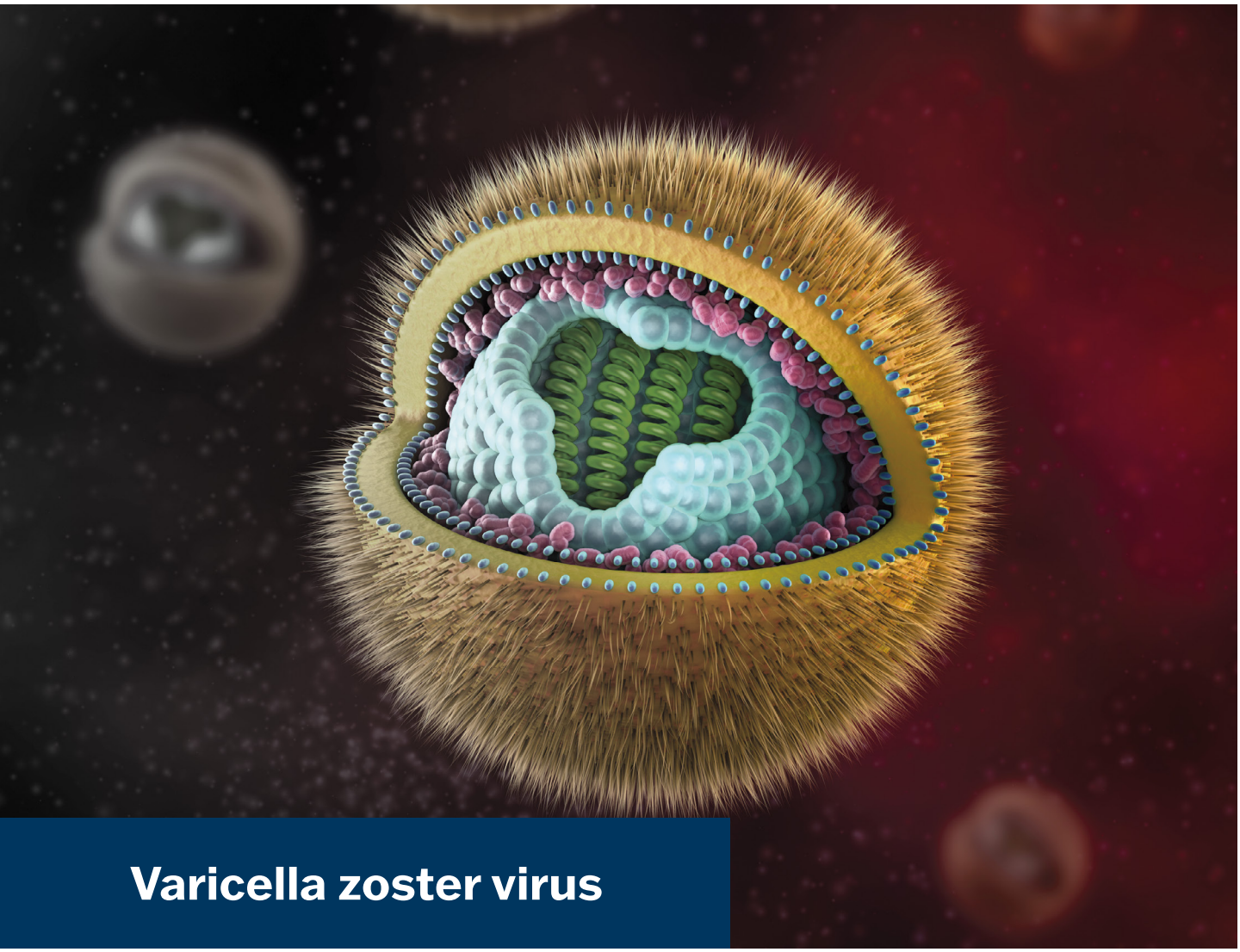


Varicella zoster virus

Enzyme immunoassay for the diagnosis of Varicella zoster virus

ELISA kits are optimized and validated for detection of IgA, IgG (including avidity) and IgM antibodies in human serum, plasma or cerebrospinal fluid

CE IVD

Diagnostic kits are intended for professional use in the laboratory.

BG TestLine®

Introduction

Varicella zoster virus (VZV, HHV-3) belongs to the Herpetoviridae family. The virus causes chicken-pox, varicella (primary infection) and shingles, herpes zoster (reactivation).

Primary VZV infection occurs mainly in childhood and it is transmitted by means of droplet infection. Up to 90% of humans without specific antibodies can be infected during close contact with an infected person. The symptoms include fever, malaise and skin itching preceding the development of characteristic exanthema. The disease usually terminates without any lasting effects. Primary infection in adolescents and adults can be generally more severe with serious complications (e.g. encephalitis, pneumonia and hepatitis) especially in immunocompromised patients. The virus can be transmitted via placenta to the foetus; this can lead to severe congenital defects. Maternal infection of a seronegative female (i.e. without specific antibodies) in late gestation presents serious risk for a newborn.

As a member of the Herpetoviridae family, the virus may persist latently in the organism and can be reactivated subsequently (reduced immunity) producing a disease known as shingles.

Diagnosis of Infection

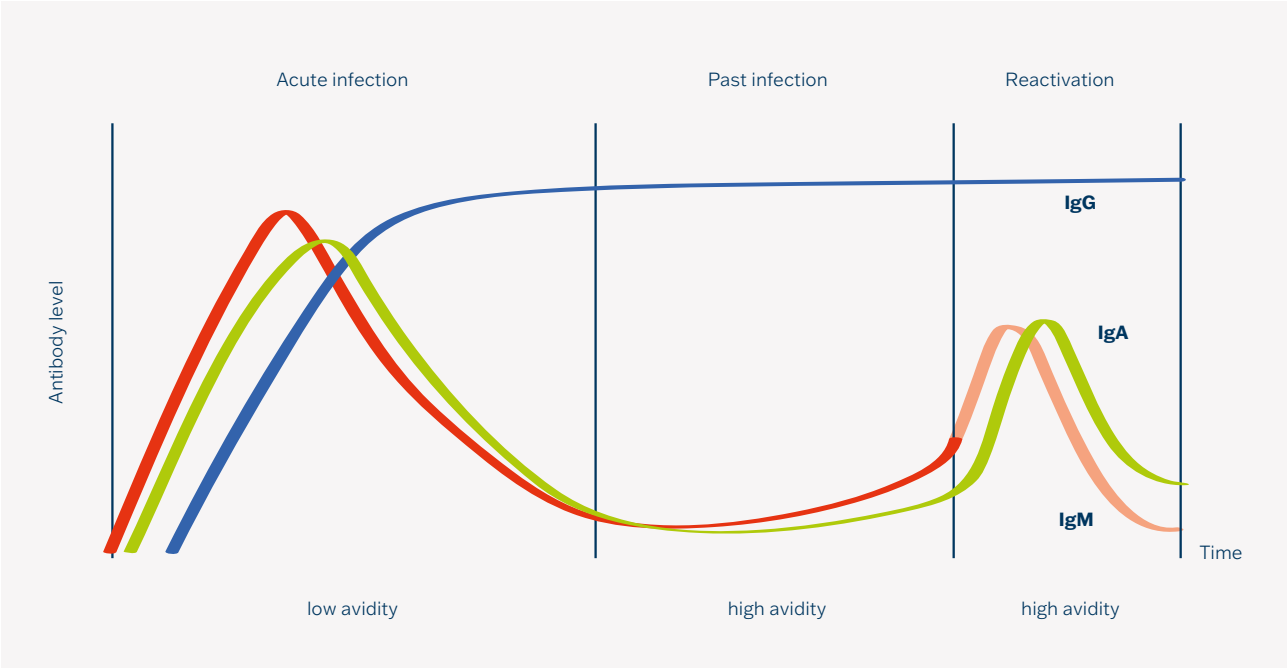
Diagnosis of the disease is based on clinical manifestation, epidemiological anamnesis and laboratory tests. The most widespread serological method used for the detection of specific IgA, IgM and IgG (avidity) antibodies to VZV in laboratory diagnosis of the infection is ELISA.

IgA, IgM: Antibodies of IgM and IgA class are a sign of an active infection (primary infection and reactivation) and disappear during convalescence. In some cases they can persist for several months.

IgG: Specific IgG antibodies are anamnestic, providing long term protection. Measurement of specific IgG antibodies is useful for assigning patient immunological status. Specific IgG antibodies typically remain at low levels throughout the entire life of the infected person.

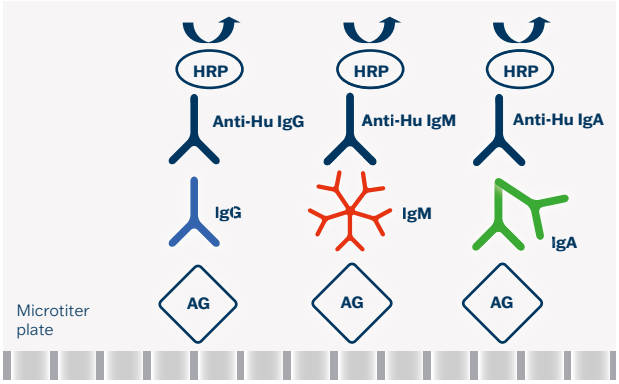
The method of IgG avidity detection is used for discrimination between primary infection and past infection or reactivation.

Antibody Response



Test Principle

The assays are based on a sandwich type of ELISA method.



Protocol Summary

Step		Test steps
	1.	Dilution of samples – serum/plasma 1:101 (10 µl + 1 ml) – cerebrospinal fluids 1:3 (50 µl + 100 µl)
	2.	Pipette Controls and diluted samples 100 µl – Including blank
	3.	Incubate 30 min. at 37 °C
	4.	Aspirate and wash the wells 5 times
	5.	Add Conjugate 100 µl – Including blank
	6.	Incubate 30 min. at 37 °C
	7.	Aspirate and wash the wells 5 times
	8.	Add 100 µl Substrate (TMB-Complete) – Including blank
	9.	Incubate 15 min. at 37 °C
	10.	Add 100 µl Stopping solution – Including blank
	11.	Read colour intensity at 450 nm

Antigens

Purified and inactivated antigen VZV with a high content of specific immunodominant epitopes.

Clinical Application

- Screening test
- Evaluating results of therapy using the semiquantitative or qualitative determination
- Disease stage diagnosis

User Comfort

- Ready-to-use, color-coded components
- Interchangeable components
- Breakable colour-coded microplate strips CUT-OFF and calibrators included
- Semiquantitative evaluation of results (Index of Positivity) or quantitative evaluation of results (IU/ml)
- Easy assay procedure

Advantages

- Identical assay procedure
- High diagnostic specificity and sensitivity
- High reproducibility
- High dynamics of antibody response
- Short total assay time
- Avidity test (EIA VZV IgG)
- Sample diluent with RF-sorbent (EIA VZV IgM)
- The quantitative evaluation in International units was derived from the WHO International Standard (W1044)
- Ready for automation
- Customer support

Test Characteristics

Parameter	Diagnostic Sensitivity	Diagnostic Specificity
EIA VZV IgA	99.9%	99.9%
EIA VZV IgG	98.9%	99.9%
EIA VZV IgM	99.9%	98.9%

Ordering Information

ELISA

Cat. No	Product	No. of Tests
VZVA96	EIA VZV IgA	96
VZVG96	EIA VZV IgG	96
VZVM96	EIA VZV IgM	96
SK-VZVA96	SmartEIA VZV IgA	96
SK-VZVG96	SmartEIA VZV IgG	96
SK-VZVM96	SmartEIA VZV IgM	96

SmartEIA kits are designed for automated processing using the Agility® analyser

TestLine®

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CERTIFIED ISO 9001 · ISO 13485

Company is certified to the quality management system standards ISO 9001 and ISO 13485 for in vitro diagnostics.

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