

SD BIOLINE ONCHOCERCIASIS AND LYMPHATIC FILARIASIS  
IgG4 BIPLEX RAPID TEST

## How to use the Quality Assurance Panel



Contents included in the Anti-Ov16/Wb123 IgG4  
Quality Assurance Panel Q5008:

- 10 panel members with 200  $\mu$ L of liquid in each vial:
 

- O: 0ng/mL, L: 0ng/mL	- O: 25ng/mL, L: 0ng/mL
- O: 0ng/mL, L: 25ng/mL	- O: 50ng/mL, L: 0ng/mL
- O: 0ng/mL, L: 50ng/mL	- O: 100ng/mL, L: 0ng/mL
- O: 0ng/mL, L: 100ng/mL	- O: 50ng/mL, L: 1000ng/mL
- O: 0ng/mL, L: 200ng/mL	- O: 500ng/mL, L: 100ng/mL
- Anti-Ov16/Wb1234 Quality Assurance Panel Product Insert, Product Number Q5008.
- SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG4 Biplex Rapid Test Quality Assurance (QA) Panel Data Form.



Materials required but not supplied:

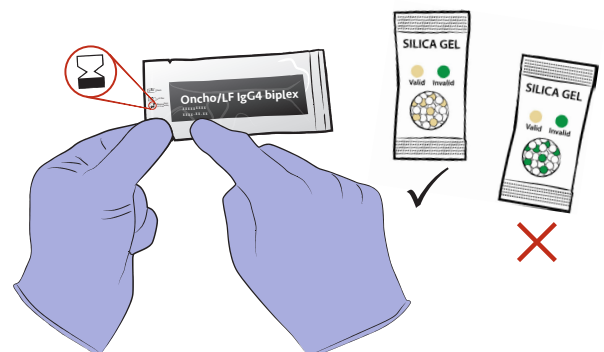
- SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG4 Biplex Rapid Test kits
  - 80 rapid tests
  - Assay diluent from test kits
- Volumetric pipette and pipette tips, appropriate for delivering 10 $\mu$ L

**STEP 1.** Remove the panel from the freezer and allow it to come up to room temperature. Tap closed vials several times to mix contents and firmly shake downward to ensure there is no liquid in the cap.

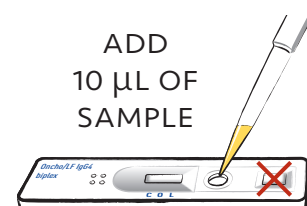
**STEP 2. Each panel member will be run on 8 separate rapid tests for a total of 80 rapid tests.**

For each rapid test:

- Check the expiration date on the rapid test pouch. Do not use a rapid test that is past the expiration date.
- Check the desiccant packet for yellow and white beads. If it contains any green beads, do not use the test.



**STEP 3.** Use a pipette to add **10  $\mu$ L** of solution to the **round sample well**. Use a new pipette tip for each panel member.

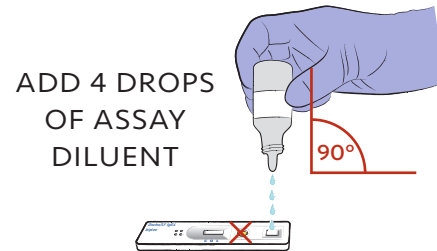




## How to use the Quality Assurance Panel

STEP 4. Add **4 drops** of assay diluent provided in the Oncho/LF IgG4 BIPlex test kit into the **square assay diluent well**.

**Do not add assay diluent to the round sample well.**



STEP 5. Wait for 30 minutes.

30 MINUTES



STEP 6. Read the rapid test results after 30 minutes have passed. Positive test results will have varying degrees of intensity.

Use the SD BIOLINE Oncho/LF IgG4 BIPlex Rapid Test QA Panel Data Form provided with the Quality Assurance Panel (Q5008) to note the result of each rapid test.

ONCHO POSITIVE (REACTIVE)  
AND LF NEGATIVE (NONREACTIVE)



ONCHO AND LF NEGATIVE  
(NONREACTIVE)



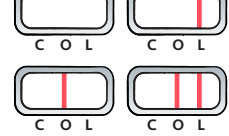
ONCHO AND LF POSITIVE  
(REACTIVE)



INVALID TEST RESULTS



LF POSITIVE (REACTIVE) AND  
ONCHO NEGATIVE (NONREACTIVE)



STEP 7. Tests must meet the criteria listed in the table. If QA results do not meet these criteria, please contact PATH at [dxinfo@path.org](mailto:dxinfo@path.org) and share your data collection forms. Dispose of used rapid tests and QA panel members in the biohazard waste.

	Onchocerciasis concentration (O)	LF concentration (L)	O line result	L line result
1	0ng/ml	0 ng/ml	Negative on all replicates	Negative on all replicates
2	0ng/ml	25 ng/ml	Negative on all replicates	Positive on at least (4/8) 50% of replicates
3	0ng/ml	50ng/ml	Negative on all replicates	Positive on at least (4/8) 50% of replicates
4	0ng/ml	100ng/ml	Negative on all replicates	Positive on all replicates
5	0ng/ml	200ng/ml	Negative on all replicates	Positive on all replicates
6	25ng/ml	0ng/ml	Positive on at least (4/8) 50% of replicates	Negative on all replicates
7	50ng/ml	0ng/ml	Positive on all replicates	Negative on all replicates
8	100ng/ml	0ng/ml	Positive on all replicates	Negative on all replicates
9	50ng/ml	1000ng/ml	Positive on all replicates	Positive on all replicates
10	500ng/ml	100ng/ml	Positive on all replicates	Positive on all replicates

This document must be printed in **color** to be valid.

For more information or training-related questions,  
contact PATH's Diagnostics Program at [dxinfo@path.org](mailto:dxinfo@path.org).

