REQUEST FOR PROPOSAL

UNITED NATIONS CHILDREN'S FUND (UNICEF) wishes to receive proposals for supply of

Zika Virus (ZIKV) Diagnostics (for testing at Point-of-Care), including for access to an Advance Purchase Commitment (APC)

FOR DELIVERY DURING THE PERIOD OF 2017-2019

RFP-DAN-2017-502425

9 February 2017

SEALED PROPOSALS must be received at the following address by 16:00 hours (Copenhagen time) on 7 March 2017.

UNITED NATIONS CHILDREN'S FUND (UNICEF)
Attention: BID SECTION RFP-DAN-2017-502425
Oceanvej 10-12
2100 Copenhagen Ø
Denmark
Tel +45 4533 5500

PROPOSALS RECEIVED IN ANY OTHER MANNER WILL BE INVALIDATED

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Supply Division

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unicef
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1. PURPOSE

The purpose of this Request for Proposal (RFP) is to establish long-term arrangements for the sustained supply of Zika Virus (ZIKV) in vitro Diagnostics (IVDs) through UNICEF for the period of 2017-2019.

The ZIKV diagnostics covered in this tender include:
- ZIKV RDT Antibody (Ab) detection technology,
- ZIKV RDT Antigen (Ag) detection technology, and
- ZIKV POC Nucleic acid testing (NAT) technology

These supplies are intended to be supplied to countries that UNICEF serve.

Additionally as part of this RFP, proposers may bid to access an Advance Purchase Commitment (APC).

The ZIKV IVDs APC aims to provide additional incentive to accelerate access to rapid, low-cost specific and sensitive ZIKV IVDs and possibly multiplex diagnostics that allow for simultaneous detection of ZIKV and other flaviviruses such as Dengue, Yellow Fever and Chikungunya viruses (ZIKV or multiplex Diagnostics).

As a result of this RFP, UNICEF will establish Long Term Arrangements (LTAs) which may include guaranteed procurement via the APC (for proposers who qualify to access the APC) and other forecasted quantities to be procured for non-APC quantities. These arrangements will provide the basis upon which purchase orders will be made for specific deliveries throughout the period.
2. BACKGROUND

2.1 ACCESS TO ZIKV POC AND RDT DIAGNOSTIC TECHNOLOGIES

In February 2015, Brazil detected cases of fever and rash that were laboratory-confirmed to be ZIKV in May 2015. In December 2015, there were 56,318 suspected cases of ZIKV disease in 29 states in Brazil.

As of 29th of December 2016, 75 countries and territories have reported evidence of mosquito-borne ZIKV transmission since 2007 (69 countries with reports from 2015). Non-vector-borne ZIKV transmission, most probably via a sexual route, have been documented in more than 13 countries. It is assumed that sexual transmission is ongoing in countries which report local transmission by mosquitoes.

The recent increase in reported cases of microcephaly and Guillain-Barré syndrome (GBS) potentially associated with ZIKV, as well as the latest scientific findings establishing a causal relationship between ZIKV and microcephaly and GBS, has highlighted the urgent need to identify individuals infected with ZIKV as well as to discriminate ZIKV infection from other flaviviruses. Accordingly, in vitro diagnostics (IVDs) with high specificity and sensitivity for ZIKV in acute specimens and of assured quality, safety and performance are required.

Currently, the bases of the routine diagnosis of ZIKV infection are the detection of viral nucleic acid by performing reverse transcriptase-polymerase chain reaction technique (RT-PCR) on serum and the detection of immunoglobulin (IgM) antibodies by IgM enzyme-linked immunosorbent assay (IgM-ELISA) in a well-equipped laboratory. The RT-PCR detection of viral nucleic acid in serum provides a confirmed diagnosis of ZIKV infection; however, viremia generally has very low levels and is transient, resulting in the most effective diagnosis by RT-PCR one week after the onset of clinical illness.

Virus-specific IgM and neutralizing antibodies typically develop towards the end of the first week of illness however cross-reaction with related flaviviruses (e.g., dengue and yellow fever viruses) is also common and presents major challenges for the interpretation of the serological test results. Plaque-reduction neutralization testing can be performed to measure virus-specific neutralizing antibodies and discriminate between cross-reacting antibodies in primary flavivirus infections.

In addition to the above challenges to confirm ZIKV infection in biological specimens, current diagnostics are limited to specialized laboratory-based techniques requiring specific specimen preparation and performed by high-skilled technicians and there are no WHO-approved POC IVDs.

Accordingly, there is an immediate need for developing simple, highly specific IVDs for detecting ZIKV in acute different biological specimens that can be used in screening / diagnosis (especially diagnosis of prenatal and antenatal ZIKV infections) and which can allow testing at point-of-care (POC).

UNICEF is working with partners and industry to transform today’s under-supplied ZIKV diagnostics market. UNICEF Supply Division hosted an industry consultation in Copenhagen on 11-12 May 2016 and convened partners and diagnostics and vaccine manufacturers to encourage the acceleration of R&D and to advance the

1 WHO ZIKA situation report: http://apps.who.int/iris/bitstream/10665/252672/1/zikasitrep29Dec15-en.pdf?ua=1
3 CDC Revised diagnostic testing for Zika, chikungunya, and dengue viruses in US Public Health
commercial environment to address gaps in vaccine and ZIKV Diagnostics (for testing at point of care) urgently required to fight ZIKV. Furthermore, UNICEF convened a ZIKV Diagnostics webinar which took place on 30 August 2016 as a follow-up on the industry consultation to update industry and partners on current developments, revised demand profiles, including UNICEF’s procurement approach and timelines for ZIKV diagnostics tender.

UNICEF has worked with USAID to develop an Advance Purchase Commitment (APC), which aims to reduce demand uncertainty risks for manufacturers who invest in R&D towards new products. We are pursuing the following objectives to transform the ZIKV diagnostics market to:

- **Secure availability of a minimum of two novel products** available by 31 December 2017 with reliable, uninterrupted supply of diagnostics to countries from multiple well-performing proposers, following appropriate regulatory approval.
- **Maximize the effect** of the APC to accelerate market availability to meet forecasted demand for ZIKV diagnostics, where demand and scale up is informed and driven by integration of ZIKV diagnostics into countries’ testing algorithms.
- **Secure access to affordable prices** through the use of APC.
- **Contribute to continued product innovation** by driving the market towards novel diagnostic assays capable of distinguishing ZIKV infection from other related flaviviruses.

In order to harvest the benefits of the competitive dynamics in a fair and transparent manner, and to drive the market towards novel diagnostics, UNICEF intends to issue two sequential tenders whereby portions of the total forecasted quantities would be awarded in each tender.

The procurement objectives for this tender have been developed based on these principles, and the achievement of the objectives will be instrumental for combatting the emerging ZIKV epidemic.

### 2.2 PROCUREMENT OBJECTIVES

The overarching goal of the UNICEF strategy for ZIKV diagnostics procurement is to ensure access and availability of affordable, quality assured, diagnostic testing at point of care (POC) for ZIKV by supporting the development of novel devices and creating a healthy and stable market. The specific objectives include:

The specific objectives for this tender are:

1. **Ensure reliable, uninterrupted supply of diagnostics to countries:**
   - Two new products available by 31 December 2017, with appropriate regulatory approval.
   - Reliable, uninterrupted supply of diagnostics to countries from multiple well-performing proposers with 40 million test units available by 2020.
   - New / innovative technologies are able to enter the market as they become available.

2. **Secure access to affordably priced, appropriate diagnostics:**
   - Maximize the effect of the Advanced Purchase Commitment to accelerate market availability of products to meet the forecasted demand for ZIKV diagnostics.

3. **Encourage healthy and sustainable competition throughout the procurement process:**
   - Engaging with both new and existing diagnostic proposers to contribute towards a healthy and competitive market, targeting 5 proposers in the market by 2018.
4. Secure access to quality diagnostics:
   ➢ Procurement of products which are WHO prequalified.
   ➢ Procurement of products which has been approved by one of the stringent regulatory authority (the five founding members of the GHTF) other than (WHO and FDA) and confirming its clinical performance by an independent lab testing in case the WHO prequalification is not available.

5. Secure access to newly innovative products:
   ➢ With novel diagnostic assays capable of distinguishing ZIKV infection from that of related flaviviruses:
     - Antibody response: Human Anti ZIKV specific antibodies (mAbs) against all ZIKV strains.
     - Antibody-mediated neutralization and enhancement of ZIKV infection: for example, Reporter virus particle RVP-based assay.
     - Molecular testing: Microfluidics/single drop assay.
   ➢ Establish access to innovative technologies (both 1st- and 2nd generations) entrants by 2018.
   ➢ Foster sustainability of innovation in post-APC period.
   ➢ Establish access to ZIKV diagnostics which simultaneously provide differential diagnosis with other flavivirus infections.

UNICEF expects to partially achieve the above objectives in the first tender and to successfully achieve them by the end of the 2nd tender.

2.3 TENDER METHODOLOGY – REQUEST FOR PROPOSALS

Proposers are expected to fully utilize the opportunity of an RFP to include all relevant information in their respective offers including procurement and contracting methodologies which allow the proposer to best possibly contribute to achieving the procurement objectives. Guiding questions associated with the qualitative aspects of the Proposer’s proposal are summarized in Qualitative Proposal sheet (Section 5).

UNICEF intends to conduct two sequential Request for Proposals (RFPs) processes as outlined below:

2017

1st Tender: “FIRST Request for Proposals”
   ➢ 10 Feb 2017  1st Request for Proposal (RFP) Issuance
   ➢ 7 March 2017  1st RFP closing date
   ➢ June 2017  Initial awards to proposers

2nd Tender: “SECOND Request for Proposals”
   ➢ Mid-August 2017  2nd RFP Issuance
   ➢ Late November 2017  2nd RFP awards to proposers

UNICEF reserves the right to amend the above schedule, especially in order to better achieve the procurement objectives.

2.4 PROCUREMENT REFERENCE GROUP

A Procurement Reference Group (PRG) has been established to build on the expertise of various stakeholders. Considering the strategic nature of the procurement to be undertaken, the PRG has provided advice with regards to objectives and procurement strategy and will frequently provide input and advice to UNICEF, during
the execution of this procurement. UNICEF will share information related to the proposal(s) and recommended award(s) with the PRG under confidentiality.

2.5 UNICEF DEMAND FORECAST

Below is an overview of the projected ZIKV diagnostics requirements to be procured through UNICEF using a forecasting model which was based on the following:

Target Cohorts:
Priority Group: The testing is primarily targeting pregnant women, with or without clinical symptoms, and their male sexual partner (asymptomatic males) by having two tests (one NAT test and one serology test) annually with a 35% coverage rate.
In addition, other cohorts were assumed to be included for testing:
- Clinically diagnosed Microcephaly assuming 1% of the priority group
- Clinically diagnosed GBS assuming 0.5% of the priority group
- Travelers from area with ongoing ZIKV transmission assuming 0.5% of the priority group

The overall target was calculated based on the combination of the priority group and the additional cohorts, the total included a 2% stockpile and a 5% wastage rate annually.

Selection of Countries:
African countries
Based on the different presumptive epidemiological scenarios, two potential gateways have been identified for the possible spread of ZIKV in Africa:
- Countries located in the West Africa sub-region adjacent to those currently reporting the presence of the Aedes vector and geographically facing the Latin American coast:
  - Benin, Burkina Faso, Cameroon, Cape Verde, Equatorial Guinea, Gambia, Ghana, Guinea, Guinea-Bissau, Gabon, Ivory Coast, Niger, Nigeria, Senegal, Sierra Leone and Togo.
- Remaining countries in Africa within the vector belt:

Other countries
Based on WHO Country classification (7 July 2016), CDC Country classification (9 July 2016) and taking into considerations the risk countries for ZIKV transmission based on Messina et al. 2016 environmental suitability model, the additional following countries were selected: Cambodia; Papua New Guinea; Philippines; Bangladesh; Nepal; Sri Lanka, Viet Nam and Indonesia.

Countries were classified in terms of likelihood to have a preparedness plan in place and ready to introduce the RDT/POC in country as, in order of likelihood (highest to lowest): “Likely”, “Probable” and “Possible” according to the information we have received from countries so far. In addition, giving their skewing effect on the model, two countries (Viet Nam and Indonesia) were classified as “Large Population - Less Likely”.

UNICEF could additionally do some of the procurement on behalf of other countries, regions and partners, but we currently have little visibility if such would materialize.

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Based on UNICEF's demand forecast model, total procurement for 2017-2019 is expected to be 40 million tests/products for 31 countries.

It should be noted that the quantities are based on an assumption of 1 NAT and 1 Serology test annually per patient as a minimum, including required buffer stocks and maximum recommended wastage rate.

2.6 ADVANCE PURCHASE COMMITMENT OPPORTUNITY

UNICEF and USAID intend to accelerate the development of rapid, low-cost, specific and sensitive ZIKV IVDs and possibly multiplex diagnostics that allow for simultaneous detection of ZIKV and other Flaviviruses such as Dengue (DENV), Yellow Fever (YF) and Chikungunya (CHKNV) viruses (ZIKV or multiplex Diagnostics) and scale-up of POC/RDT ZIKV or multiplex Diagnostics via an Advance Purchase Commitment (APC).

As part of this tender, proposers will be invited to bid for an Advance Purchase Commitment (APC) commitment via attractive and eligible offers that will significantly contribute towards reaching the objectives of this tender.

What is the ZIKV APC?
Proposers who are awarded a portion of the ZIKV IVDs APC opportunity will, subject to the product meeting pre-determined requirements (such as regulatory approval and actual manufactured product availability), receive a firm commitment from UNICEF:
- To buy a specified volume of a product, regardless of whether or not demand for the product materializes, potentially through 2019.
- Prior to availability of the product in the market, as appropriate.

The firm commitment is financially backed by an approximate $10 million grant that USAID has provided to UNICEF for this expressed purpose.

To award this firm commitment, UNICEF will consider procuring up to the following number of tests from proposers who qualify to access the APC as per the following segmentation:
- Up to 4 million test quantities dedicated to newly developed serological and molecular IVDs using RDTs and POC platforms whether in single or multiplex format (offering differential diagnosis for ZIKV among other related viruses specifically DENV, CHKNV, YF with or without WNV).
- Up to 4 million test quantities dedicated to newly developed serological and molecular IVDs using an RDT platform whether in single or multiplex format (offering differential diagnosis for ZIKV among other related viruses specifically DENV, CHKNV, YFV with or without WNV).
• Up to 7 million test quantities dedicated only to serological and molecular IVDs using RDTs and POC platforms in a multiplexing format (offering differential diagnosis for ZIKV among other related viruses specifically DENV, CHKNV, YF with or without WNV).

For those proposers who are awarded a portion of the ZIKV APC, UNICEF would establish Long Term Arrangements (LTAs) which include guaranteed procurement for the awarded APC quantities in addition to other forecasted quantities to be procured on non-APC (i.e., standard) terms. These arrangements will provide the basis upon which purchase orders will be made for specific deliveries throughout the period.

UNICEF encourages all proposers who may have relevant products available during the 2017-2019 to submit proposals to this RFP and for the APC portion, regardless of current regulatory status or current availability.

UNICEF reserves the right to adjust any of the above segmentation, and to award as much or as little of the APC, in order to best meet the procurement objectives and assure good value for money.

2.7 ALTERNATIVE PROPOSALS

An alternative offer sheet is provided for this purpose and can be submitted in several copies if multiple alternative proposals will be offered.
3. **INSTRUCTIONS TO PROPOSERS**

3.1 **PROCUREMENT ARRANGEMENTS**

3.1.1 UNICEF wishes to enter into non-exclusive Long Term Arrangements (LTAs) for the procurement of the ZIKV Diagnostics listed above, as required from time to time during the term of the LTA. It will be a provision of such Arrangements that, unless specifically stated otherwise in the contract, UNICEF will not be committed to purchase any minimum quantity of these items. UNICEF shall not be liable for any cost in the event that no purchases are made under any resulting LTAs.

3.1.2 Additionally, as part of this tender, proposers will be able to bid for an Advance Purchase Commitment (APC),

<table>
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<th>APC Duration:</th>
<th>Up to 3 years (anticipated 2017-2019)</th>
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<td>Requests for Proposals:</td>
<td>2 tender exercises: in 1Q 2017 (awards / commitments by Q2 2017), in 3Q2017 (awards / commitments by 4Q 2017)</td>
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**APC modality:**

- Proposers should provide offers for the ‘firm commitment’ (APC) and non-firm component through this RFP.
- UNICEF’s expectation is that suppliers will offer meaningful quantities in both categories of the offer. If a supplier makes an offer for APC quantities, a comparably meaningful or higher number of quantities would be expected to be offered in the non-APC quantities.
- For those suppliers who are *awarded* APC quantities, it is expected that any subsequent procurement of non-APC quantities (after exhaustion of the APC commitment) would be done at a price that is less than or equal to the contracted APC price.
- This ‘firm commitment’ would require UNICEF to purchase awarded firm volumes, regardless of materialization of demand. The ‘firm commitment’ would be contingent upon the proposer being able to develop a product according to the specifications outlined in the tender, achievement of all necessary regulatory approval(s), and making the product available as agreed to in the purchase commitment (including timelines), and other pre-determined contingencies, at the discretion of UNICEF. Prior to any key triggers or contingencies, the firm commitment would be in the form of a “conditional” firm commitment.

**Resulting Contracting**

As a result of this tender, UNICEF will establish LTAs which will include guaranteed procurement for APC (for proposers who qualify to access the APC) and other forecasted quantities to be procured on non-APC (i.e., standard) terms. These arrangements will provide the basis upon which purchase orders will be made for specific deliveries throughout the period.
Forecasted Diagnostics Test Requirement

Based on UNICEF's demand forecast model outlined in section 2.5, total procurement for 2017-2019 is expected to be 40 million tests / products for the 31 countries based upon the assumptions made under section 2.5 “Demand Forecast”. As necessary, UNICEF will communicate an updated forecast to the market.

3.1.3 Purchases will be made against Purchase Orders to be issued by UNICEF in accordance with the terms and conditions of any resulting LTA(s). Actual quantities to be purchased will vary from Purchase Order to Purchase Order.

3.1.4 The quantities outlined in this Request for Proposal (RFP), are estimated forecasts for the total requirements for the duration of the LTA(s). The estimates are provided in good faith and shall not in any way be deemed to be commitments on the part of UNICEF regarding any quantity for future purchase.

3.1.5 Any resulting LTAs intend to cover deliveries during the period 2017-2019.

3.2 TENDER MODALITY

In order to encourage the benefits of the competitive dynamics in a fair and transparent manner, and as mentioned in section 2.3 UNICEF intends to issue two sequential tenders, whereby portions of the total forecasted quantities would be awarded in each tender.

There is no restriction on which or how many tenders a proposer may submit proposals to. UNICEF will be publishing awarded prices after each award finalization.

It is important that the mechanics of the tender are fully understood by Proposers.
3.3 SCOPE OF PRODUCTS INCLUDED UNDER THIS TENDER

The ZIKV diagnostics covered in this tender are listed in Table 1 below and include:

- ZIKV RDT Antibody (Ab) detection technology
- ZIKV RDT Antigen (Ag) detection technology
- ZIKV POC Nucleic acid testing (NAT) technology

Please note that the item descriptions mentioned below should be read in conjunction with the respective item’s technical specifications mentioned in Annex 1

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<th>Material # and description</th>
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<td>Item 010</td>
<td>U481900</td>
<td>ZIKV RDT Ab detection test</td>
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<tr>
<td>Item 020</td>
<td>U481900</td>
<td>Multiplex (ZIKV / X Arbovirus) RDT Ab detection test</td>
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<tr>
<td>Item 030</td>
<td>U481900</td>
<td>Various reagents</td>
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<td>Item 040</td>
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<td>Item 050</td>
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<td>Various devices (if needed)</td>
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<th>Schedule 2: RDT antigen (Ag) detection technology</th>
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<th>Material # and description</th>
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<td>Item 060</td>
<td>U481900</td>
<td>ZIKV RDT Ag detection test</td>
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<td>Item 070</td>
<td>U481900</td>
<td>Multiplex (ZIKV / X Arbovirus) RDT Ag detection test</td>
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<td>Item 080</td>
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<td>Various reagents</td>
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<td>Item 090</td>
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<td>Various consumables</td>
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<td>Item 100</td>
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<th>Schedule 3: POC nucleic acid testing (NAT) technology</th>
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<td>Item 110</td>
<td>U481900</td>
<td>ZIKV POC NAT</td>
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<td>Item 120</td>
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<td>Multiplex (ZIKV / X Arbovirus) POC NAT</td>
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<td>Item 150</td>
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<tr>
<th>Schedule 4: ZIKV RDT/POC IVD technologies other than mentioned under schedule 1-3</th>
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<th>Material # and description</th>
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<tr>
<td>Item 160</td>
<td>U481900</td>
<td>ZIKV RDT/POC IVD test</td>
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<td>Item 170</td>
<td>U481900</td>
<td>Various reagents</td>
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<td>Item 180</td>
<td>U481900</td>
<td>Various consumables</td>
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<tr>
<td>Item 190</td>
<td>U481900</td>
<td>Various devices (if needed)</td>
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3.4 MANDATORY REQUIREMENTS

Mandatory requirements identify the minimum requirements for the proposals to be considered. Mandatory requirements will be indicated throughout this RFP by the words "mandatory", "shall", "must", or "will" in regard to obligations on the part of the Proposer. Proposals that do not meet the mandatory requirements will not be eligible for award.
Refer to Section 4.4.4 for instruction on how proposals that do not meet the technical mandatory requirements will be managed.

3.5 RESPONSE FORMAT

The Proposer is invited to develop a proposal that provides a comprehensive explanation of the offer being made. The proposal must include a signed PROPOSAL FORM in original. ANSWER SHEETS have been provided to assist in the organization of the proposal.

Each proposal should:

- Contain information on mandatory requirements for offered products (MANDATORY REQUIREMENTS SHEET)
- Contain qualitative information on account management, proven experience and past performance (QUALITATIVE PROPOSAL SHEET).
- Define the proposed diagnostics(s) (QUANTITATIVE PROPOSAL SHEET(s))
- Provide explanations to any request for exceptions or clarification on the COMMERCIAL TERMS SHEET. Technical information sheets and requested technical documents as per "TECHNICAL DOCUMENT CHECK LIST"

An additional blank ALTERNATIVE PROPOSAL SHEET is available for proposers who wish to offer alternative proposals.

The Proposer must provide sufficient information in the proposal to address each area of evaluation to ensure a fair assessment of the company can be conducted.

3.6 MARKING AND RETURNING PROPOSALS

3.6.1 Sealed proposals must be securely closed in a suitable envelope, clearly MARKED on the outside with the PROPOSAL NUMBER, and dispatched to arrive at the UNICEF office indicated NO LATER THAN the CLOSING TIME AND DATE. PROPOSALS received in any other manner will be INVALIDATED.

3.6.2 Proposals received without the PROPOSAL NUMBER will be invalidated.

3.6.3 Two (2) documents of the sealed proposal are to be submitted (only one of which is required to be original).

3.7 TIME FOR RECEIVING PROPOSALS

3.7.1 Sealed proposals received prior to the stated closing time and date will be kept unopened. The Officer of the Bid section will open the proposal when the specified time has arrived, and no proposal received thereafter will be considered.

3.7.2 UNICEF will accept no responsibility for the premature opening of a proposal which is not properly addressed or identified.

3.8 PUBLIC OPENING OF PROPOSAL

Due to the nature of the RFP, there will be no public opening of proposals.
3.9 REQUESTING INFORMATION FROM UNICEF DURING THE TENDER PROCESS

Any request for information regarding the specifications should be forwarded to the Contracts Manager, Lama Suleiman (email: lrsuleiman@unicef.org) and the Contracts Officer, Irene Ayako (email: layako@unicef.org), and NOT to the Bid Section (see front page).

Inquiries received less than seven (7) calendar days prior to the proposal closing date cannot be guaranteed any response. Only written inquiries will be entertained. A response to written queries will be provided to all Proposers in writing. Information provided verbally will not be considered a fundamental change and will not alter this RFP.

3.10 ERROR IN PROPOSAL

Proposers are expected to examine all Schedules and all Instructions pertaining to the work or proposal. Failure to do so will be at Proposers' own risk. In case of errors in the extension price, unit price shall govern.

3.11 CORRECTIONS

Erasures or other corrections in the proposal must be explained and the signature of the Proposer shown alongside.

3.12 MODIFICATION AND WITHDRAWAL

3.12.1 All changes to a proposal must be received prior to the closing time and date. It must be clearly indicated that it is a modification and supersedes the earlier proposal, or state the changes from the original proposal.

3.12.2 Proposals may be withdrawn on written or email request received from Proposers prior to the opening time and date. Negligence on the part of the Proposer confers no right for the withdrawal of the proposal after it has been opened.

3.12.3 Modifications to and possible withdrawals of proposals must only be sent to the Bid Sections Fax + 45 35 25 02 80 (secure fax).

3.13 VALIDITY OF PROPOSALS

UNICEF requests Proposals to be valid for a period through 31 December 2019. The Proposers are requested to indicate the validity period of their proposal. UNICEF may request the validity period to be extended.

3.14 CURRENCY OF PROPOSALS

Failure to quote in the currency stated in the RFP document, Terms and Conditions, will invalidate the proposal.

3.15 INCOTERMS

Failure to quote in accordance with the requested Incoterms may result in invalidation of your proposal.
3.16 PROPOSER REGISTRATION AND EVALUATION

3.16.1 UNICEF is part of the United Nations Global Marketplace (UNGM) (previously the UN Common Proposer Database.) Accordingly, all Proposers must apply to become a UNICEF proposer and this must be done via the UNGM website at http://www.ungm.org. Following this application the UNGM informs the UNICEF Quality Assurance Proposer Evaluation Unit (SEU) automatically and a determination will be made as to whether the application will be accepted. The determination is based on relevance of the products to UNICEF, together with a financial assessment.

3.16.2 Simultaneously with application to UNGM, and unless this information has already been provided to UNICEF within the previous 12 months, Proposers shall submit their most recent Audited Financial Statement and Quality System Certificate to the UNICEF Quality Assurance Proposer Evaluation Unit, UNICEF Supply Division, Oceanvej 10-12, DK-2100, Copenhagen, Denmark. This information will be used by UNICEF for evaluation and approval purposes before making an award. It is in the interest of the Proposers to provide information which is as complete as possible, as awards will only be made to proposers who meet UNICEF's proposer selection criteria.

3.17 COUNTRY OF ORIGIN

Proposers shall advise as to the country of origin of products offered. Proposers may furthermore be required to submit a Certificate of Origin of Goods issued by the Chamber of Commerce or other equivalent authority.

3.18 RIGHTS OF UNICEF

3.18.1 UNICEF reserves the right to INVALIDATE fully or partially any proposal received for the reasons mentioned above.

3.18.2 UNICEF reserves the right to INVALIDATE any proposal received from a Proposer who, in the opinion of UNICEF, is not in a position to perform the contract.

3.18.3 UNICEF reserves the right to request additional or supplementary data from the Proposer.

3.18.4 UNICEF reserves the right to re-tender should the result of the tender be deemed by UNICEF nonresponsive.

3.19 CATALOGUES

Proposers, who have not already done so, are kindly requested to send a copy of their current catalogue or list of product offerings.

3.20 ANSWER SHEETS

Only the forms and sheets provided in Section 5 should be used to present the various aspects of the proposal. Supplemental information can be provided on each of the ANSWER sheets:

- PROPOSAL FORM (S)
- TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET (S)
- QUALITATIVE PROPOSAL SHEET (S)
- QUANTITATIVE PROPOSAL SHEET(S)
• COMMERCIAL TERMS SHEET(S)
• REQUESTED DOCUMENTS LISTED IN “TECHNICAL DOCUMENT CHECK LIST”

3.21 AWARD NOTIFICATION

All Proposers will receive a written notification regarding the results of their proposal.

3.22 PUBLIC POSTING, DISCLOSURE OF PRICES AND QUANTITIES

UNICEF reserves the right to disclose price and quantity information relevant to LTAs/Purchase Orders resulting from this tender.

UNICEF will make each award public by publishing the following information on the UNICEF website: The proposer name, diagnostic(s), price, quantity, duration of award, and total award value.

3.23 RFP TERMS

This RFP, along with any proposal thereto, shall be considered the property of UNICEF and the proposals will not be returned to their originators.

In submitting the proposal, the Proposer agrees to acceptance of the decision of UNICEF as to whether the proposal meets the minimum requirements stated in this RFP; and the evaluation.

Information provided in the proposal will be treated as confidential unless otherwise noted by the Proposer.

3.24 DEBRIEFINGS

All Proposers receiving an award will be invited to a formal debriefing and award initiation meeting. Proposers not receiving an award may request a formal debriefing. During a debriefing, the strengths and weaknesses of the proposal may be discussed. Details concerning the evaluation results of other proposals will not be divulged other than outlined under 3.21 and 3.22 above.

3.25 RFP IN ELECTRONIC FORMAT

In order to assist with preparation of the proposal, the RFP will be provided in an electronic format (following the formal issuance of the RFP). All proposals however, must be returned to UNICEF in a sealed format, as defined in the Front Page.
4. TERMS AND CONDITIONS

4.1 TECHNICAL REQUIREMENTS

4.1.1 Introduction
In response to the current ZIKV outbreak and its declaration as PHEIC due to the recent cluster of microcephaly cases and other neurological disorders reported in the Americas, UNICEF aims to encourage the market to develop innovative rapid diagnostics that can enable the differential ZIKV testing at point-of-care (POC) for the surveillance/diagnosis among the high risk groups in low and medium resource settings.

4.1.2 Product specification
For all products requested under this RFP, the technical specifications for every item number are detailed in Annex 1.

4.1.3 Technical provisions
UNICEF technical provisions and requirements for ZIKV IVDs are detailed in Annex 2.

4.1.4 Review and testing of Samples
UNICEF reserves the right to request free, non-returnable samples for evaluation and testing by UNICEF or UNICEF representatives. Samples will be subject to technical review and laboratory testing and analysis where appropriate.

4.1.5 Quality Assurance Policy
UNICEF Quality Assurance policy for the procurement of Rapid Diagnostics/Point of Care Technology is detailed in Annex 3.

4.1.6 Mandatory Technical Requirements
Proposers will be eligible for award if the products meet all mandatory requirements including:
2. UNGM registration.
3. Compliance with product technical performance specification (see Annex 1) in the tender document including specifications, standards, and a service and maintenance plan in case of equipment.
4. Regulatory approved by WHO or FDA or listed under emergency listing of WHO EUAL or FDA EUA if applicable. If the product is not listed yet under any of the previous regulatory bodies, UNICEF will proceed as outlined in Section 4.4.4.
5. The quality assurance requirements laid out in the UNICEF Quality Assurance Policy for the Procurement of Rapid Diagnostics/Point of Care Technology.
6. Compliance with packing and shipping marking requirements by the time of first supply.
7. Compliance with inspection requirements by the time of first supply.

4.1.7 ZIKV RDT/POC product schedules
4.1.7.1 Schedule 1: RDT Antibody (Ab) detection technology
The request for proposal encompasses a product with a main type of serology assay to detect ZIKV specific antibodies (IgM and/or IgG) and is limited to those have met the mandatory general requirements mentioned under section 4.1.6 above and meet the following product technical requirement:
1. Submission of product dossier and satisfactory site and laboratory evaluation.
2. Meeting the minimum acceptability criteria set for clinical performance criteria in WHO EUAL or FDA EUA laboratory evaluation of ZIKV serology assays.
3. Meeting the minimum analytical sensitivity limit set in Annex 1 showing assay is calibrated/tested against biological sera reference panels representing wider geographical distribution.
4. For diagnostic products detecting in addition to ZIKV, other flavivirus (multiplex), assay is calibrated/tested against the relevant specific WHO Reference Reagent sera panels, if available.
5. Assays is tested for cross-reactivity with other flavivirus (DENV, CHKNV, YF).
6. Meeting the minimum analytical specificity detailed and limit set in Annex 1 (interfering substances, hook effect, Ig class specificity).

Table 2 illustrates the technical evaluation criteria and scoring system used to differentiate proposals based on their technical merits. The evaluation criteria are set to achieve high analytical and clinical sensitivity and specificity performance of the diagnostic assays under evaluation.

<table>
<thead>
<tr>
<th>Item</th>
<th>Technical criteria</th>
<th>Maximum Points</th>
<th>points</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Analytical sensitivity</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(or limit of detection in case of NAT assays)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≥86%</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≥95%</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• In case of NAT assays &lt; 500 copies/mL</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Analytical specificity</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≥86%</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• &gt;95%</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Multiplexing</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simultaneous detection of ZIKV/ DENV</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simultaneous detection of ZIKV/ DENV/ CHKNV</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simultaneous detection of ZIKV/ DENV/ YF</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simultaneous detection of ZIKV/ DENV/ CHKNV/YF</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>70</td>
<td>70</td>
</tr>
</tbody>
</table>

4.1.7.2 Schedule 2: RDT Antigen (Ag) detection technology
The request for proposal encompasses a product with main type of serology assay to detect ZIKV specific antigens (direct or indirect assays) and is limited to those have met the mandatory general requirements mentioned under point 4.1.6 above and meet the following product technical requirement:
1. Submission of product dossier and satisfactory site and laboratory evaluation.
2. Meeting the minimum acceptance criteria set for clinical performance criteria in WHO EUAL or FDA EUA laboratory evaluation of ZIKV serology assays.
4. For diagnostic products detecting in addition to ZIKV other flavivirus (multiplex), assay is calibrated/tested against the relevant specific WHO Reference Reagent panels, if available.
5. Meeting the minimum analytical specificity detailed and limit of detection set in Annex 1.

The above scoring system summarized in Table 2 will apply.
4.1.7.3 Schedule 3: POC Nucleic acid testing (NAT) technology
The request for proposal encompasses the main type of NAT assay to detect ZIKV specific viral nucleic acid (RNA) and is limited to those which have met the mandatory general requirements mentioned under point 4.1.6 above and meet the following product technical requirement:

1. Submission of product dossier and satisfactory site and laboratory evaluation
2. Meeting the minimum acceptance criteria set for clinical performance criteria in WHO EUAL or FDA EUA laboratory evaluation of ZIKV molecular assays
4. For diagnostic products detecting in addition to ZIKV other flavivirus (multiplex), assay is calibrated/tested against the relevant specific WHO Reference Reagent panels, if available
5. Meeting the minimum analytical specificity detailed and limit of detection set in Annex 1

The above scoring system summarized in Table 2 will apply.

4.1.7.4 Schedule 4: ZIKV RDT/POC IVD technologies other than mentioned under schedule 1-3
Proposers are invited to submit their offers for technologies that are not mentioned under schedule 1-3 and meeting the minimum assay performance and requirement mentioned in Annex 1.

The offered tests under this category will be evaluated in a similar way as the above three schedules as applicable.
4.1.8 Tender technical evaluation general elements
The following section outlines the general elements for the tender technical evaluation of the ZIKV RDT/POC
detection technologies:

Assay(s)
- Principle of the assay(s)
- Type of result (qualitative) and range
- Additional tests offered (detection of other flaviviruses)
- Accuracy and precision of the assays
- Ease of use

Instrument (in case of POC)
- Portable
- Power source requirement; time to battery charged
- Alternative charging options (i.e. solar panel, car battery, etc.)
- Ease of use (testing procedure, touch screen, optional printer, pictogram)
- Display language(s)
- Built-in memory storage capacity; connectivity options

Sample
- Sample type (WB venous, WB finger prick, plasma) and volume
- Sample preparation (none vs. how many steps)
- Sample throughput/hour, batching capability and time to result
- Interpretation of results and how it is done

Proposer support (if available)
- Training material available from proposer (online, CD, sheets, manual) and in different languages
  (English, Spanish and French)
- Proposer onsite training provided at no additional cost (in case of POC)
- Software update available at no additional cost (in case of POC)

Supply characteristics
- Reagents and/or controls have a remaining shelf life of 6 months, preferably 12 months
- Equipment life span (in case of POC)
- Storage & operation temperature (5 to 45 °C)
- Need for additional equipment to operate (e.g. centrifuge)
- Full regulatory approval by 1) WHO and / or FDA or 2) emergency listed under WHO EUAL and / or FDA
  EUA or 3) plan to be implemented
- Manufactured under Quality Management System (QMS) ISO 13485
- Integrated quality control
- Proposer’s warranty and extended warranty option, including exchange and product updates
- In country technical support hub
- Proposer after-sale support (distribution, maintenance, software update, etc.) (in case of POC)
### 4.1.9 Technical file submission

All technical documentation and information submitted for the products requested under this RFP is to be included in hard copy and submitted as per the structure in Annex 4. A check list for the documents required is detailed below:

#### RFP - Technical tender document check list

<table>
<thead>
<tr>
<th>#</th>
<th>Information requested</th>
<th>Required documents to be attached with offer</th>
<th>to be attached in Annex 4, section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Product Information sheet</td>
<td>Filled, printed and submitted in hard copy the technical information sheet for each product including item number and schedule (technical sheets are available in Annex 5 in electronic format to facilitate filling information )</td>
<td>Section 1</td>
</tr>
<tr>
<td>2</td>
<td>Product Technical file</td>
<td>Include detailed technical specifications, product design, its workflow, Analytical and clinical studies for validation and verification of the test, field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments), repeatability and reproducibility of results (addressing if any lot variations, any assay limitations...)</td>
<td>Section 2</td>
</tr>
<tr>
<td>3</td>
<td>Proposer Quality Management System (QMS)</td>
<td>Attach a readable copy of the ISO 13485 certificate (certification body, validity, issue by whom and where) of the QMS of the proposer or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF.</td>
<td>Section 3</td>
</tr>
<tr>
<td>4</td>
<td>Proposer QMS</td>
<td>Attach a readable copy of the ISO 13485 certificate (certification body, validity, issue by whom and where) of the QMS of the proposer or an equivalent QMS recognized by a regulatory authority of the founding members of the GHTF (if different from proposer)</td>
<td>Section 4</td>
</tr>
<tr>
<td>5</td>
<td>Marketing licence certificate</td>
<td>Attach a readable copy of the CE 98/79 IVD (or equivalent) marketing approval certificate of product(s) offered.</td>
<td>Section 5</td>
</tr>
<tr>
<td>6</td>
<td>Emergency listing</td>
<td>Attach a readable copy of the acceptance/valid letter to the WHO EUA or FDA EUA. If submission is under review during the tender period, a detailed plan on the timeline to obtain emergency listing approval under the PHEIC from WHO and/or FDA (or explanation reasons that these regulatory approvals are not to be pursued) to be included with following details • Information regarding the product and plans for manufacturing and licensing: • File submission to WHO and/or FDA: Status and plans. • Target date for obtaining the authorization</td>
<td>Section 6</td>
</tr>
<tr>
<td>7</td>
<td>Certificate of shelf life</td>
<td>Attach a formal shelf life certificate from proposer company on its letterhead (signed, stamped and dated) stating product total shelf life in month as well as commitment to supply in case of award products with max 3/4 of shelf life of product(s) offered.</td>
<td>Section 7</td>
</tr>
<tr>
<td>8</td>
<td>Instructions for use (IFU)</td>
<td>Attach a readable copy of the IFU of product(s) offered (minimum in English, more language preferably).</td>
<td>Section 8</td>
</tr>
<tr>
<td>9</td>
<td>Training material</td>
<td>Attach the training material available (poster, pictogram-based step-by-step) of product(s) offered.</td>
<td>Section 9</td>
</tr>
<tr>
<td>10</td>
<td>Hazardous classification</td>
<td>Attach the hazardous classification (including Material Safety Data Sheets -MSDS), including section 14 completed of product(s) offered.</td>
<td>Section 10</td>
</tr>
<tr>
<td>11</td>
<td>Packaging photos</td>
<td>Photos of primary and secondary packaging with readable label information of product(s) offered.</td>
<td>Section 11</td>
</tr>
<tr>
<td>12</td>
<td>Rental/leasing option</td>
<td>Describe the rental/leasing option for the equipment, including: type of rental, time of the leasing, ownership of equipment at the end of the leasing period, swap-out options, preventive and on-calls corrective interventions.</td>
<td>Section 12</td>
</tr>
<tr>
<td>13</td>
<td>Sustainable production/distribution</td>
<td>Please provide answer to the Sustainable procurement in UNICEF Questionnaire – 2016</td>
<td>Section 13</td>
</tr>
</tbody>
</table>
In addition, technical information sheets in Excel format (Annex 5) is available in electronic format to facilitate data entry for all items under the RFP. Only files, printed and signed product information sheets will be considered for the evaluation under this RFP.

4.1.10 Changes from specifications
Wherever items offered are not exactly in compliance with specifications in this RFP or wherever alternatives are offered, it is the proposer's responsibility to provide the Proposal with full descriptive specifications and documentation of such items. UNICEF reserves the right to determine whether any alternative Proposal is acceptable.

4.2 FINANCIAL AND COMMERCIAL REQUIREMENTS

4.2.1 PROPOSERS' REPRESENTATION
The awarded proposer represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources necessary to perform its obligations under the Arrangement.

4.2.2 ACCOUNT MANAGEMENT
The Proposer shall provide UNICEF with organizational charts and names of the responsible persons within each of the following departments: Production, Quality, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF.

UNICEF expects the primary contact person(s) to be able to execute the appropriate account management which includes: accurate and reliable planning and forecasting, efficient order processing, accurate and complete documentation, close production follow up, shipping and logistics as well as any other related issues including fast response time to inquiries. Communication and documentation are expected to be in English. The communication is seen as an important prerequisite for successful account management and needs to be frequent, timely and accurate.

Proposers are not expected to have direct contact with recipient country Governments.

4.2.3 EXPERIENCE IN DIAGNOSTIC SUPPLY & DELIVERY
The Proposer shall demonstrate proven experience and qualification in the supply and delivery of the diagnostics being proposed or any other type of diagnostics product. In addition to the following information, the Proposer may supply other information as deemed appropriate:
- Number of years of production and delivery by diagnostic (quantities);
- Customer reference list by diagnostic. This should include customer contact names and communication information (phone/e-mail/fax) (applicable to all proposers with less than 3 years' experience as a UNICEF proposer); and
- Names of regulatory bodies where products are registered, and date of original registration.

4.2.4 PAST PERFORMANCE RECORD
Proposers not previously supplying UNICEF shall demonstrate that they have been able to provide on-time deliveries and maintained production schedules, and the time period over which the on-time delivery performance has been measured. They shall also advise UNICEF of the annual production quantity.

4.2.5 MEDIUM AND LONG TERM PLANS
Proposer is requested to provide information on their medium and long term plans for production of the diagnostic(s) being offered, or on diagnostics that may be offered in the future. This includes providing an overview of business factors affecting the decision to produce the diagnostic(s) at the quantities offered.
4.2.6  CURRENCY OF PROPOSAL
The currency of the proposal shall be either 1) US Dollars or 2) US Dollars and Euro. Proposers wishing to offer in Euro are requested to offer one price in US Dollars and one price in Euro, leaving it to UNICEF’s sole discretion to determine which price to accept and consider for award. For evaluation purposes, the Euro price will be converted to US Dollars using the official UN currency exchange rate on the deadline date for receipt of proposals.

4.2.7  AFFORDABILITY OF PRICES OFFERED
The Proposer is requested to provide information on factors that influence the pricing offered to UNICEF including, the basis for any quantity-based pricing. Any price increase over previous years’ pricing should be explained. UNICEF believes in paying a price that is affordable to Governments and Donors and a price that reasonably covers proposers’ minimum requirements.

4.2.8  INCOTERMS AND UNIT PRICING
Unit pricing is to be provided on a FCA nearest international airport basis (Incoterms 2010). The name and location of the international airport is to be specified.

4.2.9  MINIMUM QUANTITY GUARANTEES AND FIRM CONTRACTING (ADVANCED PURCHASE COMMITMENT)
The quantities specified in the tender will be based on a UNICEF forecast and include procurement volumes for UNICEF. This tender includes the offer to guarantee purchasing of specified quantities between 2017 and 2019 under the Advanced Purchased Commitment as detailed in sections 2.6 and 3.1

UNICEF may enter into a conditional firm commitment to procure from proposers who meet the minimum evaluation criteria and other requirements outlined in the tender, and as assessed as part of the procurement process in line with the broader strategic goals of the project.

The firm commitment would be contingent upon the proposer being able to develop a product according to the specifications outlined in the tender, achievement of all necessary regulatory approval(s), and making the product available as agreed to in the purchase commitment (including timelines), and other pre-determined contingencies, at the discretion of UNICEF.

4.3 EVALUATION OF PROPOSALS AND BASIS FOR AWARD
The merits of each proposal will be evaluated to assess its ability to support the objectives of this tender: secure access of affordable, quality assured, diagnostic testing at point of care (POC) ZIKV products by supporting the development of novel devices, creating a healthy and stable market.

If a proposer has not been a supplying UNICEF previously, UNICEF reserves the right to introduce the proposer incrementally during the award period and assess its performance closely.

4.4 EVALUATION METHODOLOGY:
The evaluation consists of two main reviews: 1) Review of Technical Requirements (TECHNICAL PROPOSAL) 2) Review of Quantitative and Qualitative Content of the proposal (COMMERCIAL PROPOSAL).

4.4.1  REVIEW OF TECHNICAL MANDATORY REQUIREMENTS
The technical evaluation will be conducted in two steps:
Step 1: Review of technical mandatory requirements mentioned in section 4.2.6 (points 1 to 7).
Step 2: Only proposals which meet the general mandatory requirements will be considered further. As a second step, proposals that pass successfully step 1 will be evaluated against the remaining product technical criteria as explained under section 4.2.7 and will be scored according to the scoring mentioned in table 2.
Note: For an offer to be eligible for an award, all technical mandatory requirements must be met. Please refer to section 4.2.6 for further information.

If the proposal is deemed interesting in its potential ability to support the objectives of this tender and meets the mandatory technical requirements, except that the product is not yet regulatory approved by WHO and/or FDA or listed under WHO EUAL or FDA EUA, UNICEF will proceed as outlined in Section 4.4.4

### 4.4.2 EVALUATION OF QUANTITATIVE AND QUALITATIVE CONTENT

During this evaluation, the nature of the commercial proposal will be studied and compared to the evaluation criteria. In order to obtain to what extent a proposal is found satisfactory, all quantitative data will be evaluated together with the qualitative data to determine how the factors presented in each proposal will support the Procurement Strategy objectives mentioned in the strategy document.

#### Overview of Quantitative and Qualitative

**Table 3 : Quantitative and Qualitative Criteria**

<table>
<thead>
<tr>
<th>Tender Objectives</th>
<th>Quantitative Criteria</th>
<th>Qualitative Criteria</th>
</tr>
</thead>
</table>
| Affordable product                             | • Price FCA nearest main airport;  
• Incoterms offered;  
• Payment terms in-line with UNICEF payment terms.                                                                                                                                                                  | • Factors that influence the pricing offered to UNICEF.                                                                                                                                                               |
| Quality product                                 | • Gross weight and volume.                                                                                                                                                                                                | • Country feedback/Customer acceptance, if available;  
• Initiative to resolve problems in a satisfactory and fast manner;  
• Compliance with UNICEF Terms and Conditions;  
• Maintenance of reliable product quality;                                                                                                                                                                         |
| Reliable, uninterrupted supply                 | • Quantity offered and timelines;  
• Conditions of quantity offered;  
• Alternative delivery points (if any);  
• Lead-time;  
• Monthly production capacity and long term manufacturing plans;  
• Validity period of proposal;                                                                                                                                                                                     | • Account management resources (organizational charts with names) and customer service capabilities.  
• Proven capacity to supply offered and forecasted quantities;  
• Realistic quantity and timelines offered.  
• Ability to store Diagnostics if needed.                                                                                                                                                                           |
| Healthy competition                             | • Numbers of years of production and delivery (quantity);                                                                                                                                                                | • Experience in production /supply and delivery:  
• Customer reference list;  
• Sharing of information regarding plans and availability                                                                                                                                                          |
| Availability of newly innovative products       | • offered products falls under the tender and APC categories  
• number of products available beyond 2020                                                                                                                                                                              | • Proven capacity to develop ZIKV diagnostics with differential diagnosis with other flavivirus post APC                                                                                                             |
4.4.3 BASIS FOR AWARD

Upon evaluation of all proposals, taking into consideration the actual market situation for each diagnostic, the forecasted quantities will be awarded to proposers in accordance with the objectives of this tender.

4.4.4 PRODUCT REGULATORY STATUS DURING TENDER PROPOSALS FOR PRODUCTS NOT YET WHO/ FDA RECOMMENDED / AUTHORIZED FOR EMERGENCY USE

As UNICEF is targeting novel under-development diagnostics in response to the ZIKV PHEIC, UNICEF expects receiving proposals for products without a full market release status at the time of submitting an offer. Therefore, if the product offered is not listed by WHO EUAL or FDA EUA at the time of submitting an offer BUT meets all other mandatory technical requirements mentioned in section 4.2.6, the offers will be reviewed in light of the three listed scenarios below:

Scenario 1: The proposed diagnostic product has applied for WHO emergency use under EUAL but the file is still under review process during the award period:
Upon confirmation that the mandatory requirements of the RFP are met, UNICEF would consider awarding a quantity to the proposer once the product is listed under EUAL.

Scenario 2: The proposed diagnostic product has applied for FDA emergency use under EUA but the file is still under review process during the award period:
Upon confirmation that the mandatory requirements of the RFP are met, UNICEF would consider awarding a quantity to the proposer once the product is listed under EUA. In addition, complete evaluation of proposer QMS will be performed as per UNICEF Quality Assurance Policy for Procurement diagnostics provides testing at Point-of-Care including Rapid Diagnostics (RDTs) / Point of Care technology (POC) prior to issuing any purchase order under the conditional LTA.

In both above 2 scenarios, proposals must include a detailed plan on the timeline to obtain emergency listing approval that was open under the PHEIC from WHO and/ or FDA (or explanation reasons that these regulatory approvals are not to be pursued). The timeline should include the following triggers to enable considering the offers for contract awards:

- Information regarding the product and plans for manufacturing and licensing;
- File submission to WHO and / or FDA: Status and plans.
- Target date for obtaining the authorization

Scenario 3: The proposed diagnostic product is neither under consideration by either WHO or FDA emergency use under EUAL or EUA but has been released to market from one of the stringent regulatory authority (CE or equivalent as explained under the UNICEF Quality policy):
If the novel product is highly technically rated in terms of both technology and specificity, then UNICEF will:
- Evaluate the clinical performance of the product by facilitating independent lab testing as per the WHO EUAL requirement
- Fully Evaluate proposer QMS as per UNICEF Quality Assurance Policy for the Procurement of Rapid Diagnostics/Point of Care Technology.

For access to the APC, UNICEF may consider establishing conditional awards for any of the above mentioned scenarios which turn into ‘firm commitment’ upon proposer meeting appropriate triggers listed above (or others, at UNICEF’s discretion).
4.5.5 FIELD EVALUATION
UNICEF requires demonstration of a successful “field-evaluation” trial of the novel IVD ZIKV detection technologies.

- The purpose of the field evaluation will be to receive feedback from the actual target user group and prior to widespread distribution of products not supplied by UNICEF before.
- The field evaluation protocols and results will be evaluated by UNICEF Supply Division and UNICEF programme staff for acceptability.

Any award will be made contingent upon successful results of such field evaluation, and no deliveries to UNICEF will be accepted prior to completion of the evaluation.

Proposers are welcome and encouraged to submit - as part of their Proposals - protocols, including Terms of Reference, questionnaires used, number of users and products as well as results of trials conducted without UNICEF involvement for evaluation by UNICEF. Only trial provided as a part of the Proposal will be evaluated.

In the case a trial conducted by the Proposer should be deemed sufficient by UNICEF, no further UNICEF trial would be required for that product.

4.5.6. UNICEF AWARD STRATEGY
The long term arrangement(s) will be awarded to the Proposer(s) offering a combination of: the lowest acceptable prices and shortest lead time, whose products are commercially, technically and quality acceptable and whose proposal is in compliance with all instructions, specific terms and General Terms and Conditions contained in the RFP, provided the proposal is reasonable and it is in the interest of UNICEF to accept it. Proposals will be adjudicated on USD price FCA nearest airport Incoterms.

Offers that are deemed commercially, financially, technically and QA acceptable and are in line with objectives of the procurement strategy will be recommended for award as per the APC segmentation mentioned in section 3.1.

The resulting awards will be non-exclusive LTA(s) Long Term Agreement which will set out the quantities awarded and stipulate whether it includes any guaranteed procurement for APC quantities (for proposers who qualify to access the APC) and the awarded forecasted non-committed quantity to be procured for non-APC quantities.

Offers made to access the APC, must also include a non-APC price. During the tender validity period, however, any supplier who receives an APC award would be expected to have non-APC prices which are less or equal to the APC price. It is UNICEF’s expectation that suppliers will offer meaningful quantities in both categories of the offer. If a supplier makes an offer for APC quantities, a comparably meaningful or higher number of quantities would be expected to be offered in the non-APC quantities.

Even though UNICEF procurement requires regulatory approval being WHO or FDA approved or emergency authorized under WHO EUAL or FDA EUA, conditional awards may be made to proposers where their proposed products fall under any of the conditions mentioned under section 4.4.4 and can document that their products have successfully undergone field evaluations, are going through the regulatory approval process, meet the technical and QA requirements, and are available within a reasonable period during the duration of this contracting period. Such an award would then be “activated”, once such a claim is proven to fulfill all the requirements within the validity of the tender and if the product is deemed commercially, technically and QA acceptable.
4.5 SPECIAL TERMS AND CONDITIONS

4.5.1 UNETHICAL BEHAVIOUR
UNICEF strictly enforces a policy of zero tolerance concerning unethical, unprofessional or fraudulent acts of UNICEF Proposers. Accordingly, any registered Proposer that is found to have undertaken unethical, unprofessional or fraudulent activities will be suspended or forbidden from continuing business relations with UNICEF.

4.5.2 CORRUPT AND FRAUDULENT PRACTICES
UNICEF requires that all Proposers associated with this Request for Proposal observe the highest standard of ethics during procurement and execution of the work. In pursuance of this policy UNICEF

a) Defines for the purpose of this provision the terms set forth as follows:
   i. Corrupt practice means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in the execution of a contract, and
   ii. Fraudulent practice means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the client, and includes collusive practice among Proposers (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the client of the benefits of free and open competition;

b) Will reject a proposal for award if it determines that the selected proposer has engaged in any corrupt or fraudulent practices in competing for the contract in question;

c) Will declare a Proposer ineligible, either indefinitely or for a stated period of time, to be awarded a UNICEF-financed contract if at any time it determines that it has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNICEF-financed contract.

4.5.3 DISCLOSURE OF SANCTIONS OR TEMPORARY SUSPENSION
Only proposers found to be responsible or conditionally responsible are eligible to be awarded UNICEF contracts and/or to bid on UNICEF solicitations. To be deemed a responsible proposer with whom UNICEF will conduct business, a proposer should not be suspended, debarred, or otherwise identified as ineligible by the World Bank Group, any of its member governments or any other International or UN Organization. Proposers are therefore required to disclose to UNICEF whether they are subject to any sanction or temporary suspension imposed by the World Bank Group, any of its member governments or any other International or UN Organization.

4.5.4 OFFICIALS NOT TO BENEFIT
The Proposer warrants that no official of UNICEF or the United Nations has received or will be offered by the Proposer any direct or indirect benefit arising from this Request for Proposal or the award thereof. The Proposer agrees that breach of this provision is a breach of an essential term of the Request for Proposal.

4.5.5 GUIDELINES ON GIFTS AND HOSPITALITY
Proposers shall not offer gifts or hospitality to UNICEF staff members. Recreational trips to sporting or cultural events, theme parks or offers of holidays, transportation, or invitations to extravagant lunches or dinners are also prohibited.

4.5.6 MOST FAVOURED NATION
If at any time during the validity period of the Long Term Agreement, the awarded proposer offers to sell the diagnostic at a price lower than the price effective under the Long Term Agreement, the awarded proposer shall offer the same price to UNICEF for the remaining validity period of the Long Term Agreement.
4.5.7 GENERAL TERMS AND CONDITIONS
The UNICEF General Terms and Conditions attached to this bid (Annex A) shall apply to any resulting LTA and related Purchase Orders. In the case of any inconsistencies, the following order of precedence shall prevail:

(a) The Purchase Order;
(b) The LTA.

4.5.8 RIGHTS OF UNICEF
The provision “RIGHTS OF UNICEF” under the UNICEF General Terms and Conditions (GTC) which are annexed to and constitute an integral part of the present solicitation is complemented as follows:

(d) For late delivery of Goods or for items which do not meet UNICEF’s specifications and are therefore rejected by UNICEF, claim liquidated damages from the Contractor and deduct 0.5% of the value of the Goods pursuant to a Purchase Order per additional day of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Contractor from any of its other obligations or liabilities pursuant to this LTA or a Purchase Order.
5. ANSWER SHEETS

PROPOSAL FORM

PROPOSAL FORM must be completed, signed and returned to UNICEF. Proposals must be made in accordance with the instructions contained in this REQUEST. UNICEF shall not pay any costs incurred in the preparation or submission of proposals.

TERMS AND CONDITIONS OF LONG TERM ARRANGEMENT
Any Long Term Arrangement resulting from this REQUEST shall contain the UNICEF General Terms and Conditions and any other terms and conditions specified in this REQUEST.

INFORMATION
Any request for additional information regarding this REQUEST must be forwarded in writing to the attention of Contracts Manager, Lama Suleiman (email: lrsuleiman@unicef.org) with specific reference to this REQUEST, so that the query may be answered in the normal course of business.

The Undersigned, having read the Instructions to Proposers of this REQUEST RFP-DAN-2017-502425 and all related documents hereby offers to supply the goods and contributions to meet the overall objectives sought in accordance with any specifications stated and subject to all Terms and Conditions set out or specified in this REQUEST.

Signature: _______________________________________

Date: _______________________________________

Name & Title: _______________________________________

Company: _______________________________________

Postal Address: _______________________________________

Tel No: _______________________________________

Fax No: _______________________________________

E-mail: _______________________________________

Validity of Offer: _______________________________________


TECHNICAL AND FINANCIAL MANDATORY REQUIREMENTS SHEET

Please include a response to the following.

1. Does each product offered listed under WHO EVAL?

2. If the answer to the above is "No", then please provide a detailed plan on your timeline to obtain WHO pre-qualification. The timeline should include information regarding the product and plans for manufacturing and licensing, including the key milestones below. A timeline should be provided for each product offered that is not pre-qualified.
   a) File submission to WHO: Status and plans
   b) Product Development: Status and plans
   c) Clinical studies for validation and verification of the test field testing studies (accuracy and correlation with applicable standards, and its clinical effectiveness, robustness of the technology in low-income country environments, Trials conducted so far and planned, with timelines;
   d) Regulatory Registration: Status and plans for registration, including 5 stringent regulatory authorities stated in the UNICEF technical provisions

3. Please provide your United National Global Marketplace (UNGM) registration number

If your company has not yet registered through the UNGM, please submit an application through the UNGM website at
http://www.ungm.org
under

Instructions are provided on the site.

4. Please provide the technical file with the required documents mentioned under point 4.2.9 “Technical tender document check list” for technical proposal evaluation

5. Have you provided audited financial statements to UNICEF in the past 12 months?

If not, please proceed as per clause 3.15.2.
QUALITATIVE PROPOSAL SHEET

Please provide response to the following in your proposal together with any other information deemed relevant.

1. Confirm your acceptance to UNICEF general terms and Conditions attached

2. Advise the number of years that your company has of production and delivery of the offered product(s).

3. For proposers with less than 3 years of experience as a diagnostic proposer to UNICEF, please provide a full customer reference list, delivery report and delivery performance report for the minimum period of the past 3 years. Advise of the reasons for delays in deliveries and frequency, as well as measures taken to resolve the delays.

4. Provide organizational charts and names of the responsible persons within each following department: Production, Quality, Governmental Affairs, Shipping/Logistics, Sales and Marketing, specifying the name(s) of the person(s) who will be the primary contact for UNICEF.

5. Provide any country feedback /customer acceptance of the offered product(s) if available and explain your initiatives to resolve problems in satisfactory and fast manner.

6. Please confirm willingness to provide additional documentation when requested by countries.

7. Please include in your proposal your total annual production capacities for final product for each offered diagnostic.

8. Please advise whether the production of any of the diagnostics offered affects the production, or potential production, of another diagnostic being offered by your company. If yes, please advise which diagnostic.

9. Please indicate the capacity and willingness to store diagnostics on a need basis and maintain a buffer stock, indicating any conditions that may apply.

10. In the past, how has your company been able to maintain the quality level for the supplied products? If your company has faced quality problems, please provide frequency and explanations as well as measurements taken for improvement.

11. Given that UNICEF has requested prices that are affordable to the poorest country governments and donors, please indicate factors influencing your price setting. Please also confirm agreement to share information impacting pricing e.g. cost drivers, on request.

12. Please provide information on your medium and long term plans for production of the diagnostic being offered, including an overview of business factors effecting the decision to produce the diagnostic at the quantities offered to UNICEF.

13. Please provide all available detail on planned changes and improvements to the existing products, including when and how such are included in the Proposal.

14. Please use the Alternative Proposals sheet - as many as necessary - to provide proposals for alternative existing or future product presentations. The information should include all features of the offered
diagnostic, including a separate Shipping and packing information sheet, and highlight where the products differ from the current products.

15. Please provide information on your packaging and labelling for the products offered and confirm your adherence to UNICEF's packing and shipping requirements,
QUANTITATIVE PROPOSAL SHEET (1)
Schedule 1: ZIKA RDT Antibody(Ab) detection technology

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the diagnostic in quantities, at prices and within the number of days indicated below:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Unit</th>
<th>Unit price per test USD * under APC</th>
<th>Unit price per test USD ** for non APC</th>
<th>Conditions/Discounts ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>010</td>
<td>U481900 ZIKV RDT Ab detection test, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>020</td>
<td>U481900 Multiplex (ZIKV / X Arbovirus) RDT Ab detection test, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>030</td>
<td>U481900 Various reagents, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>040</td>
<td>U481900 Various consumables, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>050</td>
<td>U481900 Various devices if needed, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Offers must be quoted in USD. (If an offer is quoted only in USD, the USD column needs to be completed.) If an alternative offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Sections 4.3.7 CURRENCY OF PROPOSALS for further information.

** Offers made to access the APC, must also include a non-APC price.

***Please indicate in the columns “conditions/discounts” with check mark if there are any conditions/discounts associated with the price offered in your proposal. Please outline the details of the conditions/discounts below.

****Proposers may change the unit of measurement as applicable.

INCOTERMS (2010) FCA Nearest International Airport (Name Airport): ___________

Total annual production capacity:

Minimum shelf life for offered products:

Delivery preparation lead time
Please indicate the time required from receipt of our purchase order for preparation of delivery (administration of order, packing, markings, etc.) ready for shipment: _______ days

Country of Origin:
QUANTITATIVE PROPOSAL SHEET (2)
Schedule 2: ZIKA RDT antigen (Ag) detection technology

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the diagnostic in quantities, at prices and within the number of days indicated below:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Unit</th>
<th>Unit price per test USD * under APC</th>
<th>Unit price per test USD ** for non APC</th>
<th>Conditions/Discounts ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>060</td>
<td>U81900 ZIKV RDT Ag detection test, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>070</td>
<td>U81900 Multiplex (ZIKV / X Arbovirus) RDT Ag detection test, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>080</td>
<td>U81900 Various reagents, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>090</td>
<td>U81900 Various consumables, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0100</td>
<td>U81900 Various devices, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Offers must be quoted in USD. (If an offer is quoted only in USD, the USD column needs to be completed.) If an alternative offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Sections 4.3.7 CURRENCY OF PROPOSALS for further information.
** Offers made to access the APC, must also include a non-APC price.
*** Please indicate in the columns “conditions/discounts” with check mark if there are any conditions/discounts associated with the price offered in your proposal. Please outline the details of the conditions/discounts below.
**** Proposers may change the unit of measurement as applicable.

INCOTERMS (2010) FCA Nearest International Airport (Name Airport):

Total annual production capacity:

Minimum shelf life for offered products:

Delivery preparation lead time
Please indicate the time required from receipt of our purchase order for preparation of delivery (administration of order, packing, markings, etc.) ready for shipment: _____ days

Country of Origin:

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QUANTITATIVE PROPOSAL SHEET (3)
Schedule 3: POC nucleic acid testing (NAT) technology

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the diagnostic in quantities, at prices and within the number of days indicated below:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Unit</th>
<th>Unit price per test USD * under APC</th>
<th>Unit price per test USD ** for non APC</th>
<th>Conditions/Discounts ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>110</td>
<td>U481900 POC nucleic acid testing (NAT) technology, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>120</td>
<td>U481900 Multiplex POC nucleic acid testing (NAT) technology, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>130</td>
<td>U481900 Various reagents, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>140</td>
<td>U481900 Various consumables, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>150</td>
<td>U481900 Various devices, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Offers must be quoted in USD. (If an offer is quoted only in USD, the USD column needs to be completed.) If an alternative offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Sections 4.3.7 CURRENCY OF PROPOSALS for further information.

** Offers made to access the APC, must also include a non-APC price.
***Please indicate in the columns "conditions/discounts" with check mark if there are any conditions/discounts associated with the price offered in your proposal. Please outline the details of the conditions/discounts below.
****Proposers may change the unit of measurement as applicable.

INCOTERMS (2010) FCA Nearest International Airport (Name Airport): ____________

Total annual production capacity:

Minimum shelf life for offered products:

Delivery preparation lead time
Please indicate the time required from receipt of our purchase order for preparation of delivery (administration of order, packing, markings, etc.) ready for shipment: ______ days

Country of Origin:
ALTERNATIVE PROPOSAL SHEET (4)
Schedule 4: ZIKV RDT/POC IVD technologies other than mentioned under sheets 1-3

In compliance with terms and conditions of this Request for Proposal and all sections hereto, the undersigned offers the supply of the diagnostic in quantities, at prices and within the number of days indicated below:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Unit</th>
<th>Unit price per test USD * under APC</th>
<th>Unit price per test USD ** for non APC</th>
<th>Conditions/Discounts ***</th>
</tr>
</thead>
<tbody>
<tr>
<td>160</td>
<td>U481900 ZIKV RDT/POC IVD technologies, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>170</td>
<td>U481900 Various reagents, as per the technical specification Annex 1</td>
<td>test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>180</td>
<td>U481900 Various consumables, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>190</td>
<td>U481900 Various devices if needed, as per the technical specification Annex 1</td>
<td>Each****</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Offers must be quoted in USD. (If an offer is quoted only in USD, the USD column needs to be completed.) If an alternative offer is provided in EURO please ensure that both USD & EURO prices are given. Please refer to Sections 4.3.7 CURRENCY OF PROPOSALS for further information.
** Offers made to access the APC, must also include a non-APC price.
*** Please indicate in the columns “conditions/discounts” with check mark if there are any conditions/discounts associated with the price offered in your proposal. Please outline the details of the conditions/discounts below.
**** Proposers may change the unit of measurement as applicable.

INCOTERMS (2010) FCA Nearest International Airport [Name Airport]: ___________

Total annual production capacity:

Minimum shelf life for offered products:

Delivery preparation lead time
Please indicate the time required from receipt of our purchase order for preparation of delivery (administration of order, packing, markings, etc.) ready for shipment: _____ days

Country of Origin:
COMMERCIAL TERMS SHEET

In compliance with the Instructions to Proposers of this Request for Proposal and all sections hereto, the undersigned offers the supply of the diagnostic under the conditions and in quantities, at prices and within the number of days as indicated in the QUALITATIVE PROPOSAL SHEET AND QUANTITATE PROPOSAL SHEET(S); and the undersigned accepts in full the TERMS and CONDITIONS.

Signature: ____________________________________________

Date: ______________________________________________

Name & Title: _________________________________________

Company: ____________________________________________

Please indicate which of the following terms of payment are offered under this proposal:

(Multiple terms can be selected)

10 days 3.0% _____ 15 days 2.5% _____ 20 days 2.0% _____

30 days net _____ Other _____

Any requested EXCEPTIONS or CLARIFICATIONS are to be defined below (additional pages maybe attached):