Rapid *E. coli* Detection

UNICEF Supply Division

UNICEF Supply Division, in collaboration with the WHO/UNICEF Joint Monitoring Programme on Water Supply and Sanitation, launched a revised Target Product Profile (TPP) for Rapid *E. coli* Detection. This replaced the version issued in 2016 and incorporates the feedback collected during the Stakeholder Consultation held in November of last year.

Please note:

- The TPP is not a tender document
- TPPs are issued to guide industry to develop products that meet UNICEF's requirements
- Further information including a high level timeline is available in the TPP brief.

This TPP is now open for consultation and UNICEF is receiving questions from product developers and suppliers. To ensure transparency, all answers and clarifications will be published below. Suppliers are therefore encouraged to visit this document on a regular basis to view answers and clarifications which may be relevant to them. New questions not answered below or on the TPP page, can be sent to washsupply@unicef.org with the subject line "Rapid *E. coli* Detection".

1. **Time for detection: The TPP version 2.0 doesn't contain the footnote exception of the previous TPP ("Time to result of maximum 24 hours would be acceptable for tests with unit cost of less than $1 USD with room temperature incubation. Specificity and sensitivity remain in line with minimum requirements"). May we know the reason? Would UNICEF still be interested in such a potential product?**
   UNICEF is still interested in bringing down the cost of existing products on the market, but we have removed the footnote from the TPP as it is more in line with our regular procurement of currently available water quality tests rather than part of the innovation project to stimulate radically improved products. UNICEF always procures based on fit for purpose and value for money principles. Any reductions in costs for quality products will be seen as favorable during the commercial (financial) evaluation of bids received. Please note that the ideal requirement for unit cost is still $1 per test.

2. **Timeline: What would UNICEF advise to a product developer that has been working on the subject and seeing promising lab results but would not likely meet the new timeline (products for evaluation to be selected and lab evaluated in January 2018)?**

   The final modality and timeline for the RFP on Rapid E. coli Detection is not yet defined, but for other product innovation RFPs, we have tried to accommodate the varied development timelines of suppliers. As an example, for other innovation projects, the RFP solicited information including preliminary test results and expected timelines for development and regulatory approvals in the first phase, but suppliers had additional time (36 months) to deliver actual prototypes for testing if they were selected to pass on to phase 2. For the E. coli project, UNICEF is currently reviewing information

from the supplier base and will determine the appropriate lead time in order to ensure the maximum amount of bidders and competition.

3. **Evaluation process: When will the protocol for lab evaluation, and the protocol for field evaluations be available?**

   UNICEF is working closely with WHO to discuss the lab and field trial requirements for novel technologies. The RFP may not include a full protocol, but will include further details on the reference standard against which new solutions should be tested, and the requirements for submitting validation of results.

4. **Detection limit: Does UNICEF mean to detect viable *E.coli*, or just *E.coli*?**

   UNICEF aims to determine health risk. Traditional methods of utilizing E. coli as an indicator of potential health risk rely on detecting viable E. coli. However, novel technologies that are able to equate detection of non-viable bacteria to the same level of risk as viable could be considered.

5. **Throughput: How many tests shall be run in parallel?**

   In reference to the TPP, this would be evaluated under the "testing methodology" criteria, which indicates that the process steps should be minimal—it therefore must be considered if the ability to run multiple tests increases efficiency in comparison to an easy-to-use single test. For the data collection use cases, the ability to run multiple tests in parallel could be useful (possibly up to 10 or 20) but it may be more valuable to understand how many tests can be run in a single day rather than throughput in parallel.

6. **How will UNICEF prioritize the key criteria, including time to result, ease of use, and cost?**

   UNICEF standard process for RFPs includes both technical and financial evaluations, and utilizes a scoring system that will allocate points to the various criteria. The scoring system will be detailed in the RFP documents once published. Solutions are evaluated based on their combined financial and technical score, allowing for each proposal's benefits to be considered.

7. **Is UNICEF interested in the detection of other organisms in addition to *E. coli*?**

   The RFP will not include requirements for detection of any other organisms (e.g. vibrio cholerae), however platform technologies that can serve multiple purposes are in line with UNICEF's long term goals, and may be sought after in future.

8. **Will the protocol include positive or negative controls?**

   The protocol has not been completed yet, and may be different depending on the technology type. Suppliers will be updated on this as soon as possible.