One Step
TORCH IgM/IgG
(TOX-IgM/IgG, RV-IgM/IgG, CMV-IgM/IgG, HSV-Ⅰ-IgM/IgG, HSV-Ⅱ-IgM/IgG)
10-in-1 Rapid Test Panel
(Serum/Plasma)

Package Insert

A rapid, one step test for the qualitative detection of antibodies to Toxoplasma (TOX), Rubella virus (RV), Cytomegalo virus (CMV), Herpes simplex virus (HSV) in human serum or plasma.

For in vitro diagnostic use only.

PRODUCT NAME

One Step TORCH IgM/IgG (TOX-IgM/IgG, RV-IgM/IgG, CMV-IgM/IgG, HSV-Ⅰ-IgM/IgG, HSV-Ⅱ-IgM/IgG)

10-in-1 Rapid Test Panel

INTENDED USE

Used for the qualitative detection of IgM/IgG antibodies to TORCH (Toxoplasma (TOX), Rubella virus (RV), Cytomegalo virus (CMV), Herpes simplex virus (HSV) in human serum or plasma to determine if someone is infected by TORCH.

TORCH is an acronym of the five infections including Toxoplasma (TOX), Rubella virus (RV), Cytomegalo virus (CMV), Herpes simplex virus (HSV), which may cause the fetal women abortion, even cause congenital defects or developmental disorders.

MAIN COMPONENTS

TOX-IgM/IgG: Sample pad, colloidal gold labeled anti-human IgM/IgG, nitrocellulose membrane coated with recombinant TOX antigen and goat anti-mouse IgG/IgM antibody, absorbent pad, PVC board.

RV-IgM/IgG: Sample pad, colloidal gold labeled anti-human IgM/IgG, nitrocellulose membrane coated with recombinant RV antigen and goat anti-mouse IgG/IgM antibody, absorbent pad, PVC board.

CMV-IgM/IgG: Sample pad, colloidal gold labeled anti-human IgM/IgG, nitrocellulose membrane coated with recombinant CMV antigen and goat anti-mouse IgG/IgM antibody, absorbent pad, PVC board.

HSV-Ⅰ-IgM/IgG: Sample pad, colloidal gold labeled anti-human IgM/IgG, nitrocellulose membrane coated with recombinant HSV-Ⅰ antigen and goat anti-mouse IgG/IgM antibody, absorbent pad, PVC board.

HSV-Ⅱ-IgM/IgG: Sample pad, colloidal gold labeled anti-human IgM/IgG, nitrocellulose membrane coated with recombinant HSV-Ⅱ antigen and goat anti-mouse IgG/IgM antibody, absorbent pad, PVC board.

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, keep out of hot and direct sunlight, keep in dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw. The product is humidity-sensitive and should be used immediately after being opened.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SAMPLE REQUIREMENTS

Sample Collection:

1. Serum: Use disposable syringe (vacuum blood collection tube) to extract a certain amount of venous blood, and place at room temperature for blood coagulation, take the supernatant after centrifugation of blood for detection. Separate the serum from the clot or plasma from the packed cells as soon as possible to avoid any hemolysis.
2. Plasma: Use vacuum blood collection tube with anticoagulants to extract a certain amount of venous blood, and rock repeatedly, take plasma separation for detection.
3. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants.

Sample Storage:

Serum and plasma samples may be stored at 2-8℃ for 3 days prior to assay, and at -20 ℃ for 2 years. If testing is delayed more than 7 days, the sample should be frozen (-20°C or colder). Repeat freeze and thaw for no more than 3 times.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Sample Collection Container
2. Timer or Clock

TEST METHODS

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

1. Take off the outer packing, put the panel onto the desk with the sample window up.
2. Apply 3 full drops of serum / plasma (80μl-100μl) vertically into each sample hole of the panel. *Avoid air bubble in the pipette, a bubble may prevent the complete transfer of sample and invalidate the test. Use a new pipette for each test performed, even if using the same sample.*
3. Observe the test results immediately within 15~30 minutes, the result is invalid over 30 minutes.

INTERPRETATION OF RESULTS

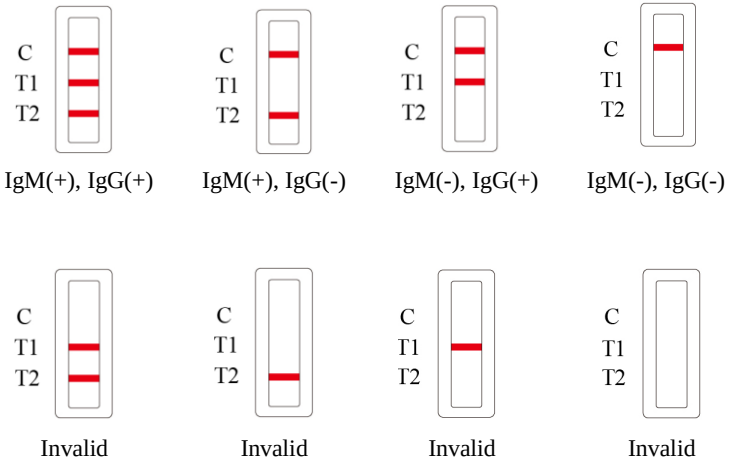
POSITIVE: Two (2) or Three (3) distinct colored lines appear. One line should be in the control region (C), one line in T1 region or one line in T2 region or both.

NEGATIVE: One (1) colored line appears in the control region(C). No apparent colored line appears in neither T1 region nor T2 region. The negative result does not indicate the absence of analytes in the sample, it only indicates the level of tested analytes in the sample is less than cut-off level.

INVALID: No colored lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.

Note:

1. Any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the sample.
2. Insufficient sample volume, incorrect operating procedure or expired tests are the most likely reasons for control line failure.
3. Control line color intensity of different items on the same cassette may be different, it is a normal phenomenon. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.



LIMITATIONS

1. This reagent is designed for the qualitative screening test. Concentration of analytes cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Negative result may occur when detecting short-term infected samples, indicate that the specific antibodies of TORCH does not exist or the concentration is below detection limit. If TORCH infection is still suspected, the sample should be collected 2 weeks later and carry the parallel detection with the first sample.
4. Negative results may occur at the beginning of acute infection, other testing method and analysis with clinical symptoms are suggested.
5. Results of patients who used to receive immunosuppressive therapy or with immune function damage (for example HIV), may have a low serology reference value.
6. Positive results of the patients who used to receive blood transfusions or other blood products therapy, should be analyzed cautiously.
7. There is a high risk of false positives in the TORCH IgM antibodies laboratory testing of pregnant woman, therefore it is not recommended to take TORCH IgM antibody screening test for asymptomatic pregnant women. The test results of this reagent should not be used as the only basis for termination of pregnancy.

PERFORMANCE CHARACTERISTICS

TOX IgM/IgG:

1. Negative specificity: The results should all be negative when detecting kits of TOX IgM/IgG negative quality control samples.
2. Positive specificity: The results should all be positive when detecting kits of TOX IgM/IgG positive quality control samples.
3. Limit of detection: Positive results may occur when detecting TOX IgM/IgG quality control material.
4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the TOX IgM/IgG standards by 10 kits of the same concentration.
5. Diagnostic specificity and sensitivity

IgM: A clinical evaluation was conducted on 469 TOX- IgM samples (including 99 positive samples and 370 negative samples). The results are as follows:

Positive samples	99	TOX-IgM test kits of MR	TOX IgM test kits of control group
		98/99（99.0%）	97/99（98.0%）
Negative samples	370	TOX-IgM test kits of MR	TOX IgM test kits of control group
		368/370（99.5%）	367/370（99.2%）

IgG: A clinical evaluation was conducted on 431 samples (including 161 positive samples and 270 negative samples). The results are as follows:

Positive samples	161	TOX IgG test kits of MR	TOX IgG test kits of control group
		158/161（98.1%）	158/161（98.1%）
Negative samples	270	TOX IgG test kits of MR	TOX IgG test kits of control group
		267/270（98.9%）	268/270（99.3%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB- IgA, varicella virus,RF, ASO,ENA, ANA, MP, HAMA, high concentration IgM/IgG, systemic lupus erythematosus and other TORCH causative

agents showed no cross-reactivity.

6.2 200 μmol/L bilirubin, 5.65mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the TOX-IgM concentration as high of 577.25 IU/mL, the hook effect will not occur even the TOX-IgG concentration as high of 504.21 IU/mL.

RV IgM/IgG:

1. Negative specificity: The results should all be negative when detecting kits of RV-IgM/IgG negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of RV-IgM/IgG positive quality control samples.

3. Limit of detection: Positive results may occur when detecting RV-IgM/IgG quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the RV-IgM/IgG standards by 10 kits of the same concentration..

5. Diagnostic specificity and sensitivity

IgM: A clinical evaluation was conducted on 411 samples (including 141 positive samples and 270 negative samples). The results are as follows:

Positive samples	141	RV IgM test kits of MR	RV IgM test kits of control group
		138/141（97.9%）	136/141（96.5%）
Negative samples	270	RV IgM test kits of MR	RV IgM test kits of control group
		267/270（98.9%）	268/270（99.3%）

IgG: A clinical evaluation was conducted on 402 samples (including 156 positive samples and 246 negative samples). The results are as follows:

Positive samples	156	RV IgG test kits of MR	RV IgG test kits of control group
		153/156（98.1%）	155/156（99.4%）
Negative samples	246	RV IgG test kits of MR	RV IgG test kits of control group
		243/246（98.8%）	243/246（98.8%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB- IgA, varicella virus,RF, ASO,ENA, ANA, MP, HAMA, high concentration IgM/IgG, systemic lupus erythematosus and other TORCH causative agents showed no cross-reactivity.

6.2 200μmol/L bilirubin, 10mmol/L total cholesterol, 6mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the RV-IgM concentration as high of 351.2 U/mL, the hook effect will not occur even the RV-IgG concentration as high of 577.25 IU/mL.

CMV IgM/IgG:

1. Negative specificity: The results should all be negative when detecting kits of CMV-IgM/IgG negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of CMV-IgM/IgG positive quality control samples.

3. Limit of detection: Positive results may occur when detecting CMV-IgM/IgG quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the CMV-IgM/IgG standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

IgM: A clinical evaluation was conducted on 442 samples (including 152 positive samples and 290 negative samples). The results are as follows:

Positive samples	152	CMV-IgM test kits of MR	CMV IgM test kits of control group
		149/152（98.0%）	147/152（96.7%）
Negative samples	290	CMV-IgM test kits of MR	CMV IgM test kits of control group
		286/290（98.6%）	288/290（99.3%）

IgG: A clinical evaluation was conducted on 462 samples (including 185 positive samples and 277 negative samples). The results are as follows:

Positive samples	185	CMV-IgG test kits of MR	CMV IgG test kits of control group
		183/185（98.9%）	182/185（98.4%）
Negative samples	277	CMV-IgG test kits of MR	CMV IgG test kits of control group
		274/277（98.9%）	273/277（98.6%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB- IgA, varicella virus,RF, ASO,ENA, ANA, MP, HAMA, high concentration IgM/IgG, systemic lupus erythematosus and other TORCH causative agents showed no cross-reactivity.

6.2 200 μmol/L bilirubin, 10mmol/L total cholesterol, 6mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the CMV-IgM concentration as high of 593.52 U/mL, the hook effect will not occur even the CMV-IgG concentration as high of 702.12 U/mL .

HSV-Ⅰ IgM/IgG:

1. Negative specificity: The results should all be negative when detecting kits of HSV-Ⅰ IgM/IgG negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of HSV-Ⅰ IgM/IgG positive quality control samples.

3. Limit of detection: Positive results may occur when detecting HSV-Ⅰ IgM/IgG quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the HSV-Ⅰ IgM/IgG standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

IgM: A clinical evaluation was conducted on 446 samples (including 170 positive samples and 276 negative samples). The results are as follows:

Positive samples	170	HSV-Ⅰ IgM test kits of MR	HSV-Ⅰ IgM test kits of control group
		166/170（97.0%）	160/170（94.1%）
Negative samples	276	HSV-Ⅰ IgM test kits of MR	HSV-Ⅰ IgM test kits of control group
		270/276（97.8%）	268/276（97.1%）

IgG: A clinical evaluation was conducted on 420 samples (including 148 positive samples and 272 negative samples). The results are as follows:

Positive samples	148	HSV-Ⅰ IgG test kits of MR	HSV-Ⅰ IgG test kits of control group
		146/148（98.6%）	145/148（98.0%）
Negative samples	272	HSV-Ⅰ IgG test kits of MR	HSV-Ⅰ IgG test kits of control group
		270/272（99.6%）	268/272（98.5%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB-IgA, varicella virus, RF, ASO, ENA, ANA, MP, and other TORCH causative agents showed no cross-reactivity.

6.2 1000 μmol/L bilirubin, 5.65mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the HSV-Ⅰ IgM/IgG concentration is high.

HSV-Ⅱ IgM/IgG:

1. Negative specificity: The results should all be negative when detecting kits of HSV-Ⅱ IgM/IgG negative quality control samples.

2. Positive specificity: The results should all be positive when detecting kits of HSV-Ⅱ IgM/IgG positive quality control samples.

3. Limit of detection: Positive results may occur when detecting HSV-Ⅱ IgM/IgG quality control material.

4. Repeatability: The results should be consistent and the coloration degree should be consistent when detecting the HSV-Ⅱ IgM/IgG standards by 10 kits of the same concentration.

5. Diagnostic specificity and sensitivity

IgM: A clinical evaluation was conducted on 431 samples (including 171 positive samples and 260 negative samples). The results are as follows:

Positive samples	171	HSV-Ⅱ IgM test kits of MR	HSV-Ⅱ IgM test kits of control group
		169/171（98.8%）	166/171（97.1%）
Negative samples	260	HSV-Ⅱ IgM test kits of MR	HSV-Ⅱ IgM test kits of control group
		256/260（98.5%）	255/260（98.1%）

IgG: A clinical evaluation was conducted on 415 samples (including 148 positive samples and 267 negative samples). The results are as follows:

Positive samples	148	HSV-Ⅱ IgG test kits of MR	HSV-Ⅱ IgG test kits of control group
		145/148（98.0%）	146/148（98.6%）
Negative samples	267	HSV-Ⅱ IgG test kits of MR	HSV-Ⅱ IgG test kits of control group
		262/267（98.1%）	260/267（97.4%）

6. Analytical sensitivity:

6.1 Cross-reactivity: The addition of HBV, HAV, EB-IgA, varicella virus, RF, ASO, ENA, ANA, MP, and other TORCH causative agents showed no cross-reactivity.

6.2 1000 μmol/L bilirubin, 5.65mmol/L triglyceride, 10g/L hemoglobin has no effect on the detection result.

6.3 Hook effect: the hook effect will not occur even the HSV-Ⅱ IgM/IgG concentration is high.

ATTENTIONS

1. For IN VITRO diagnose only.
2. Do not use after the expiration date. Avoid using the test if the package is damaged.
3. This test provides a qualitative and visual outcome. A good light source is required for reading the results.
4. Avoid touching the nitrocellulose membrane with your fingers.
5. The test kit is disposable, not reusable.
6. The test result is invalid over 35 minutes.
7. The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.
8. The color depth of the detection line was not necessarily associated with the antibody titer of the sample, positive results cannot be used as the only basis for diagnosis, further confirm experiment should be taken.
9. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use. Laboratory chemical and biohazardous wastes must be handled and discarded in accordance with all local, regional, and national regulations.
10. Do not smoke, drink, or eat in areas where samples or kit reagents are being handled.
11. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.
12. If the filtration speed is very slow or evens no filtration occurs, please test again with new sample. Samples with liquid migration velocity (stopwatch) less than 4.00mm/minis not suitable for this test kit, other detection methods are suggested to use.
13. The addition of HBV, autoantibody and EB virus IgA showed no cross-reactivity.
14. 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 6.5g/L hemoglobin has no effect on the detection result.