DO NOT open the foil pouch containing the Test Cassette until ready to test the sample. Place the Test Cassette on a clean and level surface.

All specimens must be at room temperature before testing.

Expiration Date: Check expiration on each individual test package or outer box before using. Do not use any test past the expiration date on the label.

**Test Procedure**

1. Verify that Sofia or Sofia 2 is set to the desired mode: WALK AWAY or READ NOW. See the "Using Sofia" or "Using Sofia 2" section for more information.

2. Fill a calibrated micropipette with 30 μL of the patient serum/plasma sample.

3. Add patient sample to the Reagent Vial and gently mix.

4. Fill a calibrated micropipette with 100 μL of diluted sample from the Reagent Vial.

5. Align the tip of the micropipette with the round Test Cassette sample well and empty its contents.

6. Proceed to the "Using Sofia" or "Using Sofia 2" section to complete the test.

Follow Package Insert for Specimen Collection.

**CLIA Complexity: Moderate**

**QUICK REFERENCE INSTRUCTIONS**

For use with Sofia and Sofia 2.

**IMPORTANT!** Read instructions carefully before beginning. The test procedure below is unique to the Sofia Lyme FIA and may differ from other Sofia FIA procedures.
WALK AWAY/READ NOW Modes

Refer to the Sofia User Manual for operating instructions.

Sofia may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

**WALK AWAY Mode**

In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia. The user then returns after 10 minutes to get the test result. In this mode, Sofia will automatically time the test development before scanning and displaying the test result.

**READ NOW Mode**

**Allow the test to develop for the FULL 10 minutes BEFORE placing it into Sofia.**

The user must first place the Test Cassette onto the counter or bench top for 10 minutes (outside of Sofia) and manually time this development step. Then, the user inserts the Test Cassette into Sofia. In READ NOW Mode, Sofia will scan and display the test result in approximately 1 minute. **NOTE:** Results will remain stable for an additional 10 minutes after the recommended development time of 10 minutes.
RUN TEST

1. Input the User ID using the handheld barcode scanner or manually enter the data using the key pad.

   **NOTE:** If you mistakenly scan the wrong barcode, use the Arrow Keys on Sofia to re-highlight the field and simply rescan using the correct barcode. The previous one will be overwritten with the right barcode.

2. Input the Patient ID and/or Order # using the handheld barcode scanner or manually enter the data using the key pad.

3. Press Start Test and the Sofia drawer will automatically open.

4. Verify that the correct mode, WALK AWAY or READ NOW, has been selected. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen in approximately 10 minutes. In READ NOW Mode, the test results will be displayed on the screen in approximately 1 minute. See Interpretation of Results section.

---

### Sofia Interpretation of Results

When the test is complete, the results will be displayed on the Sofia screen. The results can be automatically printed on the integrated printer if this option is selected. Test Lines, which are fluorescent, will never be visible to the naked eye.

**Results:** The Sofia screen will display results for the procedural control as being "valid" or "invalid". If the control is "invalid," retest starting with step 1 and a new Test Cassette.

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Report Result</th>
<th>Interpretation (Presumptive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM: Positive</td>
<td>Positive Test for IgM antibodies to <em>B. burgdorferi</em></td>
<td>Acute infection to <em>B. b.</em> Test the sample with IgM Western blot.</td>
</tr>
<tr>
<td>IgG: Negative</td>
<td>Positive Test for IgG antibodies to <em>B. burgdorferi</em></td>
<td>Past exposure to <em>B. b.</em> Test the sample with IgG Western blot.</td>
</tr>
<tr>
<td>Procedural Control: Valid</td>
<td>Positive Test for IgM and IgG antibodies to <em>B. burgdorferi</em></td>
<td>Recent exposure to <em>B. b.</em> Test the sample with IgM and IgG Western blot.</td>
</tr>
<tr>
<td>IgM: Positive</td>
<td>Negative Test for IgM and IgG antibodies to <em>B. burgdorferi</em></td>
<td>No evidence of <em>B. b.</em> infection.</td>
</tr>
<tr>
<td>IgG: Negative</td>
<td>Result Invalid</td>
<td>If the control is &quot;invalid,&quot; retest starting with Step 1 and a new Test Cassette.</td>
</tr>
</tbody>
</table>
From the main menu, select Run QC.

Following the prompt on the screen, scan the QC Card (located on the assay kit box).

The user will select the desired mode (WALK AWAY or READ NOW) and then run the External Controls.

Follow the External Quality Control Test Procedure in the Package Insert to test each Control, first the Positive Control followed by the Negative Control.

After both the Positive and Negative Controls have been run, the results will be displayed as “Passed” or “Failed.”

Using Sofia 2

WALK AWAY/READ NOW Modes

Refer to the Sofia 2 User Manual for operating instructions.

Sofia 2 may be set to two different modes (WALK AWAY and READ NOW). The procedures for each mode are described below.

WALK AWAY Mode

In WALK AWAY Mode, the user immediately inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time. Positive test results will be displayed between 3 and 10 minutes. Sofia 2 will display a positive result in advance of the 10-minute test time only if it detects both a positive IgM and a positive IgG result. Negative test results will be displayed at 10 minutes.

READ NOW Mode

Allow the test to develop for the FULL 10 minutes BEFORE placing it into Sofia 2.

The user must first place the Test Cassette onto the counter or bench top for 10 minutes (outside of Sofia 2) and manually time this development step. Then, the user inserts the Test Cassette into Sofia 2. In READ NOW Mode, Sofia 2 will scan and display the test result within 1 minute.
1. Input the User ID using the integrated barcode scanner or manually enter the data using the on-screen key pad. 

**NOTE:** If you mistakenly scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.

2. Input the Patient ID and/or Order # using the integrated barcode scanner or manually enter the data using the on-screen key pad.

3. Verify that the correct mode, WALK AWAY or READ NOW, has been selected. Press and open the Sofia 2 drawer.

4. Insert the Test Cassette into the drawer. Then gently close the drawer.

5. Sofia 2 will start automatically and display the progress. In WALK AWAY Mode, the test results will be displayed on the screen between 3 and 10 minutes. Sofia 2 will display a positive result in advance of the 10-minute test time only if it detects both a positive IgM and a positive IgG result. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.

---

**Sofia 2 Interpretation of Results**

When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines, which are fluorescent, will never be visible to the naked eye.

**Results:** The Sofia 2 screen will display results for the procedural control as being ✔ or ✗. If the control is ✗, retest starting with Step 1 and a new Test Cassette.

<table>
<thead>
<tr>
<th>Reader Display</th>
<th>Report Result</th>
<th>Interpretation (Presumptive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM: ✔ IgG: ✔</td>
<td><strong>Positive Test for IgM antibodies to B. burgdorferi</strong></td>
<td>Acute infection to B.b. Test the sample with IgM Western blot.</td>
</tr>
<tr>
<td>IgM: ✔ IgG: ✔</td>
<td><strong>Positive Test for IgG antibodies to B. burgdorferi</strong></td>
<td>Past exposure to B.b. Test the sample with IgG Western blot.</td>
</tr>
<tr>
<td>IgM: ✔ IgG: ✔</td>
<td><strong>Positive Test for IgM and IgG antibodies to B. burgdorferi</strong></td>
<td>Recent exposure to B.b. Test the sample with IgM and IgG Western blot.</td>
</tr>
<tr>
<td>IgM: ✔ IgG: ✗</td>
<td><strong>Negative Test for IgM and IgG antibodies to B. burgdorferi</strong></td>
<td>No evidence of B.b. infection.</td>
</tr>
<tr>
<td>IgM: ✗ IgG: ✗</td>
<td><strong>Result Invalid</strong></td>
<td>If the control is ✗, retest starting with Step 1 and a new Test Cassette.</td>
</tr>
</tbody>
</table>
From the main menu, select Run QC.

Following the prompt on the screen, scan the QC Card (located on the assay kit box).

The user will select the desired mode (WALK AWAY or READ NOW) and then run the External Controls.

Follow the External Quality Control Test Procedure in the Package Insert to test each Control, first the Positive Control followed by the Negative Control.

After both the Positive and Negative Controls have been run, the results will be displayed as ✔️ or ❌.

**INTENDED USE**
The Sofia Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from serum and plasma specimens from patients suspected of *B. burgdorferi* infection. This qualitative test is intended for use as an aid in diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. All positive results for IgM and/or IgG should be further tested by a corresponding second-tier western blot assay. Test results are to be used in conjunction with information obtained from the patient’s clinical evaluation and other diagnostic procedures.

Reference the Package Insert for Warnings and Precautions, Specimen Collection and Handling, and Quality Control.

**ASSISTANCE**
If Sofia, Sofia 2, or the assay does not perform as expected, contact Quidel Technical Support 800.874.1517 (in the U.S.), technicalsupport@quidel.com, or your local distributor.

Study the Package Insert and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.