



PRESS RELEASE

Innovative partnership brings to market new tools for neglected tropical diseases

New tools will support disease elimination for both river blindness and elephantiasis

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Seattle and Seoul, April 11, 2016 – PATH and Standard Diagnostics (SD)/Alere announced today the commercial availability of two rapid diagnostic tools for onchocerciasis and lymphatic filariasis. Designed for use in disease surveillance, the antibody-based tests are part of a suite of diagnostic innovations intended to support the elimination of neglected tropical diseases (NTDs), a group of illnesses that affect more than a billion people worldwide.

Onchocerciasis, commonly known as river blindness, is caused by a parasitic worm transmitted to humans through the bite of the blackfly. It causes itching, skin disfigurement, and, with chronic exposure, permanent blindness. Globally, an estimated 169 million people are at risk for river blindness and 37 million are infected. Of those at risk, 99 percent live in Africa. The disease typically affects poor, rural communities near streams and rivers.

Lymphatic filariasis (LF), the major cause of elephantiasis, is spread by mosquitos and damages the lymphatic system, leading to serious disability, disfigurement, and low quality of life across Africa and some parts of Asia. An estimated 120 million people are infected with LF and 1.23 billion are at risk. *Wuchereria bancrofti* (Wb) is one of three species of parasitic worms responsible for LF and accounts for 90 percent of the infections globally, including all cases on the African continent.

Both river blindness and LF commonly affect the same communities and cause great suffering, adding to the cycle of illness and poverty that impacts many remote areas of the world. The World Health Organization has targeted LF for global elimination and onchocerciasis for elimination in select countries in Africa by 2020. Control and elimination programs for both diseases use the drug ivermectin, and in the case of LF, a second drug in combination, to stop transmission. Accurate surveillance data are required to inform program decisions around stopping treatment of one or both drugs and detecting signs of reinfection.

The first test, an onchocerciasis and LF dual-detection, or “biplex,” test, is designed to fill these gaps in surveillance data for both diseases’ control programs in areas of Africa where the diseases are co-endemic. Potential advantages include reduced cost to control programs, simplified use and logistics, and improved coordination of decision-making among control programs. The biplex test can be used to support such programs as they move to the disease elimination phase by monitoring post-control areas and detecting cases in low-prevalence areas. The new biplex test, called the [SD BIOLINE Onchocerciasis](#)

[and Lymphatic Filariasis IgG₄ rapid test](#), is based on the detection of antibodies to parasite antigens Ov16 for onchocerciasis and Wb123 for LF. The Ov16 and Wb123 antigens were identified and characterized by scientists at the National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH).

Similarly, the second test, an LF monoplex test, can also be used in endemic areas where mass drug administration (MDA) has been ongoing for several years. In these areas, antibody-detection tests provide important information about recent transmission rates. Data from these surveillance studies may then be used to make critical decisions about whether to continue, halt, or reinstate MDA efforts. The new monoplex test, the [SD BIOLINE Lymphatic Filariasis IgG₄ rapid test](#), is based on the detection of antibodies to Wb123 for LF alone.

“In order to support mass treatment programs, we need to be able to conduct surveillance more easily and effectively,” said Tala de los Santos, Diagnostics Program leader at PATH. “With SD/Alere as our commercialization partner, PATH is pleased to be able to offer countries two more cost-effective diagnostic solutions for supporting surveillance activities of combined onchocerciasis and LF disease programs.”

These tests will join the [SD BIOLINE Onchocerciasis IgG4 rapid test](#), a monoplex antibody-detection test for onchocerciasis post-elimination surveillance, and the Alere Filariasis Test Strip, an antigen-detection test for use in LF disease mapping and to inform the MDA stopping decision, both marketed by SD/Alere to aid in the elimination of onchocerciasis and LF.

“We are pleased to have developed two more rapid tests with PATH,” said Byung-Ki Cho, vice president, Asia Pacific operations and R&D at SD/Alere. “The collaboration between SD/Alere and PATH is designed to help eliminate these neglected tropical diseases and will contribute to surveillance programs and public health management with qualified products.”

Funding to PATH to develop the onchocerciasis and LF bplex and LF monoplex rapid tests was provided by the Bill & Melinda Gates Foundation.

PATH is actively looking for partners to conduct demonstration and operations research studies using the new tests and will continue to offer technical assistance and training materials to implementation partners.

About PATH

PATH is the leader in global health innovation. An international nonprofit organization, PATH saves lives and improves health, especially among women and children. Accelerating innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—PATH harnesses its entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. With these key partners, PATH delivers measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

About Standard Diagnostics and Alere Inc.

Standard Diagnostics (SD), an Alere company, is based in Korea and focuses on rapid diagnostics. Alere Inc. delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical

and economic health care outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease, cardiometabolic disease and toxicology. For more information on Alere, please visit www.alere.com.

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