Innovations in Cost-Disruptive Tools for Diagnosis and Screening

Grand Challenges

Request for Proposals

Applications due no later than April 28, 2026, 11:30 a.m. U.S. Pacific Time

Before applying, applicants should familiarize themselves with the supporting documents for this Grand Challenge, including the terms and conditions of the Gates Foundation, the Rules and Guidelines, Application Instructions, and Frequently Asked Questions (FAQs).

If you are planning to apply to this RFP, we will be hosting a dedicated webinar on March 30, from 8:30-9:30 AM Pacific Time. This session will provide a comprehensive overview of the RFP details and an opportunity to have your questions answered. To participate in the webinar, please register and submit your questions in advance. If you cannot attend live, the webinar will be recorded and available on this challenge page after the session.

Background

Diagnostic Access and Affordability

Limited access to affordable diagnosis is a significant barrier to disease control and equitable healthcare in low- and middle-income countries (LMICs). Nearly half of the global population lacks essential diagnostic tests, and access is almost nonexistent for up to 81% of people in the poorest settings, driving delayed or missed disease detection at scale.[1]

Diagnostics and screening underpin clinical care, surveillance, and disease control, yet many tools remain too costly, infrastructure-dependent, or operationally complex for use. The World Health Organization's (WHO) ASSURED principles, as well as the experience with malaria rapid diagnostic tests (RDTs) and community antigen testing during COVID-19, demonstrate how decentralization, low complexity, and affordability can expand reach and strengthen surveillance.[2,3] Where mature, widely deployed diagnostic classes already meet programmatic needs, pathway-changing innovation is more likely to yield impact than incremental improvements to established formats.

Beyond lowering consumable costs, the economic model must support high-volume screening through very low per-test costs and rapid throughput. Durable device- or platform-based solutions that use minimal or no consumables and amortize capital costs across large volumes, enabling near-zero incremental cost per test, can be transformational. Such approaches may draw on cross-sector technologies including imaging, acoustics, breath or environmental analyzers, contactless physiological monitors, or modular hardware with interchangeable sensing or analyte capabilities and minimal consumable inputs. In some contexts, appropriate use of artificial intelligence (AI) may enhance performance, enable task-shifting, automate quality control, and reduce operator variability, supporting high-throughput deployment in real-world LMIC workflows.

The Challenge

This Grand Challenge seeks **cost-disruptive tools for diagnosis and screening**, defined as devices that amortize capital to near-zero incremental cost and consumable $1-class tests that materially reset the cost curve in LMICs while meeting real-world deployment constraints (see **Table 1**). For screening applications, cost targets should be interpreted per person screened; for diagnostic or monitoring applications, per test performed. Accordingly, this initiative aims to translate these cost-disruptive concepts into scalable solutions across high-priority disease areas.

We are particularly interested in transformative, high-risk, high-reward innovations that fundamentally rethink how diagnosis or screening is performed, including novel sensing modalities, software-defined diagnostics, and AI-enabled or software-only approaches that materially change performance, cost structure, or deployment models.

Table 2 outlines topic areas and use cases that are in scope for this RFP. However, applicants are not required to demonstrate existing disease-specific validation data for these use cases. Cross-sector or cross-disease innovations are explicitly encouraged. For example, platforms or technologies initially developed for non-health, non-diagnostic, or different disease applications are eligible, provided the proposal includes a clear, technically credible, milestone-based plan to adapt the technology to at least one relevant use case in **Table 2**.

The Challenge aims to:

- Source cost-disruptive devices and $1-class diagnostics for the priority conditions listed in **Table 2**, including cost-enabling manufacturing innovations.
- Advance cross-sector, platform, and multimodal solutions to enable scalable screening, same-visit decision-making, or reconfigurable use cases.
- Build a staged portfolio spanning high-risk early concepts to later-stage adaptation and scale, using milestone-based awards aligned to clear technology readiness level (TRL) criteria.

We are looking for proposals that:

- Clearly articulate the relevant LMIC disease focus area and intended use case from **Table 2**, especially transformative approaches with a technically credible adaptation pathway where disease-specific validation does not yet exist.
- Describe operational feasibility for LMIC settings (see **Table 1**), including explicit attention to high-throughput screening workflows, where applicable.
- Include a feasible workplan and milestones appropriate to the maturity of the technology.
- Provide clear evidence to justify the requested funding level.
- Present a credible pathway to population-scale economics (approximately US$1 or near-zero incremental cost), including key assumptions. For platform-based solutions, describe how multiple use cases can improve economics and sustainability.
- Commit to independent evaluation participation and appropriate ethical, regulatory, and Foundation open access policy.

Table 1: Cross-Cutting Design Criteria	
Criterion	**Expectation**
Rapid results	Provides actionable results during a single patient encounter.
Ease of use	Operable by minimally trained users in decentralized settings.
LMIC robustness	Functions reliably in low-resource environments (heat, dust, intermittent power, limited infrastructure).
Cold-chain independence	Minimizes or eliminates cold-chain requirements through thermostable reagents and temperature-stable device design.
Consumables minimization	Reduces reliance on disposable consumables and favors durable, reusable hardware architectures with negligible incremental cost per screening.
Cost	Demonstrates a credible pathway to approximately US$1 per test or near-zero incremental cost per person screened for devices.
Transformative innovation	Incorporates novel architectures such as multimodal sensing, high-order multiplexing, software-defined diagnostics, AI-enabled interpretation, or software-only approaches.
Additional Desirable Attributes:	
Attribute	**Expectation**
Multi-disease capability	Enables testing for multiple diseases from a single platform or workflow.
Data traceability and surveillance integration	Ensures diagnostic results generated at the point of care are digitally structured, traceable, and interoperable with national and global surveillance systems, enabling secure transmission from test execution through aggregation and public-health use.
Modularity	Supports expansion to additional analytes or conditions without major redesign.
Environmental sustainability	Minimizes environmental impact through biodegradable or recyclable consumables and responsible end-of-life disposal strategies

For this challenge, we are not seeking proposals that:

- Are implementation, procurement, delivery, or roll-out projects without substantive R&D or primarily consisting of large clinical trials or definitive field studies (limited, development-oriented evaluation may be appropriate).
- Are discovery-only biomarker projects without a clear pathway to a deployable prototype within three to five years, or that propose only incremental modifications of well-established approaches without a plausible step-change in cost, scalability, or screening value.
- Request funding levels that are not supported by commensurate technical readiness, feasibility evidence, and a credible pathway to validation.
- Lack a plausible pathway to meet cost and operational constraints, including reliance on expensive consumables or complex infrastructure without a credible mitigation plan.
- Are unwilling to share prototypes, reagents, and/or data as needed for third-party assessment under appropriate governance arrangements.

Award Structure

To accommodate different stages of innovation, this Challenge has multiple award sizes commensurate with technology maturity. For example:

- **Option A:** Smaller proof-of-concept awards (up to five awards of approximately US$300,000, for each selected project, with a grant term of up to 24 months) to support early feasibility and prototyping, inclusive of technically risky, out-of-the-box concepts
- **Option B**: Mid-level awards (up to three awards of approximately US$500,000 for each selected project, with a grant term of up to 24 months) to support product refinement and early validation
- **Option C**: Larger awards (up to two awards of approximately US$1,000,000, for each selected project, with a grant term of up to 36 months) to support mature platforms or advanced adaptation toward verification and field readiness, with commensurate evidence of technical readiness, feasibility, and a clear pathway to validation

Final award amounts, number of awards at each level, and duration will depend on proposal quality and strategic fit. Applicants should request funding aligned with the scope and maturity of their proposed work and include a clear milestone plan proportionate to the support requested. Indirect costs will be considered and should be included in the budget for up to the grant amount awarded (subject to the Gates Foundation's indirect cost policy).

Eligibility

This initiative is open to research institutes, nonprofit organizations, for-profit companies, international organizations, government agencies, and academic institutions. Please note that all applicants will be expected to comply with the Gates Foundation's global access requirements. We encourage applications from projects led by or collaborating with women and/or researchers at institutions based in LMICs. Individuals and organizations classified as individuals for U.S. tax purposes are not eligible to receive an award from the foundation as part of this initiative.

Table 2: In-Scope Topic Areas, and Opportunities	
Topic area	**Tuberculosis (TB)**
Background	Tuberculosis requires highly scalable and extremely low-cost tools (including assays and durable device-based technologies) for both community-level, symptom-agnostic screening and accessible near-patient diagnosis.
Opportunity	A. Community and primary-care symptom-agnostic screening tools (non-sputum approaches prioritized).
	B. Diagnostic tools or devices aligned with WHO TB diagnostic TPPs, including true POC tests that enable rapid confirmation outside centralized laboratories.
	Additional information: TB
Topic area	**Human Immunodeficiency Virus (HIV)**
Background	Sustained epidemic control hinges on decentralized viral-load (VL) monitoring, timely early infant diagnosis (EID), and reliable identification of advanced HIV disease (AHD).

Opportunity	A. Near-POC or decentralized quantitative HIV viral-load testing.
	B. POC tool for EID for infants <18 months to enable same-visit diagnosis and treatment initiation.
	C. Near-POC CD4 or AHD triage tests to identify people needing the AHD package of care.
	Additional information: HIV
Topic area	**Malaria**
Background	Malaria case management and elimination strategies depend on ultra-low-cost rapid diagnostic tests (RDTs), with current procurement prices well below US$1 per test. Key challenges include compromised sensitivity due to HRP2/3 deletions, limited species differentiation at low parasite densities, market fragmentation affecting manufacturing reliability, and insufficient tools for mass screen-and-treat (MSAT) and elimination settings.
Opportunity	A. High-throughput screening tools for asymptomatic populations, including novel device-based or noninvasive sensing approaches, with <1 minute time-to-result and sensitivity to detect low-density infections.
	B. Ultra-low-cost non-HRP2 pan-Plasmodium RDTs (LDH or equivalent) with high sensitivity/specificity and sustainable sub-$1 manufacturing pathways. RDTs based solely upon HRP-2/3 as a biomarker are out of scope.
	C. AI-enabled or digitally augmented RDT platforms to improve read accuracy, performance, offer semi-quantitative interpretation, or increase workflow efficiency without increasing cost.
	Additional information: Malaria
Topic area	**Sexually Transmitted Infections (STI)**
Background	Syndromic management leaves many STIs undetected and drives overtreatment. HPV screening and triage that enable same-visit screen-and-treat pathways are additional high-impact prevention priorities.
Opportunity	A. POC diagnostics for gonorrhea (NG), chlamydia (CT), and trichomonas (TV) in symptomatic adults.
	B. POC diagnostics for active adult and congenital syphilis with ≥90% sensitivity ≥95% specificity in populations, including neonates to inform treatment.
	C. POC tools for high-risk HPV primary screening, with ≥95% sensitivity for CIN2+ and ≥99% specificity for ≤CIN 1, enabling same-visit screen-and-treat for cervical precancer.
	D. Platforms supporting modular expansion to additional STI analytes (e.g., BV) and programmatic throughput.
	Additional information: STI
Topic area	**Maternal and Newborn Health**
Background	Timely detection of pregnancy complications, (e.g., fetal growth restriction, preeclampsia, gestational hyperglycemia, and anemia) and neonatal infections are essential to prevent avoidable maternal and neonatal morbidity and mortality.
Opportunity	A. Preeclampsia screening and diagnostics: biomarker-based approaches such as quantitative PlGF/sFlt-1 ratios or retinal biomarkers measured with tools such as fundoscopy.

	B. Cuffless or low-burden blood pressure measurement approaches that reduce reliance on traditional cuffs and consumables and enable earlier detection and management of hypertensive disorders across routine antenatal care (ANC).
	C. Simplified, non-fasting or minimally invasive new biomarker-based approaches for gestational hyperglycemia detection/monitoring.
	D. Non-invasive, device-based gestational glucose monitoring approaches that eliminate fingersticks and consumables, enabling scalable repeat or longitudinal monitoring through durable, low-cost sensing platforms suitable for routine ANC.
	E. Rapid POC tools for neonatal sepsis triage to guide treatment escalation decisions and/or identify neonates who can safely avoid or step down from intensive care.
	F. Tools for earlier identification of infectious disease outbreak clusters in neonatal intensive care units (NICU).
	Additional information: Maternal and Newborn Health
Topic area	**Anemia and Women's Health**
Background	Anemia remains highly prevalent in key risk groups (children, adolescents, women of reproductive age, pregnant women, and lactating mothers), and routine hemoglobin testing is often limited by invasive sampling and infrastructure constraints, leading to missed or delayed identification and treatment.
Opportunity	A. Non-invasive anemia screening tool for community-level mass screening or primary-care-level triage.
	B. POC, minimally invasive diagnostic to distinguish iron deficiency anemia from other causes, including for severity testing, repeat testing in ANC and postpartum, for evaluation of heavy menstrual bleeding, and for micronutrient assessment.
	C. Triage tools for heavy menstrual bleeding (HMB) to rule out structural etiologies and identify ovarian abnormalities (e.g. biomarker panel or AI-enabled tool).
	Additional information: Anemia and Women's Health
Topic area	**Nutrition Surveillance and Fortified-Food Monitoring**
Background	Nutrition programs require timely, subnational micronutrient data and practical on-site fortified-food testing to guide targeting, monitor compliance, and inform vaccine and infectious-disease policy decisions.
Opportunity	A. Micronutrient Biomarker (MNBi): Technologies, including novel device-based or multimodal sensing approaches, that are compatible with minimally invasive or remnant-specimens and capable of detecting low-concentration micronutrients (e.g., B12, folate), including in the presence of inflammation, suitable for routine, high-throughput subnational surveillance.
	B. High-throughput laboratory or multiplex workflows that support repeated biomarker measurement through integration with existing infectious disease surveillance systems.
	C. Rapid tests that give quantitative or semi-quantitative on-site readouts of micronutrient content (particularly zinc or folic acid) in fortified food matrices to inform quality assurance.
	Additional information: Nutrition Surveillance and Fortified-Food Monitoring

Topic area	**Enteric Diseases**
Background	Enteric infections (including typhoid, cholera, and pediatric diarrhea pathogens) remain a major driver of morbidity and mortality in LMICs and can trigger outbreaks requiring rapid public-health action. Accurate, near-patient diagnostics are essential not only for clinical management and antimicrobial stewardship, but also for surveillance and vaccine policy decisions, as vaccines are available or in development for several high-burden enteric pathogens.
Opportunity	A. POC test to detect acute *Salmonella enterica* serovar Typhi infection with ≥90% sensitivity and ≥90% specificity.
	B. Acute *Shigella* diagnostic that detects *Shigella spp*. with high accuracy in the same patient encounter.
	C. Acute bacterial diarrhea diagnostic with high accuracy to distinguish bacterial from non-bacterial diarrhea in the same patient encounter.
	D. Near-patient cholera confirmatory test to detect toxigenic *Vibrio cholerae* (O1/O139 and/or cholera-toxin markers) with ≥95% sensitivity and ≥97% specificity, enabling faster confirmation than centralized workflows.
	E. Quantitative, flexible, multi-target pediatric diarrhea panel that includes at minimum rotavirus and *Shigella*, with additional high-burden viral or bacterial pathogens configurable to support evolving surveillance and vaccine priorities.
	Additional information: Enteric Diseases
Topic area	**Neglected Tropical Diseases (NTDs)**
Background	NTDs control and elimination require sensitive, specific, and affordable surveillance tools for community case-finding, targeted mass drug administration (MDA), mapping, and post-MDA surveillance, especially tools that retain performance at low prevalence.
Opportunity	A. Diagnostics that detect active infection vs. prior exposure to support stopping MDA and post-validation surveillance decisions.
	B. Point-of-care tests detecting circulating parasite antigens or other biomarkers of ongoing infection (e.g., in lymphatic filariasis or onchocerciasis) to improve specificity for transmission.
	C. Non-blood-based diagnostics that reduce operational barriers such as night blood collection in lymphatic filariasis and improve feasibility in elimination settings.
	D. Diagnostic tool for identifying prepatent or early patent Guinea worm infection in dogs to facilitate surveillance and targeted containment.
	E. High-throughput, integrated serology tests for mapping post-MDA surveillance across multiple NTDs (e.g., onchocerciasis, lymphatic filariasis, schistosomiasis, soil-transmitted helminths), with high sensitivity and specificity at low prevalence.
	Additional information: NTD
Topic area	**Emerging Pathogens and Syndromic Testing**
Background	Rapid detection, scalable surveillance, and surge-ready manufacturing are critical to shortening the time from pathogen emergence to population-level response. Diagnostics must be rapidly adaptable to new analytes, support decentralized triage and screening, and integrate with surveillance and early-warning systems in low-resource settings.

Opportunity	A. Rapidly reconfigurable, modular, open-architecture platforms capable of quick adaptation for new or emerging pathogens and capable of automated reporting to public health surveillance systems, supporting true POC triage and screening.
	B. High-order multiplex serological platforms suitable for nationally representative, population-level surveillance across endemic and epidemic pathogens.
	C. Field-usable, reconfigurable multiplex / syndromic panels for undifferentiated febrile illness, respiratory pathogens, or other outbreak-prone etiologies which support co-detection/co-infection interpretation and enable sentinel and facility-based surveillance.
	D. Point-of-care stool-based or non-stool diagnostic for live poliovirus to reduce outbreak confirmation time.
	E. Low-cost multiplex platforms capable of detecting priority pathogens in wastewater or environmental samples for outbreak detection and early warning.
	Additional information: Emerging Pathogens and Syndromic Testing
Topic area	**Manufacturing Innovations**
Background	Novel manufacturing techniques that increase scale, automate processes, and/or improve usable product yield can be critical in driving down the cost of diagnostic consumables enabling existing technologies to meet the $1-class diagnostic target.
Opportunity	A. Manufacturing innovations that reduce the cost of diagnostic consumables (e.g. reagents, lateral flow assays, microfluidic cartridges).
	B. Novel approaches to reduce device component costs by leveraging the latest advances in sensors and chip technologies - enabling higher integration and functionality with fewer components and simpler system architectures.

[1] Fleming KA, et al. The Lancet Commission on diagnostics: transforming access to diagnostics. Lancet. 2021; 398(10315):1997-2050.

[2] Land KJ, et al. REASSURED diagnostics to inform disease control strategies, strengthen health systems and improve patient outcomes. Nat Microbiol. 2019; 4(1):46-54.

[3] Kerr G, et al. Lessons for improved COVID-19 surveillance from the scale-up of malaria testing strategies. Malar J. 2022; 21:223.