

INTENDED USE

The ZEUS IFA Varicella-Zoster Virus (VZV) IgG Test System is intended for the qualitative and semi-quantitative detection of VZ IgG antibody in human sera by the indirect fluorescent antibody (IFA) technique. The assay can determine or confirm a recent infection or immune status, and is for *in vitro* diagnostic use.

SIGNIFICANCE AND BACKGROUND

Varicella-Zoster Virus (VZV) is a common pathogen of humans. The clinical course of VZV in humans is generally categorized into varicella (chickenpox) and *Herpes zoster* (shingles). The major significant advance in understanding the nature of these agents was originally contributed by Weller and co-workers who demonstrated the method for isolation and serial propagation of the virus (1, 2), and more recently, the epidemiology and control (3). Viral isolates, obtained from patients with chickenpox and zoster, were demonstrated to be identical on the basis of cytopathic effect (1), antigenicity (2), and morphology (4, 5). More recently, these viruses have been shown to have identical DNA molecular weight (6), and restriction endonuclease patterns (7). The clinical symptoms of primary varicella (chickenpox) include a prodromal period of headaches, malaise, and fever preceding the exanthem or, the characteristic eruptions may be the first symptom. The rash is pleomorphic and goes through evolution from macular to papular, and then to vesicular stage. The rash characteristically develops in successive crops of new lesions over a 3 to 5-day period.

Chickenpox is endemic in the United States and generally affects children in the primary school bracket (5 - 8 years). Adults, adolescents, and newborns are also susceptible to infection. The disease appears in 2 to 5-year cycles, usually in the winter or spring, and may reach epidemic levels. Varicella infections during early pregnancy rarely have been found to cause congenital anomalies. Varicella infections occurring in susceptible pregnant women at the time of delivery may have a life-threatening infection in the newborn, as well as patients in a variety of pathologies (8 - 10). The potential spread of a nosocomial disease is not uncommon.

Herpes zoster (shingles) is a disease primarily of adults, with most of the cases occurring in the age group over 50 years. In contrast to the epidemic and seasonal nature of varicella (chickenpox) infection, *Herpes zoster* has a random pattern of occurrence. *Herpes zoster* is believed to be the reactivation of a pre-existing varicella virus which has been in a latent state since the occurrence of primary varicella infection. Persons affected with *Herpes zoster* infections do so even in the presence of pre-existing antibody levels to varicella virus. Symptoms of *Herpes zoster* are erythematous, maculopapular areas which develop over an area of skin served by an afferent nerve. Single or clumps of vesicles then appear, usually accompanied by pain which, in some cases, can be extreme (11). The diagnostic problem is differentiating *Herpes zoster* from *Herpes simplex* lesions. A differential diagnosis of varicella and *Herpes simplex* can be made if the classic acute and convalescent (paired) sera are tested, and a four-fold rise in either (but not both) is positive while the other is negative.

Based on the epidemiologic evidence that VZV is spread by droplet nuclei or air droplets, and possibly by skin squames, the portal of entry of the virus is assumed to be through the respiratory passages (12). After dissemination of VZV from the blood, it rapidly spreads to the skin and is detectable in the endothelium, and then involves the cells of the epidermis with accumulation of fluid between the prickle cell layer and outer epidermis forming a vesicle (13). The vesicle becomes the site of intense immunologic activity with initial infiltration of polymorphonuclear leukocytes that remain the predominant inflammatory cell as observed in *Herpes zoster* (14). Later, mononuclear cells migrate in the vesicle.

PRINCIPLE OF THE ASSAY

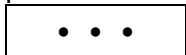
The ZEUS IFA VZV IgG Test System is designed to detect circulating IgG VZV antibodies in human sera. The assay employs VZV infected human fibroblast (derived from primary cultures of human foreskin) substrate cells and fluorescein isothiocyanate (FITC) labeled anti-human IgG antibody adjusted for optimum reactivity and free of non-specific background staining. The reaction occurs in two steps:

1. Interaction of VZV antibodies in patient sera with the VZV infected substrate cells.
2. Interaction of FITC labeled anti-human IgG antibody with the VZV IgG antibodies attached to the VZV localized in the nucleus and/or cytoplasm of the infected substrate cells.

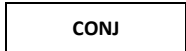
TEST SYSTEM COMPONENTS

Materials Provided:

Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on the packaging label. **NOTE: Conjugate and Controls contain a combination of Proclin (0.05% v/v) and Sodium Azide (<0.1% w/v) as preservatives. SAVe Diluent® contains Sodium Azide (<0.1% w/v) as a preservative.**



1. VZV Antigen Substrate Slides: Ten, 10-well Slides containing VZV (Ellen strain) infected human fibroblast cells in each well, and 70 to 90% uninfected cells as an internal control. Also includes absorbent blotter and desiccant pouch.



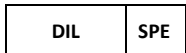
2. Conjugate: Goat anti-human IgG (γ chain specific) labeled with fluorescein isothiocyanate (FITC). Contains phosphate buffer with BSA and counterstain. One, 3.5mL, amber-capped, bottle. Ready to use.



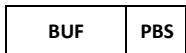
3. Positive Control (Human Serum): Will produce positive apple-green granular fluorescence in the nucleus and cytoplasm of the VZV infected cells. One, 0.5mL, red-capped, vial. Ready to use.



4. Negative Control (Human Serum): Characterized by no detectable staining of the VZV infected cells. One, 0.5mL, green-capped, vial. Ready to use.



5. SAVe Diluent®: One, 30mL, green-capped, bottle containing phosphate-buffered-saline. Ready to use. **NOTE: The SAVe Diluent® will change color when combined with serum.**



6. Phosphate-buffered-saline (PBS): pH 7.2 ± 0.2. Empty contents of each buffer packet into one liter of distilled or deionized water. Mix until all salts are thoroughly dissolved. Four packets, sufficient to prepare 4 liters.



7. Mounting Media (Buffered Glycerol): Two, 3.0mL, white-capped, dripper tipped vials.

NOTES:

1. The following components are not Test System Lot Number dependent and may be used interchangeably with the ZEUS IFA Test Systems, as long as the product numbers are identical: SAVe Diluent® (Product #: FA005CC), Mounting Media (Product #: FA0009S), and PBS (Product #: 0008S).
2. Test System also contains a Component Label containing lot specific information inside the Test System box.

PRECAUTIONS

1. For *In Vitro* diagnostic use.
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.

3. The wells of the Slide do not contain viable organisms. However, consider the Slide **potentially bio-hazardous materials** and handle accordingly.
4. The Controls are **potentially bio-hazardous materials**. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Bio-safety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual "Biosafety in Microbiological and Biomedical Laboratories": current edition; and OSHA's Standard for Bloodborne Pathogens (20).
5. Adherence to the specified time and temperature of incubations is essential for accurate results. **All reagents must be allowed to reach room temperature (20 - 25°C) before starting the assay.** Return unused reagents to their original containers immediately and follow storage requirements.
6. Improper washing could cause false positive or false negative results. Be sure to minimize the amount of any residual PBS, by blotting, before adding Conjugate. Do not allow the wells to dry out between incubations.
7. The SAve Diluent®, Conjugate, and Controls contain Sodium Azide at a concentration of <0.1% (w/v). Sodium Azide has been reported to form lead or copper azides in laboratory plumbing which may cause explosions on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing Sodium Azide. This preservative may be toxic if ingested.
8. Dilution or adulteration of these reagents may generate erroneous results.
9. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.
10. Avoid microbial contamination of reagents. Incorrect results may occur.
11. Cross contamination of reagents and/or samples could cause erroneous results.
12. Reusable glassware must be washed and thoroughly rinsed free of all detergents.
13. Avoid splashing or generation of aerosols.
14. Do not expose reagents to strong light during storage or incubation.
15. Allowing the slide packet to equilibrate to room temperature prior to opening the protective envelope will protect the wells and blotter from condensation.
16. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.:10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.
17. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing solutions. Trace amounts of bleach (Sodium Hypochlorite) may destroy the biological activity of many of the reactive reagents within this Test System.
18. Do not apply pressure to slide envelope. This may damage the substrate.
19. The components of this Test System are matched for optimum sensitivity and reproducibility. Reagents from other manufacturers should not be interchanged. Follow Package Insert carefully.
20. Unopened/opened components are stable until the expiration date printed on the label, provided the recommended storage conditions are strictly followed. Do not use beyond the expiration date. Do not freeze.
21. Evans Blue Counterstain is a potential carcinogen. If skin contact occurs, flush with water. Dispose of according to local regulations.
22. Do not allow slides to dry during the procedure. Depending upon lab conditions, it may be necessary to place slides in a moist chamber during incubations.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Small serological, Pasteur, capillary, or automatic pipettes.
2. Disposable pipette tips.
3. Small test tubes, 13 x 100mm or comparable.
4. Test tube racks.
5. Staining dish: A large staining dish with a small magnetic mixing set-up provides an ideal mechanism for washing Slides between incubation steps.
6. Cover slips, 24 x 60mm, thickness No. 1.
7. Distilled or deionized water.
8. Properly equipped fluorescence microscope.
9. 1 Liter Graduated Cylinder.
10. Laboratory timer to monitor incubation steps.
11. Disposal basin and disinfectant (i.e.: 10% household bleach – 0.5% Sodium Hypochlorite).



The following filter systems, or their equivalent, have been found to be satisfactory for routine use with transmitted or incident light darkfield assemblies:

Transmitted Light			
Light Source: Mercury Vapor 200W or 50W			
Excitation Filter	Barrier Filter	Red Suppression Filter	
KP490	K510 or K530	BG38	
BG12	K510 or K530	BG38	
FITC	K520	BG38	
Light Source: Tungsten – Halogen 100W			
KP490	K510 or K530	BG38	
Incident Light			
Light Source: Mercury Vapor 200, 100, 50 W			
Excitation Filter	Dichroic Mirror	Barrier Filter	Red Suppression Filter
KP500	TK510	K510 or K530	BG38
FITC	TK510	K530	BG38
Light Source: Tungsten – Halogen 50 and 100 W			
KP500	TK510	K510 or K530	BG38
FITC	TK510	K530	BG38

SPECIMEN COLLECTION

1. ZEUS Scientific recommends that the user carry out specimen collection in accordance with CLSI document M29: Protection of Laboratory Workers from Occupationally Acquired Infectious Diseases. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
2. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures with this assay (24, 25). No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
3. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2 - 8°C, for no longer than 48 hours. If delay in testing is anticipated, store test sera at -20°C or lower. Avoid multiple freeze/thaw cycles which may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory (27).

STORAGE CONDITIONS

	Unopened Test System.
	Mounting Media, Conjugate, SAVe Diluent®, Slides, Positive and Negative Controls.
	Rehydrated PBS (Stable for 30 days).
	Phosphate-buffered-saline (PBS) Packets.

ASSAY PROCEDURE

- Remove Slides from refrigerated storage and allow them to warm to room temperature (20 - 25°C). Tear open the protective envelope and remove Slides. **Do not apply pressure to flat sides of protective envelope.**
- Identify each well with the appropriate patient sera and Controls. **NOTE: The Controls are intended to be used undiluted.** Prepare a 1:10 dilution (e.g.: 10µL of serum + 90µL of SAVe Diluent® or PBS) of each patient serum. **The SAVe Diluent® will undergo a color change confirming that the specimen has been combined with the Diluent.**
Dilution Options:
 - As an option, users may prepare initial sample dilutions using PBS, or Zorba-NS (Zorba-NS is available separately. Order Product Number FA025 – 2, 30mL bottles).
 - Users may titrate the Positive Control to endpoint to serve as a semi-quantitative (1+ Minimally Reactive) Control. In such cases, the Control should be diluted two-fold in SAVe Diluent® or PBS. When evaluated by ZEUS Scientific, an endpoint dilution is established and printed on the Positive Control vial (± one dilution). It should be noted that due to variations within the laboratory (equipment, etc.), each laboratory should establish its own expected endpoint titer for each lot of Positive Control.
 - When titrating patient specimens, initial dilutions should be prepared in SAVe Diluent®, PBS, or Zorba-NS and all subsequent dilutions should be prepared in SAVe Diluent® or PBS only. Titrations should not be prepared in Zorba-NS.
- With suitable dispenser (listed above), dispense 20µL of each Control and each diluted patient sera in the appropriate wells.
- Incubate Slides at room temperature (20 - 25°C) for 30 minutes.
- Gently rinse Slides with PBS. **Do not direct a stream of PBS into the test wells.**
- Wash slides for two, 5 minute intervals, changing PBS between washes.
- Remove Slides from PBS one at a time. Invert Slide and key wells to holes in blotters provided. Blot Slide by wiping the reverse side with an absorbent wipe. **CAUTION: Position the blotter and Slide on a hard, flat surface. Blotting on paper towels may destroy the Slide matrix. Do not allow the Slides to dry during the test procedure.**
- Add 20µL of Conjugate to each well.
- Repeat steps 4 through 7.
- Apply 3 - 5 drops of Mounting Media to each Slide (between the wells) and coverslip. Examine Slides immediately with an appropriate fluorescence microscope.
NOTE: If delay in examining Slides is anticipated, seal coverslip with clear nail polish and store in refrigerator. It is recommended that Slides be examined on the same day as testing.

QUALITY CONTROL

- Every time the assay is run, a Positive Control, a Negative Control and a Buffer Control must be included.
- It is recommended that one read the Positive and Negative Controls before evaluating test results. This will assist in establishing the references required to interpret the test sample. If Controls do not appear as described, results are invalid.
 - Negative Control - characterized by the absence of fluorescence.
 - Positive Control - characterized by a 3+ to 4+ apple-green granular fluorescence in the nucleus and cytoplasm of the infected cells. Between 10 - 30% of the cells in any one field are infected. The remaining cells in the same field (70 - 90%) are uninfected and serve as a “within-field” Negative Control.
- Additional Controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.
NOTE: The intensity of the observed fluorescence may vary with the microscope and filter system used.

INTERPRETATION OF RESULTS

- Negative Patients:** The absence of characteristic staining in the infected cells represents a negative reaction. This reaction should compare favorably with the reaction observed in the negative control.
- Positive Patients:** The number of infected cells observed with positive patient sera should closely approximate the number of infected cells seen in the positive control well. The reactivity, depending on patient antibody concentration, may vary from 1+ to 4+ apple-green granular fluorescence in both the cytoplasm and/or nucleus of the infected cells.
- Nonspecific Reactions:** Nuclear staining alone cannot be considered positive as it is not typical for the VZ immune antibody staining pattern. If all the cells (infected and uninfected) in a test field fluoresce apple-green either in the nucleus and/or cytoplasm, an autoimmune or other antibody (*i.e.*, Anti-HLA) reaction should be considered. Test results can still be reported only if one is able to discern characteristic VZV reactivity from the non-specific fluorescence.

NOTE: All positive test sera should be titered to endpoint. Serial two-fold dilutions should be prepared in PBS starting with a 1:20 (repeating the 1:10 dilution is optional) in volumes of at least 100µL. Do not prepare serial dilutions for endpoint titers in Zorba-NS. The endpoint is the last dilution that produces positive apple-green staining (1+) in the infected cells. If, for any reason, the sample does not titer to endpoint, test results should be reported as indeterminate.

Analysis Of Titers	
Serum Titer	Significance
Less Than 1:10	No fluorescence in the substrate cells. No detectable antibody to VZ by IFA test (see Limitations of the Assay, 5 – 6).
Equal to or Greater Than 1:10 (≥ 1+ Staining)	Positive characteristic fluorescence in varicella-zoster infected cells only (see Interpretation of Results). This indicates prior varicella infection. Patient is presumed to be immune to varicella (but not zoster), (see Limitations of Assay, 2).
Four-Fold or Greater Rise In Titer	A four-fold rise, or greater, between acute and convalescent specimens is highly suggestive of a current VZV infection unless a concurrent HSV rise in titer is noted. If this occurs, the infection may be caused by either virus (see Limitations of the Assay, 1).

LIMITATIONS OF THE ASSAY

- A four-fold or greater rise in antibody titer should be used to confirm a clinical diagnosis of a typical varicella or zoster infection **only** if a patient is tested concurrently for *Herpes simplex*. Heterotypic antibody responses have been reported for both of these viruses (15, 18, 19, and 21). For immune status testing, this heterotypic reaction would not be classified as false-positive since previous exposure is assumed for this to occur.
- A definitive diagnosis for patients demonstrating rises in titer for both varicella-zoster and *Herpes simplex* viruses must be made by isolation and/or direct identification of the virus or viral antigen from a lesion. The virus causing the infection may not always demonstrate the greater rise in titer. Frequently a

differential diagnosis can be made on the basis of the fact that the antibody to the infecting type is absent, or at a very low titer in the acute phase specimen; whereas antibody to the viral heterotype is already present (21).

- Persons who have received blood products containing plasma within the past six months who present a positive test result may not have had prior varicella involvement.
- ZEUS IFA VZV IgG Test System results should be used in conjunction with information available from the clinical evaluation as well as other diagnostic procedures.
- The endpoint reactions may vary due to the type of microscope employed, the light source, age of bulb, filter assembly, and filter thickness.
- If testing of a particular sample occurs early (less than five days following onset) during a primary infection, no detectable IgG may be evident. If VZ infection is suspected, a second sample should be taken at least fourteen days later and the two specimens should be tested in parallel to look for seroconversion.
- The correlation of negative test results determined by this method (IFA) as they relate to protection from varicella infection has not yet been definitively established (22, 23).

EXPECTED RESULTS

- Population studies using diagnostic tests for antibody analysis indicate that most individuals have had previous infection with VZV by the time they are twenty years old (16).
- A comparison was made with the ZEUS IFA VZV IgG Test System versus data representing expected serological values from two hundred blood donors in Minnesota (19), see Table 1 below.

	* <1:10	* 1:10 - 1:40	* >1:40
Reference Study (19)	1% (2/200)	14% (28/200)	85% (170/200)
ZEUS Study (20)	12% (60/494)	10% (47/494)	78% (387/494)

*Results expressed at endpoint dilution.

The ZEUS study was defined by randomly collected adult male and female samples submitted to a reference laboratory. **NOTE: Expected values may vary depending on the population being tested.**

PERFORMANCE CHARACTERISTICS

- The ZEUS IFA VZV IgG Test System was compared to another IFA system available commercially. The following results were noted, see Table 2 below.

Table 2: Comparison of Indirect Fluorescent Antibody Test Systems

ZEUS IFA VZV IgG Test System		Other IFA	
Reactive	Non-Reactive	Reactive	Non-Reactive
23	13	23	13
Sensitivity = 99+ %		Specificity = 99+ %	

- The ZEUS IFA VZV IgG Test System was evaluated against a commercially available IFA test system. Random clinical serum specimens indicated a 96% agreement within the generally accepted one tube dilution variation limit for serological methods. The ZEUS IFA VZV IgG Test System revealed a two tube dilution higher on one patient than the commercially available test system, see Table 3 below.

Table 3: Endpoint Titer Analysis

Positive Results	Patient Specimens	Cumulative Agreement (Expressed As %)
Identical Titers	14/23	61%
± One Dilution	8/23	96%
± Two Dilutions	1/23	100%
Negative Results	13/13	100%

3. Reproducibility Studies:

Proper adherence to the directions for use of the ZEUS IFA VZV IgG Test System, along with a properly equipped fluorescence microscope should provide reproducible results. Thirty-five (35) serum samples with titers of low (1:40), medium (1:160), of high (1:640) were repeated twice with the ZEUS IFA VZV IgG Test System. The following results were noted:

- Intra-Run Study:** Ninety-four percent (94%) (33/35) of the determinations evaluated indicated identical titers. Six percent (6%) (2/35) of the determinations evaluated indicated titers within one tube dilution.
- Inter-Run Study:** Eighty-six percent (86%) (30/35) of the determinations evaluated indicated identical titers on two successive testings (day 1 and day 7). Fourteen percent (14%) (5/35) of the determinations evaluated indicated titers within one tube dilution of the two successive testings (day 1 and day 7).

4. Cross-Reactivity Studies:

In order to assess antigenic specificity of the ZEUS IFA VZV IgG Test System, five patients were confirmed for VZV seronegativity, and also monitored for cytomegalovirus (CMV), *Herpes simplex* viruses (HSV-1, and HSV-2), and Epstein-Barr virus (EBV) antibodies. The results were as follows in Table 4.

Table 4: Endpoint Titers Among Patient Sera with Antibody to:

Patient I.D.	VZV	HSV-1	HSV-2	CMV	EBV
1138	Neg.	1:320	1:160	1:40	1:160
0022	Neg.	Neg.	1:40	Neg.	1:320
0117	Neg.	Neg.	Neg.	Neg.	1:320
0066	Neg.	1:640	1:640	Neg.	1:160

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ZEUS IFA VZV IgG Test System

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