

**Overview****Useful For**

Determination of immune status of individuals to the varicella-zoster virus (VZV)

Documentation of previous infection with VZV in an individual without a previous record of immunization to VZV

**Method Name**

Multiplex Flow Immunoassay (MFI)

**NY State Available**

Yes

**Specimen****Specimen Type**

Serum

**Specimen Required****Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Specimen Volume:**0.5 mL

**Forms**

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-[General Request](#) (T239)

-[Microbiology Test Request](#) (T244)

**Specimen Minimum Volume**

0.4 mL

**Reject Due To**

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	14 days	
	Frozen	14 days	

## Clinical and Interpretive

### Clinical Information

Varicella-zoster virus (VZV), a herpes virus, causes 2 distinct exanthematous (rash-associated) diseases: chickenpox (varicella) and herpes zoster (shingles). Chickenpox is a highly contagious, though typically benign disease, usually contracted during childhood. Chickenpox is characterized by a dermal vesiculopustular rash that develops in successive crops approximately 10 to 21 days following exposure.(1) Although primary infection with VZV results in immunity and protection from subsequent infection, VZV remains latent within sensory dorsal root ganglia and upon reactivation, manifests as herpes zoster or shingles. During reactivation, the virus migrates along neural pathways to the skin, producing a unilateral rash, usually limited to a single dermatome. Shingles is an extremely painful condition typically occurring in older nonimmune adults or those with waning immunity to VZV and in patients with impaired cellular immunity.(2)

Individuals at risk for severe complications following primary VZV infection include pregnant women, in whom the virus may spread through the placenta to the fetus, causing congenital disease in the infant. Additionally, immunosuppressed patients are at risk for developing severe VZV-related complications, which include cutaneous disseminated disease and visceral organ involvement.(2,3)

Serologic screening for IgG-class antibodies to VZV aids in identifying nonimmune individuals.

### Reference Values

Vaccinated: Positive (> or =1.1 AI)

Unvaccinated: Negative (< or =0.8 AI)

Reference values apply to all ages.

### Interpretation

Positive: Antibody index (AI) value of 1.1 or higher:

The reported AI value is for reference only. This is a qualitative test and the numeric value of the AI is not indicative of the amount of antibody present. AI values above the manufacturer recommended cutoff for this assay indicate that specific antibodies were detected, suggesting prior exposure or vaccination. The presence of detectable IgG-class antibodies indicates prior exposure to the varicella-zoster virus (VZV) through infection or immunization. Individuals testing positive are considered immune to varicella-zoster.

Equivocal: AI 0.9-1.0

Submit an additional specimen for testing in 10 to 14 days to demonstrate IgG seroconversion if recently vaccinated or if otherwise clinically indicated.

Negative: AI of 0.8 or lower

The absence of detectable IgG-class antibodies suggests no prior exposure to the VZV or the lack of a specific

immune response to immunization.

### Cautions

IgG-class antibodies to varicella-zoster virus may be present in serum specimens from individuals who have received blood products within the past several months but have not been immunized or experienced past infection with this virus.

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Serum specimens drawn early during acute phase of infection may be negative for IgG-class antibodies to this virus.

### Supportive Data

To evaluate the accuracy of the BioPlex Varicella-Zoster Virus (VZV) IgG multiplex flow immunoassay (MFI), 500 prospective serum specimens were analyzed in a blinded fashion by the Diamedix VZV IgG EIA (Diamedix) and the BioPlex VZV IgG assay. Specimens with discordant results after initial testing were repeated by both assays during the same freeze/thaw cycle. Further discrepancies were evaluated by the SeraQuest VZV IgG EIA.(Quest International) The results are summarized below:

BioPlex VZV IgG	Diamedix VZV IgG EIA			
		Positive	Negative	Equivocal
Positive	436	0	0	
Negative	18(a)	22	4	
Equivocal	19	0	1	

a. All 18 specimens tested positive by the SeraQuest VZV IgG EIA.

Sensitivity: 92.2% (436/473); 95% CI: 89.4%-94.3%

Specificity: 100.0 (22/22); 95% CI: 82.5%-100.0%

Overall percent agreement: 91.8% (459/500); 95% CI: 89.0%-93.9%

### Clinical Reference

1. Yankowitz J, Grose C: Congenital infections. In: Storch GA, ed. Essentials of Diagnostic Virology. Churchill Livingstone. 2000, pp 187-201
2. Gnann JW, Whitley RJ: Herpes zoster. N Engl J Med. 2002;347:340-346
3. Cvjetkovic D, Jovanovic J, Hrnjakovic-Cvjetkovic I, et al: Reactivation of herpes zoster infection by varicella-zoster virus. Med Pregl. 1999;52(3):125-128
4. Whitley RJ: Chickenpox and Herpes Zoster (Varicella-Zoster virus). In Bennett JE, Dolin R, Blaser MJ, eds. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases. 9th ed. Elsevier; 2020: 1849-1856

### Performance

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## Method Description

The BioPlex 2200 Varicella-Zoster Virus (VZV) IgG assay uses multiplex flow immunoassay technology. Briefly, serum samples are mixed and incubated at 37 degrees C with sample diluent and dyed beads coated with VZV antigen. After a wash cycle, antihuman IgG-antibody conjugated to phycoerythrin (PE) is added to the mixture and incubated at 37 degrees C. Excess conjugate is removed in another wash cycle and the beads are resuspended in wash buffer. The bead mixture then passes through a detector that identifies the bead based on dye fluorescence and determines the amount of antibody captured by the antigen based on the fluorescence of the attached PE. Raw data is calculated in relative fluorescence intensity.

Three additional dyed beads, an internal standard bead, a serum verification bead, and a reagent blank bead are present in each reaction mixture to verify detector response, the addition of serum to the reaction vessel and the absence of significant nonspecific binding in serum. (Package insert: BioPlex 2200 System MMRV IgG, Bio-Rad Laboratories; 11/30/2018)

## PDF Report

No

## Day(s) and Time(s) Test Performed

Monday through Saturday, 9 a.m.

## Analytic Time

Same day/1 day

## Maximum Laboratory Time

3 days

## Specimen Retention Time

14 days

## Performing Laboratory Location

Rochester

## Fees and Codes

### Fees

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact [Customer Service](#).

### Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

### CPT Code Information

86787

### LOINC® Information



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Test ID	Test Order Name	Order LOINC Value
VZPG	Varicella-Zoster Ab, IgG, S	15410-4

Result ID	Test Result Name	Result LOINC Value
VZG	Varicella-Zoster Ab, IgG, S	15410-4
DEXG4	Varicella IgG Antibody Index	5403-1