Objective Strep A Results at Your Fingertips

- Accurate, objective and automated results in **5 minutes**
- Excellent performance compared to molecular and bacterial culture methods
- 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 Strep A+ FIA – Procedures**

**Throat Swab Procedure**

![Throat Swab Procedure Diagram]

**Sofia 2 Development Modes**

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

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

**Sofia Strep A+ FIA**

- CLIA waived
- Accurate detection with throat swab samples
- Excellent performance demonstrated in a multi-site study*
- Compatible with viral transport media
- Room temperature storage
- 24-month shelf life from date of manufacture

**Sofia Strep A+ FIA Results vs. Culture**

<table>
<thead>
<tr>
<th>Culture</th>
<th>Pos</th>
<th>Neg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofia Pos</td>
<td>164</td>
<td>38**</td>
</tr>
<tr>
<td>Sofia Neg</td>
<td>11***</td>
<td>638</td>
</tr>
<tr>
<td>Total</td>
<td>175</td>
<td>676</td>
</tr>
</tbody>
</table>

| Sensitivity | 93.7% (164/175) | Specificity | 94.4% (638/676) |

*Of the 38 discordant specimens, 24 of these specimens were positive for GAS when tested with an FDA-cleared molecular device, 14 were negative.

***Of the 11 discordant specimens, 3 were negative when tested with an FDA-cleared molecular device, 8 were positive.

*Refer to the Package Insert for additional performance claims.

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**Sofia Strep A+ FIA – 25 Test Kit: Catalog #20274**