UNICEF Target Product Profile: Real Time *E. coli* Detection

Version 1.4
September 2016

Need for the Product

Faecal matter is the principle contaminant of water that causes diarrhoea and is measured through quantification of indicator bacteria. *E. coli* is the WHO preferred indicator for faecal contamination of water. Unfortunately, the common methods used to quantify *E. coli* contamination currently available typically involve long incubation periods and a complicated process with high risks of contamination and requiring specialized training. This limits the ability of UNICEF and its partners to do water testing on-site for behavioural change communication and integration of water testing in national household surveys (e.g. Multiple Indicator Cluster Surveys).

Background

Programmatic Relevance for UNICEF

Diarrhoea is one of the main causes of under-5 mortality, with 58% of diarrhoea related diseases attributed to inadequate access to safe water, sanitation and hygiene (WHO/Prüss et al 2014). In an effort to address these challenges, UNICEF provides technical support to governments on water safety planning and water quality monitoring. In addition, UNICEF places a key focus on improving water quality at the household level through improved facilities and better awareness and education.

Current products or response utilized by UNICEF:

Due to the context in which UNICEF works, laboratory testing for *E. coli* is typically not feasible. Samples must therefore be processed on-site or nearby, typically with limited access to cold chain transport or grid electricity. Currently UNICEF typically uses the following testing methodologies for *E. coli* testing in field locations:

- **Portable lab kits**: A complete test kit with consumables capable of quantification to 1CFU coliform forming unit (CFU)/100mL. Methodology uses membrane filtration for thermos-tolerant coliform (an alternative indicator to *E. coli)* and a portable electric incubator. Results can be achieved in 14-16 hours at 44°C. Kit operation requires technical skills, and there is high risk for contamination when preparing the plates. Approximate cost: range between $1,000- $3,000 USD per kit, excluding consumables.
- **H_2S (presence/absence)**: A simple test that does not require technical training but still requires 24-hour incubation (though it can be done at room/body temperature). Quantification of *E. coli* is not possible, and it is estimated that it yields ~20% false positives, depending on the type of water source due to measuring sulphide production and not *E. coli* directly. Tests are one-time use. Approximate cost/unit: $0.50 USD/test
- **Compartmentalized Bag Test (CBT)**: A simple bag-based test for *E. coli* that quantifies contamination (using Most Probable Number) to 1CFU/100mL with an upper contamination limit of 100CFU/100mL. Requires 24-hour incubation but can be done at body temperature. Approximate cost: $10 USD/test.

- **Compact Dry Plates**: Methodology uses pre-treated plates with growth media which creates a gel when the sample is added. Quantification is possible by combining with membrane filtration, 24-hour incubation at room/body temperature is required. Some training is required, and contamination is a risk. Being piloted in some MICS/LSMS surveys. Approximate cost: $1 USD/plate.

Volume & Potential Impact

It is estimated that 1.8 billion people still rely on drinking water sources that contain evidence of faecal contamination (WHO/UNICEF 2014). In 2013, UNICEF allocated approximately $450 million USD to meeting its targets for safe drinking water.

Current UNICEF Procurement (not including procurement directly by governments or NGO partners): From 2013-2015, UNICEF has procured approximately $2 million USD in water quality testing supplies, including over 75,000 presence/absence tests and approximately 800 portable lab kits.

Potential UNICEF future demand: If a suitable product exists, the potential demand would include countries implementing national-scale household surveys, approximately 50 UNICEF-supported surveys per year. If an average survey covers 50,000 households and 1 in 5 households are tested, this could amount to at least 500,000 tests per year procured by UNICEF for this purpose alone. In addition, UNICEF would also use the product in their behavioural change communication programming which targets the 1.8 million accessing sources of contaminated drinking water sources through programmes with partner NGOs and governments in a majority of the countries in which UNICEF works.

Potential External Demand: In addition to UNICEF's planned programming for water quality, the United Nations Sustainable Development Goals (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 will play a critical role in shaping the policy agenda of governments and international organizations globally, allowing for significant resources to be allocated towards meeting the goals by 2030. (UN Sustainable Development Goals 2015)

Use of product in UNICEF context

Use case A: Household Surveys:

Household surveys are implemented to collect data on health, nutrition, education, water and sanitation, and a number of other key development indicators. This data allows governments to monitor progress and identify areas for improvement. Surveys typically cover 10,000 to 300,000 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 1-2 hours per home, asking questions and, potentially, collecting water samples. Water samples would be collected at the household level by survey teams in a subset of households in each survey.

- End-user description: UNICEF/Government trained survey teams.
- Skill/Education level: Formally educated to minimum high school level. Receive specialised training for the surveys but typically are non-WASH specialists.
- Use environment: Survey cover national scope, both urban and rural contexts. Power supply typically not available.

- Geographic location: Surveys are implemented around the world.

Use case B: Behavioural change communication – Water samples collected at multiple points in a community to demonstrate potential contamination points. Typical testing would be at the water point (e.g. river, well, hand pump, etc.), in the water transport container, at the household storage, in the drinking cup). The results would be then used for community and household level communication on the importance of safe water, its storage and transport. The ability to demonstrate results immediately, or within a minimum of 3 hours, is critical to support behaviour change (i.e., results delivered the same day as community visit).

- User description: UNICEF, government and NGO partners.
- Skill/Education level: Formally educated to minimum high school level. Will likely be WASH professionals but not have access to specialised training on device use.
- Use Environment: rural/urban/conflict zone/emergency/disaster relief
- Geographic location: Global

New Device Use Case Requirements

The Use Case Requirements outline the key functionalities and performance of the solution, with the needs of end- users and context in mind. Both the minimum required performance as well as ideal performance are described.

Attribute	Minimum Performance	Ideal Performance
Operational/Functional Requirements		
Key function	Detection of faecal contamination.	Detection of faecal contamination equivalent to *E. coli*
Method of Use	For testing drinking water	For testing drinking water
Operating Conditions	Suitable for field use in extreme weather situations	Suitable for field use in extreme weather situations
Power requirements	Battery based, recharging possible nightly.	If power is required, must be battery based, recharging possible weekly.
Testing methodology	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 field sterilization required, no incubation required.
Negative control	Sterile water	None required
Calibrators	For pH acceptable	None required
Presentation of Results	Qualitative, based on quantifiable ranges (see advice on Quantification below), e.g. “high, “medium”, “low” or “none”.	Display quantified result*. *For Use Case A only: digital recording of historical measurements is ideal.
Sample characteristic (See also: “Constraints” below)	Broad range of sample waters, including turbidity (0-10), pH (5.5-8.5), broad salinity	Broad range of sample waters, including turbidity (0-50), pH (4.5-8.5), salinity (drinkable

	(drinkable water range), does not need cold storage	water range), does not need cold storage.
Performance Requirements		
Sensitivity	Equivalent to 10 CFU/100mL	Demonstrated equivalent to 1 CFU/100mL
Specificity	False positive less than 10% False negatives less than 10%	False positive less than 5% False negatives less than 5%
Time for Result	Less than 3 hours** (**Exception: see footnote below)[i]	Less than 30 minutes
Quantification	Distinguishes no contamination, low (<10/100 mL), medium, or high contamination (>100/100 mL).	Precise quantification (number of CFU/100ml or equivalent).
Design Requirements		
Lifespan	Hardware: 2 year minimum Consumables: minimum 2 year shelf-life at temperature between 2°C - 42°C.	Hardware: 5 year minimum Consumables: >5 years shelf-life at temperature between 2°C - 42°C.
Equipment dimensions	Must be portable, lightweight, no bigger than carry-on suitcase.	Handheld or single-use test.
Materials Used	Must be durable, waterproof.	Must be durable, waterproof. Limited or no consumables.
User Requirements		
User Training	Minimum training (1 hour) that can be understood by non-technical user.	No training required, printed instructions sufficient.
Reading and Interpretation of Results	Easy and objective	Easy and objective
Commercialization Requirements		
Regulatory Approvals	Studies demonstrating equivalence to reference methods in multiple settings.	Standard for water testing equipment, relevant ISO and US EPA standards.
Safety Requirements	Device and consumables must be non-hazardous and non-toxic, including reagents or by-products.	Device and consumables must be non-hazardous and non-toxic, including reagents or by-products.
Environmental Footprint	High packing density	High packing density, recycling plan for used materials.
Target Unit price	Unit price less than $1,000 Per test cost < $5	Unit price less than $250 Per test cost < $1

a. **Assumptions:** Current WHO standards for drinking water will remain the "gold standard" for water quality for the foreseeable future. The 4th edition of the guideline can be accessed via: http://www.who.int/water_sanitation_health/publications/dwq_guidelines/en/

b. Constraints: As this TPP is does not mandate specific products or technologies, it is difficult to identify specific interferents to test against. Ultimately, solutions will be need to be tested in various field contexts, and interferents identified on a case by case basis.

References

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

WHO/Prüss et al. 2014. *Burden of disease from inadequate water, sanitation and hygiene in low- and middle-income settings: a retrospective analysis of data from 145 countries*. Tropical Medicine and International Health. Accessed via http://www.ncbi.nlm.nih.gov/pubmed/24779548

WHO/UNICEF Joint Monitoring Programme for Water Supply and Sanitation. 2015. *Progress on Sanitation and Drinking Water, Update 2015*. WHO/UNICEF. Accessed via: http://www.unicef.org/publications/files/Progress_on_Sanitation_and_Drinking_Water_2015_Update_.pdf

[i] 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 should remain in line with minimum requirements.