	250/100mg Tablet
Quinine di-HCl (Single Ingredient product)	200mg/ml 2ml/ampoule 600mg/ml 2ml/ampoule
Quinine Sulfate (Single Ingredient product)	200 mg Tablet 300mg Tablet
Quinine-Resorcine Dihydrochloride (Single Ingredient product)	200 mg/ml, 2ml ampoule 400mg/ml, 4ml ampoule

LLINS	
Insecticide	**Material**
Deltamethrin	Polyester
Alpha-cypermethrin	Polyester
Alpha-cypermethrin	Polyethylene
Permethrin	Polyethylene
Permethrin	Polyester
Deltamethrin	Polyethylene
Deltamethrin	Polypropylene
Permethrin/ Piperonyl butoxide (PBO)	Polyethylene
Deltamethrin / Piperonyl butoxide (PBO)	Polyethylene
Alpha-cypermethrin/ Piperonyl butoxide (PBO)	Polyethylene

Pharmaceutical testing laboratories

A. Mandatory Requirements

1. Pharmaceutical testing laboratories must meet at least one of the following criteria:

   a. Valid ISO 17025 accreditation (Note: The accreditation must be issued by an entity that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement).

   and/or

   b. Be included in the World Health Organization (WHO) List of Prequalified Quality Control Laboratories and/or is qualified through a Stringent Regulatory Authority

   Laboratories must have the testing parameter or assay of interest listed in the scope of their accreditation and/or prequalification.

2. Laboratories must meet the following criteria:

   a. Have a valid license to operate in the country of establishment.
   b. Laboratories may only have pharmaceutical manufacturers/vendors as clients. They shall not have any other business relationships with pharmaceutical manufacturers/vendors.
   c. Have at least 1 year of experience providing testing services of anti-malarial pharmaceuticals.
   d. Be equipped with calibrated and well-maintained testing equipment.

e. For products of oral solid and oral liquid forms, the turnaround time to provide a Certificate of Analysis shall not be more than 20 business days from the date of receipt of sample in the laboratory with up to 10 batches received at a time.
f. For products of injectable and oral forms involving microbial count testing the turnaround time to provide a Certificate of Analysis shall not be more than 25 working days from the date of receipt of sample in the laboratory with up to 5 batches received at a time.
g. For non-compendial products the turn round time for completing method transfer (method verification) shall not be more than 45 calendar days from the date of receipt of documentation, related materials and samples from the manufacturer.

B. Testing Requirements

For pharmaceutical testing, laboratories must provide a proposal by type of analysis (1. Physical/chemical and/or 2. Microbiological); labs must be able to indicate which of the tests defined within each of the two categories below they are able to perform:

1. Physical/Chemical analysis	**2. Microbiological tests**
Physical Tests	Sterility testing
pH	Endotoxins (LAL)
Water content	Microbial purity/count test
Loss on drying	Microbial assay
Tablet Hardness	
Disintegration time	
Dissolution	
Identification	
Infra-Red	
Thin Layer Chromatography	
High Performance Liquid Chromatography	
Spectrophotometry	
Basic tests (i.e. colorimetric)	
Assay, impurities and related substances	
High Performance Liquid Chromatography	
UV-VIS Spectrophotometry	
RI detection	
Gas Chromatography	
Ultra-Violet Spectrophotometry	
Volumetric titrations	
Determination of related substances and impurities	

C. Preferred pharmaceuticals criteria

Pharmaceutical testing laboratories that in addition to the mandatory criteria also meet the following criteria are preferred. However, value for money is to be taken into account and acceptance of technical compliance with the offer may be limited to laboratories meeting (only) the mandatory criteria.

1. Laboratories that are both: 1) ISO 17025 accreditation by an entity that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; and 2) listed in WHO List of Prequalified Quality Control Laboratories and/or is qualified through a Stringent Regulatory Authority
2. Laboratories that have at least 3 years of experience in providing testing services to international developing organizations and/or NGOs
3. Proof of adequate performance in a proficiency testing and/or external QA scheme for malaria pharmaceuticals.
4. Ability to perform all of the tests indicated in the Testing Requirements Section above.

LLIN Testing Laboratories

A. Mandatory Criteria

WHOPES-approved testing laboratories must meet the following criteria:

1. Valid ISO 17025 accreditation (Note: The accreditation must be issued by an entity that is a signatory to the ILAC MRA)

The lab must have the testing parameter or assay of interest listed in the scope of their accreditation.

2. Laboratories must meet the following criteria:

    a) Valid license to operate in the country of establishment
    b) Laboratories may only have LLIN manufacturers/vendors as clients. They cannot have any other business relationship with LLIN manufacturers/vendors.
    c) At least 1 year of experience in providing testing services of WHOPES-approved LLINs
    d) The turnaround time to provide a Certificate of Analysis shall not be more than 20 business days from the date of receipt of sample in the laboratory with up to 10 batches received at a time.

B. Testing Requirements

1. Ability to perform all of the following chemical analysis:
    a. Assay to quantify the content of insecticide in the treated fiber of the LLIN
    b. Other assays as specified in product specific methodologies

2. Ability to indicate which of the following physical analysis with the corresponding ISO standard (when applicable) they are able to perform:
    a. Mesh Size (ISO 139)
    b. Wash Resistance (CIPAC, MT195)
    c. Dimensional Stability (ISO 3759, ISO 5007 & ISO 6330)
    d. Bursting Strength (Durability) (ISO 13938-2)
    e. Fabric weight (mass/m^2) (ISO 3801/EN 12127)
    f. Flammability (16 CFR 1610/EN 1102)
    g. Other assays as specified in product specific methodologies

C. Preferred criteria

WHOPES-approved LLINs laboratories that also meet the following criteria are preferred. However, value for money is to be taken into account and acceptance of technical compliance with the offer may be limited to laboratories meeting (only) the mandatory criteria.

1. Laboratories that are both: 1) ISO 17025 accreditation by an entity that is a signatory to the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement; and 2) listed in WHO List of Prequalified Quality Control Laboratories.
2. At least 3 years of experience in providing WHOPES-approved LLINs testing services to international developing organizations and/or NGOs
3. Proof of adequate performance in a proficiency testing and/or external QA scheme for WHOPES-approved LLINs
4. Ability to perform all above indicated testing parameters

Offerors are encouraged to demonstrate their capacity to test multiple lots of the same product concurrently without significantly impacting timing and costing. For example, a laboratory specifies cost and time requirements to perform all of the required testing parameters for one batch of Artemether/Lumefantrine. The laboratory then receives 5 batches of the same Artemether/Lumefantrine product. Offerors should indicate how the timing and cost would increase incrementally for each batch.

II.3. Expected Deliverables

The successful offeror/s shall deliver to Chemonics the following deliverables, in accordance with the schedule set forth in II.4 below.

Deliverable No. 1:

For samples received, the successful offeror/s will inform the TO2 QA/QC Manager Mattu Bockarie-Davis, MBockarie-Davis@ghsc-psm.org within two business days of what date they are in receipt of the samples and indicate their estimated scheduled date of completion for testing

Deliverable No. 2:

The successful offeror/s will provide the lot results of all tested parameters to SGS within 3 business days of the proposed lead time to TO2 QA/QC Manager Mattu Bockarie-Davis, MBockarie-Davis@ghsc-psm.org

Deliverable No. 3:

Within 3 days of completed test results based on proposed lead times the successful offeror/s will send test results/certificate(s) of analysis. These documents should be sent to TO2 QA/QC Manager Mattu Bockarie-Davis, MBockarie-Davis@ghsc-psm.org

Section III IDIQ Subcontract (Terms and Clauses)

Any award resulting from this RFP will be in the form of an IDIQ Subcontract to be issued thereunder for selected services within the corresponding fixed service rates established in the IDIQ subcontract.

The draft terms and conditions are attached as Annex