DRG® Borrelia Blot IgG/IgM (RAP-4353)

Revised 17 Aug. 2007 **RUO in the USA**

PURPOSE
This test is used for the determination of IgG/IgM antibodies to B.burgdorferi in human serum or plasma. It is intended for in vitro use only. In the United States, this kit is intended for Research Use Only.

INTRODUCTION
The spirochete Borrelia burgdorferi infects humans through a tick vector to cause borreliosis. Characteristically a skin rash (Erythema migrans) develops in 30 to 80% of the cases at the site of the bite. Other symptoms include flu-like complaints, arthritis, low grade fever, general tiredness, headache, etc. Months or even years after the primary infection, secondary complications (neurological disorders, reactive arthritis and acrodermatitis chronica atrophicans) may occur if not treated. Borreliosis is reported to be the most prevalent tick-borne infection in the USA and has been found now in almost all areas of Europe. Diagnosis is achieved by means of antibody detection, because isolation of B. burgdorferi is not routinely successful.

PRINCIPLE OF THE TEST
The RAPID SCOPE one-step assay is a lateral flow, chromatographic immunoassay, containing purified B. burgdorferi (sensu stricto) antigen and control reagent fixed on a membrane and a blue-colored test indicator reagent. There are two reactive areas on the strip. If IgG/IgM antibodies to B. burgdorferi are present in the specimen, a blue line will appear on the antigen area (**T**) of the strip. A blue line on the control area of the strip (**C**) must appear for the test to be valid.

KIT REAGENTS AND STORAGE
1 **Test Device** sealed in aluminum sack with desiccant
2 **Sample Buffer** for single tests in plastic squeeze tubes
Store at 2-8°C

PRECAUTIONS
1. Do not ingest and avoid direct contact with the reagents. The usual safety precautions including the prohibition of eating, drinking and smoking in the laboratory have to be followed.
2. Use reagents before their expiration date.
3. Do not open the device sack until needed.
4. If not used immediately, store plasma or sera at 2-8°C for 48 hours or at - 20°C for longer periods. Do not repeatedly freeze and thaw specimens.

TEST PROCEDURE
1. Before performing the test, allow the specimen and kit components to reach room temperature. Remove the device from the sack and write the specimen identification on it. Hold the buffer container by its top (round ball) and shake any buffer in it down to the larger reservoir.
2. Pipette 20 µl of serum or plasma into the sample well (S). Add buffer as soon as the specimen is absorbed. Hold the buffer container upright and carefully twists the top (round ball) off. Squeeze the entire sample buffer into S.
3. Read the results after 10 minutes but before 30 minutes.

Interpretation of Results

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Reactive: Two blue lines appear; one next to (C) and one next to (T).

Nonreactive: One blue line appears next to (C) but no line appears next to (T).

Invalid: If no blue line appears next to (C), the test is invalid and must be repeated with a new device.
The presence of IgG and/or IgM antibodies indicates an infection with the organism at an undetermined timepoint, since IgG antibodies persist for a long time. It is recommended to clarify a reactive result using another test system such as Western Blot. A nonreactive result does not rule out an infection with B. burgdorferi if the specimen was collected before a detectable level of antibodies had developed. If clinical evidence is suggestive of borreliosis, it is advisable to test a second sample from the patient taken 2 to 6 weeks later.

PERFORMANCE
The Borrelia Detect was compared to a combined IgG/IgM immunoassay for simultaneous detection of the antibodies.

Commercial Test	Number of sera	Borrelia Detect B. Burgdorferi IgG/IgM	
		Reactive	Non-Reactive
Positive	70	70	0
Negative	88	8*	80

*The 8 discrepant sera were tested with Western Blot with the following results: One serum IgG and IgM positive. Two sera IgG negative and IgM positive. Four sera IgG positive and IgM negative. One serum IgG and IgM negative (reaction only with Flagellin).

	Initial	Corrected (to Western Blot)
Agreement:	95%	99%
Sensitivity:	100%	100%
Specificity:	91%	99%

LIMITATION
As with many other serologic tests, the results obtained using Borrelia Detect serve only as an aid to diagnosis and should not be interpreted as diagnostic in them.