

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.

# Fast and Accurate VZV Testing

A real-time PCR assay for the direct detection of the varicella-zoster virus DNA polymerase gene from only 50µL of CSF.

## 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)<sup>1</sup>. 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<sup>2</sup>.

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. Varicella-zoster virus can also complicate pregnancy; newborns of infected mothers have a small risk of developing congenital varicella syndrome or neonatal varicella<sup>2</sup>.

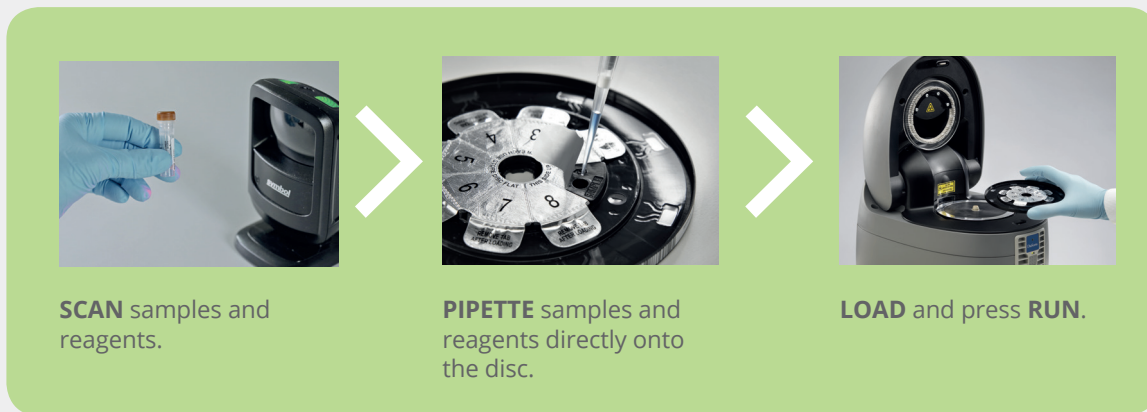
Moreover VZV is now recognized as one of the leading causes of adult encephalitis and in several encephalitis studies, VZV was the second most common etiology identified, second only to HSV<sup>3</sup>. It is estimated that greater than 90 percent of the population will acquire the disease by the age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

## 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 98% Negative Percent Agreement.



## Streamlined workflow



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 on CSF Samples.

### Simplexa™ VZV Direct Clinical Agreement<sup>5</sup>

SAMPLE TYPE	POSITIVE % AGREEMENT	NEGATIVE % AGREEMENT
CSF	100.0% (58/58) 95% CI: 93.8% to 100.0%	98.4% (120/122) <sup>a</sup> 95% CI: 94.2% to 99.5%

<sup>a</sup> The two false positive samples were contrived positive samples which were spiked using the Ellen strain at 30 copies/reaction (2X LoD).

**REFERENCES:** 1. Albrecht MA. (2017, May 31). *Diagnosis of varicella-zoster virus infection*. UpToDate. Retrieved on 06/27/2018 from <https://www.uptodate.com/contents/diagnosis-of-varicella-zoster-virus-infection>. 2. Centers for Disease Control and Prevention. (2016). *Chicken Pox (Varicella)*. Retrieved from <https://www.cdc.gov/chickenpox/hcp/clinical-overview.html>. 3. Pahud BA, Glaser CA, Dekker CL, Arvin AM, and Schmid DS. Varicella zoster disease of the central nervous system: Epidemiological, clinical, and laboratory features 10 years after the introduction of the varicella vaccine. *J Infect Dis.* 2011; 203(3): 316–323. 4. Seward J, Jumaan A. VSV: persistence in the population. In: Arvin A, Campadelli-Fiume G, Mocarski E, et al, editors. *Human Herpesviruses: Biology, Therapy, and Immunoprophylaxis*. Cambridge: Cambridge University Press; 2007. Chapter 40. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK47367/>. 5. MOL3650, Simplexa™ VZV Direct Instructions for Use.

## Your solution for VZV testing



### Ordering information – Simplexa™ VZV Direct

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL3650	Simplexa™ VZV Direct Kit*	24
MOL3660	Simplexa™ VZV Positive Control Pack	10

\*To be used with Direct Amplification Discs (3 discs, MOL1455).

## Products for HSV testing



### Ordering information – Simplexa™ HSV 1 & 2 Direct

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2150	Simplexa™ HSV 1 & 2 Direct Kit*	24
MOL2160	Simplexa™ HSV 1 & 2 Positive Control Pack	10

\*To be used with Direct Amplification Discs (3 discs, MOL1455).



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