

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test

Product Number Q5002 Lot Number 150928

Product Insert



INTENDED USE

The Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 is a panel of four members with established reactivity to the SD BIOLINE Onchocerciasis IgG₄ Rapid Test. This panel is intended to be used for assessing the quality of SD BIOLINE Onchocerciasis IgG₄ Rapid Tests received from the manufacturer or supplier. The panel may also be used as part of ongoing programs of lot acceptance for SD BIOLINE Onchocerciasis IgG₄ Rapid Tests, to isolate system errors, and in troubleshooting these assays, as a component of a quality assurance program.

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

PRODUCT DESCRIPTION

Q5002 consists of four members, manufactured from human plasma, with a range of reactivity to the SD BIOLINE Onchocerciasis IgG₄ Rapid Test (Table 1). Three panel members were formulated with various reactivities for anti-Ov16 IgG₄, and the negative member was formulated from anti-Ov16 IgG₄ negative pools. Proclin® (0.05%) was added as a preservative.

Product Number: Q5002 1 vial per member
4 members, 0.2 mL per vial

PRECAUTIONS

Members of the Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 are 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 HBe using USFDA licensed test methods. Anti-Ov16 IgG₄ stock materials are from a recombinant human IgG₄. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice. Do not pipette by mouth. Do not smoke, eat, or drink in areas where panel members or patient specimens are handled.

Discard/disposed of panel members in a manner that will inactivate pathogenic agents.

LIMITATIONS

The Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 is offered for research use only. Not for use in diagnostic procedures.

RECOMMENDED INSTRUCTIONS FOR USE

The Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 may be used with the SD BIOLINE Onchocerciasis IgG₄ Rapid Test. Testing should be conducted once all of the tests from the same lot arrive to your facility. Each lot must meet the acceptance criteria described below before commencing testing with human samples. Only individuals with appropriate background and technical skills who have been trained to run the test should use this panel. Eight replicates of each panel member should be performed on tests randomly selected from the entire shipment. Routine personal protective equipment (e.g. gloves, safety goggles, protective clothing) should always be used. The Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 should be allowed to equilibrate to room temperature before opening. Samples should be thoroughly mixed prior to use. Firmly shake vials downward several times to ensure there is no residual liquid in the cap. Sample should only be applied to the test with a volumetric pipette capable of accurately delivering 10µL. As directed by the test instructions, 10µL of sample is added to the round sample well. Let the sample absorb into the sample well. Add four drops of assay diluent to the square assay diluent well. Results are interpreted after 30 minutes and recorded on the QA data form. This is a qualitative test and any visible line in the appropriate C or T area of the result window should be interpreted as a line. See Figure 1 for the interpretation guide. Dispose of used pipette tips and tests in a manner that will inactivate pathogenic agents.

ACCEPTANCE CRITERIA

The expected results for each panel member are shown in Table 1. All tests run with 0 ng/mL panel member must be negative. All tests run with 100 ng/mL and 50 ng/mL panel members must be positive. Tests run with 25 ng/mL should be positive (reactive) on at least 4/8 replicates. Test results inconsistent with the expected results may be due to a number of factors including failure to follow the test instructions as directed, test quality, improper storage of the Anti-Ov16 IgG₄ Quality Assurance Panel Q5002, or expired materials. Contact PATH at dxinfo@path.org with detailed information for further troubleshooting.

STORAGE

Quality assurance panels are shipped at ambient temperature. Upon receipt, panel members should be stored frozen (-20°C or colder) for up to 2 years from receipt. A frost-free freezer is not recommended for storage due to temperature cycling. Prior to use, panel members may be stored refrigerated (2-8°C) for up to one week. Once a vial is opened, the panel member should be stored refrigerated (2-8°C) and discarded within 2 days. Alterations in physical appearance may indicate instability or deterioration. Discard panel members that are visibly turbid.

INTERPRETATION OF RESULTS

Individual tests should be interpreted according to test instructions (see Figure 1 for examples). The presence of only the control line (C) indicates that the test is negative for Ov16- reactive IgG₄ antibodies. The presence of the onchocerciasis test line (T) indicates that the test result is positive for Ov16-reactive IgG₄ antibodies. The absence of the control line (C) indicates an invalid result.

EXPECTED RESULTS

The Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 is formulated to the characteristics in Table 1.

Table 1 Anti-Ov16 IgG₄ Quality Assurance Panel Q5002 Description

Panel Member ID	Anti-Ov16 IgG ₄ Concentration	SD BIOLINE Onchocerciasis IgG ₄ Rapid Test Result
Oncho Rapid Test QA Panel Q5002 0 ng/mL	0 ng/mL	Negative (nonreactive) on all replicates
Oncho Rapid Test QA Panel Q5002 25 ng/mL	25 ng/mL	Positive (reactive) on at least (4/8) 50% of replicates
Oncho Rapid Test QA Panel Q5002 50 ng/mL	50 ng/mL	Positive (reactive) on all replicates
Oncho Rapid Test QA Panel Q5002 100 ng/mL	100 ng/mL	Positive (reactive) on all replicates

For assistance, contact PATH at dxinfo@path.org.

Figure 1 Interpretation of SD BIOLINE Onchocerciasis IgG₄ Rapid Test

Positive (reactive)	
Negative (nonreactive)	
Invalid	

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received:

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received:

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received:

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received:

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received:

Anti-Ov16 IgG₄ Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis IgG₄ Rapid Test
Product Number Q5002
Lot Number 150928

4 vials 0.2mL each

Store frozen (-20°C or colder)

Once thawed, store refrigerated (2-8°C) for up to 1 week

Opened panel members should be stored refrigerated (2-8°C) and be discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

PATH
2201 Westlake Ave, Suite 200
Seattle, WA 98121
USA
TEL +1.206.285.3500
FAX +1.206.285.6619
EMAIL dxinfo@path.org
www.path.org



Q5002 v 7.0

Date received: