UNICEF Target Product Profile
Rapid Water Quality Detection Tests

Version 4.0

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> ***Document Purpose**. To outline the Target Product Profile (TPP) of how UNICEF programmes will use a rapid water quality test and its minimum performance requirements to support the Sustainable Development Goals and the associated water quality targets.*

Need for the Product

Diarrhoea is one of the main causes of under-five mortality, with 60 per cent of diarrhoea-related diseases attributed to inadequate access to safe water, sanitation and hygiene (WASH) services (WHO/Prüss et al. 2019). In an effort to reduce this disease burden, UNICEF along with WHO supports governments to increase access to improved water sources and provides technical support on water safety planning and water quality monitoring.

Faecal matter is the prime source of microbiological contaminants of concern in drinking water and is 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.

Current portable kits used by UNICEF and partner governments to quantify *E. coli* contamination involve long incubation periods and complicated processes that require specialized training with multiple opportunities for error. These features limit the ability of UNICEF and partners to undertake water testing reliably in field settings at scale.

Background

In humanitarian and development contexts in which UNICEF works, laboratory testing for *E. coli* can be unfeasible or costly due to a lack of available facilities. Where testing in remote areas is required, UNICEF therefore uses a range of portable testing products (details can be found in the Annex).

Role of Diagnostics for Water Safety

UNICEF can directly procure testing equipment for UNICEF country programmes or on behalf of partner governments for use in national surveys, surveillance, emergency response and for use by community water committees globally. UNICEF currently supports the development of water safety plans with technical expertise and resources for a number of governments globally. UNICEF's Water Game Plan aims to support 60 million people across 33 countries until 2030 with sustainable water services free from contamination (UNICEF, 2020), for which regular water quality testing is a key activity.

Given the variety of use cases and geographic settings a single solution for water quality testing is unlikely so it is important that governments and communities have a variety of tools that can support a system-wide approach to water safety.

Use Cases

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.

Group 1: Local

- Community led testing
- Non-technical staff for rural water operators

Group 2: Moniroting and emergency

- Household surveys
- Research
- Emergency response

Group 3: National

- Regulatory oversight and surveillance
- Service providers monitoring at all levels (local to national)

Group 1: Local – ease of use and cost per test are key

Technical experience level low: In these settings, the use of the tests will be carried out within the community at the source or Point of Use (PoU). The tests are conducted on-site. Users may have low education and literacy levels. Water may have had some level of chlorine treatment.

Community-led testing, Behaviour change (e.g. current users of H_2S tests)

Current fluorogenic and chromogenic tests, like those that identify hydrogen sulphide (H_2S) production or presence/absence tests for Total Coliforms and/or *E. coli* are sometimes used by communities to identify the possible contamination of drinking water with bacteria. These tests are easy to use and relatively inexpensive, though availability and supply in country can be a challenge.

Results are limited to presence/absence making the results less actionable beyond a community setting, and as such these tests are largely used as a screening method, or to confirm that water treatment processes have been effective. UNICEF procures fluorogenic and chromogenic tests on an ad-hoc basis per country demand. While useful as an communication tool, due to the limited information they provide, they largely only recommend within community engagement settings. Despite the ease of use and low cost, the tests are not broadly used as part of regular water testing activities even as a screening method.

In an ideal scenario, with the right equipment, community water groups would test key water sources at regular intervals (minimum twice a year in line with WHO guidance) to identify the presence of faecal indicator bacteria in a set volume of water (normally 100 mL as per WHO guidance). The test results would then be recorded in logbooks that are reviewed by a regional/governmental water body that supports community water committees. Positive results should be reported immediately, to be followed up and tested with a fully quantified method. However, the reality is that in many cases the community is limited to simple actions based on the result (like chlorination of water) as there may not be a system to further test and treat the water, even when reported by the local state government water body.

In current settings there are some tests that are suitable for community use, they are generally funded by a wider water testing programme initiated by governments which may have some level of support from UNICEF (either through capacity development, funding or procurement support). From January 2018 - July 2022 UNICEF has procured $289 000 USD of chromogenic tests to be used in country programmes at community level. In some cases, these tests may be funded by communities themselves. In this scenario cost is a key decision factor alongside product familiarity.

The current tests are presence/absence and give results within 24 hours with incubation at room temperature (24-30˚C). The cost per test is under USD $1 for H_2S or Total Coliform, and upward of USD $2-3 for *E. coli*, which is a contributing factor to why they are used. While these tests meet a need in terms of ease of use in a community setting, the goal would be to reduce the time to result to enable actions based on the result within a 2 hour timeline.

An innovative alternative to this kind of product would be one that is similarly priced at USD $1 or less per test, requires no additional incubation equipment and gives a simple presence/absence result. It should give a result within 2 hours.

Ideal product performance
Result output: presence/absence or colour indication of safe or not (no need for UV)
Time to result: within an hour (total processing and results time under 2 hours)
Portability: one time use product that can be bought, stored, and transported in bulk on a bicycle or carried by hand
Power source: none
Space to operate: n/a
Ease of use: user to only add water sample and shake, no other preparation
Price range: up to USD $1 per test
Potential demand: It is hard to define the possible demand for this use case as current products are not used in this way, new products would enable this to be further expanded. Of the 33 Water Game Plan countries 5 have a water quality focus: Bangladesh, Ethiopia, India, Nigeria and Pakistan.

Rural Water Operators

Operators at rural water facilities are often from the communities that the water is supplying. Many have low levels of education and literacy, so are not considered in the professionally trained section below.

In this use case the tester needs a simple test to be able to make an operational decision about the water and what should happen based on the result. For example, the result should be simple enough to enable the operator to know if the water is safe (no action required), there is some concern (chlorine levels may need to be checked and dosing increased) or dangerous (water usage should stop immediately and further support sought). The testing will be done by the locally placed staff but will have a reporting system for the water provider to support actions to be taken.

Ideal product performance

Result output: presence/absence or colour indication of safe or not (no need for UV), enough information to make an operational decision (for example water: is safe, needs action, cannot be used)

Time to result: within two hours (total processing and results time under 2 hours)

Portability: one time use product that can be bought, stored, and transported in bulk on a bicycle or carried by hand

Power source: none

Space to operate: n/a

Ease of use: user to only add water sample and shake, no other preparation

Price range: up to USD $2 per test

Potential demand: An estimated 764,000 tests per year would be required in Sub-Saharan Africa for both rural and urban areas to meet WHO monitoring guidelines (Delaire, C.; Peletz, R.; Kumple, E.; Kisiangani, J.; Bain, R.; Khush, R; 2017). Based on JMP data (2020) 58% of Sub-Saharan Africa water is supplied to rural communities. Using the data from the Delaire paper (2020) this would equate to 443, 120 tests annually that would be needed to monitor these water sources.

Group 2: Monitoring and emergency response use cases – trained users but not experts

Experience level medium: Equipment is likely to be used for defined periods of testing, users will have some level of training in carrying out water quality tests with the equipment chosen by decision makers. The users may have only half a day to be trained on equipment before using it in remote and field settings without further support. Users will have some level of literacy and most likely high school or higher education.

Monitoring activities would have a defined volume of testing that would be planned for and financed ahead of time.

National surveys and regional-led monitoring (current users of membrane filtration)

Led by government bodies, testing will be part of periodical monitoring of water quality across states, regions and countries. Biological water quality tests will be carried out alongside other parameters defined by WHO (e.g. turbidity, conductivity and pH). In some cases, these results will be used to monitor progress against SDG 6.1 or in accordance with a countries water quality plan.

On a community visit a trained person will be onsite for at least two hours to carry out this type of testing and complete a predefined survey which will look at factors relating to water and sanitation. Tests will be carried out on water from the community's source and some that is stored in the house. Rapid results will simplify the work of field teams, by allowing them to finalize data entry without waiting for results after 18-24 hours of incubation it will also preserve the integrity of the sample, as it would not have had the time to deteriorate during transport back to the lab.

This test may be used in response to a positive result returned by Group 1 users to further quantify a presence/absence result.

Ideal product performance
Result output: must give a comparable result to CFU
Time to result: within an hour (total processing and results time under 2 hours)
Portability: can be transported by vehicle, motorbike
Power source: rechargeable/portable power
Space to operate: equipment can be laid out in a stable shady place to run while in the community
Ease of use: similar complexity to membrane filtration
Price range: up to USD $6 per test
Potential Demand: Based on UNICEF Water Game plan (UNICEF 2020) to monitor the improvements in water quality UNICEF could be supporting the procurement of up to USD $1 million biological tests by 2030 in this use case.

Emergency response

In emergencies and disease outbreaks, a first priority is often to chlorinate water. Water testing initially focuses on assessing levels of free and total chlorine – if sufficient chlorine is not detected then these tests are usually followed by a bacteriological test.

An innovative solution: multi-parameter bacteriological test (e.g. *E. coli*, cholera, typhoid) that can be used by trained people (community health workers, NGO staff, UN country office teams) that gives results in two hours or less to enable quick action to be taken and the further spread of disease to be limited. It should be a product that can be used in field settings and is easy to transport. Cost per test should be USD $6 or less.

Ideal product performance
Results output: presence/absence, CFU/100 mL, or colour indication of risk level (low, medium, high, very high) comparable to *E.coli*
Time to result: within an hour (total processing and results time under 2 hours)
Portability: can be transported by vehicle, motorbike
Power source: rechargeable/portable power
Space to operate: equipment can be laid out in a stable shady place to operate while in the community
Ease of use: simple, as user will not have regular training or equipment will be used as needed
Price range: up to USD $6 per test
Potential demand: 50 000 tests per year across 10 pilot countries as an estimate

Group 3: Professional level users

Experience level high: Users in this group will be trained professionals who have a technical background in water or monitoring and will regularly use equipment to monitor and report on results of water quality.

As this group includes regulatory oversight the testing would be based on annual planning for regulation and spot checks around production and supply of water. Products would need validation evidence that would be sufficient for government bodies to review to ensure performance is in line with their reporting requirements.

Regulatory oversight & state funded/run labs (current users of portable lab type products)

UNICEF support government systems and processes. For water quality testing this means supporting the development and implementation of country-wide water safety plans. Support can come in financial and/or technical support packages. In countries where this is the approach, the government body responsible for water quality testing will develop a countrywide plan with an approach to what water quality parameters will be tested and what equipment would be acceptable for doing this.

In terms of regulatory oversight, it is both a functional and institutional approach to support the variety of functions and tasks that government or other suitable bodies use to promote evidence-based regulatory decisions. For water providers and regulators, water quality testing is a core part of this function.

To support these decisions and plans, water quality testing will most likely include a mixture of laboratory and field appropriate technologies as no single approach would enable water testing targets to be reached. There are several limitations to laboratory testing, especially for rural and peri-urban locations from which water samples may deteriorate before reaching the laboratory. There are also issues in many locations with laboratories being overwhelmed, and despite receiving samples within a day, it can take 10 days or longer to have the results reported out.

In some cases, lab-based workers will use portable laboratories for testing of *E. coli* in water samples that are brought to a central location, or they may take the same equipment to suspected incidents or remote locations in the field. Current portable laboratories can process up to 20 membrane filtration plates at a time with an 18 hour or more incubation. The portable equipment is multi-faceted as it can be kept in a central location (e.g. the laboratory) and used as needed or taken to where testing is required in challenging locations. Test kits are often packaged with equipment for other water quality parameters such as pH, chlorine, conductivity and turbidity.

These tests may be used to follow up on a reported outbreak and identify the source, to carry out a regulatory enforcement action, or to respond to positive result identified by Groups 1 and/or 2.

An innovative solution for this use case would be capable of 10 or more tests per day, sensitivity comparable to 1 CFU/100 mL, portable for use in remote locations as required including the power source. Simple consumables that can easily be sourced, results in 2 hours or less.

Ideal product performance
Results output: must give a quantitative result comparable to CFU/100 mL
Time to result: within an hour (total processing and results time under 2 hours)
Portability: can be transported by vehicle
Power source: rechargeable/portable power
Space to operate: equipment can be laid out in a stable shady place to operate while in the community or used as a bench solution in a laboratory; must process at least 10 samples in an 8 hour period with each piece of hardware
Ease of use: similar complexity to membrane filtration
Price range: up to USD $10 per test
Potential Demand: 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.

Surveillance for onsite testing for use by service providers (managing onsite laboratories or having autonomy over choice of test)

Trained specialists will carry out scheduled daily testing of water at a treatment facility where batch level production/treatment takes place. Users are trained professionals who use the equipment daily and will take an immediate action based on the result. Time to result that is within 1 hour will have an immediate impact on the quality of the water being distributed and in turn the health of the users.

Since water treatment processes should remove non-faecal bacteria as well as faecal bacteria, other microbial tests may be appropriate for monitoring process integrity. Microbial testing should complement but not replace operational monitoring in treatment facilities.

Ideal product performance

Results output: must give a quantitative result comparable to CFU/100 mL but could consider measures other than *E. coli*

Time to result: within an hour (total processing and results time under 2 hours)

Portability: must easily operate on a small laboratory bench or similar fixed flat surface for the duration of operation

Power source: can be fixed power source, but capacity to operate on a battery is preferred

Space to operate: bench system; must process at least 10 samples in an 8-hour period with each piece of hardware

Ease of use: can be complex to a point, users will receive training and will use equipment daily

Price range: up to USD $10 per test

Potential Demand: 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, it is unlikely to be direct procurement.

Potential Impact

It is estimated that at least 2 billion people still rely on drinking water sources that contain evidence of faecal contamination (WHO/UNICEF 2021). 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 large number of governments that UNICEF supports are working to monitor population access to safely managed drinking water services. This includes countries participating in the UNICEF-supported Multiple Indicator Cluster Survey (MICS) programme and other national surveys that have integrated water quality testing. For example, UNICEF procured 20,000 water tests for Myanmar's 2019 mini-census. UNICEF's planned programming for water quality, based on the SDGs, sets out specific targets on water quality, safe and affordable drinking water (Target 6.1), and community management of water resources (Target 6.b).

Procurement Volume

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 by 2030.

Current UNICEF Procurement (not including procurement directly by governments or NGO partners): From 2014 to date, UNICEF has procured approximately US$4.8 million in bacteriological water quality testing supplies.

Anticipated future demand in areas where UNICEF procures:

For test kits that meet the TPP requirements, UNICEF anticipates 50,000 - 100,000 kits will be procured within the first five years of products being commercially available for Group 1 and 2. Initial pilots with key countries indicate the likelihood that this figure will increase, if products are found to meet country testing requirements and have suitable laboratory validation of performance.

Potential External Demand where UNICEF has influence and partial procurement:
Within the WASH sector there is a recognition that there needs to be a stronger focus on water safety. UNICEF is responding to this with the introduction of new programming: Basic+ (water free from contamination – this will need to be tested to evidence the change) which is included in the 2020-2030 Water Game Plan (UNICEF 2020). Our core programme countries are the ones with the smallest share today, see Figure 1; however, through initiatives like the Water Game Plan and UNICEF's presence and influence, they have the highest potential of being unlocked. UNICEF also has market presence and partnerships with governments in the 190 countries where UNICEF offices are located.

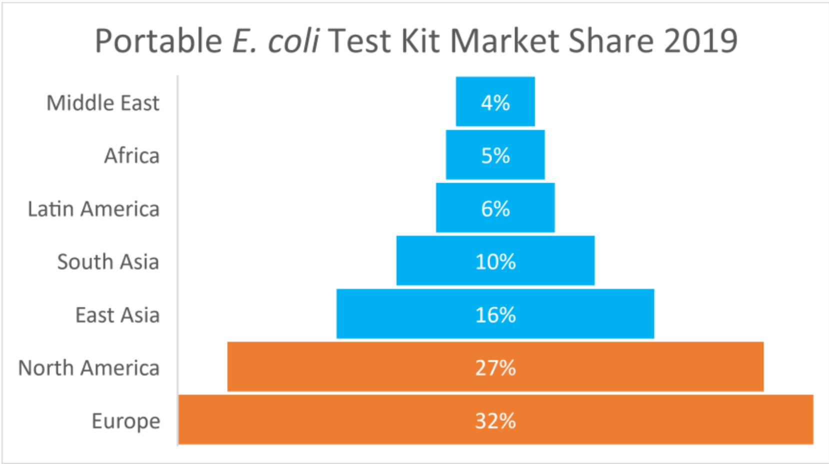

Figure 1 Overview of global portable E. coli market share in 2019, based on report commissioned by UNICEF SD in 2020

Additional water quality parameter considerations

Faecal contamination, and microbiological contamination more generally, are not the only risks to safe drinking water. Other risks include chemical contamination, such as arsenic, lead 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 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.

Finance models

UNICEF will use a process of public procurement to tender for products that can evidence they meet the TPP requirements, these products will then be tested in the field with UNICEF partners. The best performing products can then be offered a Long-Term Agreement (LTA) contract with UNICEF - this does not guarantee volumes of procurement but enables UNICEF country offices and partner governments to procure products more easily.

Financial proposals from developers should consider the best way to achieve the financial targets outlined in the specification. Prior to any tender being launched it is recommended to discuss this approach in a call with UNICEF, should this be relevant to any developers.

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 of the table describes the required functionalities which include 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 Performance	Scoring
REQUIRED FUNCTIONALITIES				
Key Function		Detection of faecal contamination equivalent to *E. coli* in drinking water		Pass/fail (Mandatory for all user groups)
Power Requirements		Can be operated in situations where power supply can fluctuate and may not be constant		
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		
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		

Attribute	Definitions	Acceptable Performance	Ideal	Scoring
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 as appropriate for each user group
Performance: False positive and false negative rates	The performance of the test when compared to proposed refence method	False Positive (FP) rate less than 15%; False Negative (FN) rate less than 15% over a range of concentrations of drinking water samples (Sub 100 CFU/100 mL) Criterion is 80% detection with 90% confidence, evidence must demonstrate a rate of FP/FN ≤15% with 90% confidence in a minimum sample size of 30.	False Positive (FP) rate less than 10%; False Negative (FN) rate less than 10% over a range of concentrations of drinking water samples (Sub 100 CFU/100 mL) Criterion is 80% detection with 90% confidence, evidence must demonstrate a rate of FP/FN ≤10% with 90% confidence in a minimum sample size of 30.	
Level of Detection ***UNICEF may procure across both categories***	Result is presence/absence only	Allows 80% detection with 90% confidence for stocks in the 50-200 CFU/mL range.	Allows 80% detection with 90% confidence for stocks in the 15-50 CFU/mL range.	
	Result is quantified	Lower level of quantitation equivalent to 20 - 100 CFU/100mL *(E. coli)* Allows 80% detection with 90% confidence for stocks in the 100-300 CFU/mL range.	Lower level of quantitation equivalent to 1 - 20 CFU/100mL *(E. coli)* Allows 80% detection with 90% confidence for stocks in the 15-60 CFU/mL range.	

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 based on user group and the expected experience level of that group
Materials used		Waterproof as a packaged product and durable for transportation on rough roads and small boats		*Consideration for user groups 1 and 2*
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. EPA), or AOAC PTM certification or equivalent, supported by a strong body of data from a recognised third party laboratory.	Weighted scores for all user groups
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 2 hours with a sample of 30 CFU/100 mL.	Less than 30 minutes with a sample of 30 CFU/100 mL.	
CORE REQUIREMENTS				
Target Unit Price	Total cost for 1000 tests; including hardware and consumables	Between US$1,001 and US$6,000	Up to US$1,000	Weighted scores for each user group

FIELD TEST REQUIREMENTS				
Operating Conditions	Field trials to be conducted in different contexts	Suitable for field use in extreme weather situations, including: - reagents and product works in temperatures ranging from 0 °C to 45°C - 40% to 88% relative humidity - daily temperature fluctuations ± 5°C to 20°C increase or decrease in field settings - no requirement for cold chain for reagents at any stage		Assessment at field trial; products will be given a target user group that will have appropriate evaluation and scoring for use by that group (products can be considered for multiple user groups)
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 quantitative result as number/text or allows for simple quantification. Presents uncertainty limits (e.g. confidence intervals) along with quantitative results. 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 including time to reach test site).	More than 10 in a working day (6 hours including time to reach test site).	

Assumptions: Current WHO guidelines for drinking water will remain the "gold standard" for water quality for the foreseeable future, including the designation of *E. coli* as the preferred indicator organism. 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/.](http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/)

***Regulatory approvals and product validation:**

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. For this project two routes to demonstrate product performance have been developed.

1. WHO (2020) have developed a laboratory protocol to assess culture based approaches to water quality testing, this process can be found in the references below. This process was used in 2021 to assess the performance of products using different challenge waters. To use this process for future tender, the product's performance would need to be evidenced by a third-party laboratory, the suitability of the laboratory would also be reviewed as part of the desktop technical evaluation of the TPP responses.

   In order to assist with the interpretation of the results, the protocol uses a 'traffic light' assessment scheme, in which results are considered to be 'green' if the results meet the statements listed in the kit's manual, 'yellow' if there is some disparity between results and the expected results or there is a potential risk of infection to the user, and 'red' if the results deviate significantly from the expected results.

2. AOAC (2022) have developed a *Performance Test Method*^{SM} (PTM) certification approach that can be found in the reference section. This approach will allow developers to validate the product's performance using a defined matrix to assess whether the performance meets the requirements of UNICEF as outlined in the TPP. UNICEF will be require a certificate (or similar) for tenders of non-culture based approaches to identify risk in drinking water, which will be assessed as part of the desktop technical evaluation of the TPP responses.

Annex

Products currently used by UNICEF for *E.coli* testing

Portable Laboratory Kits: This is a complete system including consumables and is capable of quantification down to one colony forming unit (CFU)/100mL. The methodology involves multiple steps and 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 significant 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); these tests cannot quantify the magnitude of contamination. This method does not require technical training and requires an 18-24 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.

Chromogenic/Fluorogenic Presence/Absence Test: This assay allows for the detection of both total coliforms and *E. coli* in 10 mL or 100 mL samples; these tests 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 – in effect inferring contamination levels from multiple presence/absence tests. Results should be reported with a confidence interval or some indication of uncertainty. Depending on the MPN design, they may provide more or less precise estimates. 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. The growth media includes chromogens that produce coloured colonies when *E. coli* is present. When used in combination with membrane filtration, 100 mL volumes can be tested. 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-prepared plates form part of the standard module that is routinely available for Multiple Indicator Cluster Surveys (MICS) and has been used in Demographic Health Surveys (DHS) and Living Standards Measurement Study (LSMS) surveys.

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

References

AOAC (2022) *Call for Methods Indicating Risk of Fecal Contamination in Drinking Water* https://www.aoac.org/news/call-for-methods-indicating-risk-of-fecal-contamination-in-drinking-water/

Crocker, J. and Bartram, J. (2014) *Comparison and Cost Analysis of Drinking Water Quality Monitoring Requirements versus Practice in Seven Developing Countries*. Int. J. Environ. Res. Public Health 2014, 11, 7333-7346.

Delaire, C., Peletz, R., Kumple, E., Kisiangani, J., Bain, R., Khush, R. (2017) *How Much will it Cost to Monitor Microbial Water Quality in sub-Saharan Africa? Environmental Science and Technology*. 51,11:5869-5878.

UNICEF (2020) *Water Game Plan* https://www.unicef.org/documents/unicefs-water-game-plan-universal-safe-and-sustainable-water-services-all-2030

United Nations (2015) *Sustainable Development Goals: Goal 6 Ensure Availability and Sustainable Management of Water and Sanitation for All.*

United Nations Department of Economics and Social Affairs. Accessed via: https://sustainabledevelopment.un.org/sdg6

Prüss-Ustün et al. (2019) *Burden of disease from inadequate water, sanitation and hygiene for selected adverse health outcomes: An updated analysis with a focus on low- and middle-income countries.* Int J Hyg Environ Health. https://pubmed.ncbi.nlm.nih.gov/31088724/

WHO/UNICEF (2021) *Progress on household drinking water, sanitation and hygiene 2000-2020: Five years into the SDGs* https://data.unicef.org/resources/progress-on-household-drinking-water-sanitation-and-hygiene-2000-2020/

WHO/UNICEF Joint Monitoring Programme for Water Supply, Sanitation and Hygiene (2021) *Integrating water quality testing into household surveys* https://www.who.int/publications/i/item/9789240014022