AccuDiag™
Toxoplasma IgM (T-gondii) IFA Kit

REF 431508-MD

| Test                  | Toxoplasma IgM (T-gondii) IFA Test System is designed to detect IgM class antibodies to T. gondii antigen. The assay employs T. gondii
| Method               | Indirect Fluorescent Antibody Method |
| Principle            | Qualitative                          |
| Sample               | 10 µL serum                          |
| Sensitivity          | 92.3 %                               |
| Specificity          | 100 %                                |
| Total Time           | ~ 130 min.                           |
| Shelf Life           | 12 Months from the manufacturing date |

INTENDED USE
The Diagnostic Automation, Inc. Toxoplasma IgM(T-gondii) IFA Kit Test System is an indirect fluorescent antibody assay designed for the presumptive qualitative detection of IgM antibodies to T. gondii in human serum and for the presumptive diagnosis of acute, recent, or reactive T. gondii infection. To adequately assess the patient’s serological status; testing must be performed in conjunction with an anti-T. gondii IgG antibody assay. This product is not FDA cleared (approved) for use in testing (i.e., screening) blood or plasma donors. Performance characteristics have not been established for screening sera from prenatal women or newborns.

SUMMARY AND EXPLANATION
T. gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Although cats are the definitive host, the organism can infect almost all mammals and birds. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism, although the prevalence varies among different populations.

Toxoplasma exists in three forms: trophozoite, cysts, and oocysts. The trophozoite is the invasive form present during the acute phase of infection. Tissue cysts are formed after multiplication of the organism within the host cell cytoplasm and may contain up to several thousand organisms. Oocysts develop in the intestinal epithelial cells of cats and are not found in other hosts. Oocysts are excreted in the feces of cats and mature after a few days.

Infection with man and other animals occurs after ingestion of either cysts in raw or undercooked meat, or mature oocysts in material contaminated with cat feces. Once ingested, the parasites are liberated from cysts or oocysts by digestive enzymes and invade the intestinal mucosa. The parasites multiply locally and are then transported to other organs forming tissue cysts which persist for the life of the host. Cysts are found predominantly in brain, heart, and skeletal muscle.

Infection with T. gondii is asymptomatic in the majority (80 - 90%) of cases. The most common clinical manifestation of acute toxoplasmosis in the adult is asymptomatic lymphadenopathy involving single or multiple nodes. Lymphadenopathy may be accompanied by fever, malaise, and atypical lymphocytosis symptoms which mimic infectious mononucleosis. Very rarely will more serious complications, such as encephalitis, myocarditis or pneumonitis, be seen in the normal host.

Although the normal host usually suffers no ill effects from infection with T. gondii, infection in an immunocompromised host is often fatal. Immunocompromised patients may develop severe disseminated toxoplasmosis or toxoplasplasmic encephalitis, or both. Toxoplasma is a common opportunistic infection of the central nervous system in patients with acquired immunodeficiency syndrome (AIDS). Serologic evidence indicates that toxoplasplasmic encephalitis in AIDS patients results from reactivation of latent infections. Approximately 30% of AIDS patients who are toxoplasplasma antibody positive will develop toxoplasplasmic encephalitis.

When a seronegative woman becomes infected with T. gondii during pregnancy, the organism is often transmitted across the placenta to the fetus. The severity of infection in the fetus varies with the trimester during which the infection was acquired. Infection during the first trimester may lead to spontaneous abortion, stillbirth, or overt disease in the neonate. Infection acquired later during pregnancy is usually asymptomatic in the neonate, and may not be recognized. Approximately 75% of congenitally infected newborns are symptomatic. However, nearly all children born with subclinical toxoplasmosis will develop adverse ocular or neurologic sequelae later in life. Approximately 80 - 85% develop chorioretinitis and some may also experience blindness or mental retardation.

A variety of serologic tests for antibodies to T. gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. The more widely used tests include the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, and ELISA. Serologic procedures that measure IgM class antibodies to T. gondii include indirect immunofluorescence, immunosorbent agglutination, and ELISA. High affinity IgG antibodies to T. gondii, if present in a sample, may interfere with the detection of IgM specific antibody. High affinity IgG antibody may preferentially bind to T. gondii antigen leading to false negative IgM results; also, rheumatoid factor, if present along with antigen-specific IgG, may bind to the IgG causing false positive IgM results.

Both of the above problems can be eliminated by removing IgG from the sample before testing for IgM. Several different methods of separating IgG have been used. These include gel filtration, absorption with protein A ion exchange chromatography, precipitation of IgG with anti-human IgG serum, or the use of IgG Removal Regent.

TEST PRINCIPLE
The Diagnostic Automation, Inc. T. gondii IgM Test System is designed to detect IgM class antibodies to the T. gondii antigen. The assay employs T. gondii organisms and fluorescein labeled anti-human IgM (μ chain specific). The procedure involves three steps:

1. Test sera are first treated to remove IgG and rheumatoid factor.
2. Test sera, properly treated and diluted, are added to the wells and incubated. Antigen specific IgM antibody will bind to T. gondii substrate immobilized on the slide. The Slides are washed to remove unbound antibody and other serum components.
3. Fluorescein labeled anti-human IgM Conjugate is added to the wells and the Slides are incubated. The Conjugate will react with the antigen specific IgM antibodies bound to the slides in step 2. The Slides are washed to remove unbound Conjugate. The Slides are then mounted with a coverslip and read under a fluorescence microscope.
SPECIMEN COLLECTION AND PREPARATION

1. Diagnostic Automation, Inc. recommends that the user carry out specimen collection in accordance with CLSI document M29: Protection of Laboratory Workers from Occupationally Acquired Infectious Diseases. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.
2. Only freshly drawn and properly refrigerated sera obtained by approved aseptic venipuncture procedures should be used in this assay. No anticoagulants or preservatives should be added. Avoid using hemolyzed, lipemic, or bacterially contaminated sera.
3. Store sample at room temperature for no longer than 8 hours. If testing is not performed within 8 hours, sera may be stored between 2-8°C for no longer than 48 hours. If delay in testing is anticipated, store test sera at −20°C or lower. Avoid multiple freeze/thaw cycles that may cause loss of antibody activity and give erroneous results. It is the responsibility of the individual laboratory to use all available references and/or its own studies to determine stability criteria for its laboratory
4. Reactive Reagents
Reagents contained a combination of Proclin (0.05% v/v) and Sodium Hypochlorite. Disposal basin and disposal tubing are recommended for any potentially biohazardous waste.
5. The Controls are ready to use. Slide wells do not contain viable organisms. An organism does not grow on any slide. The controls are negative for detection of Toxoplasmosis gondii. The following filter systems or their equivalent have been found to be satisfactory for routine use with transmitted or incident light darkfield assemblies:

MATERIALS AND COMPONENTS

Materials provided with the test kits
Each Test System contains the following components in sufficient quantities to perform the number of tests indicated on packaging label. NOTE: Conjugate and Controls contain a combination of Proclin (0.05% v/v) and Sodium Azide (<0.1% w/v) as preservatives. Sample Diluent contains Sodium Azide (<0.1% w/v) as a preservative.

Reactive Reagents
1. Toxoplasma gondii Antigen Substrate Slides: Ten, 8 well Slides containing T. gondii organisms (strain RH). Also includes a desiccant pouch.
2. Conjugate: Anti-human IgM (µ chain specific) labeled with fluorocyanogen (FITC). Contains phosphate buffer with BSA and counterstain. One, 3.5mL, clear-capped, vial. Ready to use.
3. Positive Control (Human Serum): Will produce positive apple-green staining around the periphery of the organisms. One, 0.5mL, red-capped, vial. Ready to use.
4. Negative Control (Human Serum): Will produce no detectable staining of the organism. One, 0.5mL, green-capped, vial. Ready to use.
5. Sample Diluent: One, 30mL, green-capped, bottle containing phosphate-buffered saline. Ready to use. Note: The Sample Diluent will change color when combined with serum.
6. Phosphate-buffered saline (PBS): pH 7.6 ± 0.2. Empty contents of each buffer packet into one liter of distilled or deionized water. Mix until all salts are thoroughly dissolved. Four packets, sufficient to prepare 4 liters.
7. Mounting media (Buffered Glycerol): Two, 3.0 mL, white-capped, dripper tipped vials.

Note: Kit also contains:
1. Component list containing lot specific information is inside the kit box.
2. Package insert providing instructions for use.

Materials required but not provided
1. Small serological, Pasteur, capillary, or automatic pipettes.
2. Disposable pipette tips.
3. Small test tubes, 13 x 100mm or comparable.
4. Test tube racks.
5. Staining dish. A large staining dish with a small magnetic mixing set-up provides an ideal mechanism for washing slides between incubation steps.
6. Cover slips, 24x60mm, thickness No. 1.
7. Distilled or deionized water.

PRECAUTIONS

1. For In Vitro Diagnostic Use.
2. Follow normal precautions exercised in handling laboratory reagents. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable protective clothing, gloves, and eye/face protection. Do not breathe vapor. Dispose of waste observing all local, state, and federal laws.
3. The wells of the Slide do not contain viable organisms. However, consider the Slide potentially bio-hazardous materials and handle accordingly.
4. The Controls are potentially bio-hazardous materials. Source materials from which these products were derived were found negative for HIV-1 antigen, HBsAg and for antibodies against HCV and HIV by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, these products should be handled at the Bio-safety Level 2 as recommended for any potentially infectious human serum or blood specimen in the Centers for Disease Control/National Institutes of Health manual “Biosafety in Microbiological and Biomedical Laboratories”; current edition; and OSHA’s Standard for Bloodborne Pathogens. Adherence to the specified time and temperature of incubations is essential for accurate results. All reagents must be allowed to reach room temperature (20 - 25°C) before starting the assay. Return unused reagents to their original containers immediately and follow storage requirements.

8. Properly equipped fluorescence microscope.
9. 1 Liter Graduated Cylinder.
10. Laboratory timer to monitor incubation steps.
11. Disposal basin and disinfectant (i.e. 10% household bleach – 0.5% Sodium Hypochlorite).
12. Incubation 35-37°C.
13. IgG Removal System (see Limitations of Procedure)
7. The Sample Diluent, Conjugate, and Controls contain Sodium Azide at a concentration of <0.1% (w/v). Sodium Azide is known to form lead or copper azides in laboratory plumbing which may cause explosions on hammering. To prevent, rinse sink thoroughly with water after disposing of solution containing Sodium Azide. This preservative may be toxic if ingested.

8. Dilution or adulteration of these reagents may generate erroneous results.

9. Never pipette by mouth. Avoid contact of reagents and patient specimens with skin and mucous membranes.

10. Avoid microbial contamination of reagents. Incorrect results may occur.

11. Cross contamination of reagents and/or samples could cause erroneous results.

12. Reusable glassware must be washed and thoroughly rinsed free of all detergents.

13. Avoid splashing or generation of aerosols.

14. Do not expose reagents to strong light during storage or incubation.

15. Allowing the slide packet to equilibrate to room temperature prior to opening the protective envelope will protect the wells and blotter from condensation.

16. Collect the wash solution in a disposal basin. Treat the waste solution with disinfectant (i.e.: 10% household bleach - 0.5% Sodium Hypochlorite). Avoid exposure of reagents to bleach fumes.

17. Do not expose any of the reactive reagents to bleach-containing solutions or to any strong odors from bleach-containing. Trace amounts of bleach (Sodium Hypochlorite) may destroy the biological activity of many of the reactive reagents within this Test System.

18. Do not apply pressure to slide envelope. This may damage the substrate.

19. The components of this Test System are matched from optimum sensitivity and reproducibility. Reagents from other manufacturers should not be interchangeable. Follow Package insert carefully.

20. Unopened/ opened components are stable until the expiration date printed on the label, provide the recommended storage conditions are strictly followed. Do not use beyond the expiration date. Do not freeze.

21. Evans Blue Counterstain is a potential carcinogen. If skin contact occurs, flush with water. Dispose of according to local regulations.

22. Assay reproducibility has not been established.

23. Depending upon lab conditions, it may be necessary to place slide in a moist chamber during incubations.

ASSAY PROCEDURE

1. Remove slides from storage and allow them to warm to room temperature (20-25°C). Tear open the protective envelope and remove slides. DO NOT APPLY PRESSURE TO FLAT SIDES OF PROTECTIVE ENVELOPE.

2. Identify each well with the appropriate patient sera and Controls. NOTE: The Controls are intended to be used undiluted.

3. Diluting Patient Sera:
   a. It is recommended that test sera are pre-treated to remove IgG. Precipitation with anti-human IgG is recommended because this procedure is effective in removing all subclasses of human IgG and is less cumbersome to perform than other methods. After the pretreatment step, test sera should be at a 1:10 screening dilution. (e.g.: 10µL of serum + 90 µL of Sample Diluent or PBS).
   b. If patient samples are to be titrated to endpoint, one should pre-treat the serum to remove IgG and then make any subsequent dilutions with Diluent. NOTE: The Diluent will undergo a color change confirming the combination of specimen with Diluent.
   c. As an option, users may titrate the Positive Control to endpoint to serve as a semi-quantitative (+1 Minimally Reactive) Control. In such cases, the Control should be diluted two-fold in Sample Diluent. When evaluated by DAI an endpoint dilution is established and printed on the Positive Control vial (± one dilution). It should be noted that due to variations within the laboratory (equipment, etc.), each laboratory should establish its own expected end-point titer for each lot of Positive Control.
   d. With suitable dispenser (listed above), dispense 20µL of each Control and each diluted patient sera in the appropriate wells.
   e. Incubate Slides at room temperature (35 - 37°C) for 60 ± 5 minutes.

4. Gently rinse Slides with PBS. Do not direct a stream of PBS into the test wells.

5. Wash Slides for two, 5 minutes intervals, changing PBS between washes.

6. Remove Slides from PBS. Rinse Slides briefly with distilled water and air dry Slides. Do not disturb the organism in the wells.

7. Add 20 µL of Conjugate to each well. Incubate Slides at 35-37°C for 30 ± 5 minutes.

8. Repeat steps 6 through 8.

9. Apply 3-5 drops of Mounting Media to each Slide (between the wells) and coverslip. Examine Slides immediately with an appropriate fluorescence microscope.

NOTE: If delay in examining Slides is anticipated, seal coverslip with clear nail polish and store in refrigerator. It is recommended that Slides be examined on the same day as testing.

RESULTS

<table>
<thead>
<tr>
<th>Titer</th>
<th>Clinical Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1:10</td>
<td>Negative: No detectable IgM antibody to T. gondii. A negative result indicates no primary or recent infection with T. gondii and implies that such individuals are presumed to be susceptible to primary infection. However, specimens taken too early during a primary infection may not have detectable levels of IgM antibody. If a primary infection is suspected, another specimen should be taken within 7 days to look for the presence of T. gondii specific IgM. If the second specimen is positive, a primary or recent infection with T. gondii is indicated. Alternatively, additional sera may be drawn 2-8 weeks later and analyzed for the presence of Toxo-specific IgG. The appearance of Toxo-specific IgG in a patient previously shown to be negative for T. gondii IgG indicates that a primary infection has occurred. A polar staining reaction is considered negative for specific antibody to T. gondii. Finally, it should be noted that a non-confluent or beaded fluorescent pattern is also considered negative for specific antibody to T. gondii.</td>
</tr>
<tr>
<td>&gt;1:10</td>
<td>Positive: Detectable IgM antibody to T. gondii. This indicates a primary or recent infection with T. gondii. Such individuals are presumed to be at risk of transmitting T. gondii infection.</td>
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</table>

<table>
<thead>
<tr>
<th>Anti-T. gondii IgM Result</th>
<th>Anti-T. gondii IgG Result</th>
<th>Report/Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>It is presumed the patient has not been infected with and is not undergoing an acute infection with T. gondii. If symptoms persist submit a new specimen within three weeks.</td>
</tr>
<tr>
<td>Negative</td>
<td>Positive</td>
<td>From this testing it cannot be determined whether the patient is or is not undergoing a reactivated T. gondii infection. It appears the patient has been previously infected with T. gondii. Infection occurred more than one year ago.</td>
</tr>
<tr>
<td>Negative</td>
<td>Equivocal</td>
<td>Obtain a new specimen for further testing. Patient may not be undergoing an acute infection with T. gondii. Determining whether the patient has been previously infected with T. gondii is not possible.</td>
</tr>
<tr>
<td>Equivocal</td>
<td>Negative</td>
<td>Obtain a new specimen for determination of IgM antibodies to T. gondii. It cannot be determined if the patient is undergoing an acute T. gondii infection. It appears the patient has not been previously infected with T. gondii. If the new specimen result is positive or equivocal for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.</td>
</tr>
<tr>
<td>Equivocal</td>
<td>Positive</td>
<td>Obtain a new specimen for determination of IgM antibodies to T. gondii. It cannot be determined if the patient is undergoing or has undergone an acute T. gondii infection. It appears the patient has been previously infected with T. gondii. If the new specimen result is equivocal or positive for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.</td>
</tr>
<tr>
<td>Equivocal</td>
<td>Equivocal</td>
<td>Obtain a new specimen for further testing. It cannot be determined if the patient is undergoing an acute infection or has been previously infected with T. gondii. If the new specimen result is equivocal or positive for IgM antibodies, the specimen should be sent to a reference laboratory with experience in the diagnosis of toxoplasmosis for further testing.</td>
</tr>
</tbody>
</table>
Since the IgG-Toxoplasma samples were clearly negative. One sample early negative for IgM was also confirmed negative by a commercial reference laboratory Toxo IgM capture ELISA. The new specimen should be retested on the DAI T. gondii IgM IFA Test System was compared to a commercially available IgM Capture ELISA for the detection of IgM antibodies to T. gondii. In this study, a total of 156 serum samples were evaluated. Twenty-six T. gondii IgM positive samples were obtained from a Toxoplasma Reference Lab, and 130 samples were from normal plasma donors from Southeastern United States. For all IgM IFA testing, IgG was removed IgG Removal Reagent. The presence of T. gondii-specific IgM in the samples from the reference laboratory was supported by the following information: positive by the Sabin-Feldman dye test, positive by reference laboratory Toxo IgM capture ELISA, and clinical diagnosis. Discrepant samples were evaluated using a commercial T. gondii IgM IFA test system. The results of these studies are summarized below:

**Table 1: DAI T. gondii IgM IFA Test System Initial Comparison to a Commercial Toxo IgM Capture ELISA.**

<table>
<thead>
<tr>
<th>Sample ID</th>
<th>DAI T. gondii IgM IFA</th>
<th>Commercial Toxo IgM IFA</th>
<th>Commercial* Toxo IgM IFA</th>
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<tbody>
<tr>
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<td>-</td>
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<tr>
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<tr>
<td>156</td>
<td>-</td>
<td>+</td>
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**2. Cross Reactivity:**

Studies were performed to assess interference in the test procedure by rheumatoid factor (RF), EBV-IgM, CMV-IgM, Rubella IgM, and antibodies to nuclear antigens (ANA). Nine samples containing EBV-IgM antibodies (IFA titer range = 1:10 to 1:5120), and 33 samples positive for RF by latex agglutination (titer range = 1:20 to 1:640) were negative when tested with the DAI T. gondii IgM IFA Test System. One sample, strongly positive for T. gondii IgG and Rheumatoid Factor (1:160) produced a low to mid-positive IgM result when tested with the DAI T. gondii IgM IFA Test System prior to IgG absorption. Following IgG absorption, the DAI T. gondii IgM IFA Test System result was clearly negative. Two samples positive for CMV-IgM antibody by DAI ELISA, and four samples positive for Rubella-IgM antibody by the DAI ELISA were tested on the DAI T. gondii IgM IFA Test System. All CMV samples, and three of the four Rubella samples were clearly negative. One Rubella IgM positive sample yielded a very weak (+) beaded fluorescent pattern. Finally, four samples exhibiting antibodies to nuclear antigens were tested on the DAI T. gondii IgM IFA Test System. All samples were clearly negative for Toxoplasma IgM, yet two samples did display a very weak non-specific fluorescent pattern. The results of the cross-reactivity investigation show that there exists little or no cross-reactivity with the DAI T. gondii IgM IFA Test System.
QUALITY CONTROL

1. Every time the assay is run, a Positive Control a Negative Control and a Buffer Control must be included.

2. It is recommended that one read the Positive and Negative Controls before evaluating test results. This will assist in establishing the references required to interpret the test sample. If Controls do not appear as described, results are invalid.

   a. **Negative Control** – Characterized by the absence of staining along the periphery of the substrate organism. The organisms will appear reddish, or dull green, with no yellow-green fluorescence. Use the reaction of the negative control serum as a guide for the interpretation of patient results.

   b. **Positive Control** - Characterized by confluent 1+ to 4+ apple-green fluorescent staining along the periphery of the organisms. A 1+ reaction is one that shows weak but distinct apple-green fluorescence and represents the endpoint reaction in a titration. A 4+ reaction is one that shows very strong apple-green staining at the periphery of the organisms.

3. Additional Controls may be tested according to guidelines or requirements of local, state, and/or federal regulations or accrediting organizations.

**NOTES:**
The intensity of the observed fluorescence may vary with the microscope and filter system used.

LIMITATIONS OF PROCEDURE

1. IgG antibodies, if present in the sample, may interfere with determination of IgM titers to the organism. High affinity IgG antibodies may preferentially bind to antigenic determinants leading to false negative IgM titers. Also, IgM rheumatoid factor may bind to the antigen specific IgG leading to false positive IgM titers. Both of these problems can be eliminated by removing IgG from the samples before testing for IgM. Several different methods of separating IgG have been used. These include gel filtration, absorption with protein A, ion exchange chromatography, precipitation of IgG with anti-human IgG serum, or the use of IgG Removal Reagent.

2. Results of the DAI T. gondii IgM IFA Test System are not by themselves diagnostic and should be interpreted in light of the patient's clinical condition and the results of other diagnostic procedures.

3. Samples taken too early during the course of a primary infection with T. gondii may not contain detectable levels of IgM-specific antibody. In some patients, IgM specific antibody results may revert to negative levels within three weeks after infection with T. gondii. Measurement of T. gondii-specific IgG antibodies may also be of some value in the serological assessment of these patients. With T. gondii. Measurement of T. gondii-specific IgG antibodies may also be of some value in the serological assessment of these patients.

4. T. gondii-specific IgM antibody may not be demonstrable in patients who are immunocompromised and in some patients with congenital toxoplasmosis.

5. Naturally occurring T. gondii-specific IgM antibodies, with or without the occurrence of IgG antibodies, have been reported. Neither the stimulus nor the significance of naturally occurring IgM antibodies directed against T. gondii is understood at this time.

6. Heterotypic IgM antibody responses may occur in patients infected with Epstein-Barr Virus and give false positive results on the DAI T. gondii IgM IFA Test System.

7. T. gondii-specific IgG antibody may compete with specific IgG for antibody binding and cause false negative results. Rheumatoid factor (IgM), if present with T. gondii-specific IgG, will cause false positive results. The absorbent incubation step will functionally remove greater than 99% of IgG from the test specimen and significantly reduce the possibility of false positive or negative results.

8. False positive anti-T. gondii results have been reported for patients having autoimmune disease.

9. The performance of the DAI T. gondii IgM IFA Test System has not been validated using neonatal samples.

10. A negative result for Toxo IgM does not preclude the possibility of an acute infection in the immunocompromised patient. T. gondii-specific IgG antibodies are generally low and T. gondii-specific IgM antibodies may be undetectable in patients who are immunocompromised.

11. Due to the apparent low prevalence of anti-T. gondii IgM in the United States the performance characteristics cited below may not be representative of the population at each users laboratory.

12. With very low prevalence analyses, such as anti-T. gondii IgM there is the increased possibility that a positive result is truly a false positive, reducing the assay’s positive predictive value.

EXPECTED VALUES

T. gondii-specific IgM antibodies rise sharply just before or shortly after onset of symptoms, and reach peak titers within one month. T. gondii-specific IgM falls to low levels in most patients within 4 to 6 months. In some patients, IgM-specific antibodies may be detectable for 8 months to one year. In a study conducted by DAI, 108 samples were tested for T. gondii IgM using the DAI T. gondii IgM IFA Test System. These samples (from Northeastern U.S.) were sent to a reference laboratory for routine Toxo serological analysis. Five of the 108 samples (4.6%) were reactive for T. gondii IgM. As with any serological method, the expected values are highly dependent upon the population type being tested. Each laboratory should establish their own expected values based upon the population type tested. As part of the clinical study, a group of 130 asymptomatic, ‘normal’ specimens were tested. A summary of this testing is shown in Table 3.

REFERENCES


STORAGE

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-8°C</td>
<td>Unopened Test System Mounting Media, Conjugate, Diluent, Slides, Positive and Negative Controls, Rehydrated PBS (Stable for 30 days)</td>
</tr>
<tr>
<td>2-25°C</td>
<td>Phosphate-buffered-saline (PBS) Packets</td>
</tr>
</tbody>
</table>

DAI CODE #2

ISO 13485
ISO 9001