



Sofia®

Lyme FIA

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit for the Sofia Lyme FIA?

The suggested CPT codes are:*

- IgM: 86618
- IgG: 86618-59

The Medicare National Limit amount** is \$18.92

Since my test is being run utilizing an analyzer, reader or system, is there an additional code which I can use in submitting for Lyme reimbursement?

According to CMS guidelines, the payment for CPT codes 86618 and 86618-59 includes the use of the reader or analyzer.

What is the CLIA complexity of this test?

This test is moderately complex for serum and plasma specimens.

Can the Sofia Lyme FIA be visually interpreted without Sofia?

No, the fluorescence-based chemistry is not detectable without Sofia. Do not try to interpret the results without proper use of Sofia. This is an important feature and ensures objectivity.

What are Quidel's recommendations for external quality control and calibration testing for this kit?

The Calibration Check Procedure should be performed every 30 days. Refer to the Sofia User Manual for calibration instructions. If the Calibration Check does not perform as expected, contact Quidel Technical Support.

External Positive and Negative Controls are supplied in the kit and should be tested using the External Quality Control Test Procedure. Quidel recommends that Positive and Negative Controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements. If the Controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

What is the shelf life and how should the kit be stored?

The kit shelf life is 18 months from date of manufacture. The kit should be stored at room temperature.

How should the specimens be collected and stored when using the Sofia Lyme FIA?

Collect and process serum or plasma per standard procedures. Samples may be stored refrigerated (2°C to 8°C) up to 48 hours, at room temperature (15°C to 30°C) up to 8 hours, and frozen (–20°C) up to 2 freeze/thaw cycles.

Make sure sample is at room temperature before using in the test, and for samples that have been previously refrigerated or frozen, mix well by fully thawing and inverting the tube 10 times.

Which blood collection tubes are compatible with the Sofia Lyme FIA?

Performance of the Sofia Lyme FIA has been established with the following tubes:

- Serum Separator Tube (RED)
- Serum Separator Tube (TIGER)
- Lithium Heparin
- Sodium Heparin

Note: EDTA is NOT compatible with the Sofia Lyme FIA.

How should a sample be added to the Test Cassette?

Use a calibrated micropipette to dispense 100 µL of diluted sample to the round Test Cassette sample well.

Can Lyme disease be contracted from contact with the controls?

No. All controls contain non-infectious material.

What Proficiency Testing Programs are available for testing with the Sofia Lyme FIA?

- AAB – Lyme Disease (2009433)
- AAFP – Lyme Serology (654)
- API – Lyme Disease (418)
- CAP – Tick Transmitted Diseases (TTD)
- WSLH – Lyme Disease Serology (PT04200)

How accurate is the Sofia Lyme FIA?

Performance characteristics are listed as follows:

Lyme IgM Results for Sofia Compared to Predicate Assay

| Category | n | Sofia IgM | | | | Predicate IgM | | | | |
|---------------------------------------|----|-----------|-----|--------|------------|---------------|-------|-----|--------------------|------------|
| | | Pos | Neg | % Sens | 95% CI | Pos | Equiv | Neg | %Sens ¹ | 95% CI |
| Acute, < 1 month, with EM | 64 | 39 | 25 | 60.9% | 48.7-72.0% | 28 | 8 | 28 | 56.3% | 44.1-67.7% |
| Acute, 1-2 months, with EM | 4 | 3 | 1 | 75.0% | 28.9-96.6% | 2 | 0 | 2 | 50.0% | 15.0-85.0% |
| Convalescent, 3-12 months, with EM | 15 | 11 | 4 | 73.3% | 47.6-89.5% | 6 | 2 | 7 | 53.3% | 30.1-75.2% |
| Late Lyme (>1 yr), Neuro or Arthritic | 12 | 8 | 4 | 66.7% | 38.8-86.5% | 7 | 3 | 2 | 83.3% | 54.0-96.5% |
| All Categories | 95 | 61 | 34 | 64.2% | 54.2-73.1% | 43 | 13 | 39 | 58.9% | 48.9-68.3% |

¹Of the 13 samples that were “equivocal” by the predicate, 12 of 13 were negative by FDA approved western blot.

Lyme IgG Results for Sofia Compared to Predicate Assay

| Category | n | Sofia IgG | | | | Predicate IgG | | | |
|---------------------------------------|----|-----------|-----|--------|-------------|---------------|-----|--------|------------|
| | | Pos | Neg | % Sens | 95%CI | Pos | Neg | % Sens | 95%CI |
| Acute, < 1 month, with EM | 64 | 50 | 14 | 78.1% | 66.5-86.6% | 28 | 36 | 43.8% | 32.3-55.9% |
| Acute, 1-2 months, with EM | 4 | 4 | 0 | 100.0% | 54.3-100.0% | 3 | 1 | 75.0% | 28.9-96.6% |
| Convalescent, 3-12 months, with EM | 15 | 10 | 5 | 66.7% | 41.5-85.0% | 6 | 9 | 40.0% | 19.8-64.3% |
| Late Lyme (>1 yr), Neuro or Arthritic | 12 | 12 | 0 | 100.0% | 78.4-100.0% | 10 | 2 | 83.3% | 54.0-96.5% |
| All Categories | 95 | 76 | 19 | 80.0% | 70.8-86.9% | 47 | 48 | 49.5% | 39.6-59.4% |

Sofia Lyme FIA and Predicate Analytical Specificity

| | n | Sofia IgM | Predicate IgM* | | Sofia IgG | Predicate IgG |
|--------------------|------------|--------------|----------------|--|--------------|---------------|
| Endemic | 100 | 92.0% | 95.0% | | 89.0% | 97.0% |
| Non-Endemic | 100 | 88.0% | 86.0% | | 91.0% | 100.0% |
| Total | 200 | 90.0% | 90.5% | | 90.0% | 98.5% |

*Includes positive and equivocal results.

Refer to the Package Insert on our website at quidel.com for additional performance claims.

**Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.* Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov.

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