金标英文说明书(TORCH Panel Test)
尺寸:285x210mm、70g双胶纸、双面黑白印刷(对折)
01.05.03.1615-230201

InTec PRODUCTS, INC.

REF ITP63001-TC25
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Rapid TORCH Panel Test (Whole Blood/Serum/Plasma)

For in vitro diagnostic use only. IVD
Please read the instructions for use carefully prior to use and strictly follow the instructions.

INTENDED USE

The Rapid TORCH Panel Test is a colloidal gold enhanced, rapid immunochromatographic assay for the qualitative detection of IgG and IgM antibodies to *Toxoplasma gondii* (TOXO), rubella virus (RUB), cytomegalovirus (CMV), herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) in human whole blood, serum or plasma. This test serves as an aid in the diagnosis of TORCH infections. It only provides preliminary analysis results but not critical diagnosis criteria, the obtained results should be analyzed in connection with other clinical information, e.g. clinical symptoms, and using more specific alternative diagnosis methods to make final decision. This test is a screening test, and all positives must be confirmed using an alternate test.

SUMMARY

TORCH is an acronym for a group of infection diseases that can adversely affect the pregnant women and the fetus, newborn children including birth defects and often leading to abortion. The pathogens are *Toxoplasma gondii* (TOXO), rubella virus (RUB), cytomegalovirus (CMV), herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2). The infections usually cause few, if any, symptoms in the pregnant woman, but pose greater risks of serious birth defects for neonates.-*Toxoplasma gondii* is usually an asymptomatic and benign infection in immunocompetent individuals, but during pregnancy, the infected women may undergo miscarriage, stillbirth, and intrauterine malformations in the fetus. Rubella virus can cause a series of severe damage to the fetus, including hearing impairment, cataracts, and cardiac defects, collectively known as congenital rubella syndrome (CRS). Cytomegalovirus is a kind of common virus with species-specific. Humans are the hosts of this virus, which can infect the same type of virus again, as well as its variant type. The virus transmits through direct contact with saliva, urine and genital secretions. It is considered to be the most common cause of viral intrauterine infections. Herpes simplex virus is the most common sexually transmitted viral disease worldwide. HSV-1 is transmitted during childhood by non-sexual contacts, while HSV-2 is always transmitted sexually and is the major cause of genital herpes.

TEST PRINCIPLE

The Rapid TORCH Panel Test consisting of 5 test strips assembled in one cassette is designed to simultaneously detect and differentiate IgG and IgM antibodies of 5 pathogens in whole blood, serum or plasma. For each test strip, colloidal gold-conjugated pathogen antigens are embedded in the conjugate pad. IgG antibodies, if present in the specimen, will bind to the target antigen conjugates. The immunocomplex is allowed to migrate along the test strip and then captured by the pre-coated mouse anti-human IgG on the membrane forming a colored G line, indicating an IgG positive result for that particular disease. IgM antibodies, if present in the specimen, will bind to the target antigen conjugates. The immunocomplex is then captured by the precoated mouse anti-human IgM on the membrane forming a colored M line, indicating an IgM positive result for that particular disease. Absence of any test lines (G,M) suggests a negative result for that particular test strip. Each test strip contains a control line (C line) which should exhibit a colored line at the end of test procedure regardless of the results of test lines. If the C line does not develop, the test result for that test strip is invalid, and the specimen must be retested with another device. Each test is read independently. One invalid test does not disqualify the results of other valid tests.

REAGENTS AND MATERIALS PROVIDED

- Test cards individually foil pouched with a plastic dropper and a desiccant.....25
- Buffer bottles.....2
- Instructions for use.....1

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Blood sampling tools (lancet, capillary, venous puncture device, etc.)
- Antiseptic alcohol swab and sterile gauze pad
- Biohazard disposal container
- Disposable gloves

STORAGE AND STABILITY

The shelf life of the Rapid TORCH Panel Test is 24 months from date of manufacturing. Store unused kits unopened at 2-30℃.

WARNINGS AND PRECAUTIONS

1. Bring all reagents to room temperature (15-30℃) before use.
2. The test is intended for in vitro diagnostic use only.
3. This test is a rapid test used as an aid for diagnosis and all positive results must be confirmed using an appropriate test.
4. Treat all specimens as though potentially infectious. Wear gloves and protective clothing when handling specimens.
5. Operate according to standard safety precautions when dispose bio-hazardous materials.
6. Devices used for testing should be autoclaved before disposal.
7. Do not use kit materials beyond their expiration dates.
8. Do not interchange reagents from one kit lot to another.
9. Do not re-use the test cards or any single use accessories.
10. Do not use the test if the foil pouch is damaged.

SPECIMEN COLLECTION AND STORAGE

FINGERSTICK WHOLE BLOOD

1. Using an antiseptic alcohol swab, clean the finger of the person being tested. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Using a sterile lancet, puncture the skin just off the center of the finger pad. Hold the finger downward. Apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed. Wipe away this first drop of blood with a sterile gauze pad. Allow a new drop of blood to form.
2. Pick up an unused specimen collection plastic dropper or pipette to collect the drop of blood.

VENIPUNCTURE WHOLE BLOOD

1. Using standard venous phlebotomy procedure, collect a whole blood specimen using a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate.
2. Pick up an unused specimen collection plastic dropper or pipette to collect the drop of blood.

SERUM OR PLASMA

1. SERUM

Use the standard venous phlebotomy procedure to collect a whole blood specimen by a tube NOT containing any anticoagulants. Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

2. PLASMA

Use the standard venous phlebotomy procedure to collect a whole blood specimen by a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. And then centrifuge blood to get a plasma specimen.

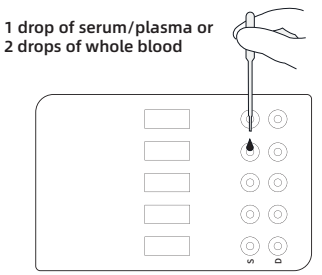
NOTE:

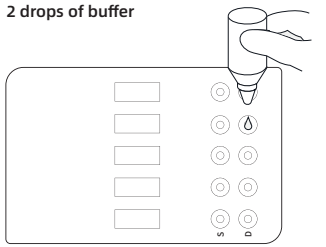
1. Whole blood specimens should be stored at 2-8℃, if the test is to be run within 3 days of collection. Do not freeze whole blood specimens.
2. Serum or plasma specimens can be stored at 2-8℃ for up to 5 days. For long term storage, specimens should be kept at -20℃ or below (avoid multiple free-thaw cycles, 3 at most). Prior to testing, bring frozen specimens to room temperature slowly and mix gently.
3. Specimens containing visible particulate matter should be clarified by centrifugation before testing. Do not use samples demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.
4. Remove the serum or plasma from the clot or red cells as soon as possible to avoid hemolysis.

ASSAY PROCEDURES

Please read the instructions for use first before testing. Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH ≤70%) within 1 hour.

1. Bring all reagents and specimens to room temperature (15-30℃).
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Holding the plastic dropper vertically, dispense 1 drop (about 10 μL) of serum/plasma or 2 drops of whole blood (about 20 μL) into the center of the "S" well on the card.
4. Then add 2 drops of buffer into the "D" well with bottle positioned vertically.
5. Read the results within 10-15 minutes.





NOTE:

1. Applying sufficient amount of buffer is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer to "D" well.
2. Avoid trapping air bubbles in the "S" well or "D" well of the test card.
3. Positive specimens with a high concentration of TORCH antibodies may display results already before 10 minutes. Confirm negative results at the end of the 15 minutes only. Do not interpret the result after 15 minutes.
4. No test provides absolute assurance that a specimen does not contain low levels of TORCH antibodies such as those present at a very early stage of infection. A negative result does not preclude the possibility of exposure to or infection with TORCH viruses.

INTERPRETATION OF THE TEST RESULETS

POSITIVE

1. IgM positive: In addition to the presence of the C line, if the M line develops in any of the five tests, it indicates the presence of IgM antibodies for that particular infection in the specimen. The result is IgM positive.
2. IgG positive: In addition to the presence of the C line, if the G line develops in any of the five tests, the test indicates the presence of IgG antibodies for that particular infection in the specimen. The result is IgG positive.
3. IgG and IgM positive: In addition to the presence of the C line, if both the M and G line develop in any of the five tests, the test indicates the presence of both IgM and IgG antibodies for that particular infection in the specimen. The result is IgM and IgG positive.

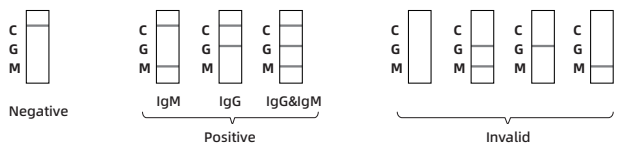
NEGATIVE

If only the C line develops, the test indicates that antibodies to the target infection are not detected in the specimen. The result is negative.

INVALID

If no C line develops in any of the five tests, the test is invalid for that particular test regardless of any color development on the test lines (G and M) as indicated below. Repeat that particular test with a new device.

NOTE: It is normal to have a slightly lightened control line with very strong positive specimens as long as it is distinctly visible. Each test is read independently. One invalid test does not disqualify the results of other valid tests.



PERFORMANCE CHARACTERISTICS

1. Limit of detection

Panel Member	LOD	Reference
TOXO	2.5 IU/mL	WHO International Standard Anti-Toxoplasma IgG, Human NIBSC code: 01/600
Rubella	15 IU/mL	WHO International Standard Anti Rubella Immunoglobulin, Human NIBSC code: RUBI-1-94

2. Cross-reactivity

No cross-reactivity result was observed from the following listed potentially cross-reactive specimens.

No.	Bacteria or virus name	No.	Bacteria or virus name	No.	Bacteria or virus name	No.	Bacteria or virus name
1	TOXO	6	HAV	11	*T. pallidum*	16	TB
2	Rubella	7	HBV	12	*H .pylori*	17	hCG
3	CMV	8	HCV	13	*M. pneumoniae*	18	HAMA
4	HSV-1	9	HEV	14	Dengue	19	ANA
5	HSV-2	10	HIV	15	Malaria	20	RF < (300 IU/mL)

3. Interference

The following interfering substances were added to the negative and low positive level specimens of IgG or IgM respectively. No interference was found with any of the substances at the following concentrations:

Substance	Bilirubin	Triglyceride	Hemoglobin	Glucose	Albumin	Heparin	EDTA
Concentration	342.0 μmol/L	14.1 mmol/L	5.0 g/L	5.0 g/L	60 g/L	100 IU/mL	0.1 mg/mL

4. Sensitivity and Specificity

Rapid TORCH Panel Test was compared with leading commercial ELISA TOXO, Rubella, CMV, HSV-1 and HSV-2 tests. Comparison for all subjects showed the following sensitivity, specificity and accuracy:

TOXO IgM

Method		TOXO IgM ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	32	4	36
	Negative	3	225	228
Total Results		35	229	264

Sensitivity: 91.43% (95%CI: 77.62%~97.04%)
Specificity: 98.25% (95%CI: 95.60%~99.32%)
Accuracy: 97.35% (95%CI: 94.63%~98.71%)

TOXO IgG

Method		TOXO IgG ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	90	3	93
	Negative	5	265	270
Total Results		95	268	363

Sensitivity: 94.74% (95%CI: 88.27%~97.73%)
Specificity: 98.88% (95%CI: 96.76%~99.62%)
Accuracy: 97.80% (95%CI: 95.71%~98.88%)

Rubella IgM

Method		Rubella IgM ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	21	3	24
	Negative	2	223	225
Total Results		23	226	249

Sensitivity: 91.30% (95%CI: 73.20%~97.58%)
Specificity: 98.67% (95%CI: 96.17%~99.55%)
Accuracy: 97.99% (95%CI: 95.39%~99.14%)

Rubella IgG

Method		Rubella IgG ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	182	3	185
	Negative	9	59	68
Total Results		191	62	253

Sensitivity: 95.29% (95%CI: 91.29%~97.50%)
Specificity: 95.16% (95%CI: 86.71%~98.34%)
Accuracy: 95.26% (95%CI: 91.89%~97.27%)

CMV IgM

Method		CMV IgM ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	138	9	147
	Negative	12	129	141
Total Results		150	138	288

Sensitivity: 92.00% (95%CI: 86.54%~95.36%)
Specificity: 93.48% (95%CI: 88.07%~96.53%)
Accuracy: 92.71% (95%CI: 89.11%~95.18%)

CMV IgG

Method		CMV IgG ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	199	8	207
	Negative	16	65	81
Total Results		215	73	288

Sensitivity: 92.56% (95%CI: 88.25%~95.37%)
Specificity: 89.04% (95%CI: 79.84%~94.34%)
Accuracy: 91.67% (95%CI: 87.90%~94.34%)

HSV-1 IgM

Method		HSV-1 IgM ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	26	12	38
	Negative	2	216	218
Total Results		28	228	256

Sensitivity: 92.86% (95%CI: 77.35%~98.02%)
Specificity: 94.74% (95%CI: 91.03%~96.96%)
Accuracy: 94.53% (95%CI: 91.03%~96.71%)

HSV-1 IgG

Method		HSV-1 IgG ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	285	3	288
	Negative	12	37	49
Total Results		297	40	337

Sensitivity: 95.96% (95%CI: 93.07%~97.67%)
Specificity: 92.50% (95%CI: 80.14%~97.42%)
Accuracy: 95.55% (95%CI: 92.79%~97.28%)

HSV-2 IgM

Method		HSV-2 IgM ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	28	6	34
	Negative	2	218	220
Total Results		30	224	254

Sensitivity: 93.33% (95%CI: 78.68%~98.15%)
Specificity: 97.32% (95%CI: 94.28%~98.77%)
Accuracy: 96.85% (95%CI: 93.91%~98.40%)

HSV-2 IgG

Method		HSV-2 IgG ELISA Test		Total Results
		Positive	Negative	
Rapid TORCH Panel Test	Positive	38	5	43
	Negative	4	205	209
Total Results		42	210	252

Sensitivity: 90.48% (95%CI: 77.94%~96.23%)
Specificity: 97.62% (95%CI: 94.55%~98.98%)
Accuracy: 96.43% (95%CI: 93.35%~98.11%)

LIMITATIONS OF PROCEDURE

1. The test is limited to the qualitative detection of antibodies to *Toxoplasma gondii*, rubella virus, CMV, HSV-1, and HSV-2 in human whole blood, serum or plasma. It is not designed to determine the quantitative concentration of antibodies.
2. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated. The results of this test alone should not be used as a basis for terminating a pregnancy.
3. Positive test results should be rechecked and confirmed by different methodologies. The depth of the color band at the test line does not have linear correlation with the titer of the analyte in the specimen.
4. A negative result can occur if the quantity of the anti- *Toxoplasma gondii*, rubella virus, CMV, HSV-1, and HSV-2 antibodies present in the specimen is below the detection limits of the assay or the antibodies that detected are not present during the stage of the disease in which a sample is collected.
5. If the clinical symptoms from any of the 5 individual infections persist, even if the test results were negative, it is recommended to test with an alternative test method for that particular infection. A negative result does not at any time preclude the possibility of the infection.

Key to symbols used

	MANUFACTURER		Date of manufacture		DO NOT REUSE		USE-BY DATE
	BATCH CODE		CONSULT INSTRUCTIONS FOR USE		CONTAINS SUFFICIENT FOR (N) TESTS		STERILIZED USING ETHYLENE OXIDE
	TEMPERATURE LIMITATION		IN VITRO DIAGNOSTIC MEDICAL DEVICE		DO NOT USE IF PACKAGE IS DAMAGED		CATALOGUE NUMBER


InTec PRODUCTS, INC.
332 Xinguang Road, Xinyang Industrial Area,
Haicang, 361022, Xiamen, Fujian, P.R. China

Tel: +86 592 6807188
Website: www.intecasi.com
Email: intecproducts@asintec.com