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Mindray ToRCH* Panel

Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and CMV IgM



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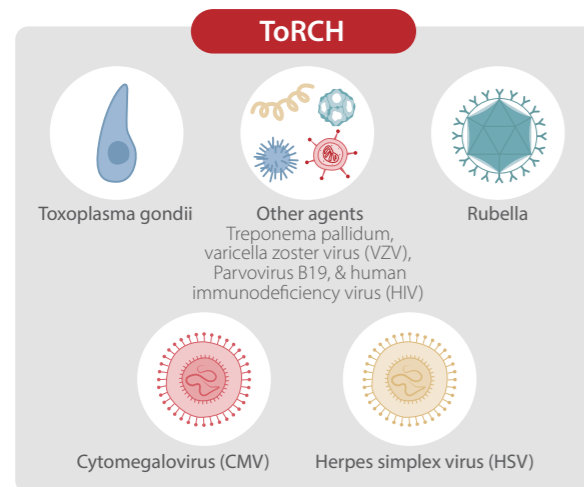
P/N:ENG-Mindray ToRCH* Panel – Toxo IgG, Toxo IgM, RV IgG, RV IgM, CMV IgG, and CMV IgM-210285X8P-20220714
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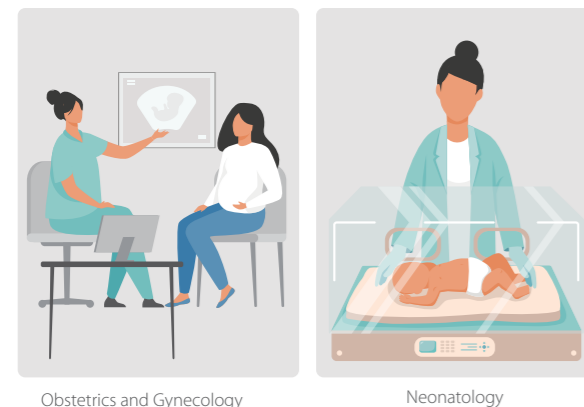
Application

ToRCH Infections

ToRCH is the acronym for (T)oxoplasmosis, (O)ther Agents, (R)ubella, (C)ytomegalovirus, and (H)erpes Simplex. ToRCH infections may cause illness in pregnant women and may cause birth defects in their newborns depending on the stage of pregnancy when the mother is infected. The ToRCH serology test is usually used to screen for two different antibodies to these infections: immunoglobulin G (IgG) and immunoglobulin M (IgM).



Clinical scenarios



The ToRCH serology test is usually conducted on pregnant women who have been exposed to certain infectious diseases and newborns who have congenital abnormalities that may be caused by an infection with one of these organisms.



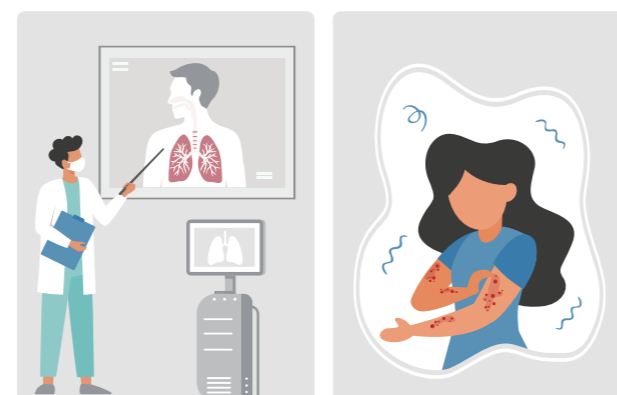
Infection department

In the infection department, patients will get a ToRCH test to identify reasons for the infection.



Transplantation department

In the transplantation department, it is common practice to test patients for CMV before and after surgery to avoid and monitor CMV infection.



Respiratory department

Dermatology

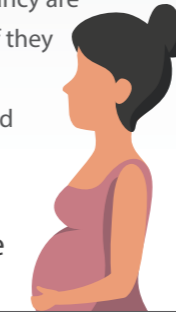
In the respiratory or dermatology department, some doctors may advise patients with allergic symptoms to get a CMV test.

Susceptible populations

Since infection during pregnancy will introduce the risk of mother-to-child infection and lead to congenital infection in infants, early screening during pregnancy is important to prevent transmission to the fetus.

Women who are preparing pregnancy are supposed to take serologic tests. If they are diagnosed with an acute Toxo infection, they should be counseled to wait before attempting to become pregnant.

Pregnant women and those preparing pregnancy



ToRCH infections can cause a range of diseases in immunosuppressed populations. If not treated in time, they can lead to adverse fetal outcomes, and even life-threatening infections in those who are HIV positive.

Therefore, it is necessary for immunosuppressed populations to undergo ToRCH tests periodically.



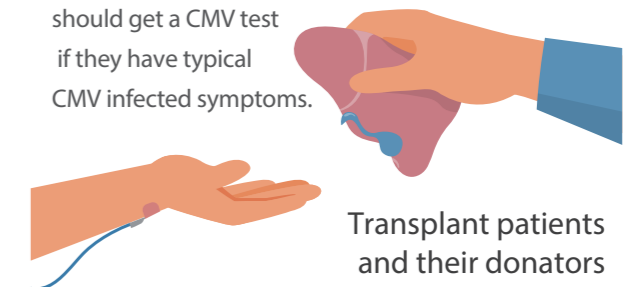
Immunosuppressed populations

If a woman becomes infected with ToRCH during her pregnancy, the baby may also become infected. In this case, ToRCH tests can be conducted to check for several different infections in a newborn.



Neonates

It is important to test the patient for CMV before the transplant surgery. This is because CMV negative patients and their donors tested positive for CMV, the physicians will strengthen anti-virus prophylaxis, and monitor CMV status more regularly after surgery. CMV infection can be troublesome to transplant patients after surgery since it may induce rejection reactions. Therefore, it is suggested that patients should get a CMV test if they have typical CMV infected symptoms.



Transplant patients and their donors

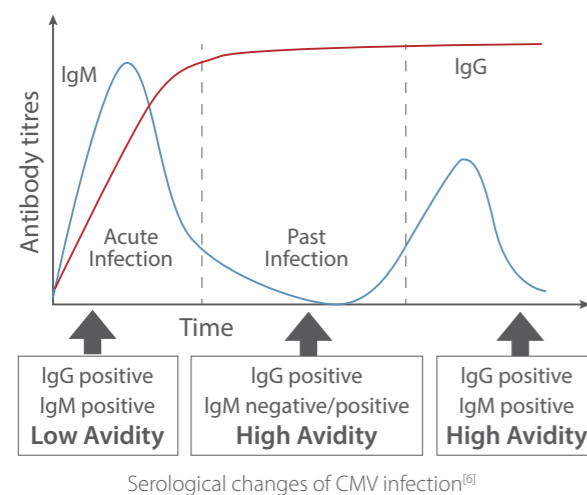
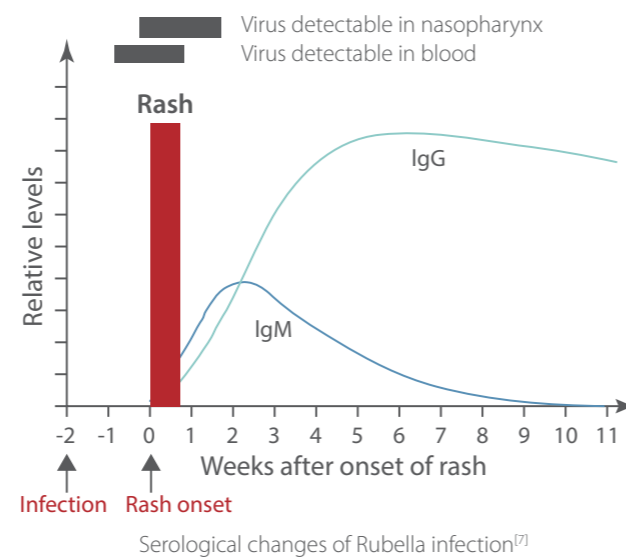
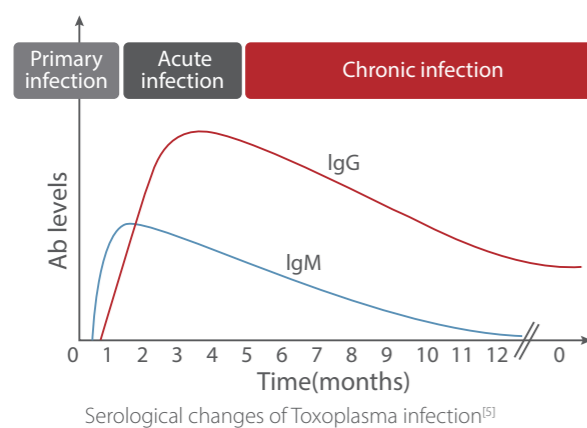
Guidelines for ToRCH Screening During Pregnancy

Toxo, CMV, RV	
IgG-, IgM-	<ol style="list-style-type: none"> 1. Can get pregnant if not infected; 2. Dynamic monitoring of IgG and IgM in early pregnancy. Once positive, prenatal diagnosis should be carried out.
IgG+, IgM-	<ol style="list-style-type: none"> 1. Past infected women can get pregnant; 2. Recurrent infection and reinfection (CMV, RV) should be paid attention to during pregnancy, especially in the first trimester. If there is a quadruple increase in serum IgG+ in consecutive duplicates, the likelihood of recurrent infection is greater.

IgG-, IgM+	<ol style="list-style-type: none"> 1. May be acute infection; 2. May also be false positives for IgM or long-term lasting IgM positive; 3. Review or send to a reference laboratory after 2 weeks. If the IgG turns positive, it is an acute infection, and the pregnancy is postponed for those who are not pregnant. For those who are pregnant, whether the fetus is infected should be determined (estimated gestational age or prenatal diagnosis). If the IgG does not turn positive, it is not an acute infection and IgM result is considered to be false positive.
IgG+, IgM+	<ol style="list-style-type: none"> 1. For Toxo, it may be a current infection, and for other viruses, it may be during reinfection period. Send to reference laboratory for confirmation. 2. IgM may be false positive or long-term lasting positive. IgG avidity test should be added and re-check whether IgG is four-fold increased in consecutive double serums. 3. If it is an acute infection, postpone the pregnancy. Prenatal diagnosis can be conducted according to advice of the physician.

Guidelines for ToRCH Screening During Pregnancy^[1-4]

Interpretation of test results



After the body is infected, serological and antibodies changes of toxoplasma, rubella virus and cytomegalovirus vary. In such situation, in order to make correct judgement, it is required to quantify the degree of change in the antibody.

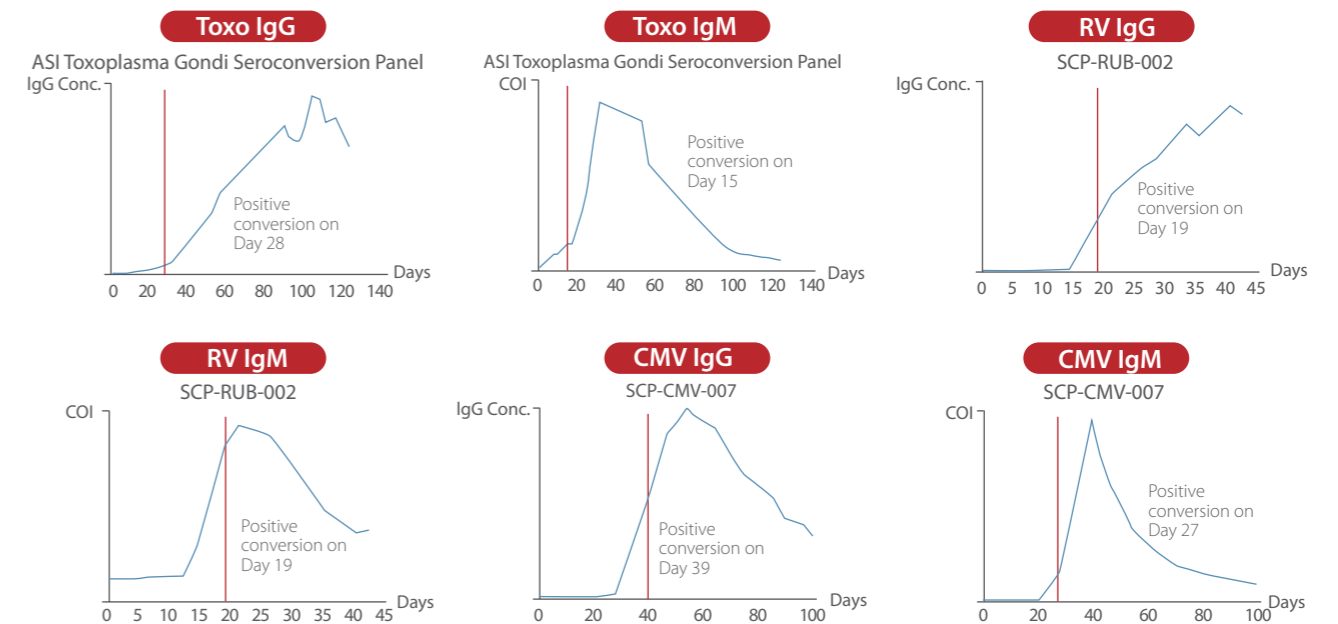
Performance

Mindray provides reliable ToRCH screening assays

• Traceability

Item	Toxo IgG	RV IgG	CMV IgG
Standard material	NIBSC 01/600, 2004	NIBSC 1 st , RUBI-1-94, 1997	WHO 1 st , 136616/17, 2017

• Excellent seroconversion sensitivity

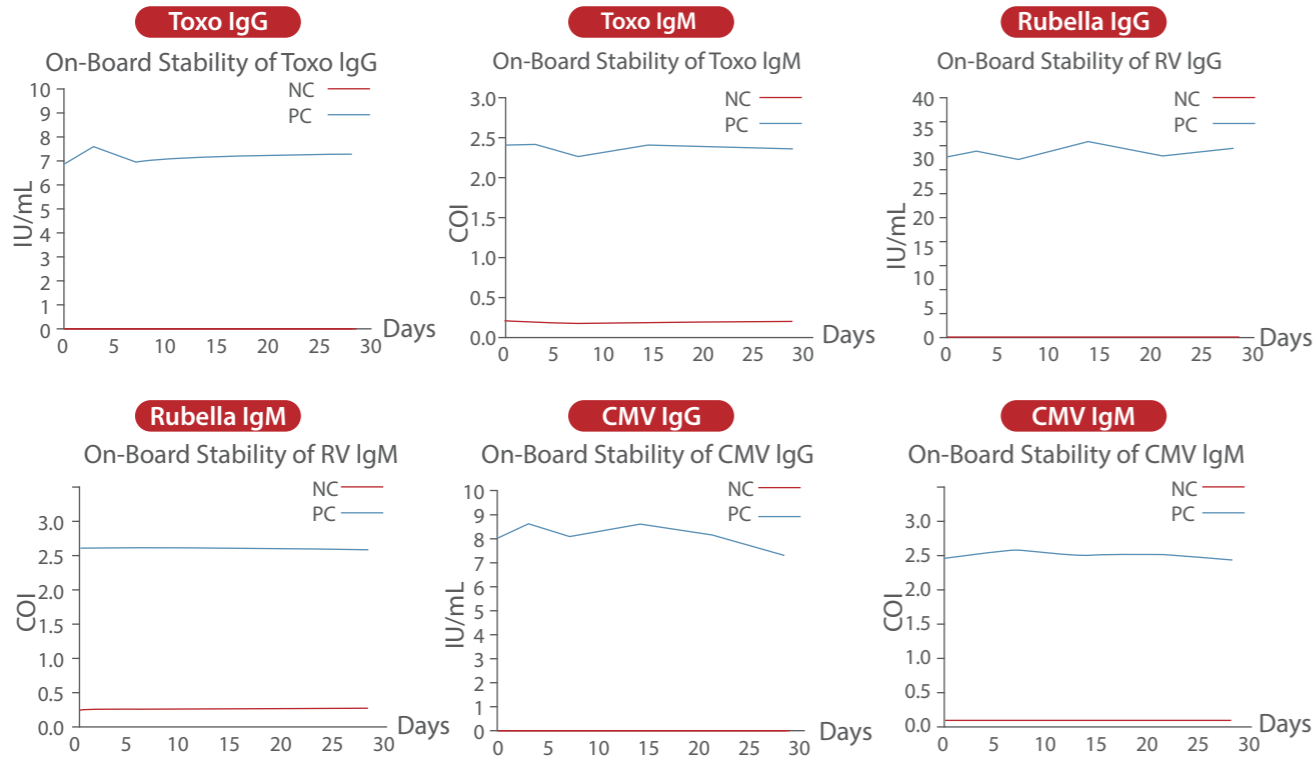


• High precision

Item	Sample	Mean	Repeatability		Within Laboratory	
			SD	CV	SD	CV
Toxo IgG	NC	0.00 IU/mL	0.01 IU/mL	N/A	0.01 IU/mL	N/A
	PC	6.11 IU/mL	0.12 IU/mL	1.90%	0.21 IU/mL	3.40%
Toxo IgM	NC	0.21 COI	0.01 COI	N/A	0.01 COI	N/A
	PC	2.36 COI	0.05 COI	2.21%	0.09 COI	3.87%
Rubella IgG	NC	0.00 IU/mL	0.00 IU/mL	N/A	0.03 IU/mL	N/A
	PC	31.13 IU/mL	0.56 IU/mL	1.80%	1.49 IU/mL	4.79%
Rubella IgM	NC	0.55 COI	0.01 COI	1.54%	0.02 COI	4.23%
	PC	2.45 COI	0.04 COI	1.52%	0.09 COI	3.50%
CMV IgG	NC	0.00 IU/mL	0.00 IU/mL	N/A	0.00 IU/mL	N/A
	PC	7.68 IU/mL	0.11 IU/mL	1.48%	0.18 IU/mL	2.30%
CMV IgM	NC	0.08 COI	0.00 COI	N/A	0.01 COI	N/A
	PC	2.61 COI	0.04 COI	1.35%	0.09 COI	3.59%

*Representative data; results in individual laboratories may vary.
NC: Negative Control; PC: Positive Control

• Good onboard stability



• Wide detection range

Item	Toxo IgG	Rubella IgG	CMV IgG
Detection Range	0.50 IU/mL – 200.00 IU/mL	1.00 IU/mL – 350.00 IU/mL	0.30 IU/mL – 60.00 IU/mL

Mindray's ToRCH IgG assays provide a wide detection range and a 10-time auto-dilution expanding the reportable range, making the detection of increased IgG levels easier.

Mindray provides easy-to-use ToRCH kits

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, 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.

Product Information

Order Information

• Assay kits

Full Name	Abbreviation	P/N	Package	P/N	Package
Toxoplasma gondii IgG (CLIA)	Toxo IgG	105-012527-A0	2*50 T/Kit	105-012528-A0	2*100 T/Kit
Toxoplasma gondii IgM (CLIA)	Toxo IgM	105-012533-A0	2*50 T/Kit	105-012534-A0	2*100 T/Kit
Rubella Virus IgG (CLIA)	RV IgG	105-012521-A0	2*50 T/Kit	105-012522-A0	2*100 T/Kit
Rubella Virus IgM (CLIA)	RV IgM	105-012515-A0	2*50 T/Kit	105-012516-A0	2*100 T/Kit
Cytomegalovirus IgG (CLIA)	CMV IgG	105-012539-A0	2*50 T/Kit	105-012540-A0	2*100 T/Kit
Cytomegalovirus IgM (CLIA)	CMV IgM	105-012545-A0	2*50 T/Kit	105-012546-A0	2*100 T/Kit

*Calibrator is included in the kit package.
Mindray HSV kit is under development

Controls

Full Name	P/N	Package	P/N	Package
ToRCH IgG/IgM Negative Control	105-024824-A0	1×3.0 mL/vial	105-024825-A0	3×3.0 mL/vial
	105-024826-A0	3×1.0 mL/vial	105-024827-A0	6×1.0 mL/vial
ToRCH IgG Positive Control	105-024832-A0	1×3.0 mL/vial	105-024833-A0	3×3.0 mL/vial
	105-024834-A0	3×1.0 mL/vial	105-024835-A0	6×1.0 mL/vial
ToRCH IgM Positive Control	105-024840-A0	1×3.0 mL/vial	105-024841-A0	3×3.0 mL/vial
	105-024842-A0	3×1.0 mL/vial	105-024843-A0	6×1.0 mL/vial

References

- [1] Montoya, Jose G, and J. S. Remington. "Clinical Practice: Management of Toxoplasma gondii Infection during Pregnancy." *Clinical Infectious Diseases* 47.4(2008):554-566.
- [2] A, T. Lazzarotto, et al. "Update on the prevention, diagnosis and management of cytomegalovirus infection during pregnancy." *Clinical Microbiology and Infection* 17. 9(2011):1285-1293.
- [3] "Cytomegalovirus, parvovirus B19, varicella zoster, and toxoplasmosis in pregnancy." *OBSTETRICS & GYNECOLOGY*. 2015 Jun;125(6):1510-1525.
- [4] Pamela Palasanthiran, Mike Starr, Cheryl Jones and Michelle Giles. "Management of Perinatal Infections." *Australasian Society for Infectious Diseases* 2014.
- [5] Teimouri, A., et al. "Role of Toxoplasma gondii IgG avidity testing in discriminating between acute and chronic toxoplasmosis in pregnancy." *Journal of Clinical Microbiology* (2020).
- [6] P Rice. "Cytomegalovirus (CMV) in pregnancy." (2008).
- [7] Emeritus Prof JE Banatvala FRCPATH, DWG Brown FRCPATH. "Rubella." *The Lancet*, Volume 363, Issue 9415, 3 April 2004, Pages 1127-1137