PRESS RELEASE

Innovative partnership expanded to bring to market dual detection test for neglected tropical diseases

PATH, SD/Alere and NIAID to collaborate on combined point-of-care rapid test for both river blindness and elephantiasis

Seattle and Seoul, February 18, 2015—PATH, an international nonprofit organization focused on global health innovation, and Standard Diagnostics (SD)/Alere, a global leader in rapid diagnostics, have expanded their partnership to bring to market a dual detection, or "biplex," test for the neglected tropical diseases (NTDs) onchocerciasis and lymphatic filariasis (LF). PATH and SD/Alere are working with the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health, to advance this novel diagnostic test. The new test will build on the momentum of the current partnership between PATH, SD/Alere and NIAID to manufacture and distribute the recently launched SD/Alere SD BIOLINE Onchocerciasis IgG4 rapid test.

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 disfiguration, and, with chronic exposure, permanent blindness. Globally, an estimated 126 million people are at risk for river blindness and 23 million are infected. Of those at risk, 99 percent live in Africa. The disease typically affects poor, rural communities near streams and rivers.

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 1.39 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 both diseases for elimination by 2020. Control and elimination programs for the diseases both 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 new biplex 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 NIAID, which has been working with PATH since 2011 on developing and testing the recently launched river blindness rapid test, Alere SD BIOLINE Onchocerciasis IgG4, and is now extending this work to the biplex test.

The dual detection capability of the Ov16/Wb123 biplex rapid test is designed to fill gaps in both onchocerciasis and LF 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 Ov16/Wb123 biplex rapid 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.

“We are pleased to collaborate with PATH to develop another rapid test, this time for detecting onchocerciasis and lymphatic filariasis within one device,” said Byung-Ki Cho, vice president, Asia Pacific operations and R&D at SD/Alere. “The collaboration between SD/Alere, PATH and NIAID will help eliminate and eradicate neglected tropical diseases and will contribute to surveillance programs and public health management with qualified products.”

“We are very happy to continue with SD/Alere as our commercialization partner for the new Ov16/Wb123 biplex rapid test,” said Tala de los Santos, director of diagnostics at PATH. “The new test bears great promise as a cost-effective diagnostic solution for supporting integrated surveillance activities of the two disease programs.”

This partnership paves the way for PATH to transfer the technology to SD/Alere to manufacture and distribute the only antibody test for dual detection of onchocerciasis and LF designed for use in rural and remote settings.

Funding to PATH to develop the Ov16/Wb123 biplex rapid test is provided by the Bill & Melinda Gates Foundation.

Field evaluations of the Ov16/Wb123 biplex rapid test will be conducted in the first half of 2015.

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 healthcare 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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