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"See Now" Toxoplasma IgG/IgM Test
Serum/ Plasma/ Whole Blood
For in vitro Diagnosis Use
Product Code: SN 10.2

INTENDED USE
"See Now" *Toxoplasma gondii* (TOXO) Antibody Test is a colloidal gold-antibody complex immunoassay for *in vitro* qualitative determination of TOXO IgG and IgM antibodies in human serum, plasma or whole blood. It is intended for professional use as an aid in the diagnosis of Toxoplasmosis.
This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the results of the test.

SUMMARY OF TEST
Toxoplasma gondii is an obligate intracellular protozoan parasite with a worldwide distribution. Serological data indicates that approximately 30% of the population of most industrialized nations is chronically infected with the organism. A variety of serologic tests for antibodies to Toxoplasma gondii have been used as an aid in diagnosis of acute infection and to assess previous exposure to the organism. These tests are the Sabin-Feldman dye test, direct agglutination, indirect hemagglutination, latex agglutination, indirect immunofluorescence, and ELISA. Recently, lateral flow chromatographic immunoassay, such as the Toxo IgM/IgG rapid test (Whole blood/Serum/Plasma) was introduced into the clinic for the serodiagnosis of Toxoplasma gondii infection. **See Now** TOXO IgG/IgM Test is a simple, visual qualitative test that detects TOXO antibodies in human Whole Blood/serum/plasma.

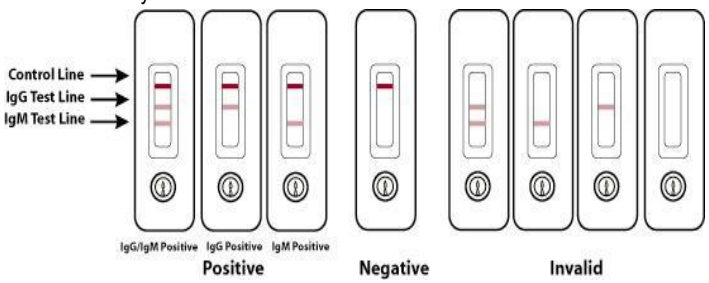
Materials Provided
Pouch Contents: Cassette, Sample Dropper, Desiccant, Test instruction, buffer bottle.

Materials needed but not provided
- Clean, specimen collection container.
- Clock or timer.

SPECIMEN COLLECTION & PREPARATION
- Collect blood in a tube without anticoagulant for serum samples and allow to clot.
- For whole blood / plasma samples, collect the blood in a tube containing anticoagulant.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

TEST PROCEDURE
1. Remove the testing device from the sealed pouch by tearing at the notch. Then place the testing device on a leveled surface.
2. Holding the sample dropper vertically add one drop **10µL** of specimen into the sample well, then using buffer bottle add 2 drops, around **80µL,** of buffer.
3. Read the result at 15 minutes. Ensure that the background of the test area is white before interpreting the result.

INTERPRETATION OF RESULTS
Negative: Only one pink color band appears on the control region. There is no apparent color band on the test region.
Positive: Distinct pink color bands appear at the control and either/both IgG and IgM test line regions.
Invalid: A total absence of color in both regions and no colored line appears in the control (C) region is an indication of procedure error and/or test reagent deterioration. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



LIMITATIONS
This product is designed for in vitro diagnostic use only.
There is always a possibility that false results will occur due to factors beyond the control of the manufacturer, such as technical or procedural errors associated with the testing.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.

STORAGE AND STABILITY
The test kit can be stored at temperatures between 4 to 30ºC in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiry date.
3. The test device should not be reused.
4. *The instructions for use and reading of the test must be followed exactly in order for the test to perform properly.*
5. *Standard guidelines for handling infection agents and chemical reagents should be observed throughout all procedures.*

Performance Characteristics
IgG Results

Method		*T.Gondii* EIA (IgG)		Total Results
Toxo IgG/IgM Rapid Test Cassette for IgG	Results	Positive	Negative	
	Positive	63	3	66
	Negative	4	298	302
Total Results		67	301	368

Relative Sensitivity: >95.4%
Relative Specificity: >98.6%
Accuracy: 97.82%

IgM Results

Method		*T.Gondii* EIA (IgM)		Total Results
Toxo IgG/IgM Rapid Test Cassette for IgM	Results	Positive	Negative	
	Positive	80	1	81
	Negative	1	199	200
Total Results		81	200	281

Relative Sensitivity: > 98.7%
Relative Specificity: > 99.5%
Accuracy: 99.28%