Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel

For use with SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex Rapid Test

Product Number Q5008 Lot Number 150928

Product Insert

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EMAIL dxinfo@path.org
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INTENDED USE

The Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 is a panel of 10 members with established reactivity to the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex Rapid Test. This panel is intended to be used for assessing the quality of SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex 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 and Lymphatic Filariasis IgG_4 Biplex 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

Q5008 consists of 10 members, manufactured from human plasma, with a range of reactivity to the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex Rapid Test (Table 1). Five panel members were formulated with various reactivities for anti-Ov16 IgG_4, six panel members were formulated with various reactivities for anti-Wb123 IgG_4, and the negative member was formulated from anti-Ov16 and anti-Wb123 IgG_4 negative pools. Proclin® (0.05%) was added as a preservative.

Product Number: Q5008 1 vial per member
10 members, 0.2 mL per vial

PRECAUTIONS

Members of the Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 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 HBc using USFDA licensed test methods. Anti-Ov16 and anti-Wb123 IgG_4 stock materials are from a recombinant human IgG_4. The potential for transmission of infectious agents exists, and these materials should be handled following good laboratory safety practice. Do not pipette by mouth. Caution. Biohazard. Use Universal Precautions. Do not smoke, eat, sleep, or drink in areas where panel members or patient specimens are handled.

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

LIMITATIONS

The Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 is offered for research use only. Not for use in diagnostic procedures

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- and Wb123- reactive IgG4 antibodies. The presence of the onchocerciasis test line (O) indicates that the test result is positive for Ov16-reactive IgG4 antibodies. The presence of the lymphatic filariasis test line (L) indicates that the test result is positive for Wb123-reactive IgG4 antibodies. The absence of the control line (C) indicates an invalid result.

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

EXPECTED RESULTS

The Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 is formulated to the characteristics in Table 1.

Table 1 Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 Description

Panel Member ID		Anti-Ov16 IgG_4 Concentration	Anti-Wb123 IgG_4 Concentration	Acceptance Criteria Anti-Ov16 IgG_4	Acceptance Criteria Anti-Wb123 IgG_4
1	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 0ng/mL, L: 0ng/mL	0 ng/mL	0 ng/mL	Onchocerciasis negative (nonreactive) on all replicates	Lymphatic Filariasis negative (nonreactive) on all replicates
2	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 0ng/mL, L: 25ng/mL	0 ng/mL	25 ng/mL	Onchocerciasis negative (nonreactive) on all replicates	Lymphatic Filariasis positive (reactive) on at least (4/8) 50% of replicates
3	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 0ng/mL, L: 50ng/mL	0 ng/mL	50 ng/mL	Onchocerciasis negative (nonreactive) on all replicates	Lymphatic Filariasis positive (reactive) on at least (4/8) 50% of replicates
4	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 0ng/mL, L: 100ng/mL	0 ng/mL	100 ng/mL	Onchocerciasis negative (nonreactive) on all replicates	Lymphatic Filariasis positive (reactive) on all replicates

5	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 0ng/mL, L: 200ng/mL	0 ng/mL	200 ng/mL	Onchocerciasis negative (nonreactive) on all replicates	Lymphatic Filariasis positive (reactive) on all replicates
6	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 25ng/mL, L: 0ng/mL	25 ng/mL	0 ng/mL	Onchocerciasis positive (reactive) on at least (4/8) 50% of replicates	Lymphatic Filariasis negative (nonreactive) on all replicates
7	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 50ng/mL, L: 0ng/mL	50 ng/mL	0 ng/mL	Onchocerciasis positive (reactive) on all replicates	Lymphatic Filariasis negative (nonreactive) on all replicates
8	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 100ng/mL, L: 0ng/mL	100 ng/mL	0 ng/mL	Onchocerciasis positive (reactive) on all replicates	Lymphatic Filariasis negative (nonreactive) on all replicates
9	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 50ng/mL, L: 1000ng/mL	50 ng/mL	1000 ng/mL	Onchocerciasis positive (reactive) on all replicates	Lymphatic Filariasis positive (reactive) on all replicates
10	Oncho/LF Biplex Rapid Test QA Panel Q5008 O: 500ng/mL, L: 100ng/mL	500 ng/mL	100 ng/mL	Onchocerciasis positive (reactive) on all replicates	Lymphatic Filariasis positive (reactive) on all replicates

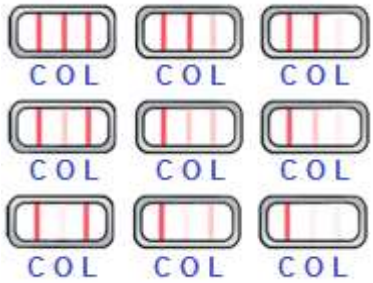
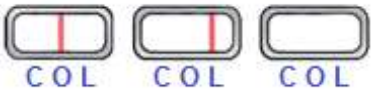
RECOMMENDED INSTRUCTIONS FOR USE

The Anti-Ov16 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 may be used with the SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex 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 above 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 and Anti-Wb123 IgG_4 Quality Assurance Panel Q5008 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/QC data form. This is a qualitative test and any visible line in the appropriate C, O, or L 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. For QA Program panels members with 25ng/ml or 50 ng/ml concentrations of LF and 25 ng/ml concentrations of onchocerciasis, it is expected that these concentrations would be positive (reactive) on at least 4/8 replicates. These concentrations represent low positives and test-to-test variability exists, therefore these samples may have mixed reactivity, it is not necessarily expected that all 8 replicates are positive (reactive). Test results inconsistent with the expected results in Table 1 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 and Anti-Wb123 IgG4 Quality Assurance Panel Q5008, or expired materials. Notify your supervisor as appropriate and contact PATH at dxinfo@path.org with detailed information for further troubleshooting.

Figure 1 Interpretation of SD BIOLINE Onchocerciasis and Lymphatic Filariasis IgG_4 Biplex Rapid Test

Onchocerciasis positive (reactive)	
Lymphatic Filariasis positive (reactive)	
Onchocerciasis and Lymphatic Filariasis positive (reactive)	
Negative (nonreactive)	
Invalid	

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Product Number Q5008
Lot Number 150928

10 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 discarded within 2 days

For Research Use Only
Not for use in Diagnostic Procedures

Caution: Biohazard. Use Universal Precautions

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Q5008 v 3.0

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