

Size : 137 x 218 mm

Toxocheck™

Rapid test for detection of IgM & IgG antibodies to *T. gondii* in human serum/plasma

DEVICE

INTENDED USE

Toxocheck™ is a rapid, qualitative immunochromatographic test for the detection of IgM & IgG antibodies to *Toxoplasma gondii* (*T. gondii*) in human serum or plasma. It can be used as a screening test and as an aid for diagnosis of infection with *T. gondii*.

SUMMARY

Toxoplasmosis is an infectious disease caused by the parasite *Toxoplasma gondii* and affects both animals and humans. In humans this infection is usually acquired by ingesting inadequately cooked meat or from feces of infected cats. Approximately 25-50% of the adult population are asymptotically affected with Toxoplasmosis. Acquired Toxoplasmosis is usually asymptomatic and benign. In pregnant women however, the infection acquires a special significance as the parasite may enter the fetal circulation through placenta and cause congenital Toxoplasmosis. The consequences of congenital Toxoplasmosis range from spontaneous abortion and prematurity to generalised and neurological symptoms. Some infants with congenital Toxoplasmosis may also remain asymptomatic at birth and develop the disease during childhood or adolescence. Congenital toxoplasmosis is a serious but preventable and treatable disease.

Serological detection of *T. gondii* specific IgM & IgG antibodies is the primary method for diagnosis of Toxoplasmosis and helps in determining the risk of congenital toxoplasmosis during pregnancy. The use of recombinant antigens in assay systems has improved the serodiagnosis of toxoplasmosis.

Toxocheck™ is a rapid, qualitative, immunochromatographic test using a recombinant *T. gondii* antigen for detection of IgM & IgG antibodies to *Toxoplasma gondii* (*T. gondii*) in human serum or plasma.

PRINCIPLE

Toxocheck™ is based on the principle of agglutination of antibodies/antisera with respective antigen in immuno-chromatography format along with use of nano gold particles as agglutination revealing agent. The specific Agglutinating sera for human IgM and specific Agglutinating sera for human IgG are immobilized on the nitrocellulose membrane as two individual test bands (IgM and IgG) at region 'M' and region 'G' respectively.


As the test sample flows through the membrane assembly within the test device, the recombinant *T. gondii* antigen colloidal gold conjugate complexes with specific antibodies (IgM and/or IgG) to *T. gondii*, if present in the sample. This complex moves further on the membrane to the test region where it is immobilized by the specific Agglutinating sera for human IgM and/or Agglutinating sera for human IgG coated on the membrane leading to formation of colored band/s which confirms a positive test result. Absence of these colored bands in the test region indicates a negative test result for IgM & IgG antibodies to *T. gondii*.

A built-in control band in the control area marked 'C' appears when the test has been performed correctly, regardless of the presence or absence of the *T. gondii* antibodies in the specimen. It serves to validate the test performance of each device.

REAGENTS AND MATERIALS SUPPLIED

Toxocheck™ kit contains:

- Individual pouches, each containing:
 - DEVICE**: Membrane assembly pre-dispensed with *T. gondii* specific recombinant antigen colloidal gold conjugate, streptavidin gold conjugate, Agglutinating sera for Human IgM at test region 'M', Agglutinating sera for Human IgG at test region 'G' & Biotinylated BSA at control region 'C'.
 - Desiccant pouch.
- BUF**: Sample running buffer in a dropper bottle.
- Package insert

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	10 T	25 T

OPTIONAL MATERIAL REQUIRED BUT NOT PROVIDED

Calibrated micropipette capable of delivering 5µl specimen accurately. Stop watch.

STORAGE AND STABILITY

The sealed pouches in the test kit and kit components may be stored at 4°C to 30°C for the duration of the shelf life as indicated on the pouch/carton. After first opening of the sample running buffer bottle, the buffer is stable until the expiry date mentioned on the buffer label, if kept at 4°C to 30°C for the remaining duration of its shelf life. DO NOT FREEZE.

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NOTES

1. For in vitro diagnostic use and professional use only. NOT FOR MEDICINAL USE.
2. Do not use the kit beyond expiry date and do not re-use the test device.
3. Read the instructions carefully before performing the test.
4. Do not intermix the reagent or devices from different lots.
5. Any modification to the test procedure and / or use of other reagents will invalidate the test procedure.
6. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.
7. Handle all specimens as if potentially infectious. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
8. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
9. Sample running buffer contains Sodium Azide (0.1%), avoid skin contact with this reagent. Azide may react with lead and copper in the plumbing and form highly explosive metal oxides. Flush with large volumes of water to prevent azide build up in the plumbing.





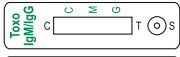
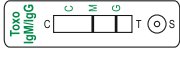
SPECIMEN COLLECTION AND PREPARATION

1. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
2. Though fresh serum/plasma is preferable, serum/plasma specimen may be stored at 2°C to 8°C for up to 72 hours, in case of delay in testing. Refrigerated specimens must be brought to room temperature prior to testing.
3. Do not use haemolysed or contaminated specimens.
4. Turbid specimens should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.
5. Repeated freezing, thawing of the specimen should be avoided.

TESTING PROCEDURE

1. Bring the **Toxocheck™** kit components to room temperature prior to testing.
2. Open the foil pouch by tearing along the "notch" and remove the test device.
3. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colorless or pink, discard the test device and use another device. **Once opened, the device must be used immediately.**
4. Label the device with specimen identity.
5. Place the device on a flat horizontal surface.
6. Tighten the cap of the buffer bottle in the clockwise direction to pierce the dropper bottle nozzle.
7. Using a precision micropipette, carefully add 5 µl serum or plasma specimens into the specimen port (S).
8. Add **two drops** of sample running buffer into the same specimen port (S) and immediately start the stopwatch.
9. Read the final result at the end of **15 minutes**.

INTERPRETATION OF RESULTS

	Negative Result The presence of only single pink-purple colored band in the control area marked 'C', indicates the absence of specific antibodies against <i>T. gondii</i> or that the amount of antibodies is below the detection limit of the test.
  	Positive Result In addition to the control band in the control area marked 'C', appearance of two pink-purple colored bands in the test region 'M' and region 'G', indicates the presence of <i>T. gondii</i> specific IgM and IgG antibodies. In addition to the control band in the control area marked 'C', appearance of a pink-purple colored band in the test region 'M', indicates the presence of <i>T. gondii</i> specific IgM antibodies. In addition to the control band in the control area marked 'C', the appearance of a pink-purple colored band in the test region 'G', indicates the presence of <i>T. gondii</i> specific IgG antibodies.
 	Invalid Result The test result is invalid if no bands appear on the device. The test should also be considered invalid if only the test band appears and no control band appears. In such cases, verify the test procedure and repeat the test with a new device.

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PERFORMANCE CHARACTERISTICS

Sensitivity:

In an in-house evaluation study, **Toxocheck™** was evaluated with a panel of 66 known *T. gondii* positive serum/plasma samples (IgM and IgG positive) in comparison with a commercially available Rapid Test and ELISA. The results obtained were as follows:

Specimen type	No. of specimens tested	Commercial Rapid Test	Commercial ELISA	Toxocheck™
Positive for IgM Ab to <i>T. gondii</i>	10	10	10	10
Positive for IgG Ab to <i>T. gondii</i>	51	51	51	51
Positive for IgM & IgG Ab to <i>T. gondii</i>	5	5	5	5
Total no. of specimens tested	66	66	66	66

Based on above data, the sensitivity of **Toxocheck™** is 100%.

Specificity:

In an in-house evaluation study, **Toxocheck™** was evaluated with 211 known *T. gondii* negative serum/plasma samples (IgM and IgG negative) in comparison with a commercially available Rapid Test and ELISA. The results obtained were as follows:

No. of specimens tested	Commercial Rapid Test	Commercial ELISA	Toxocheck™
211	209	211	208

Based on above data, the specificity of **Toxocheck™** is 98.58%.

LIMITATIONS OF THE TEST

1. **Toxocheck™** detects the presence or absence IgM and /or IgG antibodies to *T. gondii* in the human serum/plasma specimen. It should not be used as sole criteria for the diagnosis of Toxoplasma infection.
2. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should rather be made by a clinician after all clinical findings have been evaluated.
3. A negative test result indicates that IgM and IgG antibodies to *T. gondii* are either not present or at levels undetectable by the test.
4. **Toxocheck™** has not been validated on specimens from neonates.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor may affect expected results.
6. In a pregnant woman whose sample is taken in the second trimester rather than ideally in the first trimester, and she is found IgG positive but IgM negative, it is more advisable to perform IgG avidity test.
7. Do not interpret the test results beyond 30 minutes.

WARRANTY
















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BIBLIOGRAPHY

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2. Congenital toxoplasmosis: evaluation of serological methods for the detection of anti-Toxoplasma gondii IgM and IgA antibodies. Rodrigues IMX et al, Mem Inst Oswaldo Cruz, Vol. 104(3):434-440, May 2009.
3. Montoya JG, Rosso F. Diagnosis and management of toxoplasmosis. Clin Perinatol. 2005, 32(3):705-26.
4. Laboratory diagnosis of Toxoplasma gondii infection and Toxoplasmosis. Dr. Joss G. Montoya. JID 2002;185 (1).
5. Serological diagnosis of Toxoplasma gondii infection recommendations from the French National Reference Center for Toxoplasmosis. O. Villard et al. Diagnostic Microbiology and infectious Disease 84 (2016) 22-33.
6. Point-of-care testing for Toxoplasma gondii IgG/IgM using Toxoplasma ICT IgG-IgM test with sera from the United States and implications for developing countries. Ian J. Begeman et al. PLOS Neglected Tropical Diseases, June 26, 2017
7. Data on file: Zephyr Biomedicals.

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SYMBOL KEYS

	Temperature Limitation		Manufacturer		Device	 Harmful if swallowed. Do not breathe vapour. If swallowed, seek medical advice immediately and show this container or label. Avoid release to the environment. Refer to special instructions.
	Use by		Consult Instructions for use		Sample Running Buffer	
	Date of Manufacture		Catalogue Number		This side up	
	Batch Number / Lot Number		In vitro Diagnostic Medical Device		Do not use if package is damaged	
	Contains sufficient for <n> tests		Do not reuse			



Manufactured by:

Zephyr Biomedicals

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