BioVendor Group CLIA

Toxoplasma

Antibody determination

Toxoplasma IgA, IgG, IgM

Diagnostic panels:
TORCH

IVD CE 2265

Diagnostic kits are intended for professional use in the laboratory.

Designed for the platform Kleeya®

Introduction

Toxoplasmosis is a widespread parasitic disease caused by protozoan *Toxoplasma gondii* – a parasite with a complicated life cycle consisting of several morphologically different stadia.

Primary hosts are members of the feline family. Humans and most warm-blooded animals can be infected by either primarily infected food (insufficiently heat-treated meat) or by ingestion of oocysts (secondary contaminated food or contaminated fingers, objects, etc.).

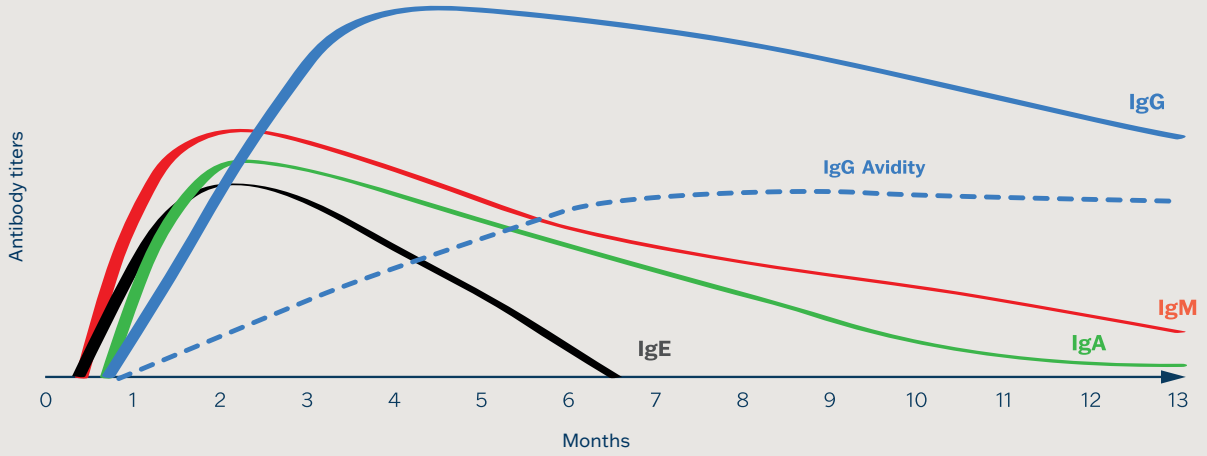
Acquired toxoplasmosis in immunocompetent individuals is usually asymptomatic or can manifest itself with flu-like symptoms (subfebrility, fatigue, lymphadenopathy, muscle aches), but without lasting ill effects. Severe life-threatening infections (encephalitis, hepatitis, chorioretinitis, myocarditis, generalized form of the disease) may develop in immunocompromised patients usually because of a reactivation of a latent infection.

Congenital toxoplasmosis is caused by transmission of infection from mother to foetus. The mother has been primary infected with toxoplasmosis shortly before becoming pregnant or during pregnancy. Congenital toxoplasmosis might result in severe damages of the foetus (brain calcification, hydrocephalus, vision disorders, mental affections), still birth or abortion.

Diagnosis of the disease is based on epidemiological anamnesis, clinical manifestation and laboratory tests. Direct detection of the parasite is not available for routine diagnostics.

Serology is the most important tool for laboratory diagnostics of toxoplasmosis. Determination of specific IgA, IgM, IgG antibodies is performed by CLIA, ELISA and confirmation of results by immunoblot method.

Antibody response



Clinical applications

– Diagnostics and differentiation of toxoplasmosis stage by detection of IgA, IgG a IgM specific antibodies in human serum or plasma in the general population.

Antigens

CLIA Toxoplasma IgA, IgG, IgM
Purified and inactivated native *Toxoplasma gondii* antigen (RH strain)

Test characteristics

Kit	Calibration scale	Diagnostic sensitivity	Diagnostic specificity
CLIA Toxoplasma IgA	0–320 IU/ml *	92.86%	92.76%
CLIA Toxoplasma IgG	0–320 IU/ml *	99.03%	95.00%
CLIA Toxoplasma IgM	0–320 IU/ml *	92.39%	99.47%

* Quantitative evaluation in international units was derived from the international standard NIBSC 13/132.

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)	9.03%	8.13%	9.71%
	Within-laboratory precision	13.35%	9.41%	8.06%

Clinical function

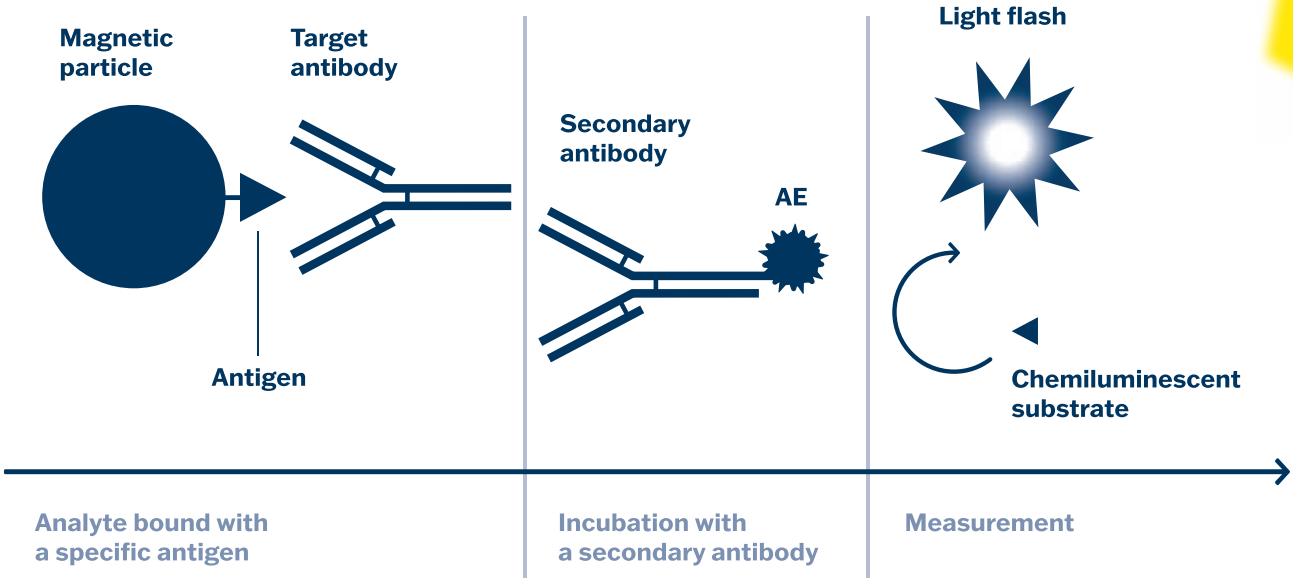
The quality of the CLIA Toxoplasma IgA, IgG, IgM kits were verified within an external clinical performance study at a specialized laboratory according to the strict requirements of the European IVDR directive.

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

	IgA	IgG	IgM
Comparison with the reference method	92.78%	97.90%	97.14%

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.



The scheme illustrates a sandwich-type reaction.
The CLIA Toxoplasma IgA and CLIA Toxoplasma IgM kits are designed with a different reaction type – capture.

CLIA kits

Diagnostic CLIA kits are intended for the diagnosis and screening of *Toxoplasma gondii* infection using IgA, IgG and IgM 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/ml.

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 or 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 and screening of *Toxoplasma gondii* infection using IgA, IgG and IgM antibodies in human serum or plasma on a KleeYa® analyser.

Kit	Catalogue number	Number of tests
CLIA Toxoplasma IgA	CL-TgA100	100
CLIA Toxoplasma IgG	CL-TgG100	100
CLIA Toxoplasma IgM	CL-TgM100	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 Toxoplasma IgA	CL-TgACON	2 x 20
Control set CLIA Toxoplasma IgG	CL-TgGCON	2 x 20
Control set CLIA Toxoplasma IgM	CL-TgMCON	2 x 20

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