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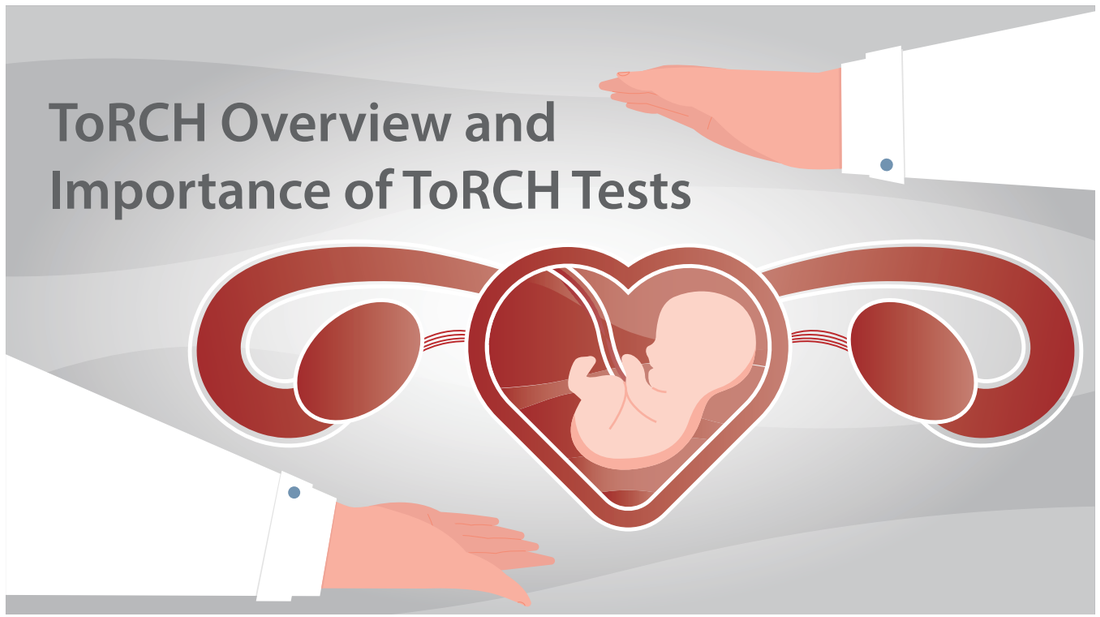
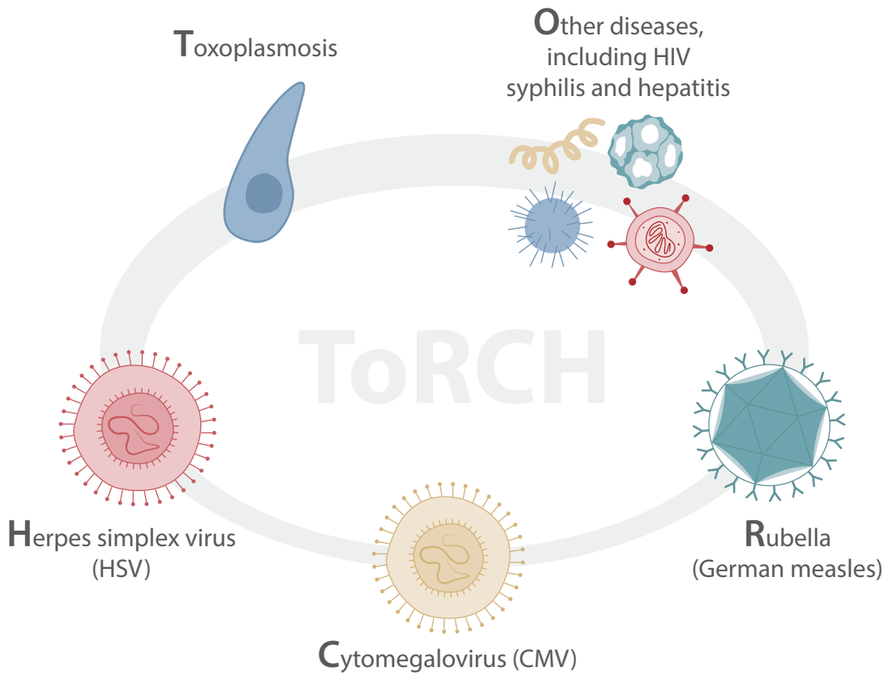
CLIABook III

Improve antenatal care with ToRCH tests

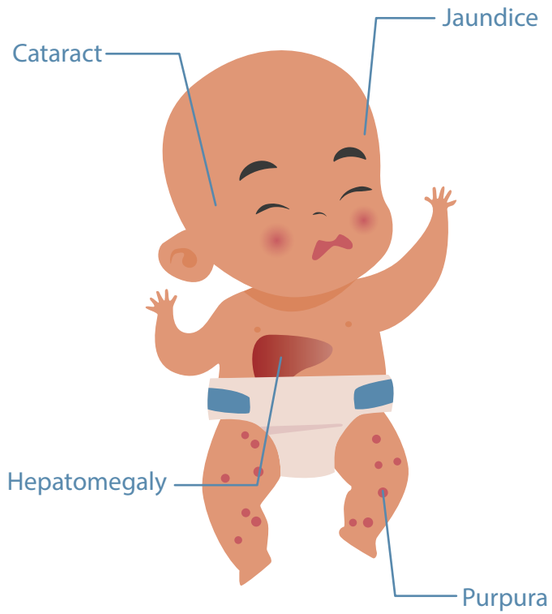
Content



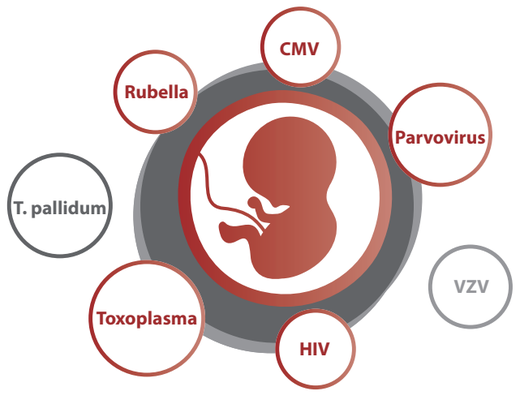
The ToRCH syndrome is an infection of a developing fetus or newborn that can occur in utero, during delivery, or after birth, which is caused by any group of infectious agents[1].



The exact symptoms vary depending on the specific underlying infection, but TORCH infections can share some non-specific signs and symptoms[2].

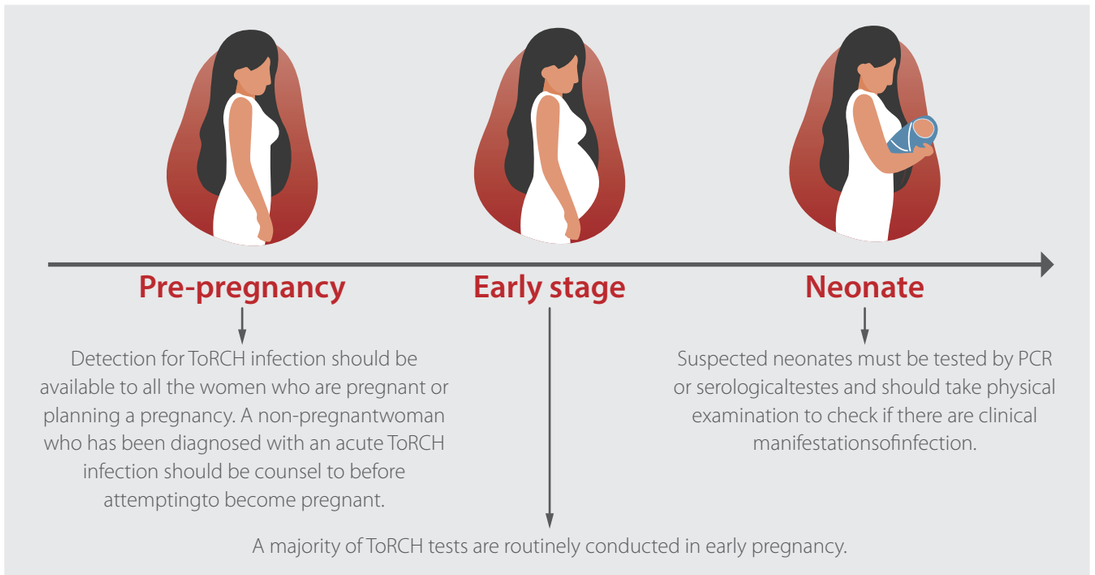


In general, ToRCH infections are responsible for 2% to 3% of all congenital disorders, or disorders present at birth. These infections can cause a variety of complications, including preterm birth, delayed development of the fetus, physical malformations, and miscarriages[3].



* Abbreviation:
- T. pallidum: Treponema pallidum
- VZV: Varicella zoster virus
- CMV: Cytomegalovirus
- HIV: Human immunodeficiency virus

Due to the severe consequences of ToRCH infections, it is important to take ToRCH serological tests from pre-pregnancy to after birth to protect the fetus against ToRCH infections.



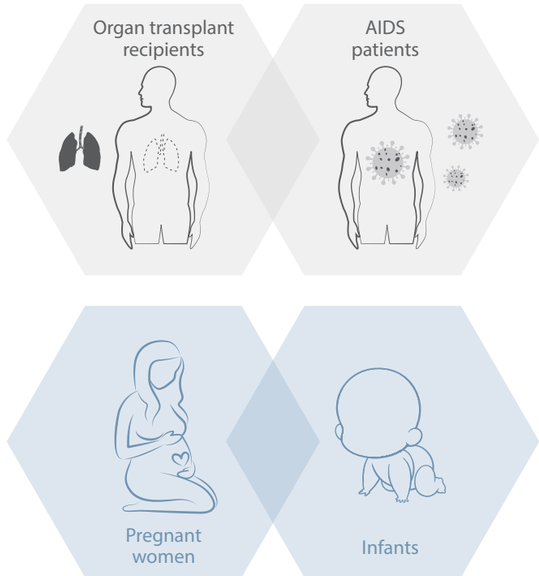
Toxoplasma gondii is a protozoan parasite that infects most species of warm-blooded animals, including humans, and causes toxoplasmosis.

Toxoplasmosis usually occurs after eating undercooked contaminated meat, exposure to infected cat feces, or mother-to-child transmission during pregnancy[4].

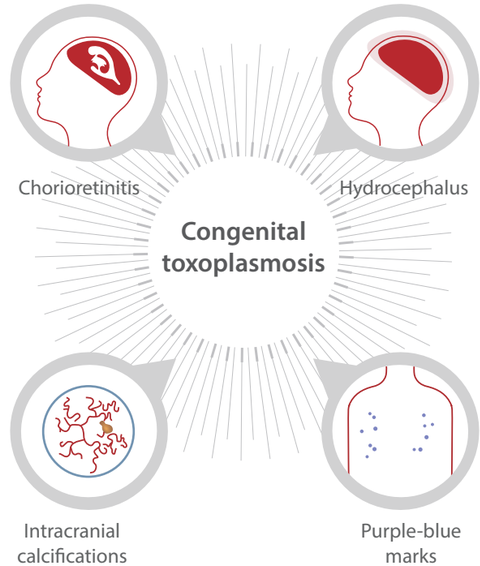
Mother-to-child transmission | Contact with cat feces | Consumption of undercooked meat

Besides pregnant women and infants, AIDS patients and organ transplant recipients are also vulnerable to Toxoplasma gondii.

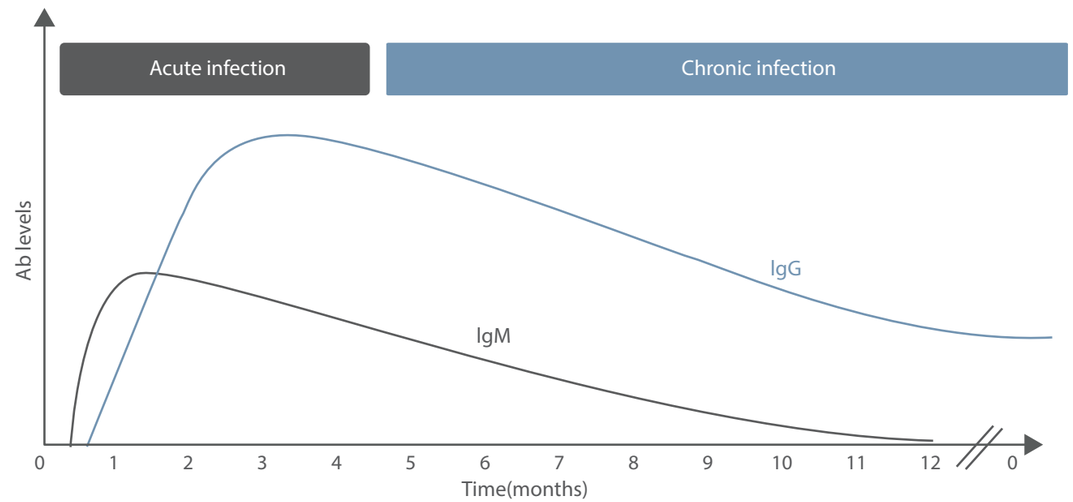
Population at risk



The most common manifestations of congenital toxoplasmosis include chorioretinitis, hydrocephalus, and intracranial calcifications. Some babies with congenital toxoplasmosis may exhibit multiple purple-blue marks in the skin.



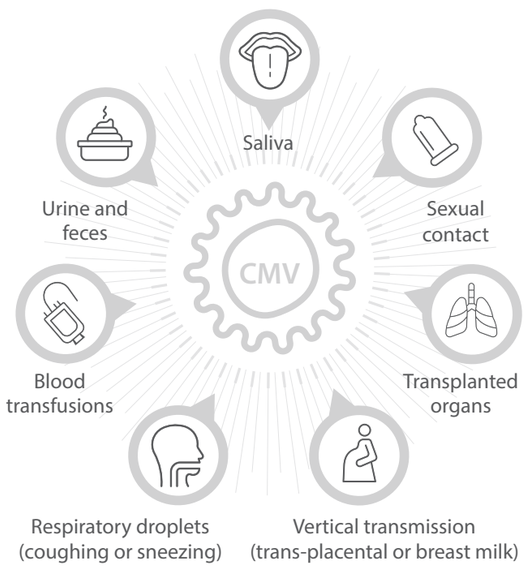
According to CDC (Centers for Disease Control and Prevention), the detection of Toxoplasma-specific antibodies is a primary diagnostic method to determine infection with Toxoplasma. Newborn infants suspected of congenital toxoplasmosis should be tested by both IgM- and IgA-capture EIA. Also, this detection is recommended for immunocompromised patients, such as AIDS patients[5].



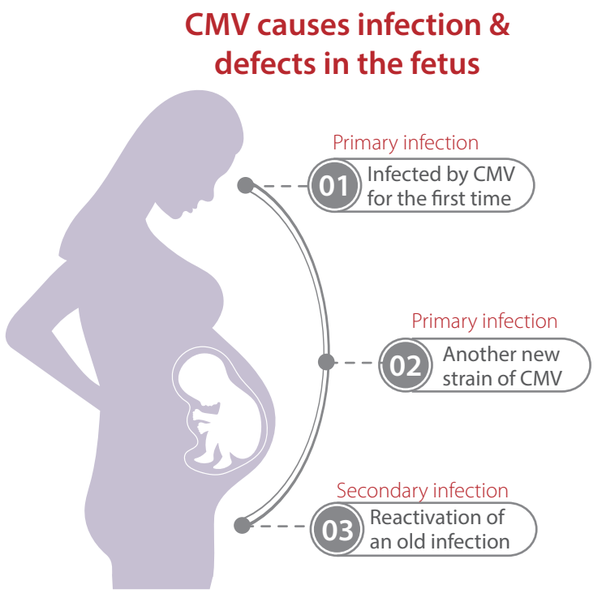
Serological changes of Toxoplasma infection[6]

Clinical Application of CMV Detection in Various Departments

Cytomegalovirus (CMV) is a common virus that is usually harmless and transmitted through sexual contact or contact with blood and other body fluids of an infected person, or from transplanted organs. The virus can also spread from an infected mother to the growing fetus through the placenta.

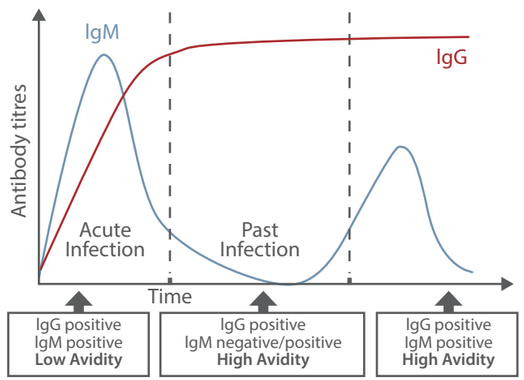


A pregnant woman can pass CMV to her fetus following infection by CMV for the first time, reinfection with a different CMV strain, or reactivation of a previous infection during pregnancy.



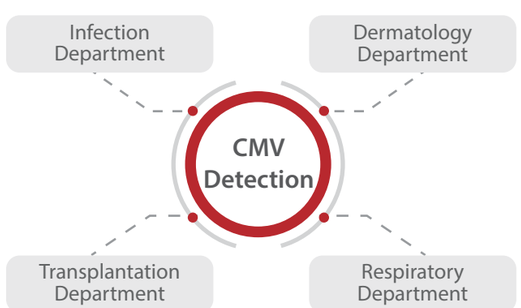
Primary CMV infection in pregnant women will cause about 30% intrauterine infection and 60% to 80% of their infected neonates will develop sequelae. In contrast, pregnant women with secondary CMV infection have only a 0.2% -2% risk of causing intrauterine infection. This is why it is important to identify primary CMV infection as early as possible.

According to CDC, serological tests that detect CMV antibodies (IgM and IgG) are widely available in commercial laboratories. IgM positive results in combination with low IgG avidity results are considered reliable evidence for primary infection[7].



Serological changes of CMV infection[8]

CMV testing can not only be used in Obstetrics and Neonatology, it can also be applied in some special departments since primary CMV infection is generally asymptomatic in healthy adults but can cause severe and even fatal diseases in immunocompromised individuals and transplant recipients. Since the numbers of both HIV and transplantation patients are increasing, there has been a growing demand for CMV tests in infection and transplantation departments. Respiratory and dermatology departments may also prescribe CMV tests for patients with allergic symptoms.



Value of CMV Tests in Infection Department

In the infection department, patients are often seen to have an unexplained fever. All of them need to take CMV tests to rule out infection factors. Both IgG/IgM and DNA need to be detected due to the urgency, especially for HIV patients.

Usually, every HIV patient should be tested for CMV every three months, regardless of whether they are outpatients or inpatients.

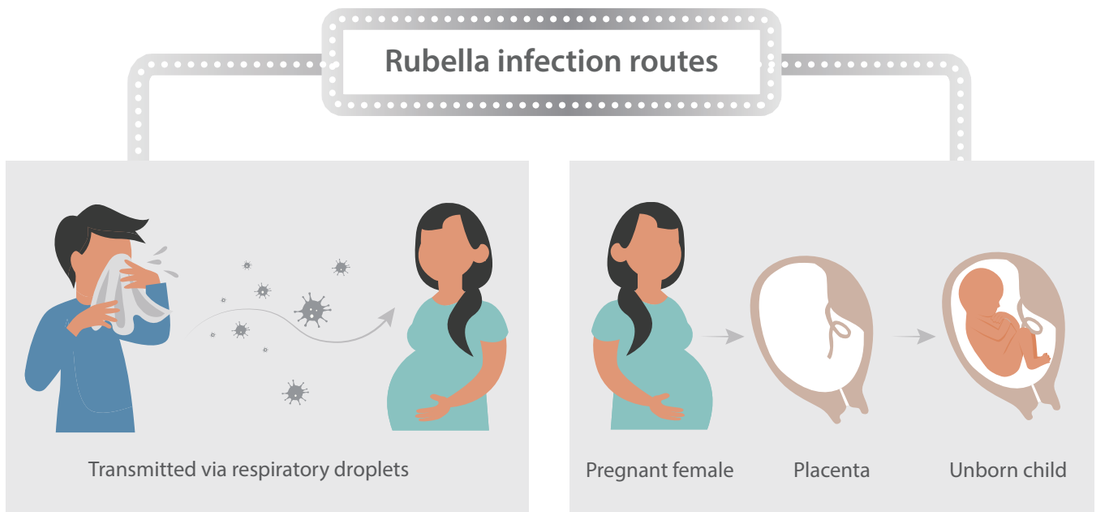
Value of CMV Tests in Transplantation Department

Before operation, both the donor and recipient need to take CMV serological tests to improve the prognosis after transplantation.

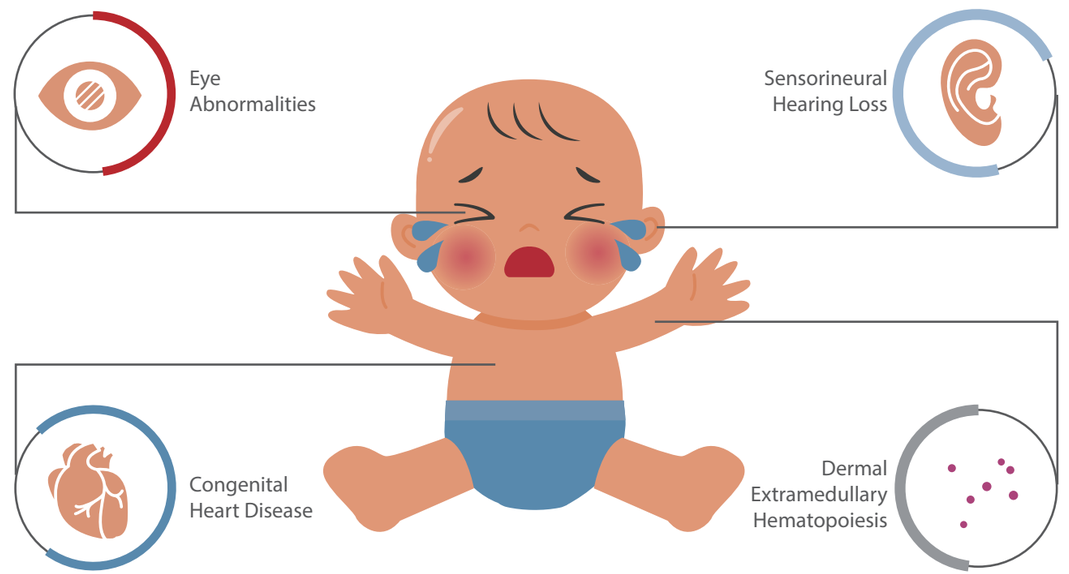
After operation, the recipient needs to take CMV serological tests periodically since CMV infection can be troublesome to transplant patients.

Rubella, also known as "German Measles", is caused by the rubella virus and it can be transmitted to a pregnant woman via respiratory droplets. Most children from 12 to 15 months of age get the MMR vaccine against measles, mumps, and rubella.

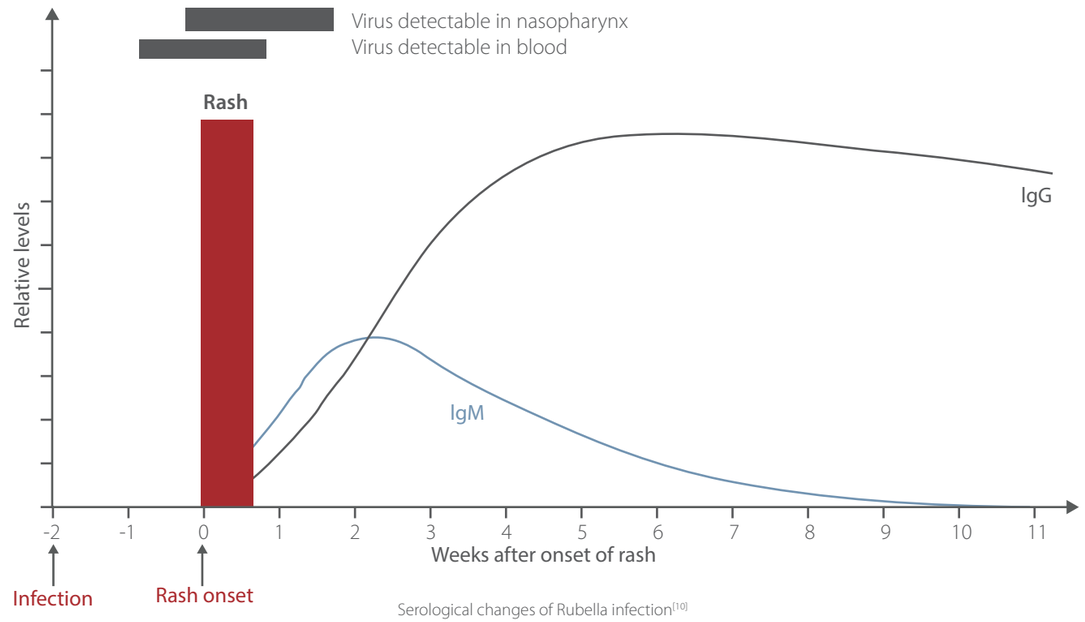
Rubella virus can be transmitted to a pregnant woman via respiratory droplets. Another route for Rubella to spread is from a pregnant woman to her unborn child, through the placenta. This causes congenital rubella syndrome in the fetus.



Neonates born with congenital rubella syndrome usually have a tetrad of symptoms: hearing loss or deafness, eye abnormalities, dermal extramedullary hematopoiesis and congenital heart disease.

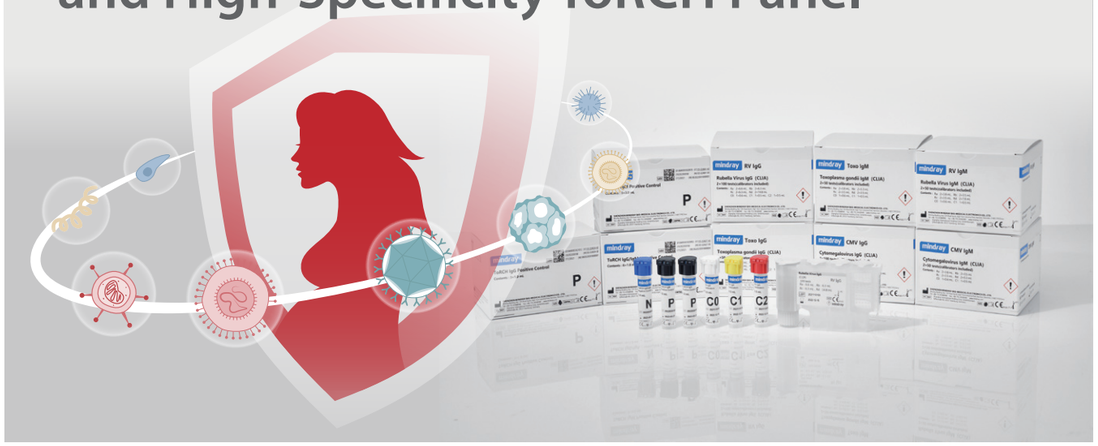


Congenital Rubella Syndrome (CRS), which can occur when a woman is infected with rubella during pregnancy, can lead to a variety of possible birth defects. According to CDC, CRS cases can be diagnosed in newborns and infants through rubella IgM detection. Suspected cases should be tested as close to birth as possible and again at 1 month of age if the initial IgM test result is negative[9].



Serological changes of Rubella infection[10]

Mindray Launches High-Sensitivity and High-Specificity ToRCH Panel



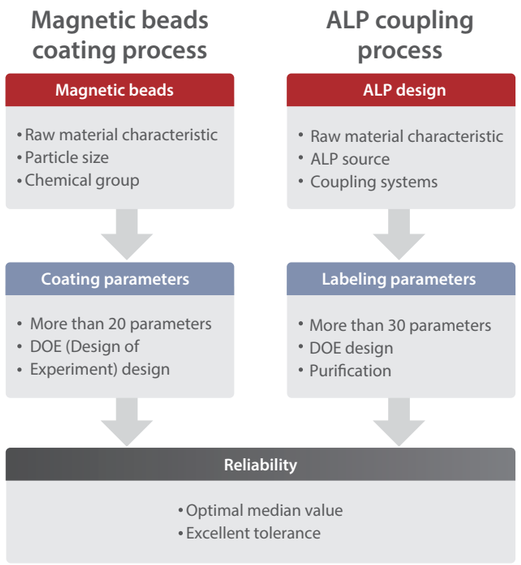
Mindray has recently launched the ToRCH Panel, a result of our ongoing commitment to innovation. With this panel, we provide high-quality assays to meet different clinical needs.

High sensitivity and specificity

To achieve high sensitivity and specificity, Mindray has been working consistently to improve the raw materials, processes, formulas, and reaction models. High quality materials are fundamental to ensure high sensitivity and specificity of CLIA assays. To cater to different projects and process requirements, Mindray invested a lot of resources in the design and development of immunodominant proteins and immunodominant epitopes.

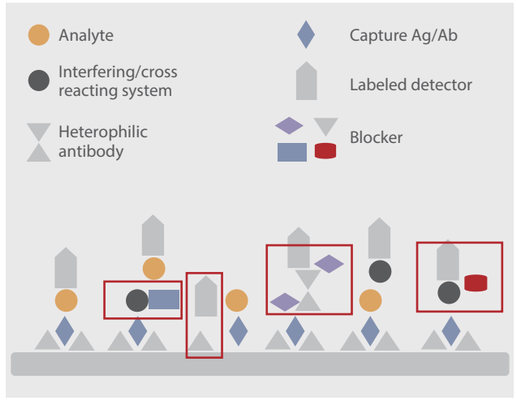
Efficient processes

Mature, stable and innovative technology is another guarantee of satisfactory performance. For the coating and labeling processes, Mindray R&D team selected the particles and ALPs that can best meet the assay requirements. To improve the sensitivity and specificity, Mindray experts spent a considerable amount of time thoroughly studying the parameters using a DOE approach. With a robust design, the boundary of each parameter was determined to ensure the reproducibility of the process.

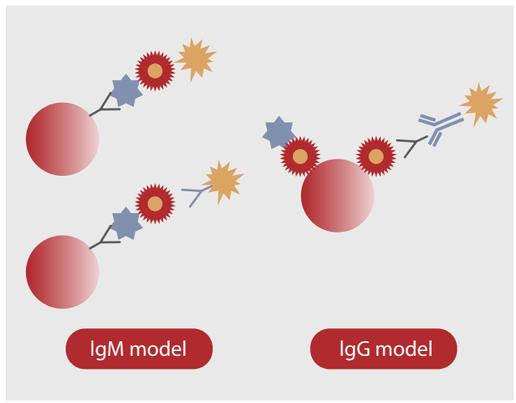


Advanced formulas and reaction models

At the formulation level, Mindray R&D experts investigated the interference mechanism and classified the interference into four different types to help enhance the anti-interference capacity.

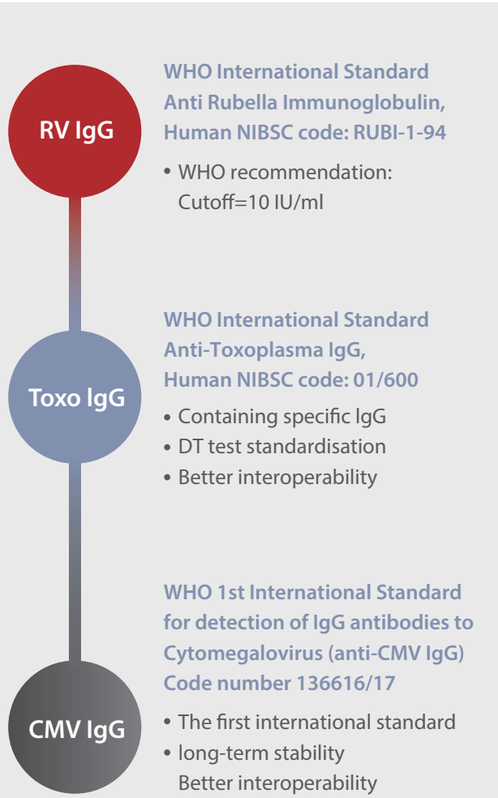


Hundreds of commercial and uniquely designed blockers were studied and applied to minimize each type of interference. For instance, Mindray R&D team designed a capture method for the IgM assay to minimize the interference of IgG and RF (Rheumatoid Factor).



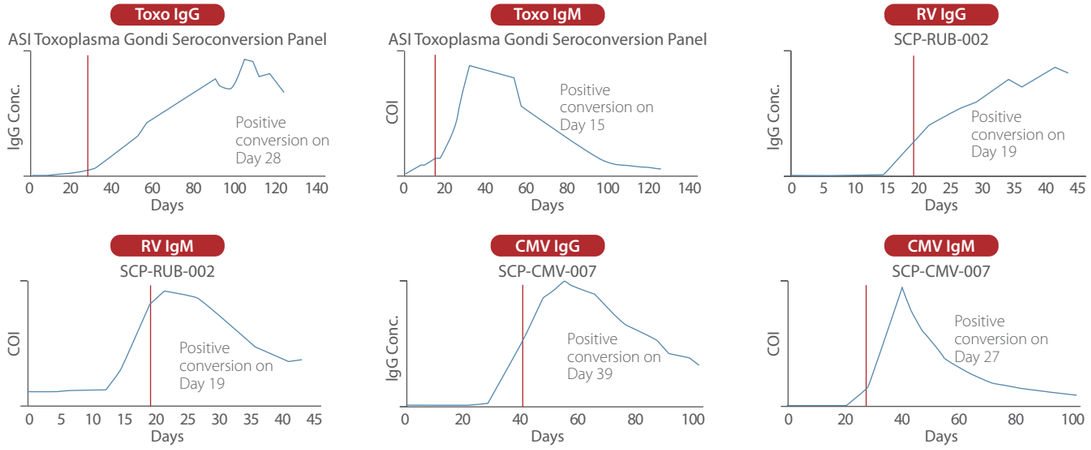
Traceability of IgG for reliable medical determination

The above three quantitative kits of Mindray ToRCH panel are fabricated with materials with international standard units and the latest standardized traceability. Toxo IgG contains specific IgG and features DT test standardization. CMV IgG adopts the first international standard and features long-term stability. RV IgG comes with a cutoff value of 10 IU/mL as recommended by WHO.



Seroconversion sensitivity[12]

Thanks to the improved raw materials, processes, formulas, reaction models, and standardized traceability, Mindray ToRCH reagents deliver excellent seroconversion sensitivity. Mindray ToRCH has a good detection rate for both samples that are positive in multiple systems and true positive samples such as seroconversion panels. The combined examination by Mindray ToRCH IgG and IgM can accurately reveal previous infections and promptly detect ToRCH infections that failed to be ruled out previously.



*The X axis 'Day' stands for the days counted from the first day when the patient's serum was collected, and doesn't indicate any diagnosis or contact tracing information

Excellent clinical performance

To demonstrate the sensitivity and specificity of the Mindray ToRCH kits, Mindray conducted tests in over five clinical sites both in and outside China.

Performance	Items	China sites[13]
Sensitivity	Toxo IgG	/
	RVIgG	97.63%-100.0%(total 2223)
	CMV IgG	98.45%-99.77%(total 2772)
Specificity	Toxo IgG	97.59%-98.60%(total 2459)
	RV IgG	94.62%-99.00%(total 193)
	CMV IgG	/
Specificity	Toxo IgM	97.45%-98.42%(total 4224)
	RV IgM	97.37%-99.71%(total 3558)
	CMV IgM	96.63%-98.47%(total 4011)

Although the positive rate varies among different countries and regions, Mindray ToRCH kits have exhibited great specificity for Toxo IgG and ToRCH IgM and excellent sensitivity for RV IgG and CMV IgG. In addition, given the wide coverage of the clinical tests, there are no significant differences between the Chinese and international sites.

Flexible blood collection and transportation

Mindray ToRCH kits support diverse sample types with less quality controls and sample volumes, which ensures great ease and convenience during clinical detection.
By bringing the clinical benefits of ToRCH Panel into play and addressing the key requirements for the reagents, Mindray has solved the ToRCH detection challenges facing clinical laboratories and made Mindray ToRCH assays accessible in clinical application.

Support diverse sample types

- 3 types of serum collection tubes: no additive tube, Pro-coagulation tube, gel and clot activator tube
- 4 types of plasma collection tubes: EDTA, Sodium Heparin, Lithium Heparin and Sodium Citrate

Multiple quality controls

- Only 3 control products are required for the whole panel: 1 negative control for all 6 assays, 1 positive control for the 3 IgG assays, and 1 positive control for the 3 IgM assays.

Low sample volume

- Only 53 µL of sample volume is required for the 6 assays combined, which is friendly to newborns and infants.

Mindray CLIA Test Menu

Mindray's CLIA test penal so far has 79 high-performance reagents which are developed to work with Mindray's CL series chemiluminescence immunoassay analyzers. By combining the strength of HyTest, a global leading provider of antibodies and antigens acquired by Mindray, our test menu will reach more than 100 assays in the near future. Mindray uses liquid, ready-to-use reagents which come in two packages, 50 tests and 100 tests, to suit customers with different requirements.

Thyroid
FT3
FT4
T3
T4
TSH
Anti-Tg
Anti-TPO
Tg
rT3
TRAb*

Infectious Disease
HIV Combo
HBsAg
Anti-HBs
HBeAg
Anti-HBe
Anti-HBc
Anti-HCV**
Anti-TP (Syphilis)
HAV IgM*

Fertility
Total β-HCG
FSH
LH
Prolactin
Estradiol
Estriol
TESTO
PROG
AMH
Free testosterone*
17-OH PROG*
SHBG*

Tumor marker
CEA
AFP
CA125
CA15-3
CA19-9
Free PSA
Total PSA
NSE
CYFRA 21-1
CA72-4
PG I
PG II
SCCA
HE4
ProGRP
CA50
CA242
PIVKA-II*
AFP-L3%*
Hp IgG*
G-17*
S100*

Bone Metabolic
Intact PTH
Calcitonin
Vitamin D total

Cardiac
CK-MB
Myoglobin
Troponin I
BNP
hs-cTn I*
NT-proBNP*

ToRCH
Toxo IgG*
Toxo IgM*
Rubella IgG*
Rubella IgM*
CMV IgG*
CMV IgM*
HSV-1/2 IgG*
HSV-1/2 IgM*
HSV-1 IgG*
HSV-2 IgG*

Adrenal Function
DHEA-S
Cortisol
ACTH

COVID-19
SARS-COV-2 IgG
SARS-COV-2 IgM
SARS-COV-2S-RBD IgG
SARS-COV-2 Neutralizing Antibody

Diabetes
Insulin
C-peptide

Growth Hormone
GH*
IGF-1*

Anemia
Ferritin
Vitamin B12
Folate
RBC Folate

Hypertension
Renin
Aldosterone

Inflammation
Procalcitonin
IL-6*
sCD14-ST*

DS' Screening
PAPP-A*
Free β-HCG*

Liver Fibrosis
Laminin
Hyaluronic Acid
PIIINP
Collagen IV

*: Under development
**: Non-CE

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