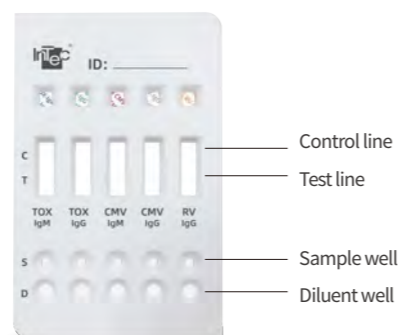


Rapid ToRCH Antibody (TOX-IgM/IgG,CMV-IgM/IgG,RV-IgG) Test



Intended use

The kit is intended to qualitatively detect Toxoplasma IgM, Toxoplasma IgG, Cytomegalovirus IgM, Cytomegalovirus IgG and Rubella virus IgG in human serum, plasma or whole blood in vitro. It is suitable for clinical auxiliary diagnosis of Toxoplasma infection, Cytomegalovirus infection and Rubella virus infection as well as their epidemiological investigation.

Product parameters

- Specimen: whole blood/serum/plasma
- Storage temperature and shelf life: 2~30°C, 24 months

Table 1 Comparison with TOX-IgM EIA kit

Method	Reference	TOX-IgM EIA kit		Total
		Positive	Negative	
Results of InTec test	Positive	132	1	133
	Negative	3	264	267
Total		135	265	400

Sensitivity coincidence rate=97.8%(132/135) Specificity coincidence rate=99.6%(264/265) Total coincidence rate=99%(396/400)

Table 2 Comparison with TOX-IgG EIA kit

Method	Reference	TOX-IgM EIA kit		Total
		Positive	Negative	
Results of InTec test	Positive	133	3	136
	Negative	5	259	264
Total		138	262	400

Sensitivity coincidence rate=96.4%(133/138) Specificity coincidence rate=98.8%(259/262) Total coincidence rate=98.5%(392/400)

Table 3 Comparison with CMV-IgM EIA kit

Method	Reference	TOX-IgM EIA kit		Total
		Positive	Negative	
Results of InTec test	Positive	194	2	196
	Negative	4	200	204
Total		198	202	400

Sensitivity coincidence rate=98%(194/198) Specificity coincidence rate=99%(200/202) Total coincidence rate=98.5%(394/400)

Table 4 Comparison with CMV-IgG EIA kit

Method	Reference	TOX-IgM EIA kit		Total
		Positive	Negative	
Results of InTec test	Positive	252	2	254
	Negative	3	143	146
Total		255	145	400

Sensitivity coincidence rate=98.8%(252/255) Specificity coincidence rate=98.6%(143/145) Total coincidence rate=98.7%(395/400)

Table 5 Comparison with TOX-IgG EIA kit

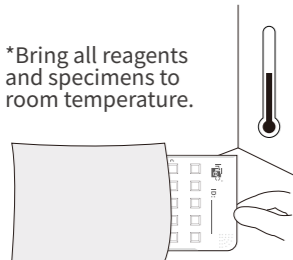
Method	Reference	TOX-IgM EIA kit		Total
		Positive	Negative	
Results of InTec test	Positive	247	0	247
	Negative	3	150	153
Total		250	150	400

Sensitivity coincidence rate=98.8%(247/250) Specificity coincidence rate=100%(150/150) Total coincidence rate=99.2%(397/400)

Test procedures

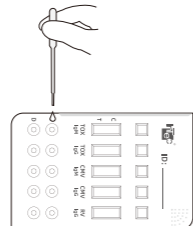
1. Prepare test

*Bring all reagents and specimens to room temperature.

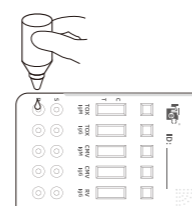


*Remove the test card from the foil pouch and place on a clean dry surface.

2. Add sample and diluent

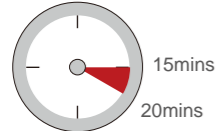


*Dispense 1 drop (10µl) specimen into each "S" well.



*Add 2 drops (80µl) buffer into each "D" well.

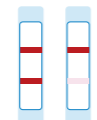
3. Read result




*Interpret test results at 15~20mins. Do not read after 20mins.

Result interpretation

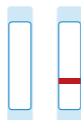
Control band
Test band



Positive



Negative



Invalid

Ordering information

Product	Cat. No.	Type	Pack size	Specimen*
ToRCH	ITP62001-TC25	Cassette	25T/Kit	S/P/WB

*Specimen: WB=Whole Blood, S=Serum, P=Plasma