

# Anti-Ov16 IgG<sub>4</sub> Daily QC Sample

For use with SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test

Product Number Q5011

Lot Number 170228

Product Insert



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TEL +1.206.285.3500  
FAX +1.206.285.6619  
EMAIL [dxinfo@path.org](mailto:dxinfo@path.org)  
[www.path.org](http://www.path.org)

## INTENDED USE

The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 is a single sample with established reactivity to the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test. This sample is intended to be used for daily quality control activities in the field prior to using the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and/or SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test with human samples.

For Research Use Only. Not for use in diagnostic procedures.

## PRODUCT DESCRIPTION

Q5011 consists of one sample manufactured from human plasma with specific reactivity to the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test (Table 1). Proclin®(0.05%) was added as a preservative.

Product Number: Q5011      0.1 mL per vial

## PRECAUTIONS

The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 is manufactured from defibrinated human plasma that is negative for HBV DNA, HCV RNA, HIV-1 RNA, Human Parvovirus B19 DNA, and HAV RNA using nucleic acid amplification methods, and nonreactive for HBsAg and antibodies to HIV-1, HIV-2, HCV, HTLV I, HTLV II, HBs, and HBc using USFDA licensed test methods. Anti-Ov16 IgG<sub>4</sub> stock materials are from a recombinant human IgG<sub>4</sub>. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice. Caution. Biohazard. Use Universal Precautions. Do not pipette by mouth. Do not smoke, eat, sleep, or drink in areas where panel members or patient specimens are handled.

Discard/dispose of samples in a manner that will inactivate pathogenic agents.

## LIMITATIONS

The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 is offered for research use only. Not for use in diagnostic procedures.

## RECOMMENDED INSTRUCTIONS FOR USE

It is recommended for the Daily QC Samples to be run every day by each field team prior to field testing. Daily QC Samples should be used prior to using a new lot of tests. The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 may be used with either the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test or the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test. The Daily QC sample should be treated as an individual sample and used according to test instructions. Routine personal protective equipment (e.g. gloves, safety goggles, protective clothing) should always be used. The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 should be allowed to equilibrate to room temperature before opening. Thoroughly mix the sample prior to use. Firmly shake vial downward several times to ensure there is no residual liquid in the cap. Sample should be applied to the test with the disposable capillary pipette provided in the kit. Use a new capillary pipette for each sample obtained from the vial. As directed by the test instructions, sample is collected as follows: Gently squeeze and hold the capillary pipette. Place the pipette tip on the sample and release squeeze to collect sample up to the fill line. Sample is added to the test by placing the capillary pipette into the round sample well and gently squeezing to release the sample. Let the sample absorb into the round sample well. Add four drops of assay diluent to the square assay diluent well. Results are interpreted after 30 minutes for the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and 30 minutes for the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test. The tests are qualitative and any visible line in the appropriate C, T, O, or L area of the result window should be interpreted as a line. Dispose of used capillary pipette(s) and tests in a manner that will inactivate pathogenic agents.

Once a sample vial is opened, it should be stored at ambient temperature (<45°C) for no longer than 3 days before discarding. Daily QC Samples should be disposed of in a manner that will inactivate pathogenic agents.

If test results are inconsistent with the expected results (Table 1) immediately contact a supervisor prior to testing with human samples. Results inconsistent with expected results may be due to a number of factors including test is not performing as intended, failure to follow the test instructions as directed, improper storage of the Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011, or expired materials. If repeat testing continues to yield test results that are inconsistent with the expected results, contact PATH at [dxinfo@path.org](mailto:dxinfo@path.org) with detailed information for further troubleshooting.

## STORAGE

Daily QC Samples are shipped at ambient temperature. Upon receipt the samples should be stored frozen (-20°C or colder) for up to 2 years from receipt or refrigerated (2-8°C) for up to 14 weeks from receipt. Prior to use, samples may be removed from frozen or refrigerated storage and stored at ambient temperature (<45°C) for an additional 2 weeks. Once samples are removed from frozen or refrigerated storage they must be used or discarded. DO NOT RETURN SAMPLES TO FROZEN OR REFRIGERATED STORAGE. Once a vial is opened, the sample can be stored at ambient temperature (<45°C) for up to 3 days. Unopened samples stored longer than 2 years frozen (-20°C or colder), 14 weeks refrigerated (2-8°C), or 2 weeks ambient temperature (<45°C) should be discarded. Opened samples stored at ambient temperature (<45°C) should be discarded within 3 days of opening. Alterations in physical appearance may indicate instability or deterioration. Discard samples that are visibly turbid.

## INTERPRETATION OF RESULTS

The Anti-Ov16 IgG<sub>4</sub> Daily QC Sample Q5011 should be positive when tested with the SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and positive (reactive) for only Onchocerciasis (not Lymphatic Filariasis) when tested with the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bipler Rapid Test.

Table 1: Expected results

Test	Expected result
SD BIOLINE Onchocerciasis IgG <sub>4</sub> Rapid Test	Onchocerciasis positive (reactive) 
SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG <sub>4</sub> Bipler Rapid Test	Onchocerciasis positive (reactive) 

For assistance, contact PATH at [dxinfo@path.org](mailto:dxinfo@path.org).

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For use with SD BIOLINE Onchocerciasis IgG<sub>4</sub> Rapid Test and/or  
SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG<sub>4</sub> Bplex Rapid Test  
Product Number Q5011  
Lot Number 170228

0.1mL each

Upon receipt store frozen (-20°C or colder) for up to 2 years or  
refrigerated (2-8°C) for up to 14 weeks  
Afterwards ambient temperature (<45°C) up to 2 weeks  
Opened samples should be discarded within 3 days

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