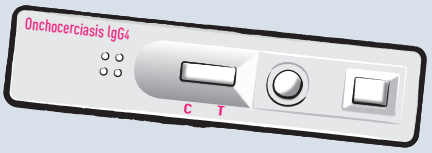
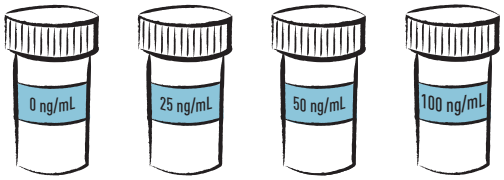
SD BIOLINE ONCHOCERCIASIS IgG4 RAPID TEST

How to use the Quality Assurance Panel



Contents included in the Anti-Ov16 IgG4 Quality Assurance Panel Q5002:

- 4 panel members with 200 µL of liquid in each vial:
  - 0 ng/mL
  - 25 ng/mL
  - 50 ng/mL
  - 100 ng/mL



- Anti-Ov16 IgG4 Quality Assurance Panel Product Insert, Product Number Q5002.
- SD BIOLINE Onchocerciasis IgG4 Rapid Test Quality Assurance (QA) Panel Data Form.

Materials required but not supplied:

- SD BIOLINE Onchocerciasis IgG4 Rapid Test kits
  - 32 rapid tests
  - Assay diluent from test kits
- Volumetric pipette and pipette tips, appropriate for delivering 10µL

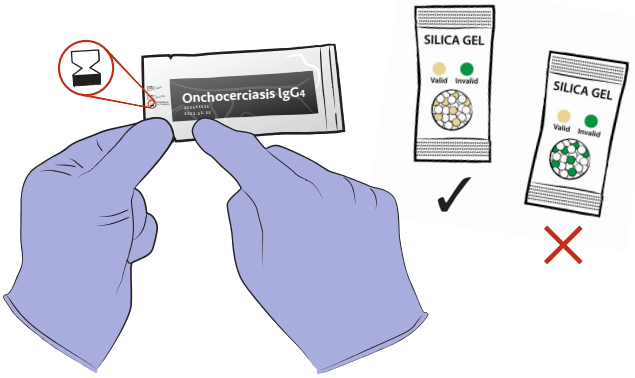
STEP 1. Remove the panel from the freezer and allow it to come up to room temperature. Tap closed vials several times to mix contents and firmly shake downward to ensure there is no liquid in the cap.

STEP 2. **Each panel member will be run on 8 separate rapid tests for a total of 32 rapid tests.**

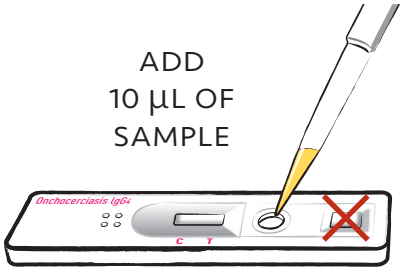
For each rapid test:

a. Check the expiration date on the rapid test pouch. Do not use a rapid test that is past the expiration date.

b. 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 µL** of solution to the **round sample well**. Use a new pipette tip for each panel member.



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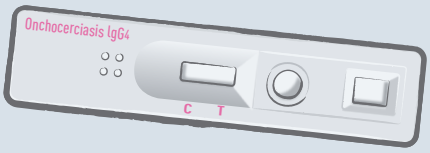
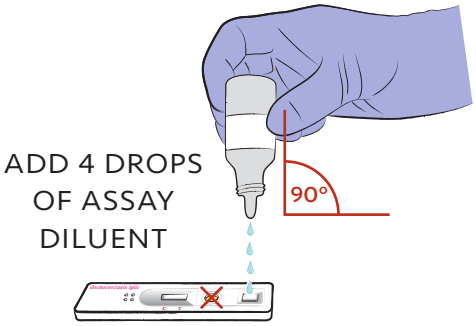


STEP 4. Add **4 drops** of assay diluent provided in the Onchocerciasis IgG4 test kit into the **square assay diluent well**.

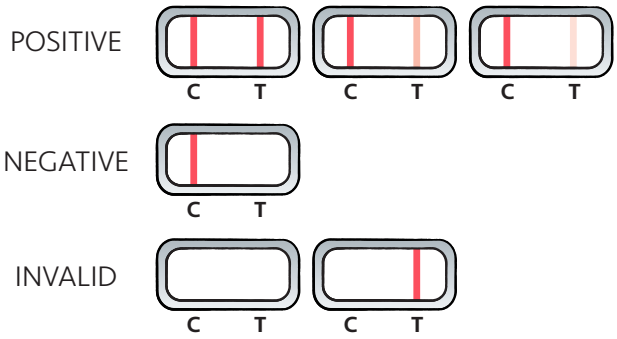
Do not add assay diluent to the round sample well.



STEP 5. Wait for 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 Onchocerciasis IgG4 Rapid Test QA Panel Data Form provided with the Quality Assurance Panel (Q5002) to note the result of each rapid test.



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 and share your data collection forms. Dispose of used rapid tests and QA panel members in the biohazard waste.

	Oncho concentration	Result
1	0 ng/ml	Negative on all replicates
2	25 ng/ml	Positive on at least 4/8 replicates
3	50 ng/ml	Positive on all replicates
4	100 ng/ml	Positive on all replicates

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For more information or training-related questions, contact PATH's Diagnostics Program at dxinfo@path.org.

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