



Sofia² Lyme FIA

CLIA Complexity: Waived for
finger-stick whole blood

QUICK REFERENCE INSTRUCTIONS

For use with Sofia 2.
Rx only



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

Instructional video available
online at quidel.com/sofia2lyme.

IMPORTANT! Read instructions carefully before beginning. The test procedure below is unique to the Sofia 2 Lyme FIA and may differ from other Sofia and Sofia 2 FIA procedures.

Certificate of Waiver is required to perform the test in a waived setting. Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test (42 CFR 493.15(e)(1)).

Test Procedure

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

All materials and samples should be brought to room temperature if they were stored refrigerated. Performing the test outside the recommended temperature, 59°F to 86°F (15°C to 30°C) and relative humidity, 20% to 85% non-condensing, may cause erroneous results.

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.

Precautions: Users should adhere to standard Universal Precautions when performing this Test Procedure. Precautions may include the use of nitrile gloves, safety glasses and the covering of any cuts or abrasions on the hands. Wash hands thoroughly after performing this Test Procedure.

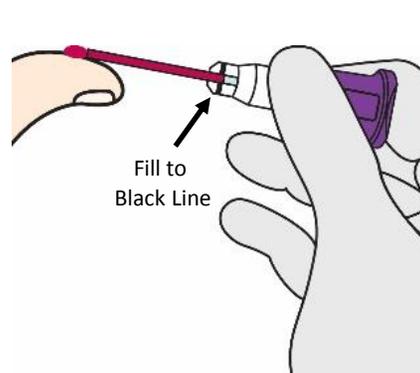
1

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

Follow Package Insert for Specimen Collection.

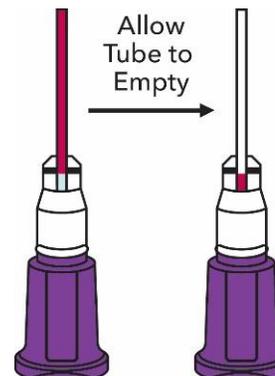
2

Hold the provided Capillary Tube **horizontally** and touch the tip to the patient blood sample. Blood will automatically draw into the Capillary Tube. **Fill to the black line.**



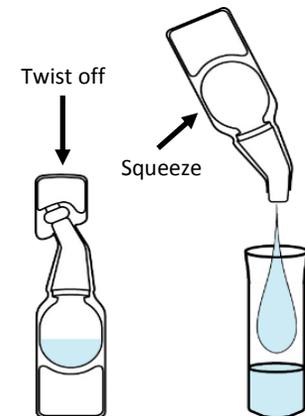
3

Stand Capillary Tube on a flat surface or hold vertically to allow the blood to drain below the fill line.



4

Dispense **ALL** of the Reagent Solution into the Reagent Tube.



NOTE: Only use the Reagent Solution provided in the kit.

Test Procedure (continued)

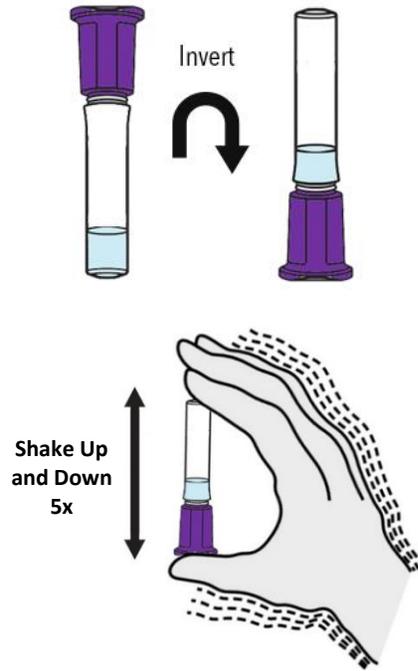
5

Insert Capillary Tube into Reagent Tube. Ensure that it is sealed tightly.



6

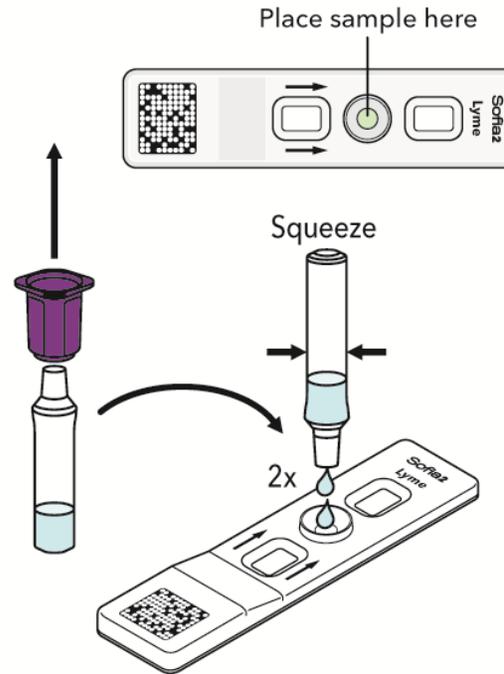
- Immediately invert the tube.
- Vigorously shake up and down 5 times.



NOTE: After shaking, immediately proceed to Step 7 and transfer the sample to the Test Cassette. Sample preparation should not be interrupted.

7

Remove the purple cap from the Reagent Tube and carefully dispense 2 drops into the round Test Cassette sample well.



NOTE: Solution may remain blue or change color. If either Viewing Window is light-to-dark red due to excess hemolysis, repeat test with a new patient sample.

8

Proceed to the next section, "Using Sofia 2", to complete the test.

Using Sofia 2

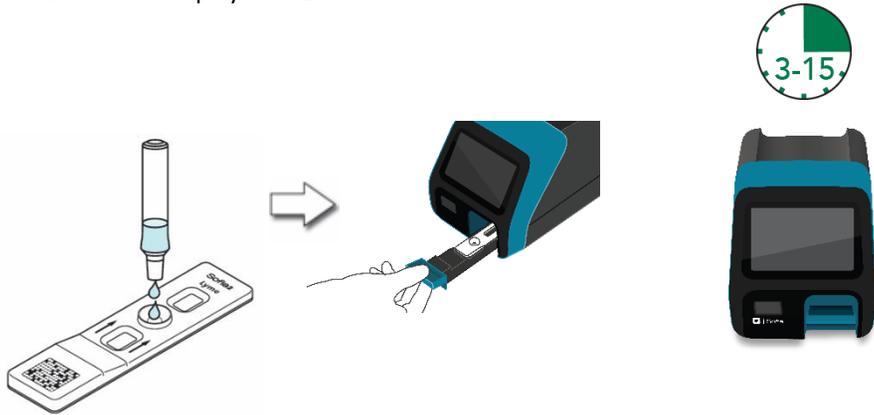
WALK AWAY/READ NOW Modes

Refer to the *Sofia 2 User Manual*.

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

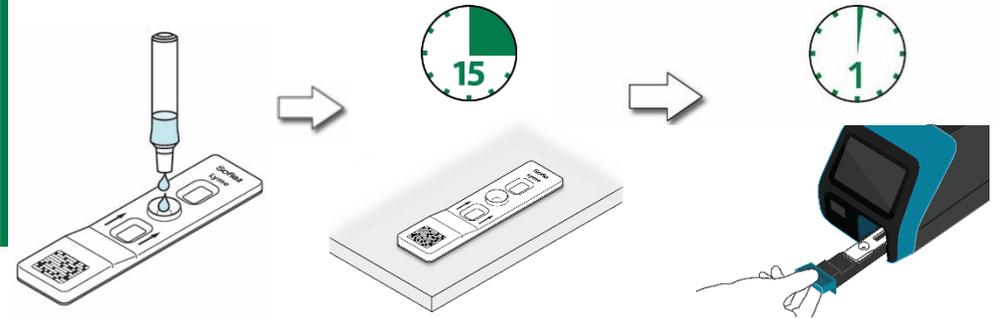
In WALK AWAY Mode, the user **immediately** inserts the Test Cassette into Sofia 2. Sofia 2 scans the Test Cassette periodically during the test development time. Positive test results will be displayed between 3 and 15 minutes. Negative test results will be displayed at 15 minutes.



READ NOW Mode

Allow the test to develop for the FULL 15 minutes BEFORE placing it into Sofia 2.

The user **MUST** first place the Test Cassette onto the counter or bench top for 15 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. Note: Results remain stable for an additional 15 minutes after the recommended development time of 15 minutes.



RUN TEST

1. Input the User ID with the integrated barcode scanner or enter the data using the on-screen key pad.

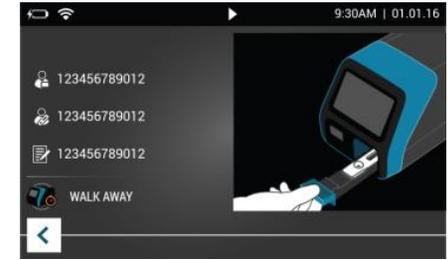
NOTE: If you scan the incorrect barcode, select the field again to re-highlight it. Then simply rescan using the correct barcode, and the previous one will be overwritten with the correct barcode.



2. Input the Patient ID and/or Order # (if applicable) using the integrated barcode scanner or 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 and display the progress. In WALK AWAY Mode, the test results will be displayed in 3-15 minutes. In READ NOW Mode, the test results will be displayed on the screen within 1 minute. See Interpretation of Results section.

Interpretation of Results

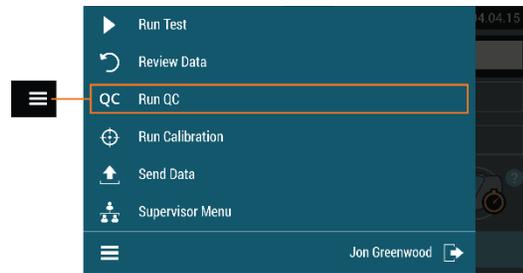
When the test is complete, the results will be displayed on the Sofia 2 screen. Test Lines will not be visible to the naked eye.

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.

Reader Display	Report Result	Interpretation (Presumptive)
IgM + IgG - Control ✓	Positive Test for IgM antibodies to <i>B. burgdorferi</i> (<i>B.b</i>)	Acute infection to <i>B.b</i> . Test the sample with IgM Western blot.
IgM - IgG + Control ✓	Positive Test for IgG antibodies to <i>B. burgdorferi</i>	Past exposure to <i>B.b</i> . Test the sample with IgG Western blot.
IgM + IgG + Control ✓	Positive Test for IgM and IgG antibodies to <i>B. burgdorferi</i>	Recent exposure to <i>B.b</i> . Test the sample with IgM and IgG Western blot.
IgM - IgG - Control ✓	Negative Test for IgM and IgG antibodies to <i>B. burgdorferi</i>	No evidence of <i>B.b</i> . infection.
Control ✗	Result Invalid	If the control is ✗, retest starting with Step 1 and a new Test Cassette.

External Quality Control

- 1 From the main menu, select Run QC.



- 2 Follow the prompt on the screen. Scan the QC Card (located on the assay kit box).
- 3 Sofia 2 prompts the user to select the desired mode (WALK AWAY or READ NOW). Run the External Controls.
- 4 Follow the External Quality Control Test Procedure in the Package Insert to test each Control, first the Positive Control followed by the Negative Control.
- 5 After both the Positive and Negative Controls have been run, the results will be displayed as ✓ or ✗.

Quidel recommends that Positive and Negative External Controls be run:

- Once for each new untrained operator
- Once for each new shipment of kits – provided that each different lot received in the shipment is tested
- As deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State and Federal regulations or accreditation requirements

Limitations

Failure to follow the Test Procedure may cause erroneous results or invalidate the test result. The following steps are very important:

- The blood sample must be filled to the black line on the provided Capillary Tube
- The blood sample and Reagent Solution must be adequately mixed
- A minimum of 2 drops must be added to the Test Cassette

INTENDED USE

The Sofia 2 Lyme FIA employs immunofluorescence for the rapid differential detection of human IgM and IgG antibodies to *Borrelia burgdorferi* from finger-stick whole blood specimens from patients suspected of *B. burgdorferi* infection of at least 2 weeks' duration. The Sofia 2 Lyme FIA is intended for use as an aid in diagnosis of Lyme disease. A negative result does not preclude infection with *B. burgdorferi*. Positive results must be confirmed by testing with a corresponding second-tier *B. burgdorferi* Western blot assay. Test results are to be used in conjunction with information obtained from the patient's clinical evaluation and other diagnostic procedures. The assay is to be performed on the Sofia 2 instrument. Professional guidelines should be consulted regarding testing and treatment for Lyme disease when acute *B. burgdorferi* infection is suspected.

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

ASSISTANCE

If you have any questions regarding the use of this product or if you want to report a test system problem, please call Quidel Technical Support **800.874.1517** (in the U.S.), **858.552.1100** (outside the U.S.), technicalsupport@quidel.com, or your local distributor.



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