The ART of Lyme Testing

- Accurate, objective and automated results in **as few as 3 minutes**
- **Secure, remote instrument management** through the Virena ecosystem
- **Excellent performance** compared to Western Blot
- **Integrated data management** automatically stores test and user history
- **Flexible, dual mode testing and simple, CLIA-waived procedures** for a variety of laboratory environments
- **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

**Sofia 2 Development Modes**

**WALK AWAY Mode** – Walk away and multitask

**READ NOW Mode** – Batch multiple samples per hour

**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
- 24-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>
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<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