

Anti-Wb123 IgG₄ Proficiency Panel

For use with SD BIOLINE Lymphatic Filariasis IgG₄ Rapid Test

Product Number Q5006

Lot Number 150928

Product Insert



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EMAIL dxinfo@path.org
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INTENDED USE

The Anti-Wb123 IgG₄ Proficiency Panel Q5006 is a panel of six members with established reactivity to the SD BIOLINE Lymphatic Filariasis IgG₄ Rapid Test. This panel is intended to be used for determining operator proficiency in the performance of SD BIOLINE Lymphatic Filariasis IgG₄ Rapid Tests.

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

PRODUCT DESCRIPTION

Q5006 consists of six members, manufactured from human plasma, with a range of reactivity to the SD BIOLINE Lymphatic Filariasis IgG₄ Rapid Test (Table 1). Individual panel member tubes are identified only by their member number, blinding the operator to their reactivity. Four panel members were formulated with various reactivities for anti-Wb123 IgG₄, and two panel members were formulated from anti-Wb123 IgG₄ negative pools. Proclin® (0.05%) was added as a preservative.

Product Number: Q5006 1 vial per member
6 members, 0.1 mL per vial

LIMITATIONS

The Anti-Wb123 IgG₄ Proficiency Panel Q5006 is offered for research use only. Not for use in diagnostic procedures.

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 Wb123-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.

EXPECTED RESULTS

The Anti-Wb123 IgG₄ Proficiency Panel Q5006 is formulated to the characteristics in Table 1.

Table 1 Anti-Wb123 IgG₄ Proficiency Panel Q5006 Description

	Panel Member ID	Anti-Wb123 IgG ₄ Concentration	SD BIOLINE Lymphatic Filariasis IgG ₄ Rapid Test Result
1	LF Rapid Test Proficiency Panel Q5006 Member 1	0 ng/mL	Negative (nonreactive)
2	LF Rapid Test Proficiency Panel Q5006 Member 2	200 ng/mL	Positive (reactive) with medium intensity
3	LF Rapid Test Proficiency Panel Q5006 Member 3	100 ng/mL	Positive (reactive) with low intensity
4	LF Rapid Test Proficiency Panel Q5006 Member 4	0 ng/mL	Negative (nonreactive)
5	LF Rapid Test Proficiency Panel Q5006 Member 5	500 ng/mL	Positive (reactive) with high intensity
6	LF Rapid Test Proficiency Panel Q5006 Member 6	100 ng/mL	Positive (reactive) with low intensity

PRECAUTIONS

Members of the Anti-Wb123 IgG₄ Proficiency Panel Q5006 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-Wb123 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/dispose of panel members in a manner that will inactivate pathogenic agents.

STORAGE

Proficiency panels are shipped at ambient temperature. Panel members should be stored refrigerated (2-8°C) for up to 14 weeks from receipt. Prior to use, panel members may be stored at ambient temperature (<45°C) for up to two weeks. Once a vial is opened, the panel member can be stored at ambient temperature (<45°C) for up to 2 days. Unopened proficiency panel members stored longer than 14 weeks at 2-8°C or two weeks at ambient temperature (<45°C) should be discarded. Opened proficiency panel members stored at ambient temperature (<45°C) should be discarded within 2 days of opening. Alterations in physical appearance may indicate instability or deterioration. Discard panel members that are visibly turbid.

For assistance, contact PATH at dxinfo@path.org




RECOMMENDED INSTRUCTIONS FOR USE

The Anti-Wb123 IgG4 Proficiency Panel Q5006 may be used with the SD BIOLINE Lymphatic Filariasis IgG₄ Rapid Test. Each panel member 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-Wb123 IgG₄ Proficiency Panel Q5006 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 be applied to the test with the disposable capillary pipette provided in the kit. Use a new capillary pipette for each sample obtained from each panel member. 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. Add four drops of assay diluent to the square assay diluent well. Results are interpreted after 30 minutes. This is a qualitative test and any visible line in the appropriate C or L area of the result window should be interpreted as a line. See Figure 1 for interpretation guide. Dispose of used capillary pipette(s) and tests in a manner that will inactivate pathogenic agents.

Once a panel member tube is opened, it should be stored at ambient temperature (<45°C) for no longer than 2 days before discarding. Panel members should be disposed of in a manner that will inactivate pathogenic agents.

For purposes of demonstrating operator proficiency, it is recommended that each trained operator run each panel member, blinded to its reactivity, and interpret the results correctly. Additional training materials may be available. Contact PATH at dxinfo@path.org for availability of training materials.

Test results inconsistent with the expected results (Table 1) may be due to a number of factors including failure to follow the test instructions as directed, improper storage of the Anti-Wb1236 IgG₄ Proficiency Panel Q5006, or expired materials. If repeat testing continues to yield test results that are inconsistent with the expected results, contact PATH at dxinfo@path.org with detailed information for further troubleshooting.

Figure 1 Interpretation of SD BIOLINE Lymphatic Filariasis IgG ₄ Rapid Test	
Positive (reactive)	
Negative (nonreactive)	
Invalid	

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6 vials 0.1mL each

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Afterwards ambient temperature (<45°C) up to 2 weeks
Opened panel members should be discarded within 2 days

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Date received:

Caution: Biohazard. Use Universal Precautions

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Q5006 v 3.0

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