CLINTON HEALTH ACCESS INITIATIVE

Renaissance Philanthropy

# Rapid, low-cost tool for blood lead level testing

## TARGET PRODUCT PROFILE
## JULY 2026

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Cover photo: Sujata Khanna / CHAI

# Acknowledgments

This Target Product Profile (TPP) was developed through a structured, consensus-based process led by a multi-stakeholder Steering Committee, with input from a multidisciplinary Expert Advisory Group (EAG). Additional input was gathered through focus group discussions, stakeholder consultations, and a public comment process. The Clinton Health Access Initiative (CHAI) and Renaissance Philanthropy are grateful to all who contributed their time and expertise.

The Steering Committee coordinated the TPP development process, including defining the scope, reviewing and synthesizing stakeholder input, and supporting the Expert Advisory Group to reach consensus on the product characteristics and target values included in the final profile. The Steering Committee comprised (in alphabetical order): Randy Allen (CHAI); Dr. Akhil Bansal (Independent Consultant); Robbie Barbero (Renaissance Philanthropy); Hiba Bouji (CHAI); Chris Connolly (CHAI); Dahlia Elgonemy (CHAI); Grant Heskamp (CHAI); Trevor Peter (CHAI); and Lara Vojnov (Facilitator, Independent Consultant).

The Expert Advisory Group was established to provide technical validation and strategic guidance, as well as to serve as the final decision maker throughout the TPP development process. Members were selected by the Steering Committee based on their expertise and experience relevant to the development, introduction, and scale-up of improved blood lead diagnostics. Expert Advisory Group members contributed in their individual capacities, and the views expressed during the development process do not necessarily reflect those of their affiliated organizations.

Collectively, members contributed expertise across national government and public health leadership; implementation and service delivery; clinical practice; laboratory practice; epidemiology and public health; medical devices and diagnostics; regulation; health economics; environmental health; policy and advocacy; research and development; technology transfer and innovation; and philanthropy and donor strategy.

CHAI and Renaissance Philanthropy thank the following Expert Advisory Group members (listed in alphabetical order): Dr. Godson Ana (Department of Environmental Health Sciences, University of Ibadan, Nigeria); Dr. Indu Bhushan (Pahlé India Foundation); Laigden Dzed; Ludovica Gazze (University of Warwick); Dr. Evelyn Gitau (Science for Africa Foundation); Grace Jairo (CDC Foundation); Dr. Robert Jones; Dan Kass (Vital Strategies); Dr. Yenew Kebede (Africa Centres for Disease Control and Prevention); Rui Liu (Asian Development Bank); Dr. Joanna Lowell (Pure Earth); Robyn Meurant (ACT-IVD); Dr. Bhavesh Modi (Indian Council of Medical Research); Emily Nash (UNICEF); Dr. Jessica Ocampos (Pan American Health Organization, Camnexus); Anne-Laure Page; Mercedes Perez; Dr. Md. Mahbubur Rahman (International Centre for Diarrhoeal Disease Research, Bangladesh); William Seitz (World Bank); and Dr. Martha M. Téllez-Rojo (National Institute of Public Health, Mexico).

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CHAI and Renaissance Philanthropy also thank the 20 focus group participants, who shared their time and frontline experience across clinical, laboratory, and field settings. We are equally grateful to the experts who contributed through bilateral consultations, whose specialized input strengthened the feasibility and rigor of the profile, and to all those who provided input through the public comment process.

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# Declarations of interest

To support the credibility, transparency, and integrity of the TPP development process, Expert Advisory Group members were asked to complete a Declaration of Interests form disclosing any financial, professional, institutional, or other interests that could reasonably be perceived to influence their objectivity in relation to the development of a rapid, low-cost tool for blood lead level (BLL) testing. Disclosures covered interests related to blood lead testing; lead screening and diagnostic technologies; relevant sample collection or laboratory testing approaches; and any products, companies, organizations, or institutions that could be affected by, or benefit from, the outcomes of the TPP.

The Steering Committee reviewed the completed declarations to identify actual, potential, or reasonably perceived conflicts of interest. Declared interests included prior involvement in the development of existing blood lead testing products, regulatory consulting for in vitro diagnostics (IVD) manufacturers, a financial interest in a software platform potentially relevant to diagnostic or data systems, and organizational relationships with suppliers of blood lead testing products.

Following review, the Steering Committee concluded that there were no conflicts of interest requiring exclusion from the TPP development process and that all declared conflicts could be managed through transparency, documentation, and continued disclosure obligations. This determination was based on the nature and relevance of each disclosure, whether the interest was direct or indirect, whether it involved a current financial stake in a specific product or supplier, and the role of the Expert Advisory Group in providing input on generic product requirements rather than selecting, procuring, funding, or endorsing any specific technology.

# Glossary

*All glossary terms are italicized in the main body.*

| | |
|---|---|
| **Acceptable characteristic** | Specific and measurable expression of an attribute at lowest satisfactory output |
| **Administrator** | Person responsible for overseeing the implementation of a testing program, without performing or interpreting the test. For example: program managers, public health officials, or supervisors of *end users* |
| **Attribute** | Property or dimension of the target product (e.g., cost per test, time to result) |
| **Bias** | Estimate of a systematic measurement error (1) |
| **Clinical setting** | A healthcare facility (e.g., primary care center, outpatient clinic, hospital outpatient unit) where testing is performed under controlled conditions, with reliable infrastructure (e.g., electricity, lighting, dedicated sample collection space) and by trained healthcare staff. Corresponds to Level 1 (primary care) and above in the WHO health system tiers (2) |
| **Confirmatory testing** | A test that is specific and reduces or eliminates false positive results (3) |
| **Desirable characteristic** | Specific and measurable expression of an attribute at the ideal, but achievable, output |
| **End user** | Person responsible for administering the test |
| **Field setting** | A decentralized or community-based location outside formal healthcare facilities (e.g., households, schools, community meeting areas, mobile clinics, outreach campaigns) where testing is performed near the individual being screened, often under variable environmental conditions and with limited infrastructure. Corresponds to Level 0 (community and outreach) in the WHO health system tiers (2) |
| **Imprecision** | Dispersion of independent results of measurements obtained under specified conditions. For quantitative measurement procedures, it is expressed numerically as standard deviation or coefficient of variation. (1) |
| **Invalid rate** | Proportion of tests that fail to produce a valid result due to device-, specimen-, or end-user-related issues (4) |
| **Lower Limit of Quantitation (LLoQ)** | An estimate of the lowest concentration of the analyte in a sample that can be reliably measured with acceptable *bias* and precision (5) |
| **Point-of-care** | Testing performed at or near the site where patient care is delivered. This offers rapid turnaround times (6) |

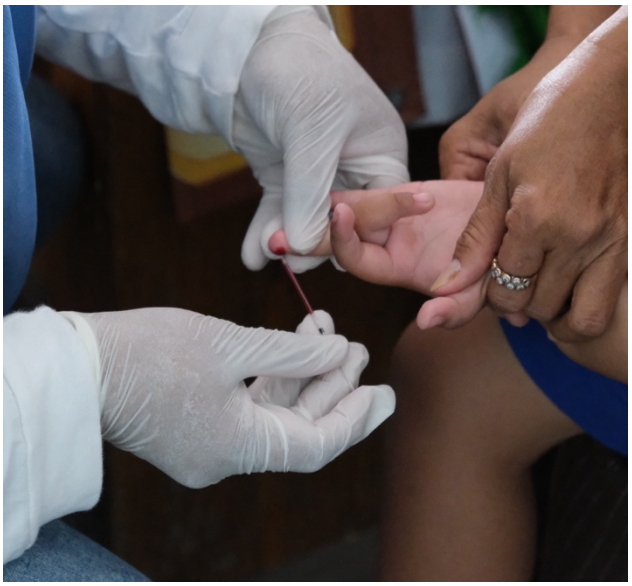
| | |
|---|---|
| **Precision step** | Refers to an action that requires accuracy and reproducibility, typically involving the use of calibrated instruments such as precision pipettes to dispense exact volumes of reagents or samples (e.g., addition of extraction buffer) to ensure the reliability of the test result |
| **Screening test** | Screening tests are used to detect the presence of a pathogen, biomarker, or other biological or physiological state associated with a disease or disorder, in individuals without signs or symptoms of the target condition. These tests are designed to evaluate an individual's current state (4) |
| **Semi-quantitative** | Measurement output expressed on an ordinal scale, sometimes with a reference card (e.g., litmus paper tests used to measure pH) |
| **Sensitivity** | True positive rate; proportion of individuals who truly have an outcome that are correctly identified by a screening or diagnostic method (7) |
| **Specificity** | True negative rate; proportion of individuals who truly do not have an outcome that are correctly identified by a screening or diagnostic method (7) |
| **Trained lay provider** | A person who has been trained and supervised to independently perform functions related to health care delivery and to deliver specific services, but who has received no formal professional or paraprofessional certificate or tertiary educational degree. Peers can be trained to function as lay providers (8) |
| **User step** | A step is defined as a significant and distinct action within a diagnostic procedure (e.g., collecting the sample, adding the sample to the cartridge, adding the buffer solution) (4) |

# Introduction

## Background

An estimated one in three children have blood lead levels (BLLs) above the World Health Organization's (WHO) current threshold of 5 µg/dL (a value that prompts action, not a safe level, since no amount of lead in blood is safe) – amounting to one billion children globally (9). Despite bans on leaded gasoline in the 1990s, lead exposure persists through a variety of sources, such as paints, pipes, plumbing materials, cookware, spices, cosmetics, and e-waste (9). Lead exposure causes irreversible cognitive impairment, as well as neurological and behavioral problems in children. Long-term effects in adults include cardiovascular disease and increased risk of chronic kidney failure, hypertension, anemia, liver damage, and reproductive dysfunction. Over 3.5 million deaths globally were attributable to lead exposure in 2023 (10). This leads to a global welfare cost for adults estimated at $1.9–6.0 trillion per year, or 2.2%–6.9% of global GDP (11). Additionally, in 2019, lead exposure was estimated to cause 765 million lost IQ points globally, 95% of them in low- and middle-income countries (LMICs), translating into roughly $1.4 trillion in lost lifetime income, or about 1.6% of global GDP and up to 8.3% in low-income countries (9). Momentum is growing amongst funders and governments to address this issue comprehensively, with the inauguration of the Partnership for a Lead-Free Future, Bloomberg Philanthropies' Lead Poisoning Prevention Initiative, Coefficient Giving's Lead Exposure Action Fund, and Pure Earth's 2026 Audacious Project Grant.

Although blood lead testing is recognized as essential and is included on the WHO Model List of Essential In Vitro Diagnostics (the Essential Diagnostics List, or EDL) (12), existing diagnostic tests for BLLs are not easily accessible in all geographies and do not adequately meet user needs. In LMICs, pricing that exceeds many health system budgets and procurement challenges limit the availability of BLL diagnostic tests for most children. In the United States, an estimated one third of children enrolled in mandatory routine screening programs do not receive their BLL test (13, 14). Complex workflows involving blood sample collection, handling, and preparation make test results particularly susceptible to lead contamination from skin surfaces or airborne particulates, as well as from blood-collection consumables such as lancets, capillary tubes, and diluents that may themselves carry trace lead. These same workflows pose a high burden on users where strict adherence to workflow is required to ensure result accuracy. Furthermore, available products are generally designed for use in clinical settings, leading to difficulties operating equipment in field settings. Recognizing these challenges, Homeworld Collective, Renaissance Philanthropy, and Pahlé India Foundation published the first draft TPP for blood lead level testing in November 2024, which this TPP builds upon (see Methods section below) (15).



*Health worker conducting blood lead level test in Indonesia. Photo: Vital Strategies*

## Objectives and target audience

The purpose of this TPP is to describe the desired characteristics of a rapid, low-cost tool for blood lead levels (BLLs) in children and other at-risk groups. Increased adoption of such a tool could support global efforts to reduce lead exposure by enabling broader uptake of screening programs, supporting case management where applicable, identifying geographic or population-level hotspots, informing the targeting of interventions, measuring the effectiveness of lead interventions, accelerating research on lead exposure and associated health outcomes, and generating political will for action. In settings where *confirmatory testing* and intervention capacity are

limited, affordable *point-of-care* testing can also help jurisdictions prioritize scarce resources by identifying individuals most likely to have elevated BLLs and directing follow-up accordingly.

The tool is intended to support the early identification of individuals with elevated BLLs who may benefit from additional assessment, *confirmatory testing*, and/or follow-up actions in accordance with local clinical and public health guidelines. Data generated through testing may also support population-level surveillance activities, including monitoring programs, research studies, and health risk assessments.

This TPP was developed to provide clear, consensus-based product guidance for developers, manufacturers, procurement agencies, health ministries, regulatory authorities, funders, and other stakeholders involved in reducing lead exposure. It is intended to support broader efforts to accelerate the availability of affordable *point-of-care* blood lead testing. This TPP does not provide regulatory guidance or set validation requirements; each regulatory agency should determine these within its own jurisdiction, prioritizing the attributes and specifications that need validation. Meeting the stated product characteristics is therefore not sufficient on its own. Manufacturers should provide objective evidence, generated through scientifically sound, internationally recognized verification and/or validation methods as appropriate to each characteristic, that the device performs as intended under representative conditions and throughout its expected lifecycle. Where relevant, this includes maintaining lifecycle processes such as software lifecycle management, cybersecurity risk management, post-market surveillance, software change control, and vulnerability management, in line with applicable regulatory requirements and recognized international standards.

## Scope

This TPP's primary intended use case is screening for elevated BLL across individuals of any age, in both high-income countries (HICs) and LMICs. This reflects the highest priority for maximum health impact and sustainable future demand across health systems. In most cases, individuals being screened have no visible signs of lead poisoning, so the test would serve as an initial screening test. While the test is intended to be applicable across the general population, screening programs should prioritize the populations at greatest risk, including young children (especially those under 6 years), pregnant women, occupationally exposed workers, and populations living near known sources of lead. As such, the test will be used in both clinical and field conditions. Additionally, while the *point-of-care* product currently closest to this profile uses anodic stripping voltammetry, this TPP is agnostic of analytical method and does not prescribe or favor any one.

The TPP defines acceptable and desirable requirements for each characteristic. Acceptable requirements represent the lowest satisfactory level, while desirable requirements are aspirational but intended to be realistically achievable. Products should aim to meet all acceptable requirements and as many desirable requirements as feasible. Where trade-offs are necessary, performance, cost, public health impact, and operational considerations should be assessed together; the characteristics should therefore be viewed as indicative rather than absolute. Developers are encouraged to pursue desirable requirements where possible, while avoiding unnecessary delays to innovation and product development.

# Methods

The methodology for developing this TPP was designed to be structured, transparent, and iterative. It combined evidence review, technology and market landscape analysis, expert consultation, end-user input, and formal consensus-building to ensure that the final TPP reflects both technical ambition and practical implementation realities across HICs and LMICs.

## Relationship to prior 2024 TPP

This TPP was developed by building on the TPP for Rapid, Accessible, and Low-Cost Blood Lead Level Testing published by Homeworld Collective, Renaissance Philanthropy, and the Pahlé India Foundation in November 2024 (15). That document established a foundational framework for the characteristics a next-generation *point-of-care* BLL test should meet, and several contributors to that prior work were also involved in this updated process.

While the 2024 TPP serves as an important starting point, this updated process was designed to substantially strengthen the evidence base and stakeholder engagement underpinning the final attributes. Specifically, this TPP development process added a formal Expert Advisory Group with a structured Delphi-like survey, focus group discussions across clinical and field settings, and an open public consultation period.

## Overview of the TPP development process

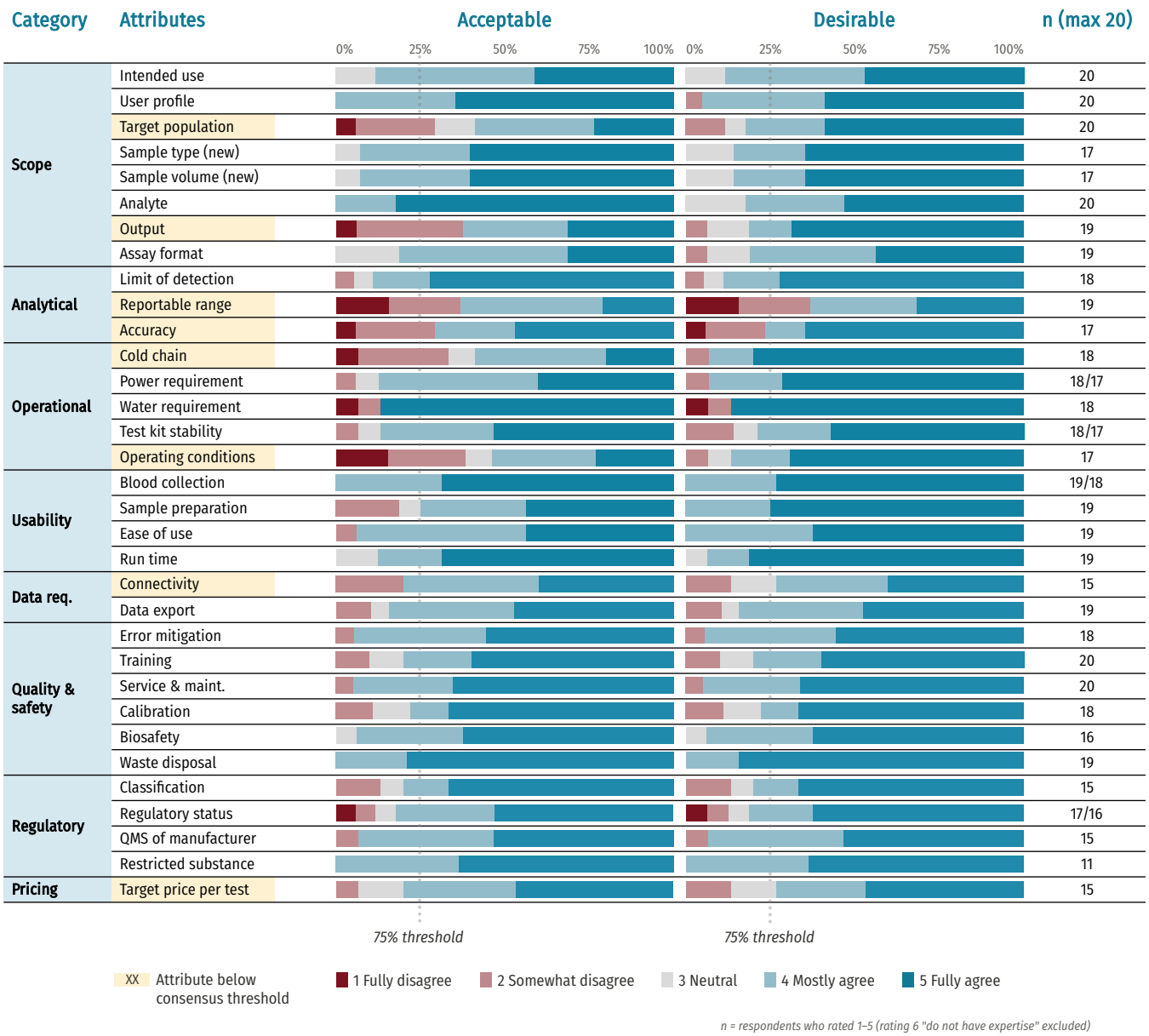
The TPP was developed through a seven-phase process designed to move from evidence gathering to structured consensus. The phases proceeded broadly sequentially, though some activities, particularly Expert Advisory Group consultation, focus groups, and bilateral stakeholder consultations, ran in parallel. To ensure alignment with best practice, established TPP development methodologies (including the WHO methodology), WHO generic TPPs, and a range of other published TPPs were systematically reviewed. Key design decisions were benchmarked against these references, including the composition of the Expert Advisory Group (see Acknowledgments for details), the decision to incorporate a public comment period, the inclusion of focus groups, the selection of attributes included in the initial draft, and the structure of the Delphi-like survey and consensus workshops (15, 16).

| Phase | Stage | Key activities |
|---|---|---|
| 1 | **Scoping & initiation** | Formed Steering Committee; mapped stakeholder landscape; reviewed prior BLL TPP; defined possible use cases and target populations |
| 2 | **Evidence & landscape review** | Conducted technology and market landscape analyses; reviewed published literature; benchmarked analogous diagnostic TPPs; identified evidence gaps |
| 3 | **Initial draft TPP** | Steering Committee drafted initial TPP attributes and thresholds, drawing on landscape review and 30+ bilateral consultations; produced initial TPP draft presented to Expert Advisory Group |
| 4 | **Expert Advisory Group consultation** | Convened Expert Advisory Group (made up of voting members and observers); administered modified Delphi-like survey; conducted consensus workshops to refine and validate attributes |
| 5 | **End-user focus groups** | Facilitated three structured focus group discussions across clinical and field settings to ground TPP attributes in real-world implementation experience |
| 6 | **Public consultation** | Published near-final draft for 21-day open public comment; reviewed all submissions; held final Expert Advisory Group consensus workshop to address comments raised and proposed changes |
| 7 | **Finalization & publication** | Integrated all stakeholder feedback; achieved final EAG approval; published and disseminated final TPP |

## Delphi-like survey

A modified Delphi-like survey was developed and administered to Expert Advisory Group voting members as the primary structured mechanism for collecting expert quantitative input on draft TPP attributes and identifying areas of convergence and disagreement in advance of consensus workshops.

For the purposes of survey analysis, an attribute was treated as having reached preliminary consensus if at least 75% of non-abstaining Expert Advisory Group voting members indicated agreement. This 75% threshold was selected because it reflects the median consensus threshold identified across published Delphi methodology literature and falls within the commonly recommended range of 70%–80% (17). Attributes meeting this threshold were presented to the Expert Advisory Group primarily for confirmation unless qualitative comments warranted further discussion, while attributes falling below the threshold were flagged as priority items for focused discussion during consensus workshops. See table below with survey data.




*n = respondents who rated 1–5 (rating 6 "do not have expertise" excluded)*

## Consensus workshops and public comment outcomes

Four consensus workshops were held with the Expert Advisory Group following analysis of the survey results in May and June 2026. The workshops were designed to review survey findings, work through attributes that had not reached the preliminary consensus threshold, consider relevant evidence and stakeholder perspectives, and refine TPP attributes as needed, with the goal of reaching consensus for each attribute. The draft TPP was published online for 21 days (June 17 to July 8, 2026) for public comment.

A final consensus workshop was held following the close of the public consultation period in July 2026, at which the Expert Advisory Group reviewed all substantive issues raised through public comment and confirmed the final attributes.

## Focus groups

Three focus groups were held in May and June 2026, each organized around a distinct stakeholder group to support targeted discussion of setting-specific needs, workflows, and constraints:

- Clinical administrators and program managers in field settings
- *End users* (e.g., nurses, laboratory technicians, community health workers) in clinical settings
- *End users* in field settings

Each group comprised 5-8 participants, consistent with established focus group methodology. Participants were individuals with direct experience conducting or organizing BLL testing, including clinicians, nurses, program implementers, laboratory and facility managers, and others involved in BLL testing, surveillance, or related operational decision-making. Participants had experience working with existing POC BLL testing devices.

Input from the focus groups was synthesized and used by the Steering Committee to inform the draft and to identify priority issues for Expert Advisory Group discussion; focus group participants did not participate directly in the consensus process.

# Target product profile

For each attribute, an *acceptable* and *desirable characteristic* is specified. In some cases, only one characteristic is specified. This reflects the acceptable characteristic. In the rightmost column, notes are included where needed to provide further information.

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **Scope** | | | |
| **1. Primary intended use case** | Screening of individuals for elevated* blood lead levels | | Screening programs typically target children, but the test should be applicable to all ages.<br>*Relative to jurisdiction-specific thresholds. |
| **2. End user** | *Trained lay provider* | | More highly trained or qualified health professionals (e.g., medical doctors, nursing and midwifery professionals) are also covered by this requirement.<br>Does not include self-trained users. See Training required for additional details. |
| **3. Use setting** | *Clinical setting* | *Field setting* | |
| **4. Target population** | Individuals of any age | | Screening programs should prioritize populations at greatest risk, including children (especially under 6 years), pregnant women, and occupationally exposed workers; the test should remain applicable to individuals of any age. |
| **5. Sample type** | Capillary whole blood | Capillary whole blood and venous whole blood | Capillary whole blood is the primary specimen type. Venous whole blood could be used for validation/verification purposes but is not expected to be the main specimen type because it requires a higher degree of training to collect and its invasive nature leads to high patient, parent, or caregiver refusal, particularly among children. Other biological samples were considered, including sweat, saliva, and urine, but were ultimately excluded because (i) no reference values exist for these sample types, (ii) sample collection can be prone to contamination, and (iii) lead measurements reflect either cumulative exposure (e.g., bone XRF) or acute exposure (e.g., urine). |
| **6. Sample volume** | ≤50 µL | | Sample volume refers to the volume needed for processing, not the volume collected. Different collection methods (e.g., capillary pool sample) may collect larger volumes than what is processed to account for sample compromise during handling. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **7. Analyte** | Lead | Lead, with capability for expanding to additional analytes | Additional analytes could include other environmental contaminants (examples include Hg, Cd, Cr, Ni, but further research is required to determine which specific additional analytes should be covered) and any other clinically relevant biomarkers associated with lead exposure (e.g., ferritin, zinc protoporphyrin, free erythrocyte protoporphyrin).<br>If additional analytes are included, consideration should be given to analytical interference and must not compromise either test's performance, cost (e.g., reagents), or usability (e.g., *user steps*, sample volume). |
| **8. Output** | *Semi-quantitative* | Quantitative | Thresholds and reportable range are specified under the Reportable range attribute. |
| **9. Assay format** | Disposable test kit with portable (handheld or benchtop) analyzer | Disposable test kit only or disposable test kit compatible with smartphone-based sensing application | |
| **Analytical performance** | | | |
| **10. Reportable range** | <u>Semi-quantitative output:</u><br>At least one threshold, with the lowest threshold ≤5 µg/dL* | Two or more thresholds, with at least one ≤5 µg/dL* | *The lowest threshold should align with the applicable national or jurisdictional reference value (e.g., 3.5 µg/dL per US CDC; 5 µg/dL in other settings).<br>When only one threshold is used, a risk-based approach to screening with *confirmatory testing* is recommended. |
| | <u>Quantitative output:</u><br>2-45 µg/dL | 1-65 µg/dL | A higher upper limit is acceptable; results above the upper quantification limit should be reported as above the level of quantification (e.g., ">65", "out of range").<br>Lower bound of the reportable range should align with the assay's *LLoQ*. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **11. Accuracy** | <u>Semi-quantitative output:</u><br>*Sensitivity* ≥95% and *Specificity* ≥95% at the threshold value (e.g., ≤5 µg/dL) | *Sensitivity* ≥95% and *Specificity* >95% across all chosen thresholds | *These limits accommodate the imprecision of the method, which should be < 0.7 µg/dL at low concentrations.<br>Analytical and clinical performance for blood lead is concentration-dependent and thus cannot always be adequately captured by a single fixed value across the full measuring interval. They are generally hardest to constrain at the low concentrations most relevant to current clinical action levels. These criteria are provisional and subject to revision as consensus standards and reference materials evolve.<br>Manufacturers should demonstrate that the combined effects of analytical *bias* and *imprecision* do not result in clinically significant misclassification or otherwise compromise the intended clinical performance of the device, particularly at relevant testing and clinical action thresholds. |
| | <u>Quantitative output:</u> (1)<br>≤±2 µg/dL below 20 µg/dL *<br>±10%, above 20 µg/dL | ≤±1 µg/dL below 20 µg/dL,<br>±5%, above 20 µg/dL | |
| **Operational requirements** | | | |
| **12. Power requirement** | <u>Disposable test kit compatible with a portable analyzer:</u><br>Portable power supporting continuous use for >6 hours, powered by commonly available sources (e.g., alkaline or lithium AA/AAA batteries, rechargeable batteries, and/or USB). | Portable power operation capable of continuous use for >10 hours under routine operating conditions. Battery-primary operation, where plug-in (external) power charges the battery only and does not power the test directly, so power fluctuations and interruptions cannot disrupt a running test. Compatibility with low-resource charging options (USB-compatible or solar-assisted charging) is preferred. | Where rechargeable batteries are used, they should be replaceable without servicing the unit. |
| | <u>Disposable test kit only or disposable test kit compatible with a smartphone-based sensing application:</u><br>None required (4) | | |
| **13. Water requirement** | None required (4) | | This refers to the testing procedure itself; hand-washing for the operator before capillary collection is assumed but not part of this attribute. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **14. Test kit stability** | 18 months at 10–35°C; ≤70% humidity | >24 months at 4–50°C; ≤75% humidity (4); conforms to ISO 23640:2011 | No cold chain requirement. Should be resistant to intermittent freezing (e.g., during transport in cold environments). |
| **15. Operating conditions** | 15-35°C; ≤75% humidity; altitude up to 2,500 m*; operable in low-light settings | 5-50°C; ≤90% humidity (18); altitude up to 3,500 m*; operable in low-light settings | Certain lead measurement analytical methods depend on chemical reactions (e.g., anodic stripping voltammetry) which are affected by temperature.<br>*Altitude requirements reflect the relative distribution of target populations at high altitudes, with an altitude of 2,500 m covering 99% of the world's population and 3,500 m covering 99.8% (19). |
| **16. Environmental Ingress Protection** | IP43 (protected against solid foreign objects of 1mm in diameter and greater; protected against spraying water) | IP65 (dust-tight; protected against low-pressure water jets) | Attribute applies to operating conditions. The entire test system should be considered, including analyzer, charging ports, cartridges, battery compartment, smartphone attachments, and connectors.<br>Critical device interfaces and consumable insertion points should maintain functional integrity under intended environmental operating conditions. |
| **Usability** | | | |
| **17. Blood collection method** | Blood sample collection kit* with safety lancet** | Collected within a closed-loop system*** (sealed sample path) | *Should include alcohol wipe, bandage, and gloves<br>**Safety lancet specifications should be appropriate to each intended target population. For example, heel-prick capillary sampling in neonates requires different lancet specifications than fingerstick collection (20) in older children and adults.<br>***Mechanism where blood is captured directly from skin to test with no open transfer or manual handling. This structurally minimizes the contamination risk posed by environmental lead – for example, vacuum-assisted micro sampling where blood is captured into a closed container. |
| **18. Additional third-party consumables** | All included in test kit, except blood sample collection kit | | Any third-party consumables required for specimen collection, test performance, or result generation should comply with applicable regulatory requirements, be validated for compatibility with the test system, and not adversely affect analytical performance or user safety. |
| **19. Sample preparation** | Minimal, no more than two steps and no *precision steps** or timing required (4, 19) | Integrated (on-board sample processing); transfer directly to test (4) | *Example of a *precision step* is the use of calibrated instruments such as precision pipettes to dispense exact volumes of reagents or samples. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **20. Ease of use** | ≤2 *user steps**, no steps requiring laboratory pipetting skills, 1 or no non-automated timed steps (4) | | Steps under consideration begin after sample preparation and exclude any additional steps for decontamination (e.g., hand washing) and device calibration.<br>*Example of a *user step* is adding the sample to the cartridge. |
| **21. Run time** | ≤15 minutes | ≤5 minutes | Run time excludes all sample preparation. |
| **Data requirements** | | | |
| **22. Data transmission** | <u>Disposable test kit compatible with a portable analyzer or disposable test kit compatible with a smartphone-based sensing application:</u><br>Mobile, network, Wi-Fi, or Bluetooth and USB; with test always able to be performed with local data storage | <u>Disposable test kit compatible with a portable analyzer or disposable test kit compatible with a smartphone-based sensing application:</u><br>Same as Acceptable, plus geolocation tagging, printer connectivity, and bidirectional communication | Where a connectivity technology is included (e.g., Wi-Fi, Bluetooth, cellular), it should support current, vendor-maintained versions that continue to receive security updates.<br>Geolocation data allows for aggregation of BLL results to support hotspot identification, environmental source attribution, and lead exposure surveillance.<br>Any data saved by the device should align with privacy-by-design principles, in line with the requirements outlined in the Security and privacy attribute. |
| | <u>Disposable test kit only:</u><br>Not applicable (4) | | |
| **23. Data export format** | <u>Disposable test kit compatible with a portable analyzer or disposable test kit compatible with a smartphone-based sensing application:</u><br>User-initiated export; encrypted data transmission for any export; CSV or similar format; both test results and device metadata exportable | <u>Disposable test kit compatible with a portable analyzer or disposable test kit compatible with a smartphone-based sensing application:</u><br>Same as Acceptable, plus scheduled or automatic synchronization with laboratory, clinical, or surveillance information systems using interoperable formats (e.g., HL7, FHIR, JSON-based exchange) | |
| | <u>Disposable test kit only:</u><br>Not applicable (4) | | |

| Attribute | Acceptable Desirable | Notes |
|---|---|---|
| **24. Data storage** | Disposable test kit compatible with a portable analyzer or a smartphone-based sensing application:<br><br>The deploying institution can specify where device data is stored; control rests with the local or national government or institution rather than the supplier by default. Suppliers may access limited operational data (e.g., status, error codes) under service arrangements, with a federated approach preferred.<br><br>Disposable test kit only:<br><br>Not applicable | Data governance policies (e.g., those that ensure privacy protection, deidentification, and anonymization) of test manufacturers and administrative institutions should align.<br><br>Suppliers may be granted access to limited operational data by the deploying institution (e.g., device status, error codes), particularly for error resolution and under all-inclusive service arrangements. A federated approach is preferred, in which operational data can be accessed without moving individual or patient-level data. |
| **25. Security and privacy** | Disposable test kit compatible with a portable analyzer or a smartphone-based sensing application:<br><br>To facilitate use by health programs in accordance with the laws, regulations, and policies in their settings and with best practices, the reader shall provide configurable features so that personal data can be*:<br>• gathered lawfully, fairly and transparently to users and patients<br>• collected and processed only for specified, explicit, and legitimate purposes compatible with the health program's purposes<br>• adequate, and limited to what is relevant and necessary<br>• collected and kept up to date accurately<br>• stored in identifiable form no longer than necessary, and<br>• secured for integrity and confidentiality, with encryption at rest and in transmission<br><br>Disposable test kit only:<br><br>Not applicable, unless linked to an external digital data system (e.g., RDT reader). If so, the above apply. | *Represents an abridged interpretation of the European Union General Data Protection Regulation 2016/679 (GDPR), article 5, sec. 1 |
| **26. Software and OS maintenance** | Disposable test kit compatible with a portable analyzer or a smartphone-based sensing application:<br><br>As applicable, the device should allow routine software or OS maintenance (automatically or manually). Updates should occur on a regular basis, *end users* should be informed of updates, and updates should remain compatible with existing versions and require minimal downtime so as not to affect testing throughput<br><br>Disposable test kit only:<br><br>Not applicable | |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **27. Language and localization** | For each country in which the test is deployed, the instructions for use, labeling, and training materials should be available in the main local language (the official or de facto national language), plus any language mandated by local regulatory or trade compliance requirements. On-screen software should be usable by intended *end user*, favoring image or icon-based interfaces | Same as Acceptable, plus additional languages that enable use by further residents of the location of deployment, and full localization of on-screen software into the main local language | |
| **Quality and safety requirements** | | | |
| **28. Invalid rate** | ≤5% (4) | | |
| **29. Invalid/error mitigation** | Assay identifies potential pre-analytical, analytical, and post-analytical sources of error with specific importance to error caused by contamination | | Validation should demonstrate resistance to clinically significant contamination from environmental lead sources under representative field-use conditions, including high-dust and outdoor environments. This includes contamination during specimen collection, handling and testing.<br>Required indicators include: (a) validity indicator (procedural/process control, QC lockouts, expired-reagent lockouts), (b) contamination indicator or safeguard, (c) sample sufficiency indicator<br>Pre-analytical includes contamination, insufficient sample. Analytical includes reagent/device failure. Post-analytical includes transcription, transmission, result-display errors. |
| **30. Training required** | ≤1 hour with image-based instructions, including a dedicated module on contamination avoidance and safe reagent handling; instructions provided with test kit or via smartphone-based software (4) | ≤30 minutes with image-based or video instructions, including contamination-avoidance module, safe reagent handling, and built-in competency check; instructions provided with test kit or via smartphone-based software (4) | Periodic requalification of operators recommended (e.g., quarterly or semi-annual), but treated as a deployment-context decision rather than an assay attribute. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **31. Service and maintenance** | <u>Disposable test kit compatible with a portable analyzer:</u><br>Swap-out or replacement of instrument/reader at the point of use without specialized servicing; software and firmware updates implementable by *end users* (4) | Minimal routine maintenance and downtime; no specialized servicing required for standard operation; remote diagnostics and remote software/firmware updates supported (4) | |
| | <u>Disposable test kit compatible with a smartphone-based sensing application:</u><br>Application updates implementable by *end users*; no specialized maintenance required | Minimal routine maintenance; no specialized servicing required; user-manageable application updates and OS compatibility | |
| | <u>Disposable test kit only:</u><br>Not applicable (4) | | |
| **32. Calibration** | <u>Disposable test kit compatible with a portable analyzer:</u><br>Automated, factory-set, self-checking, or remotely managed calibration at ≥12 months intervals. No user-performed calibration required, but calibration status must be verifiable by the operator (4) | Fully automated calibration with integrated verification; no user action required (4) | |
| | <u>Disposable test kit only or disposable test kit compatible with smartphone-based sensing application:</u><br>Not applicable (4) | | |
| **33. Biosafety precautions** | Inactivation step or self-contained system; no hazards when observing universal blood safety/body fluid precautions and all materials are free of components with a GHS classification H (particularly H350, H340, H360) (4) | | |
| **34. Waste disposal** | Waste disposal in biosafety bin following standard guidelines, including sharps containers for disposal of lancets, capillary tubes, etc. Appropriate disposal method for excess specimens and processing consumables (e.g., latrine, incineration). Standard operating procedure provided (4) | | The standard operating procedure should account for jurisdictional variation in sharps regulation.<br>For analyzer formats, the procedure should address end-of-life disposal of electronic components (e-waste), especially where waste infrastructure is limited. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **35. Packaging and component material safety** | Sample-contact materials and primary packaging verified trace-metal-free for lead, with material-introduced lead contribution materially below clinical decision thresholds. Manufacturer verification testing required for critical components | Independent ICP-MS verification at fresh stock and end-of-shelf-life under representative transport conditions. Documented change-control process requires re-verification on any sample-contact or packaging material substitution | Materials in scope: lancets, capillary tubes, micro-collection vials, cartridge components, reagent containers, transfer devices, and primary packaging. |
| **Regulatory and manufacturing requirements** | | | |
| **36. Classification** | Suitable for decentralized use by minimally trained operators in field or near-patient settings, with no laboratory infrastructure required | | A CLIA waiver (United States) (21) or its equivalent in other jurisdictions is one way to prove suitability for decentralized use. |
| **37. Regulatory status** | Approval by a WHO-Listed Authority (WLA), OR via WHO Prequalification (PQ) or Expert Review Panel for Diagnostics (ERPD) listing where applicable | Two or more of the pathways under "Acceptable," plus national registration in priority deployment markets, including via regulatory reliance or collaborative procedures (e.g., WHO collaborative registration, African Medicines Regulatory Harmonization initiative) | Approvals by national regulatory authorities will be required for additional markets. Pathways could be reliance-based or abbreviated based on jurisdiction. |
| **38. Quality management system of manufacturer** | Manufacturing of test kit and device (if applicable) complies with ISO 13485:2016 (4) | Same as Acceptable, plus either (a) MDSAP (Medical Device Single Audit Program) certification*, or (b) proactive post-market surveillance aligned with IVDR Article 83/84 expectations** | QMS scope includes software components and accessories.<br>*MDSAP allows a single audit to satisfy QMS requirements across five regulators (FDA, Health Canada, ANVISA, PMDA, TGA), reducing duplication for multi-jurisdictional access.<br>**IVDR Articles 83 and 84 set the EU's framework for proactive, systematic post-market surveillance, including active data collection on quality and performance, trend analysis, and feedback into design. |
| **39. Restricted substance compliance** | Manufacturing process and output comply with REACH (Annex XVII) (22), RoHS (23), and applicable national restricted-substance frameworks across the full test system: lancets, capillary tubes, cartridges, reagents, buffers, packaging, analyzer components, batteries, and electronic accessories | | Demonstrated absence of impact due to lead-containing components in any element of the test system is essential for a BLL test specifically.<br>Where hazardous substances cannot be avoided, manufacturers must provide documented justification, user-protective design controls, safety data sheets (SDS), safe-handling and disposal instructions.<br>Supplier declarations are insufficient for critical components; manufacturer verification expected. |

| Attribute | Acceptable | Desirable | Notes |
|---|---|---|---|
| **Pricing requirements** | | | |
| **40. Target price per test** | <u>Semi-quantitative output:</u><br>≤4 USD<br><br><u>Quantitative output:</u><br>≤6 USD | <br>≤2 USD<br><br><br>≤3 USD | Instrument cost should be low enough that, when amortized over the expected lifespan of the device and anticipated testing volume, it does not materially raise the per-test price. The target prices assume instrument cost is amortized into the cost per test.<br><br>The target price is all-inclusive, covering the amortized device plus the sample-collection kit.<br><br>Pricing should be achievable at scale, i.e., at the high procurement volumes expected for population-level screening programs. Targets are LMIC access prices (World Bank-defined LMICs), anchored to benchmarks of comparable products; the closest comparable is reimbursed at ~$13 per test in the US. |

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