UNICEF Target Product Profile
Rapid *E. coli* Detection tests

Version 3.0

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Purpose of the UNICEF Target Product Profile (TPP): *The medical and pharmaceutical industries often use TPPs as a planning or strategic document during the research and development phases of new devices or drugs. TPPs typically include information on how the new product will be used, by or for whom, and both the minimum and ideal criteria for its functionality or performance. UNICEF has chosen to adopt this format for communicating the needs and requirements for new products to be used in the unique context in which UNICEF and its partners work.*

Need for the Product

Faecal matter is the prime source of microbiological contaminants of concern in drinking water. Many of these are pathogens that cause diarrhoea, which is still a major cause of child death in developing countries. Faecal contamination is currently measured through the quantification of viable indicator bacteria. *E. coli* is the World Health Organization's (WHO) preferred indicator for faecal contamination of drinking water (including water intended for household use such as for food preparation or personal hygiene). Unfortunately, the main methods that are currently available and used by UNICEF and its partners in the field to quantify *E. coli* contamination typically involve long incubation periods and complicated processes that require specialized training with multiple opportunities for error, leading to the possibility of inaccurate results. These features limit the ability of UNICEF and its partners to do water testing on site, understand and communicate risk, launch community-led water quality monitoring programmes, and integrate water testing into national household surveys (e.g. Multiple Indicator Cluster Surveys).

Background

Role of Diagnostics for Water Safety

Faecal contamination, and microbiological contamination more generally, are not the only risks to safe drinking water. Other risks include chemical contamination, such as arsenic and fluoride, which must also be identified and addressed. The assessment of water quality is only one aspect of a larger systematic approach to ensuring safe drinking water. While the information on water quality is critical for understanding health risks or monitoring progress, it must be coupled with strong regulatory frameworks and policies at national and sub-national levels, as well as efforts to improve and maintain infrastructure, and strengthen community awareness, water resource management and education. Given that regulations and policies often differ across countries and regions, standards for establishing and monitoring water quality can vary substantially. As a result, a single solution for water quality testing is not possible and it is important that governments and communities have a variety of tools that can support a system-wide approach to water safety.

Programmatic Relevance for UNICEF

Diarrhoea is one of the main causes of under-five mortality, with 58 per cent of diarrhoea-related diseases attributed to inadequate access to safe water, sanitation and hygiene (WASH) services (WHO/Prüss et al. 2014). In an effort to reduce this disease burden, UNICEF supports governments to increase access to improved water sources and provides technical support on water safety planning and water quality monitoring. In addition, UNICEF places a key focus on improving water quality at the household level through activities that promote household water treatment and safe storage, raise awareness, encourage social accountability, and provide education and training.

Current products or response utilized by UNICEF:

In humanitarian and development contexts in which UNICEF works, laboratory testing for *E. coli* is often not feasible due to a lack of necessary infrastructure available in such environments. Samples must therefore be processed on site or nearby, typically with limited access to cold chain transport or reliable electricity. Currently UNICEF uses the following testing methodologies for *E. coli* testing in field locations:

Portable Lab Kits: This is a complete system including consumables and is capable of quantification to one colony forming unit (CFU)/100mL. The lengthy methodology uses membrane filtration, a growth medium specific for *E. coli* or thermotolerant coliforms (an alternative indicator to *E. coli)* and a portable electric incubator. Results can be achieved within 14-18 hours at 44°C or 37°C. Kit operation requires technical skills and ancillary components such as a pressure cooker or autoclave for sterilizing equipment between samples and preparing the growth medium. There is also a high risk of cross-contamination when filtering samples and placing the filters on plates with a growth medium.

- Approximate cost: Ranges between US$1,000 - US$3,000 per kit, excluding consumables.

H_2S Presence/Absence Test: This is a simple method for detecting the presence of hydrogen sulphide producing bacteria (an alternative indicator of faecal contamination) but cannot quantify the magnitude of contamination. This method does not require technical training but still requires a 24-hour incubation period (though it can be done at room/body temperature). This test can yield false positives, depending on the type of water source, due to the natural presence of these bacteria in tropical soils. Tests are one-time use.

- Approximate cost: US$0.50 - US$2 per test.

Fluorogenic Presence/Absence Test: This assay allows for the detection of both total coliforms and *E. coli* in 10mL or 100mL samples but cannot quantify the magnitude of contamination. Tests are typically conducted using pre-prepared bottles, tubes, or plates, and incubated (in some cases at ambient or body temperatures) for 24 hours before reading. A visual colour change indicates total coliform presence, and fluorescence under a UV light indicates presence of *E. coli*. Tests are one-time use.

- Approximate cost: US$3 - US$5 per test.

Most Probable Number Tests (MPN): This involves a sterile collection bag, multi-well tray, or tube test-based system for detecting *E. coli* that quantifies contamination using the MPN method. MPN tests have no quantification of the levels of *E. coli* and performance can vary depending on the type of water source due to the measurement of hydrogen sulphide production rather than more specific markers of *E. coli*. In most cases, 18-24 hours of incubation is required and depending on the growth media, the incubation temperature may require control (e.g. at 35°C) or could be done at body or room temperature, provided this exceeds 25°C. Tests are one-time use.

- Approximate cost: US$6 - US$10 per test.

Pre-Prepared Plates: This methodology uses plates that have been pre-prepared with dehydrated growth media, which creates a gel when the sample is added. Quantification is possible by combining it with membrane filtration. A 24-hour incubation at room/body or fixed temperature is required. Training for membrane filtration is required and special care is needed to avoid contamination of the water samples. Pre-treated plates form part of the standard module that is available for Multiple Indicator Cluster Surveys (MICS) and has been piloted in Living Standards Measurement Study (LSMS) surveys.

- Approximate cost: US$1 per test; US$1,500 per kit.

Use of the Product by UNICEF and Partners

There are a number of uses for water quality tests in both high and low-resource settings, and in large and small water systems alike. This document describes the key Use Cases for UNICEF and its partners, focused primarily on low-resource settings.

Use Case A: Household Surveys and MICS

Household surveys are implemented to collect data on key development indicators for health, nutrition, education and WASH programming. The surveys are typically conducted every three to five years and the data allows governments and service providers to monitor progress and identify areas for improvement. They cover 1,000 to 20,000 households depending on the country and may require up to 80 survey teams working full time for a number of months. Typically, a survey team will spend one to two hours per home asking questions. For collecting data on water quality, a water sample will be collected for a subset of households. Data on faecal contamination of drinking water are the primary objectives for water quality testing, and in most surveys, faecal contamination is measured using *E. coli*.

For those households where a water sample is collected, the household will be asked to provide a “glass of drinking water members of the household would usually drink” and will also be asked for information on the location of the water source. Source water is then tested at the point of collection which can range from a dug well to a public tap or borehole. Samples are then processed in the field (which takes approximately 10 minutes for membrane filtration), and then incubated for a period of at least 24 hours, after which results can be recorded

Use Case A: Household Surveys	
End-user description:	Government survey teams trained by UNICEF/WHO. Teams typically receive extensive training on survey methodology with 3-4 days allocated to the water quality module.
Skill/Education level:	Team members are formally educated to a minimum high school level. They receive specialized training for the surveys but typically are non-WASH specialists and do not have previous laboratory experience.
Use environment:	Surveys are usually national in scope, covering both urban and rural contexts. Power supply is not always available.
Geographic location:	Surveys are implemented around the world in all climates and in both high and low-income countries.
Purpose of the data collected:	Primarily national/country-wide data on water quality is collected to monitor progress over time and understand water quality for different regions/population groups. It may also be used for monitoring progress of the Sustainable Development Goals (SDG). Where appropriate, a rapid test could offer the opportunity to provide households with immediate feedback on water quality.
Current products used:	Pre-treated plates, Portable lab kits, and some Fluorogenic Presence/Absence tests.
Priority TPP criteria:	Quantification, Sensitivity, Specificity, Testing methodology, and User Training.
Demand Forecast for Ideal Solution:	An easy-to-use, rapid test would allow significantly more surveys to integrate water testing and a larger sample size per survey. In the period of Jan-Aug 2019 UNICEF procured 130,000 tests, an increase of 88 per cent from the year before (for MICS purposes only). UNICEF expects an upward trend to continue as more countries work with UNICEF to adopt the MICS water survey module.

Use Case B: Community-led monitoring, Behaviour change, and Emergency preparedness

There are a number of water testing activities that can be considered to enable the recording of water quality results at the community level, either by community workers, co-operatives or individuals. The results inform communities and decision makers about changes needed to water treatment processes and dosing, in addition to prompting advocacy activities to spark change in behaviour practices related to bacterial water borne diseases.

i. **Community-led monitoring**

Community-led monitoring allows communities to take responsibility for the surveillance of their own water source. This may be through local health workers, local government actors or community-based organisations. Current water testing kits are often easy to use, however, not accurate enough to base an action upon (presence/absence), or they too complicated and therefore not used (portable lab kits, MPN) at the community level. If a more simple, quicker and easier to interpret test available, it could allow for increased community-led monitoring.

Water quality tests are also essential for monitoring activities such as verifying if a water safety plan has been put in place, and for monitoring its effectiveness. Critical to building and sustaining trust with communities is having reliable and consistent data on faecal contamination. Test results can heavily influence community decision-making, and therefore need to be reliable and accurate.

ii. **Behaviour Change Communication (BCC)**

An important aspect of community-led monitoring is it creates opportunities for BCC which integrates into community-led water safety planning amongst other behaviour change activities. This is a participatory process in which the community identifies and mitigates risks of contamination to their drinking water sources.

Water quality testing can play a critical role in triggering community awareness, especially when it provides a visual indication of contaminated water. However, the ability to demonstrate results immediately, or within a minimum of six hours, is critical to support adoption of improved behaviours around drinking water (i.e. results delivered the same day during a community visit), as this would help to reinforce the messages and behaviours shared with the community at the time of activity.

iii. **Emergency preparedness and response**

Working with Disaster Risk Reduction actors and undertaking risk mapping allows for a better understanding of monitoring water sources in hot spots which could prevent outbreaks (e.g. seasonal Cholera in Zimbabwe) and create risk maps to support other preventative activities. A similar approach can be used in emergency situations to identify contaminated water sources and carry out public health activities to prevent further escalation.

Use Case B: Community-led Monitoring, Behavior change and Emergency preparedness	
End-user description:	UNICEF, Government and NGO partners.
Skill/Education level:	Educated to a minimum high school level. Will likely be a community-based monitoring person or WASH professional but without access to specialised training on device use.
Use environment:	Rural, Urban, Conflict zone, Emergency, and Disaster relief.

Geographic location:	Global, Resource-constrained settings.
Purpose of the data collected:	Communities, local authorities or local water committees can monitor their own water sources, providing timely feedback to households or communities on the safety of their water and encouraging behaviour change, management practices and social accountability.
Current products used:	Presence/Absence and Most Probably Number (MPN).
Priority TPP criteria:	Time to result, Specificity, User Training, Testing Methodology, and Cost.
Demand Forecast for Ideal Solution:	Forecast is limited by the absence of an adequate test, so there is no recent precedent. However, based on the size of programming demand in this area, this could range between 50,000 - 100,000 tests per year across an estimated 10 pilot countries.

Use Case C: Regulatory Oversight & Surveillance for onsite Testing

This Use Case targets staff of water utility companies, national regulatory agencies responsible for monitoring water services, government agencies responsible for providing water services, and other small public and private water providers. Microbial testing by government agencies with a regulatory or surveillance function is usually based in central laboratories and staffed by highly skilled technicians. In many of the countries where UNICEF works, regulatory and surveillance agencies face major hurdles in testing drinking water quality, especially in rural areas. Collecting water samples and transporting these, ideally on ice and within six hours, is not always possible, and the information generated may not be acted upon quickly. Large utilities also regularly perform operational testing, generally utilizing their own laboratories.

This Use Case focuses on onsite testing which complements, and is not expected to replace, standard laboratory methods for ensuring compliance to national water quality standards. The cost and complexity of existing methods limits the ability to monitor water safety, especially in rural areas. There is a clear need for new products to facilitate testing on site and provide actionable results on the same day. Improvements to the cost, simplicity and time to result would allow water suppliers and community water managers to better monitor water quality as part of water safety management and implement control measures in a timely fashion, ensuring that limited resources are used wisely. They would enable regulatory agencies to expand surveillance beyond easy to reach communities and those connected to formal water services.

While WHO and UNICEF do not typically procure large quantities of tests for this purpose, both organizations provide technical advice, training and support to government agencies responsible for local and national monitoring systems as part of WASH programming. UNICEF also has programmes in place to support governments in monitoring improved water sources for water safety and contamination free water quality objectives which are being introduced in 2020 and are designed to stimulate government adoption and support of contamination free water safety plans in primarily lower income countries.

Use Case C: Regulatory and Surveillance	
End-user description:	Staff of water utility companies, national regulatory agencies, government agencies, small public and private water providers, and community water committees.
Skill/Education level:	In some cases this could include laboratory staff with training, though minimal training should be assumed.
Use environment:	Primarily rural, but possible for urban or peri-urban environments. To be used for field testing or mobile laboratories, not fully-equipped and well-resourced laboratories.
Geographic location:	Resource-constrained settings.
Purpose of the data collected:	Regulatory monitoring and surveillance of distributed water system safety to determine risk levels, issue alerts, or make improvements to the system. Successful monitoring of newly established improved water sources. Not necessarily for establishing "compliance".
Current products used:	Portable kits and national standard methods in laboratories.
Priority TPP criteria:	Level of detection, Sensitivity, Specificity, and Cost.
Demand Forecast for Ideal Solution:	This is the largest Use Case for *E. coli* testing but is not currently a primary focus of UNICEF procurement. In this Use Case WHO and UNICEF's role is to provide technical advice and product recommendations to government stakeholders. If they accept the recommendations made, governments can then choose to buy directly from suppliers or can procure via UNICEF. This is a Use Case UNICEF influences but does not lead the procurement of. An estimated 764,000 tests per year would be required in Sub-Saharan Africa to meet WHO monitoring guidelines (Delaire, C.; Peletz, R.; Kumple, E.; Kisiangani, J.; Bain, R.; Khush, R; 2017). Based on a study by Crocker and Bartram (2014), the unmet demand in just three Indian states is 2.5 million tests. The global demand is unmapped.

Volume & Potential Impact

It is estimated that at least 1.8 billion people still rely on drinking water sources that contain evidence of faecal contamination (WHO/UNICEF 2014). SDG 6.1 focuses on access to drinking water with indicator 6.1.1 measuring the "proportion of population using safely managed drinking water." A number of governments that UNICEF supports are working to measure this figure, some in partnership with the MICS programme but others are taking the initiative on their own such as the governments of India and Myanmar. The monitoring of SDG 6 is a significant motivator for several potential users of water testing kits. UNICEF has identified 32 priority countries as part of a water quality initiative towards SDG 6. Within these countries an estimated one billion rural-living people will require water contamination testing of improved water sources to support water safety plans by 2030.

Current UNICEF Procurement (not including procurement directly by governments or NGO partners): From 2014 to 2018, UNICEF has procured approximately US$3.5 million in water quality testing supplies.

Anticipated future demand in areas where UNICEF procures: Approximately 130,000 tests per year are anticipated to be procured by UNICEF for the purpose of household surveys over the next five years. With test kits that meet the TPP requirements UNICEF anticipates 50,000 - 100,000 kits will be procured for behaviour change practices and community-led initiatives for initial pilots with a likelihood that this figure will increase.

Potential External Demand where UNICEF has influence and partial procurement: In addition to UNICEF's planned programming for water quality, the SDGs set out specific targets on water quality (Target 6.3), safe and affordable drinking water (Target 6.1), and community management of water resources (Target 6.b). The SDGs play a critical role in shaping the policy agenda of governments and international organizations globally, who have an obligation to measure and improve water quality under SDG 6.1. As part of this there is increased motivation for governments to monitor water quality for reporting purposes. For example, UNICEF procured 20,000 tests for Myanmar to carry out a water census in 2019. The Afghanistan Income Expenditure and Labour Force Survey, also carried out in 2019, had a water quality module demonstrating a growing trend to have more inclusion of water quality results by governments for monitoring purposes.

These instances demonstrate the increase in prioritizing the monitoring of water quality within the development sector. There are also potential markets with private water source management where there is a non-centralised approach to water quality, such as private boreholes in the United States, and remote communities in Canada and Australia where portable testing is increasingly encouraged. Therefore, it is an assumption that there is an untapped market beyond UNICEF's influence where simple, quick and reliable water quality tests may also be available to address the need.

New Product Requirements

The table below outlines the key functions and performance requirements for new water quality testing products or methods for the different Use Cases described above. The first part in the table describes the required functions which consists of pass/fail criteria. This implies that all required functions must be met to be considered. The remaining criteria will have weighted scores, where the ideal performance will be evaluated as higher than the "acceptable performance."

Attribute	Definitions	Acceptable Performance	Ideal	Scoring
REQUIRED FUNCTIONALITIES				
Key Function		Detection of fecal contamination equivalent to *E. coli* in drinking water		Pass/fail (Mandatory)
Power Requirements		Can be operated on site with a portable power source or no power requirement		
Safety Requirements		Device and consumables must be non-hazardous and non-toxic per WHO standards, including reagents or by-products		
Equipment dimensions		For 10 tests: smaller than 50cm x 20cm x 35cm, maximum 10kg weight for all the testing equipment		
Performance: Sensitivity and Specificity	The performance of the test when compared to reference standards in laboratory and field testing.	False positive less than 10%; False negative less than 10% over a range of concentrations of drinking water samples (Sub 100 CFU/100 mL)		
Life Span		Hardware: 2 year minimum; Consumables: minimum 1 year shelf-life at variable temperature with no cold chain required		
Mass production capacity	This is an estimate and not a commitment of volumes that UNICEF will procure.	Bidders should have capacity to produce at least 50 test kits per month and 20,000 consumables per year once the LTA has been issued		

PERFORMANCE REQUIREMENTS				
Sample size Characteristic (see constraints below)		Broad range of sample waters, including turbidity (0-10 NTU), pH (5.5-8.5), broad salinity (drinkable water range)	Broad range of sample waters, including turbidity (0-50 NTU), pH (4.5-8.5), salinity (drinkable water range)	Weighted scores
Level of Detection ***UNICEF may procure across all 3 categories***	Result is presence/absence only	Product is able to clearly demonstrate if *E.coli* (or acceptable equivalent) is present in the 100 mL water sample		
	Result is semi quantified	Differentiation between presence/absence as well as low/moderate (1-100 per 100 mL) and high levels (>100 per 100 mL	Differentiation across four risk levels (0, 1-10, 11-100, >100 per 100 mL)	
	Result is quantified	Lower level of detection equivalent to 10 CFU/100mL *(E. coli)*	Lower level of detection equivalent to 1 CFU/100mL *(E. coli)*	
USER REQUIREMENTS				
Testing Methodology	Process steps including activities required by the user to capture the sample, prepare it for analysis, interpret results, and dispose of any consumables or by-products of the test.	Minimum number of process steps, rapid incubation allowed, preferred at room/body temperature (<25°C)	Minimum number of process steps, no reagent mixing required, no incubation required	Weighted scores
Materials used		Waterproof as a packaged product and durable for transportation on rough roads and small boats		
VALIDATION REQUIREMENTS				
Regulatory Approvals	Performance evaluated against reference methods or regulatory approvals obtained.	Studies demonstrating equivalence to reference methods in multiple settings.	Standard for water testing equipment, from stringent regulatory body e.g. US EPA standards, supported by a strong body of evidence.	Weighted scores

Time to Result	Time to result measured from the time the sample is considered prepared to the time the result can be read, including incubation time, but not including sample preparation or disposal.	Less than 6 hours in a sample of 30 CFU/100mL.	Less than 30 minutes in a sample of 30 CFU/100mL.	
CORE REQUIREMENTS				
Target Unit Price	Total cost for 1000 tests; including hardware and consumables	*Between US$1,001 and US$6,000*	Up to or below US$1,000	Weighted scores
FIELD TEST REQUIREMENTS				
Operating Conditions	Field trials to be conducted in different contexts	Suitable for field use in extreme weather situations, including: - temperatures ranging from 0 °C to 45°C, - 40% to 88% relative humidity - withstand daily temperature fluctuations from 25°C to 40°C - must not require cold chain		Assessment at field trial
User Training	User training approach in different use cases, for example MICS and WSP.	Training process (maximum half day) that can be understood by non-technical user.	Training process (maximum half day), sufficient for self-trained user based on video or written instructions.	
Environmental Footprint	Adverse impact on the environment minimized through reducing consumables and packaging, reuse of equipment and/or recycling.	Minimal number of consumables, minimal excess packaging, high packing density.	Minimal number of consumables, minimal excess packaging, high packing density, recycling plan for used materials.	

Presentation and Interpretation of Results	How the results are delivered to the end-user and interpreted by them. Could include presentation through colour change, digital display screen, etc.,	Presents qualitative ranges either through clear visual cues or text, based on quantifiable ranges, e.g. "high, "medium", "low" or "none". Interpretation: easy, but a degree of subjectivity.		Displays quantified result as number/text or allow for simple quantification. Interpretation: easy and objective.	
Equipment Dimensions	Based on carrying from road to site for a minimum of 30 minutes each way.	Must be portable, lightweight, no bigger than carry-on suitcase that can accommodate at least 10 tests in a working day.		Handheld or pocket-size that can accommodate at least 10 tests in a working day.	
Number of samples processed in a working day	Number of samples the product should be able to process in a working day (8 hours) and to produce result read-outs.	5-10 in a working day (6 hours taking into account time to reach test site).		More than 10 in a working day (6 hours taking into account time to reach test site).	

a. **Assumptions:** Current WHO guidelines for drinking water will remain the "gold standard" for water quality for the foreseeable future, including that *E. coli* will continue to the be preferred indicator. The fourth edition of the guideline can be accessed via: http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/

b. **Constraints:**
   - As this TPP does not mandate specific products or technologies, it is difficult to identify specific interferents to test against. Ultimately, solutions will need to be tested in various field contexts, and interferents identified on a case by case basis.
   - Regulatory approval processes and standards for new products vary country by country which may provide limitations to reaching the performance requirements set forth in this document.

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