

**BioVendor
Group**

CLIA



TORCH

**Toxoplasma
Rubella
Cytomegalovirus**

**Parvovirus B19
Varicella zoster virus
Herpes simplex virus**

Diagnostic panel

Designed for the platform

KleeYa®



TORCH infections

TORCH infections refer to a group of specific infectious diseases that can cause risky pregnancies and fetal damage in pregnant women. The most common cause of congenital infections can be summarized by the acronym „TORCH“ - **T**oxoplasma gondii, **O**ther (syphilis, Varicella zoster virus, Parvovirus B19, and Human immunodeficiency virus (HIV)), **R**ubella virus, **C**ytomegalovirus (CMV), and **H**erpes simplex virus (HSV). Infection of the mother shortly before conception or during pregnancy can lead to miscarriage, stillbirth, or the birth of a child with varying degrees of damage. The severity of fetal damage may vary depending on the timing of infection during pregnancy.

Toxoplasma gondii is a parasite that can cause congenital toxoplasmosis. In intrauterine infection, encephalomyelitis occurs with subsequent development of malacic lesions and miliary granulomas in the CNS leading to fetal abnormalities (hydrocephalus, chorioretinitis, and intracranial calcification).

Rubella virus is an RNA virus with the highest teratogenicity, which can cause congenital rubella syndrome. Typical fetal abnormalities include hearing and vision loss, heart defects, and mental disabilities.

Cytomegalovirus is a DNA virus that is the most common cause of intrauterine infection. It can result in fetal death, miscarriage, or the formation of malformations (petechial rash, hearing impairment, chorioretinitis, mental retardation, or hydrocephalus).

Herpes simplex virus (HSV) (HSV) is a DNA virus, and intrauterine transmission is rare in the 1st trimester (5%). Congenital infection can manifest as CNS malformations (calcifications, microcephaly) and eye (cataracts, microphthalmia) or skin lesions.

Parvovirus B19 is a single-stranded DNA virus that can cause fetal hydrops. The virus attacks erythrocyte precursors, causing myocarditis and anemia, which can lead to heart failure.

Varicella-zoster virus (VZV) (VZV) is a DNA virus. Primary infection during pregnancy can cause limb hypoplasia, chorioretinitis, microcephaly, and mental retardation. A specific problem is maternal disease around delivery with the risk of developing fulminant hemorrhagic varicella, visceral varicella (especially affecting the lungs and liver).

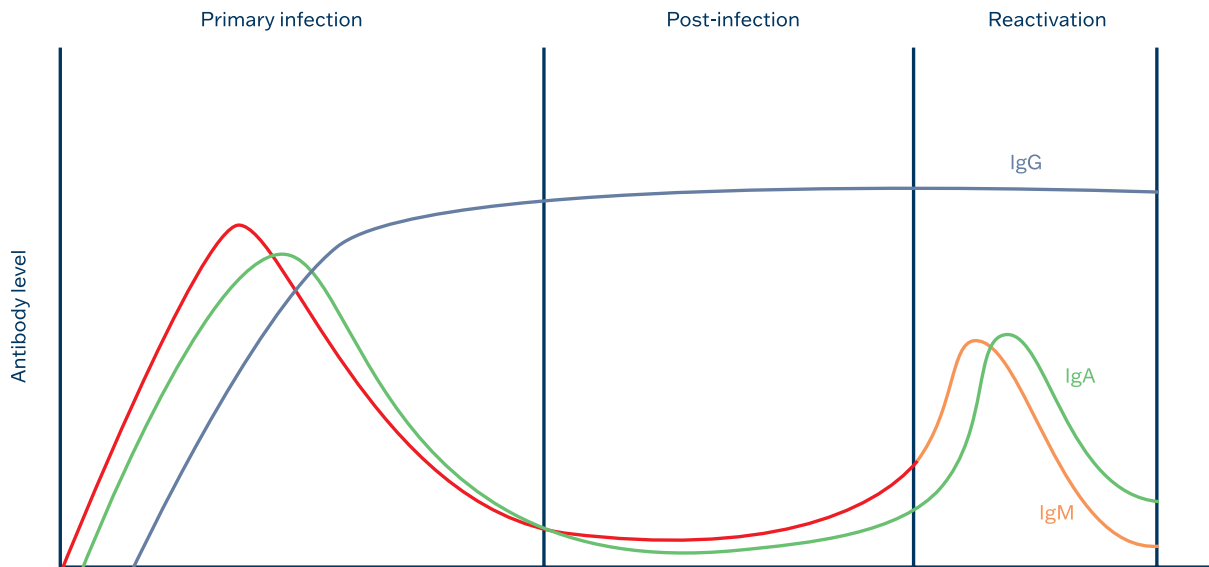
Overall, accurate and timely diagnosis of TORCH infections is crucial for the prevention of fetal abnormalities and complications. Serological tests are an essential tool in the diagnosis of these infections, and the dynamic nature of antibodies can provide important insights into the timing and severity of the infection. It's important to note that TORCH infections can have overlapping symptoms, and accurate diagnosis requires a combination of clinical assessment, laboratory testing, and appropriate treatment. Early detection and treatment can help reduce the risk of fetal damage and improve outcomes for both the mother and the baby.



Antibody response

The presence of IgM and/or IgA antibodies indicates recent infection, whereas the presence of IgG antibodies indicates past infection. IgM antibodies usually appear within a week of infection and can persist for several weeks, while IgG antibodies

typically appear later (around 2-3 weeks after infection), reach the maximum level in serum after a few months and can last for years. Significant rise in IgM and/or IgA titers is typical for reinfections.



Clinical applications

- Screening pregnant women for TORCH infections
- Diagnosis of congenital TORCH infections
- Assessment of immunity
- Differential diagnosis
- Monitoring treatment
- Epidemiological studies

Antigens

CLIA Toxoplasma

Purified and inactivated antigen of *Toxoplasma gondii* (RH strain)

CLIA Rubella

Purified and inactivated antigen from HPV-77 strain with high content of specific immunodominant epitopes

CLIA CMV

Purified and inactivated antigen isolated from CMV AD 169 strain with a high content of specific immunodominant epitopes

CLIA HSV 1+2

Mixture of inactivated and purified HSV-1 and HSV-2 strains

CLIA Parvovirus B19

VP2 recombinant protein

CLIA VZV

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

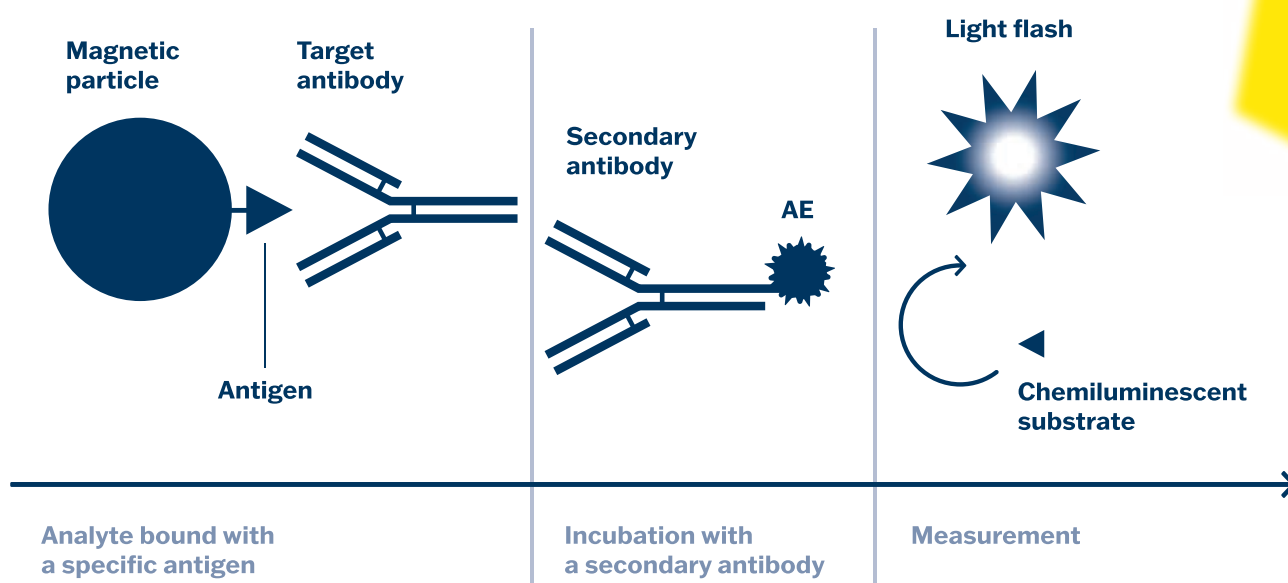
Test characteristics

Kit	Calibration range	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%
CLIA Rubella IgG	0,1–200 IU/ml	97.83%	96.00%
CLIA Rubella IgM	0,5–160 U/ml	99.99%	99.99%
CLIA CMV IgA	2–160 U/ml	93.75%	94.20%
CLIA CMV IgG	0,1–160 U/ml	98.31%	98.33%
CLIA CMV IgM	0,5–160 U/ml	93.33%	99.29%
CLIA HSV 1+2 IgG	0,5–160 U/ml	89.22%	97.50%
CLIA HSV 1+2 IgM	3–160 U/ml	94.59%	87.37%
CLIA Parvovirus B19 IgG	0,5–120 IU/ml	98.89%	98.88%
CLIA Parvovirus B19 IgM	0,5–320 IU/ml	90.48%	99.99%

How does CLIA method work?

CLIA is a fully automated, fast, specific and sensitive method. It combines magnetic particle-mediated antigen / antibody immunocomplex separation and flash chemiluminescence to achieve 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 used to determine specific antibodies in human serum or plasma on a KleeYa® analyzer. The results are reported in U/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
- Ready-to-use reagents in the reaction cartridges
- Control sera available as independent sets
- Quantitative determination (U/ml)

Advantages

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



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Ordering information

CLIA kits

CLIA diagnostic kits are used to determine IgA, IgG and IgM antibodies to the dominant antigens of TORCH infections in human serum or plasma of the KleeYa® analyzer.

Kit	Catalogue number	Number of tests	
CLIA Toxoplasma IgA	CL-TgA050	50	IVD C € 2265
CLIA Toxoplasma IgG	CL-TgM100	100	IVD C € 2265
CLIA Toxoplasma IgM	CL-TgG100	100	IVD C € 2265
CLIA Rubella IgG	CL-RubG100	100	IVD C €
CLIA Rubella IgM	CL-RubM100	100	IVD C €
CLIA CMV IgA	CL-CMA100	100	IVD C €
CLIA CMV IgG	CL-CMG100	100	IVD C €
CLIA CMV IgM	CL-CMM100	100	IVD C €
CLIA HSV 1+2 IgG	CL-HSVG100	100	IVD C € 2265
CLIA HSV 1+2 IgM	CL-HSVM100	100	IVD C € 2265
CLIA Parvovirus B19 IgG	CL-PVG050	50	IVD C € 2265
CLIA Parvovirus B19 IgM	CL-PVM050	50	IVD C € 2265
CLIA VZV IgA	CL-VZVA100	100	IVD C € 2265
CLIA VZV IgG	CL-VZVG100	100	IVD C € 2265
CLIA VZV IgM	CL-VZVM100	100	IVD C € 2265

Control sets

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
Control set CLIA Rubella IgG	CL-RubGCON	2 x 20
Control set CLIA Rubella IgM	CL-RubMCON	2 x 20
Control set CLIA CMV IgA	CL-CMACON	2 x 20
Control set CLIA CMV IgG	CL-CMGCON	2 x 20
Control set CLIA CMV IgM	CL-CMMCON	2 x 20
Control set CLIA HSV 1+2 IgG	CL-HSVGCON	2 x 20
Control set CLIA HSV 1+2 IgM	CL-HSVMCON	2 x 20
Control set CLIA Parvovirus B19 IgG	CL-PVGCON	2 x 20
Control set CLIA Parvovirus B19 IgM	CL-PVMCON	2 x 20
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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