Simplexa® VZV Direct Kit

Fast and Accurate VZV Testing

Direct detection of varicella-zoster virus DNA in CSF samples

The quality of treatment starts with diagnosis.
VZV causes a wide spectrum of clinical manifestations

Varicella-zoster virus infection causes two clinically distinct forms of disease, depending on whether an individual is experiencing a primary (chickenpox) or secondary infection (shingles)\(^1\). Varicella-zoster virus is highly contagious, spread by exposure to an individual shedding virus from either a varicella or herpes zoster infection. The virus can be spread from person to person by direct contact, inhalation of aerosols from vesicular fluid of skin lesions of acute varicella or zoster and possibly through infected respiratory secretions that also may be aerosolized\(^2\).

Common complications of VZV infection are bacterial infections of the skin and soft tissue in children and pneumonia in adults. Severe complications include encephalitis, pneumonia (either direct viral pneumonia or secondary bacterial pneumonia), bronchitis (either viral bronchitis or secondary bacterial bronchitis), visceral dissemination (VZV infection of internal organs) and postherpetic neuralgia in immunocompromised individuals. VZV can also complicate pregnancy; newborns of infected mothers have a small risk of developing congenital varicella syndrome or neonatal varicella\(^2\).

Moreover VZV is recognized as one of the leading causes of adult encephalitis and in several studies, VZV was the second most common etiology identified, second only to HSV\(^3\). It is estimated that greater than 90 percent of the population will acquire the pathogen by the age of 15 and each of these persons is at risk for developing encephalitis caused by VZV\(^4\).

Rapid and easy VZV molecular testing

- **The smallest sample volume:**
  Only requires 50 µL of precious CSF sample.

- **Sample-to-answer workflow with timely results:**
  CLIA moderate complexity providing results in about an hour - No DNA extraction required.

- **High performance:**
  100% Positive Percent Agreement and greater than 99% Negative Percent Agreement.
  CLIA moderate complexity with minimal hands-on time providing results in about an hour.

- **Flexibility to run as few as 1 and up to 8 samples at a time.**
Streamlined, simple workflow

SCAN samples and reagents.

PIPETTE samples and reagents directly onto the disc.

LOAD and press RUN.

Simple and easy workflow enabling the assay to be run on any shift and bypass conventional DNA extraction procedures.

Proven performance that you can count on

The Simplexa® VZV Direct assay demonstrated high performance with excellent clinical agreement against PCR/bi-directional sequencing for both prospective and contrived CSF samples. Contrived samples were tested across the clinical range of the Simplexa® VZV Direct assay. For each of the two strains, VZV Ellen and VZV 9939, 60% of the positive samples were contrived as low positive samples close to the LoD of the test.

Simplexa® VZV Direct Clinical Agreement

<table>
<thead>
<tr>
<th>CSF SAMPLE POPULATION</th>
<th>POSITIVE % AGREEMENT</th>
<th>NEGATIVE % AGREEMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prospective Samples</td>
<td>100.0% (12/12) 95% Cl: 75.7% to 100.0%</td>
<td>99.7% (623/625) 95% Cl: 98.8% to 99.9%</td>
</tr>
<tr>
<td>Contrived Samples</td>
<td>100.0% (120/120) 95% Cl: 96.9% to 100.0%</td>
<td>N/A</td>
</tr>
</tbody>
</table>

a One (1) of two (2) discordant results were positive with an alternate NAAT used by collection site during routine testing.

5. MOI3650, Simplexa® VZV Direct Instructions for Use.
Your solution for VZV testing

Ordering information – Simplexa® VZV Direct

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
<th>DESCRIPTION</th>
<th>REACTIONS/KIT</th>
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</thead>
<tbody>
<tr>
<td>MOL3650</td>
<td>Simplexa® VZV Direct Kit*</td>
<td>24</td>
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<tr>
<td>MOL3660</td>
<td>Simplexa® VZV Positive Control Pack</td>
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</tbody>
</table>

*Direct Amplification Discs are included with kit.

Products for HSV testing

Ordering information – Simplexa® HSV 1 & 2 Direct

<table>
<thead>
<tr>
<th>CATALOG NUMBER</th>
<th>DESCRIPTION</th>
<th>REACTIONS/KIT</th>
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<tbody>
<tr>
<td>MOL2150</td>
<td>Simplexa® HSV 1 &amp; 2 Direct Kit*</td>
<td>24</td>
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<tr>
<td>MOL2160</td>
<td>Simplexa® HSV 1 &amp; 2 Positive Control Pack</td>
<td>10</td>
</tr>
</tbody>
</table>

*Direct Amplification Discs are included with kit.

Contact DiaSorin Molecular today!
Call +1 (562) 240-6500 or visit: www.molecular.diasorin.com

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Product availability subject to required regulatory approvals.