The onchocerciasis rapid test: Designed and developed to meet a global need

Mass drug administration and vector control, implemented through international partnerships, have reduced the prevalence of onchocerciasis worldwide. As programs move toward elimination, appropriate diagnostics are needed to support widespread surveillance.

The onchocerciasis rapid test was designed and developed to meet this need. This new tool is the result of an innovative public-private partnership between PATH; the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health; Standard Diagnostics, Inc.; and the broader onchocerciasis community.

It is fast, easy to use, appropriate for field use, and minimally invasive.

By improving surveillance, the onchocerciasis rapid test has the potential to help end the suffering caused by onchocerciasis.

PATH/Dunia Faulx

Resources and information

PATH can provide materials and information pertaining to training, uptake and implementation, protocols for Ov16 ELISA, and quality assurance, including an Ov16 positive control antibody.

Ordering, manufacturing, and distribution of the test are provided by Standard Diagnostics, Inc. (www.standardia.com).

Alere™ SD STANDARD DIAGNOSTICS, INC.

Cat. No.	Product Name
61FK10	SD BIOLINE Onchocerciasis IgG_4 Rapid Test

Learn more at **go.path.org/oncho**.

For all questions, please contact the PATH Diagnostics Program at **dxinfo@path.org**.

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

PATH www.path.org

Cover photo: PATH/Doune Porter

JULY 2015

ONCHOCERCIASIS SURVEILLANCE RAPID TEST

SD BIOLINE Onchocerciasis IgG_4: A new tool for control and elimination programs

Surveillance is critical to monitor progress toward elimination of onchocerciasis. The onchocerciasis rapid test will help.

PATH/Dunia Faulx

The onchocerciasis rapid test detects prior exposure to *Onchocerca volvulus*, the parasite that causes onchocerciasis. The test is based on the detection of antibodies to a parasite antigen called Ov16.

The test was developed to help onchocerciasis control and elimination programs by improving surveillance.

The onchocerciasis rapid test is:

- Fast.
- Easy to use.
- Appropriate for field use.
- Minimally invasive.

About the onchocerciasis rapid test

- Analyte: IgG_4 antibodies against Ov16 antigen.
- Specimen: Whole blood, serum, or plasma.
- Time to result: 20 minutes; results valid for 24 hours.
- Required training: Minimal.
- Storage: 1°C–40°C.
- Shelf life: 24 months.

PERFORMANCE OF THE ONCHOCERCIASIS RAPID TEST WITH WHOLE BLOOD

		Rapid test results at 20 minutes (with whole blood)	
		Positive	Negative
Reference test (Ov16 ELISA with plasma/ serum)	Positive	60	2
	Negative	1	112
	Sensitivity	96.80%	
	Specificity	99.1%	

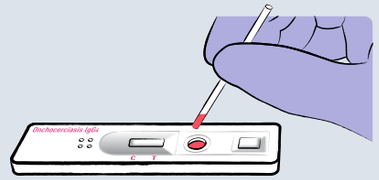
Source: Faulx D, et al. Field evaluation of Standard Diagnostics' onchocerciasis IgG4 rapid diagnostic test prototypes. Presented at: American Society of Tropical Medicine & Hygiene annual conference, November 3, 2014; New Orleans [poster presentation].

ONCHOCERCIASIS

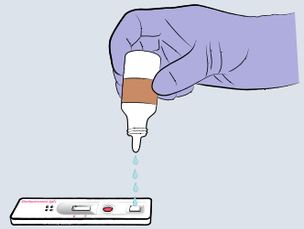
- Commonly called "river blindness."
- Caused by *Onchocerca volvulus* parasite.
- Transmitted by blackflies, *Simulium damnosum*.
- 37 million people infected worldwide, 99% in Africa.
- 169 million people at risk.
- Symptoms include severe itching, disfiguring skin conditions, and visual impairment, including permanent blindness.
- Elimination targeted by 2020 in several countries by the World Health Organization.
- More than 1 billion treatments donated by the Mectizan Donation Program since 1987.

Simple to use

ADD SAMPLE



ADD ASSAY DILUENT



WAIT 20 MINUTES

VIEW RESULT

NEGATIVE

POSITIVE

For full instructions, visit **go.path.org/oncho**.