The ART of Lyme Testing

Accurate, objective and automated results in as few as 3 minutes

Excellent performance compared to Western Blot

Flexible, dual mode testing and simple, CLIA-waived procedures for a variety of laboratory environments

Secure, remote instrument management through the Virena ecosystem

Integrated data management automatically stores test and user history

User and patient ID captured with onboard barcode scanner

Sofia 2 with Advance Result Technology
Delivering accurate, objective and automated results in as few as three minutes!
Sofia 2 Lyme FIA – Procedure

**Finger-stick Whole Blood**

1. Fill to Black Line
2. Allow Tube to Empty
3. Twist off
4. Squeeze
5. Shake Up and Down 5x
6. Invert
7. Place sample here

---

**Sofia 2 Development Modes**

<table>
<thead>
<tr>
<th>WALK AWAY Mode – Walk away and multitask</th>
<th>READ NOW Mode – Batch multiple samples per hour</th>
</tr>
</thead>
</table>

---

**Sofia 2 Lyme FIA**

- Differentiated IgM and IgG results with a single test
- Objective and automated results with no equivocal zone
- CLIA-waived for finger-stick whole blood samples
- Room temperature storage
- 18-month shelf life from date of manufacture

---

**Agreement with Predicate Assay and Western Blot***

<table>
<thead>
<tr>
<th>Result Type</th>
<th>Comparator Method</th>
<th>IgM</th>
<th>IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier One PPA</td>
<td>Predicate Assay</td>
<td>82.4%</td>
<td>88.9%</td>
</tr>
<tr>
<td>Tier One NPA</td>
<td>Predicate Assay</td>
<td>79.8%</td>
<td>85.9%</td>
</tr>
<tr>
<td>Tier Two PPA</td>
<td>Western Blot</td>
<td>94.1%</td>
<td>95.7%</td>
</tr>
</tbody>
</table>

**Specificity***

<table>
<thead>
<tr>
<th>Category</th>
<th>IgM</th>
<th>IgG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endemic</td>
<td>86%</td>
<td>95%</td>
</tr>
<tr>
<td>Non-Endemic</td>
<td>93%</td>
<td>98%</td>
</tr>
</tbody>
</table>

*Refer to the Package Insert for additional performance claims.

---

Sofia 2 Lyme FIA – 15 Test Kit: Catalog #20319