BioVendor Group

CLIA

# TORCH

**Toxoplasma**
**Rubella**
**Cytomegalovirus**
**Parvovirus B19**
**Varicella zoster virus**
**Herpes simplex virus**

**Diagnostic panel**

Designed for the platform

Kleeya®

# TORCH infections

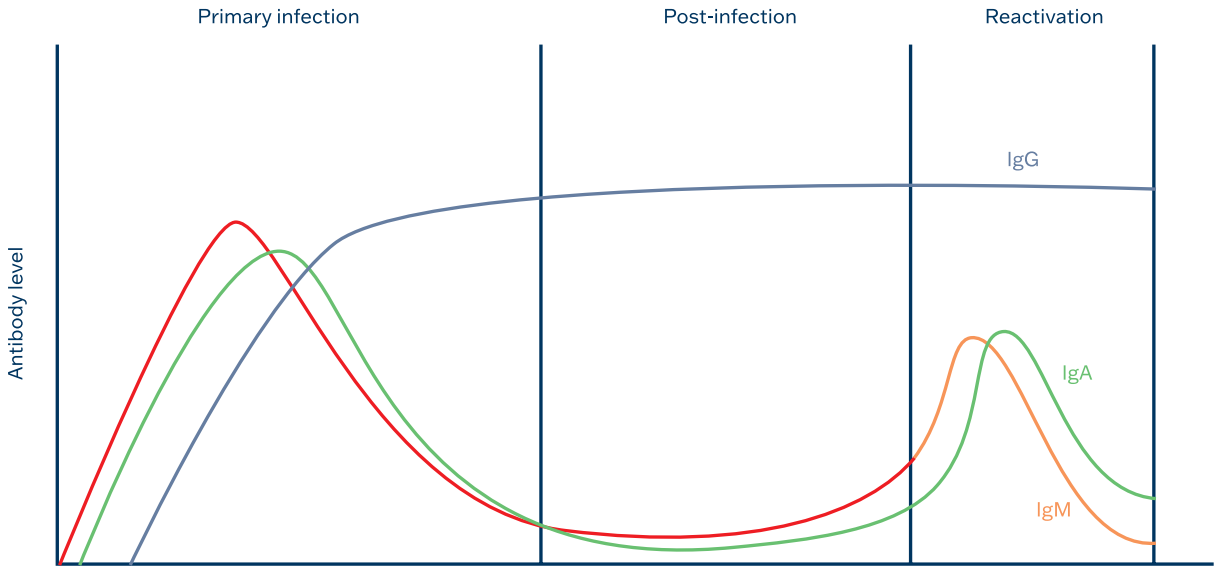
TORCH infections refer to a group of specific infectious diseases that can cause risky pregnancies and fetal damage in pregnant women. The most common cause of congenital infections can be summarized by the acronym „TORCH“ - **T**oxoplasma gondii, **O**ther (syphilis, Varicella zoster virus, Parvovirus 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 malatic 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

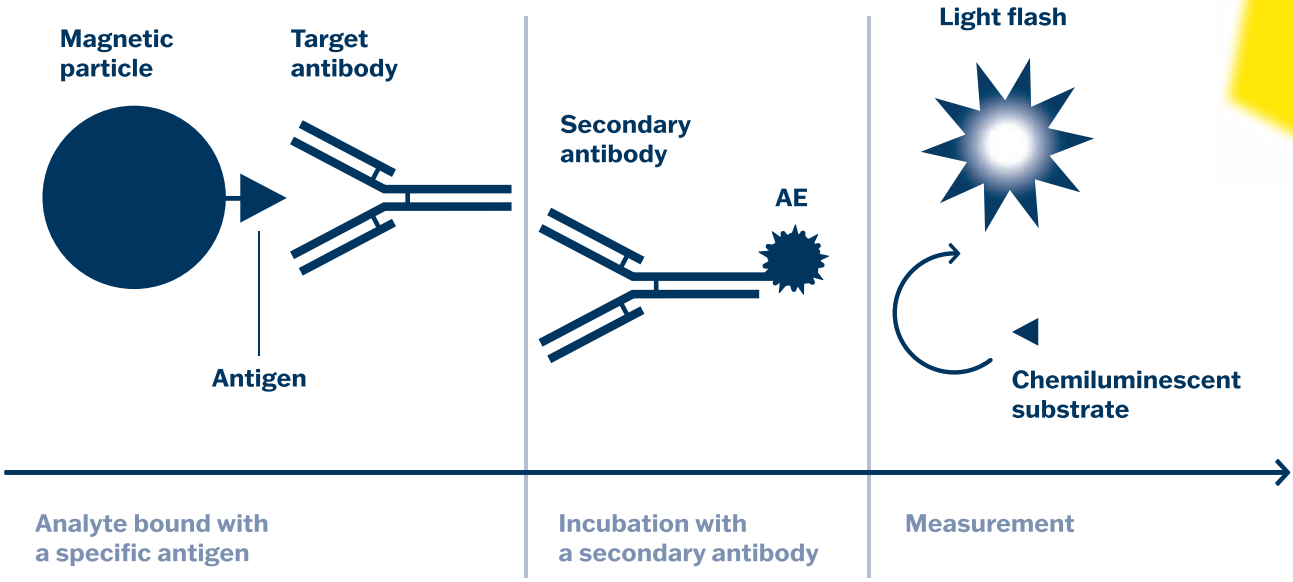
## Test characteristics

| Kit | Calibration range | Diasgnostic sensitivity | Diagnostic specificity |
|---|---|---|---|
| CLIA Toxoplasma IgA * | 0–320 IU/ml | - | - |
| CLIA Toxoplasma IgG | 0–320 IU/ml | 99,99% | 99,99% |
| CLIA Toxoplasma IgM * | 0–320 IU/ml | - | - |
| 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 | - | - |
| CLIA HSV 1+2 IgM * | 3–160 U/ml | - | - |
| 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% |

* Data not available yet

# 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.




# 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

FOLLOW US

# 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 | |
| CLIA Toxoplasma IgG * | CL-TgM100 | 100 | |
| CLIA Toxoplasma IgM * | CL-TgG100 | 100 | |
| CLIA Rubella IgG | CL-RubG100 | 100 | IVD CE |
| CLIA Rubella IgM | CL-RubM100 | 100 | IVD CE |
| CLIA CMV IgA | CL-CMA100 | 100 | IVD CE |
| CLIA CMV IgG | CL-CMG100 | 100 | IVD CE |
| CLIA CMV IgM | CL-CMM100 | 100 | IVD CE |
| CLIA HSV 1+2 IgG * | CL-HSVG100 | 100 | |
| CLIA HSV 1+2 IgM * | CL-HSVM100 | 100 | |
| CLIA Parvovirus B19 IgG | CL-PVG050 | 50 | IVD CE 2265 |
| CLIA Parvovirus B19 IgM | CL-PVM050 | 50 | IVD CE 2265 |
| CLIA VZV IgA * | CL-VZVA100 | 100 | |
| CLIA VZV IgG * | CL-VZVG100 | 100 | |
| CLIA VZV IgM * | CL-VZVM100 | 100 | |

** Validation CLIA kits for the determination of antibodies in human serum and plasma - pre-market testing.
* Coming soon

## 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 |

**Contact us at**

**clia@biovendor.group**

**or visit our website**

**clia.biovendor.group**

BIOVENDOR.GROUP

PRODUCER:

TestLine®

**TestLine Clinical Diagnostics s.r.o.**
Křižíkova 68
612 00 Brno
Czech Republic

ENDX1202