Access to the best medical treatment often relies on the availability of appropriate tools and infrastructure to accurately diagnose a disease or condition. When diagnostics are intentionally designed and applied, they help to increase access to high-quality care, driving improvements in health outcomes and equity.

With over 35 years of experience in diagnostics development, PATH advances affordable and targeted innovations that guide earlier access to care and clinical decision-making, fill gaps in health care needs, support surveillance, and inform health policy development.

PATH accelerates development across the entire diagnostics ecosystem to ensure that quality-assured, fit-for-purpose diagnostics are available and affordable to people and communities in low-resource settings.

Providing technical support for end-to-end diagnostics development.

**Product definition**
- Identification and verification of clinical needs.
- Articulation of intended use statement.
- Concept feasibility, definition, target product profile, and specification documentation.

**Research and development**
- Reagent and formulation development.
- Experience with a range of assay types and platforms.
- Development of verification protocols.
- In-house de novo product development.
- Independent verification and validation of prototypes.
- Technology transfer.

**Performance evaluation and quality assurance**
- Lab assessments, analytical benchmarking, and environmental stability testing.
- Quality assurance program, including protocol development and implementation.
- Qualified resources to support product development and post-market surveillance.

**Technology transfer and collaboration with manufacturers and developers**
- Due diligence of manufacturers before technology transfer.
- Enabling tools and technologies for developers.
- Technical collaboration, feedback, and support for manufacturers.
- Annotated images to support digital readers and automated quality control systems.

**Clinical studies and evidence generation**
- Early-user research and expert/naive usability assessments.
- Design and execution of clinical studies to support product validation.
- Technical training for study teams.
- Data analysis, and reporting.
- Laboratory evidence of diagnostic performance.
- Technical documentation to facilitate regulatory pathways for registration and country adoption.
Product definition
PATH promotes the development of right-fit diagnostics with technical feasibility through upstream identification and articulation of the clinical need, use case, intended use, and target specification. A robust understanding of user needs and technical feasibility facilitates the preparation and development of target product profiles and functional specifications to guide development and set performance criteria for manufacturers and other stakeholders.

Performance evaluation and quality assurance
PATH creates highly characterized panels of target analytes for comparative evaluation of diagnostic technologies. Performance evaluations conducted in-house can range from iterative prototype refinement and environmental stability testing to benchmarking of commercial products and in-depth detection-limit analysis and impact modeling. Complementary to these evaluations, PATH develops and implements quality assurance programs and protocols to support long-term product quality in the hands of users. Finally, PATH provides external post-market diagnostics testing in a controlled laboratory setting to help ensure manufacturing consistency in the global health supply chain.

PATH Diagnostics maintains a 5,000-square-foot biosafety level 2 laboratory in Seattle, which houses state-of-the-art instrumentation operated by a highly skilled and qualified workforce. Our expertise includes:
- Lateral flow technology development and prototyping.
- Research and development for molecular testing in low-resource settings.
- Characterized panels of specimens and digital images and outputs to support the development and evaluation of early-stage diagnostic tools.
  - Immunoassays and serologic assays.
  - Molecular/nucleic acid amplification technologies.
  - Developing and validating machine-learning algorithms for cell phone image/scoring of rapid tests.
- Sample transport and processing technologies.

Research and development
PATH’s diagnostic-test experience encompasses immunoassay, serology, and molecular-based tests across platforms such as lateral flow and flow-through tests, enzyme-linked immunosorbent assays, and molecular platforms, including polymerase chain reaction and isothermal amplification.

PATH can de-risk research and development by evaluating critical diagnostic reagents—such as antigens and antibodies—and assessing the translation of lab-based to point-of-care platforms for new diagnostics. Using commercial and novel reagents from collaborators, PATH conducts in-house de novo proof-of-concept prototype development, product development, early-stage evaluation, and preparation of technology transfer package.

Technology transfer and collaboration with manufacturers
PATH assesses a manufacturer’s technical capabilities and business alignment—supporting the long-term goals of test availability to low-resource markets in need—to determine the right fit for technology transfer. Nascent digital applications are supported by the PATH image repository of rapid diagnostic test results. By providing active technical collaboration, laboratory evaluation of first-run tests, and support for documentation, market access, and clinical evaluations to manufacturers, PATH works to ensure technology transfer to commercial availability is a success.

Clinical studies and evidence generation
PATH supports and sponsors clinical studies for regulatory submission and WHO prequalification. Technical staff are integrated into clinical study activities, including data analysis, performance reporting, and developing a richer performance context based on combined clinical- and laboratory-performance data and modeled analysis of predicted performance and impact.

Contact
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PATH is a global nonprofit dedicated to achieving health equity. With more than 40 years of experience forging multisector partnerships, and with expertise in science, economics, technology, advocacy, and dozens of other specialties, PATH develops and scales up innovative solutions to the world’s most pressing health challenges.

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