BioVendor Group CLIA

VZV

Antibody determination

***Varicella zoster virus* IgA, IgG, IgM**

Diagnostic panels:
TORCH
Herpes viruses

IVD CE 2265

The kits are CE-IVD certified and intended for professional use.

Designed for the platform

Kleeya®

Introduction

Varicella zoster virus (VZV, HHV-3) belongs to the *Herpetoviridae* family. The virus causes chickenpox, 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 fetus; this can lead to severe congenital defects. Maternal infection of 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.

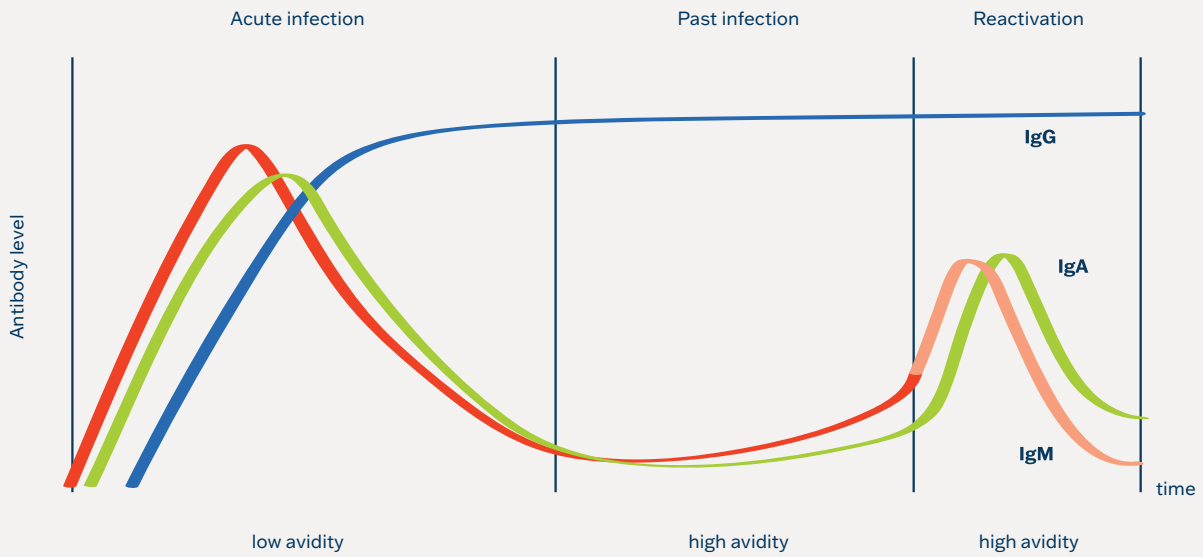
Diagnosis of the disease is based on clinical manifestation, epidemiological anamnesis and laboratory tests. The most widespread serological method used for the detection of specific IgA, IgM and IgG. Specific IgG antibodies have anamnestic character and serve for patient immunological status assignment.

Antibody determination

Diagnostic importance of antibody classes

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.

Specific IgG antibodies mostly remain in reduced 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.



Clinical application

– The diagnosis, monitoring and screening of VZV infection using IgA, IgM and IgG antibodies in human serum or plasma in the general population.

Antigens

Varicella zoster virus IgA, IgG, IgM
Mixture of highly purified native antigen and VZV glycoprotein

Test characteristics

Kit	Calibration scale	Diagnostic sensitivity	Diagnostic specificity
CLIA VZV IgA	0,50–160 U/ml	97.87%	95.28%
CLIA VZV IgG	1–2 500 IU/l *	96.55%	97.56%
CLIA VZV IgM	1–160 U/ml	97.30%	95.28%

* Quantitative evaluation in international units was derived from the WHO international standard (W1044).

Correlation of methods

CLIA kits were compared to established ELISA kits from TestLine of the BioVendor Group. 96–99% agreement was found among the compared methods.

Accuracy and analytical sensitivity

High precision ensures consistent and reliable results of each measurement:

		IgA	IgG	IgM
Repeatability	Intra assay (within run)	6.39%	4.97%	6.32%
	Within-laboratory precision	9.24%	8.50%	12.90%

Clinical function

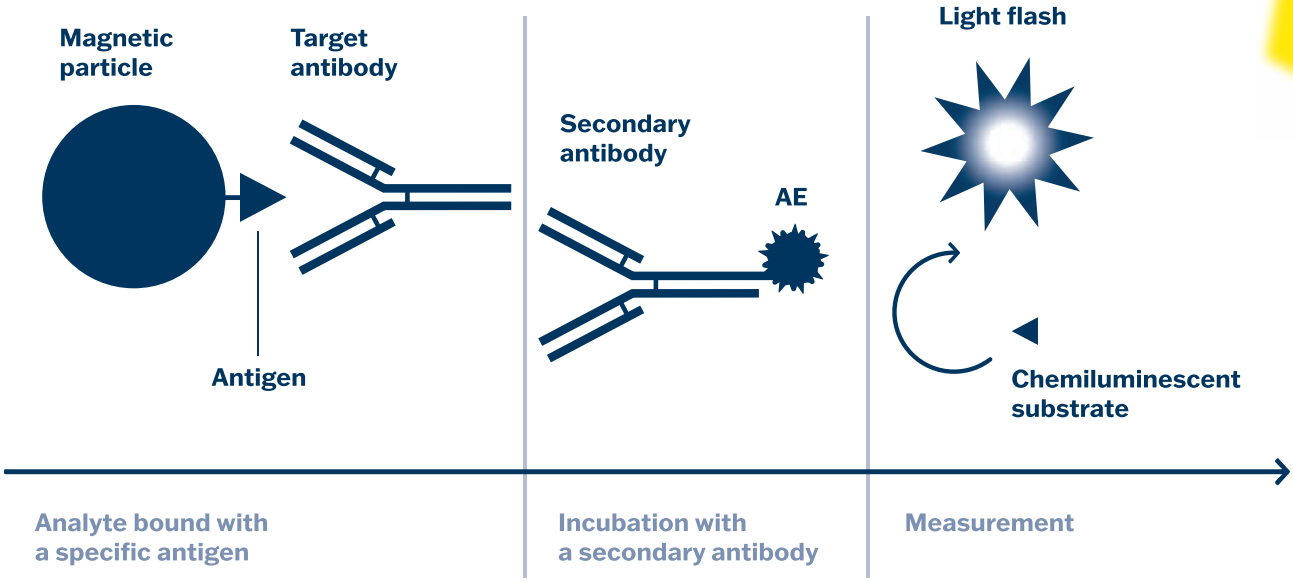
The quality of the CLIA VZV IgA, IgG and IgM kits were verified within an external clinical performance study at a specialized laboratory according to the strict requirements of the European IVDR directive.

The obtained comparison of clinical samples with the reference commercial kits demonstrated high level of agreement:

	IgA	IgG	IgM
Comparison with the reference method	96.08%	96.82%	95.80%

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa® automated platform.



CLIA kits

Diagnostic CLIA kits are intended for the diagnosis, monitoring and screening of VZV infection using IgA, IgM and IgG antibodies in human serum or plasma in the general population. The quantitative automated assay is designed for professional use in a laboratory on a KleeYa® analyzer. Results are reported in U/ml or IU/l.

Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.

Ease of use

- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Working strength reagent solution
- Control sera available as independent sets
- Results in U/ml, IU/l

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30–40 min)
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service

Ordering information

CLIA kits

Diagnostic CLIA kits are intended for the diagnosis, monitoring and screening of VZV infection using IgA, IgM and IgG antibodies in human serum or plasma on a KleeYa® analyser.

Kit	Catalogue number	Number of tests
CLIA VZV IgA	CL-VZVA100	100
CLIA VZV IgG	CL-VZVG100	100
CLIA VZV IgM	CL-VZVM100	100

Control set

Each set contains two vials of positive and two vials of negative control serum with the predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Kit	Catalogue number	Number of tests
Control set CLIA VZV IgA	CL-VZVACON	2 x 20
Control set CLIA VZV IgG	CL-VZVGCON	2 x 20
Control set CLIA VZV IgM	CL-VZVMCON	2 x 20

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