

Evaluation of the Rapid Quidel Sofia 2 Lyme Immunoassay as a First-Tier Test in a Two-Tier Testing Algorithm for Lyme Disease: Comparison to the Zeus ELISA *Borrelia* VlsE1/pepC10 IgG/IgM assay

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Background:

Two-tiered serologic testing for Lyme disease usually is formed using an enzyme-linked immunosorbent assay (ELISA) as the first-tier test. The Quidel Sofia 2 Lyme test is a relatively new first-tier assay on the market using novel methodology: a lateral flow assay with immunofluorescence-based detection of reactivity, intended to provide more rapid turnaround time. Here, we evaluated its performance in comparison to a commercial ELISA method. The test is well suited for laboratories and outpatient settings that wish to perform rapid Lyme testing on demand as opposed to many Lyme assays that require batching in a central laboratory.

Methods:

We compared the Quidel Sofia 2 assay to the Zeus VlsE1/pepC10 IgG/IgM ELISA test, using each as a first-tier test and in a standard two-tiered testing algorithm with Western blot confirmation on 181 consecutive serum samples sent to our microbiology laboratory from patients with suspected Lyme disease.

Results:

Comparison of the Sofia 2 as a first-tier test to the Zeus VlsE1/pepC10 IgG/IgM test showed an overall agreement of 89% with a Kappa statistic of 0.732 (95% confidence interval 0.622-0.842; "substantial" agreement based on published standards). When the individual first-tier tests were followed by Western blot confirmation in a standard two-tier testing algorithm the overall agreement was 98.9% with a Kappa statistic of 0.973 (95% confidence interval 0.913-1.000; "almost perfect" agreement).

Conclusions:

In conclusion the Quidel Sofia Lyme test performs well when compared to the Zeus VlsE1/pepC10 IgG/IgM test as a first-tier test in a standard two-tiered testing algorithm. Obtaining samples to validate Lyme tests can be challenging and for this reason our data should prove useful for medical facilities considering the use of the Quidel Sofia 2 assay.

Table 1: Comparison of the Sofia 2 to the Zeus ELISA *Borrelia* VlsE1/pepC10 IgG/IgM test as a first tier Lyme test

Quidel Sofia Lyme vs VLSE			
Sofia Lyme	VLSE Lyme		Total
	Positive	Negative	
Positive	41	9	50
Negative	11	120	131
Total	52	129	181
Sensitivity	79% (41/52) [95% CI: 66% to 88%]		
Specificity	93% (120/129) [95% CI: 87% to 96%]		
PPV	82% (41/50) [95% CI: 69% to 90%]		
NPV	92% (120/131) [95% CI: 86% to 95%]		
Accuracy	89% (161/181) [95% CI: 84% to 93%]		

Table 2: Comparison of the Sofia 2 to a standard two-tiered VlsE1/pepC10 IgG/IgM test followed by western blot

Quidel Sofia Lyme vs STTT			
Sofia Lyme	STTT		Total
	Positive	Negative	
Positive	50	0	50
Negative	2	129	131
Total	52	129	181
Sensitivity	96% (50/52) [95% CI: 87% to 99%]		
Specificity	100% (129/129) [95% CI: 97% to 100%]		
PPV	100% (50/50) [95% CI: 93% to 100%]		
NPV	98.5% (129/131) [95% CI: 95% to 100%]		
Accuracy	99% (179/181) [95% CI: 96% to 100%]		