QUIDEL

Sofia 2

Lyme FIA

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the Sofia 2 Lyme FIA?
The suggested CPT code is 86618QW.* For the current Medicare/Medicaid National Limit amount** click here.

Relevant CPT/CMS Guidance:

CPT 2021 Professional Edition p. 654:

- *"…if multiple assays are performed for antibodies of different immunoglobulin classes, each assay should be coded separately."*

NCCI Manual 2021 Ch.10, Section M.15 (pp. X-25-X-26)

- *"15. In the case of tests for infectious agents, methodologies include detection by immunofluorescence, immunoassay, or nucleic acid probe techniques. A single laboratory procedure shall be reported as one unit of service whether it generates one or multiple results. CPT codes that test for a single infectious agent that employ one procedure, one methodology, or one test kit are reported with one unit of service.*

  CPT codes that test for multiple infectious agents are reported with one unit of service if one procedure, one methodology, or one test kit is used to perform the test (e.g., 87300, 87451, 87800, 87801). When multiple procedures, multiple methodologies, or multiple kits are medically necessary and used to perform a test for multiple infectious agents, the units of service reported for CPT codes that identify multiple infectious agents equals the number of different procedures, methodologies, or kits used to perform the test.

  For example, if a provider/supplier tests for 5 different species of an infectious agent using a single multiple-result test kit, only 1 unit of service for that test kit may be reported. However, if a provider/supplier tests for 3 different species of an infectious agent by using 3 different single result test kits, the provider/supplier may report 3 UOS of the appropriate CPT code."

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 code 86618 includes the use of the reader or analyzer.

What is the CLIA complexity of this test?
This test is CLIA waived.

Can the Sofia 2 Lyme FIA be visually interpreted without Sofia 2?
No, the fluorescence-based chemistry is not detectable without Sofia 2. Do not try to interpret the results without proper use of Sofia 2. 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 2 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 2 Lyme FIA?
Collect the finger-stick whole blood using the Capillary Tube provided in the kit and **immediately** test the sample as described in the test procedure.

Can Lyme disease be contracted from contact with the controls?
No. All controls contain non-infectious material.

How accurate is the Sofia 2 Lyme FIA?
Performance characteristics are listed as follows:

Lyme IgM Results for Sofia 2 Lyme FIA with Sofia 2 Compared to Predicate Assay
IgM Method Comparison: 1st Tier PPA and NPA Analysis

		Predicate Lyme IgM				
		Positive	**Equivocal**	**Negative**	**% Agreement**	**95% CI**
Sofia 2 IgM	**Positive**	57	18	47	**PPA** = 82.4% (75/91)	73.2%-89.0%
	Negative	5	11	186	**NPA** =79.8% (186/233)	74.2%-84.5%
Total		62	29	233		

Lyme IgG Results for Sofia 2 Lyme FIA with Sofia 2 Compared to Predicate Assay
IgG Method Comparison: 1st Tier PPA and NPA Analysis

		Predicate Lyme IgG			
		Positive	**Negative**	**% Agreement**	**95% CI**
Sofia 2 IgG	**Positive**	48	38	**PPA** = 88.9% (48/54)	77.5%-95.2%
	Negative	6	232	**NPA** = 85.9% (232/270)	81.2%-89.6%
Total		54	270		

Sofia Lyme FIA with Sofia 2 and Predicate Analytical Specificity

	n	**Sofia IgM**	**Predicate IgM***	**Sofia IgG**	**Predicate IgG**
Endemic	100	86.0%	80.0%	95.0%	98.0%
Non-Endemic	100	93.0%	93.0%	98.0%	99.0%
Total	**200**	**89.5%**	**86.5%**	**96.5%**	**98.5%**

*Equivocal results were considered Positive.

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

*"QW" modifier is added to report use of CLIA-waived test system(s) for Medicare/Medicaid claims. For the Clinical Laboratory Fee Schedule, visit cms.gov.

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.

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