Simplexa® *C. difficile* Direct Kit

An Essential Component of *Clostridium difficile* Infection Testing

Direct detection of toxigenic *C. difficile* using real-time PCR

The quality of treatment starts with diagnosis.
**Simplexa® C. difficile Direct Kit**

**An Essential Component of Clostridium difficile Infection Testing**

A real-time PCR assay targeting the *C. difficile* toxin B gene (tcdB) present in unformed stool samples that can fit into any testing algorithm.

**Fast, simple and accurate molecular *C. difficile* testing**

- **Improved workflow with timely results:** CLIA moderate complexity with results in about an hour.
- **True sample-to-answer solution:** No DNA extraction required.
- **Reliable performance you can count on.**

In a thorough study of over 2,300 prospective samples, our Simplexa® *C. difficile* Direct assay demonstrated excellent clinical agreement against three US on-market assays.

<table>
<thead>
<tr>
<th>METHOD</th>
<th>N</th>
<th>Simplexa® POSITIVE % AGREEMENT</th>
<th>Simplexa® NEGATIVE % AGREEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAAT 1</td>
<td>829</td>
<td>93.4%</td>
<td>96.6%</td>
</tr>
<tr>
<td>NAAT 2</td>
<td>776</td>
<td>93.9%</td>
<td>94.0%</td>
</tr>
<tr>
<td>NAAT 3</td>
<td>721</td>
<td>84.8%</td>
<td>99.2%</td>
</tr>
<tr>
<td>Direct Culture</td>
<td>2330</td>
<td>95.7%</td>
<td>92.1%</td>
</tr>
</tbody>
</table>
Streamlined, simple workflow

- **DIP** swab into stool specimen and dilute in TE Buffer.
- **SCAN** samples and reagents.
- **PIPETTE** samples and reagents directly onto the disc.
- **LOAD** and press **RUN**.

Reduce costly delays and repeat testing with lower invalid rates

≥4.4x fewer invalids compared to other NAAT Assays

![Graph showing invalid rate comparison between Simplexa Direct and competitors]

**Simplexa® Direct Invalid rate** 0.65% (n=2351)

**Competitors Direct Invalid rate**
- 2.90% (n=697)
- 3.10% (n=1860)
- 3.20% (n=2208)

**REFERENCES:** 1. MOL2950, Simplexa® C. difficile Direct instructions for use.
Simplify your *C. difficile* Testing Today

**Ordering information – Simplexa® *C. difficile* Direct**

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
<th>DESCRIPTION</th>
<th>REACTIONS/KIT</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOL2950</td>
<td>Simplexa® <em>C. difficile</em> Direct Kit*</td>
<td>24</td>
</tr>
<tr>
<td>MOL2960</td>
<td>Simplexa® <em>C. difficile</em> Positive Control Pack</td>
<td>10 x 100 µL</td>
</tr>
</tbody>
</table>

* Direct Amplification Discs included in kit.

**Also available for higher throughput needs**

**Simplexa® *C. difficile* Universal Direct**

- Perform up to 94 patient samples per run
- Simple workflow: No DNA extraction required
- Fast: Results in about an hour

**Ordering information – Simplexa® *C. difficile* Universal Direct**

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
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<th>REACTIONS/KIT</th>
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</thead>
<tbody>
<tr>
<td>MOL2975</td>
<td>Simplexa® <em>C. difficile</em> Universal Direct Kit</td>
<td>100</td>
</tr>
</tbody>
</table>

**Contact DiaSorin Molecular today!**

Call +1 (562) 240-6500 or visit: www.molecular.diasorin.com