IVD TECHNOLOGIES

Toxoplasma gondii Antibody Test Kit

FOR DETECTION OF TOXOPLASMA GONDII ANTIBODY IN SERUM OR PLASMA

Product Number: TOXG-1000

ALL SPECIES TOXO

INTENDED USE

The Toxoplasma gondii Antibody Test Kit is used for the detection of Toxoplasma gondii antibodies in serum or plasma.

ANALYTICAL PRINCIPLE

Toxoplasma gondii specific antibodies in serum or plasma samples and HRP Conjugate are allowed to complex on a Toxoplasma gondii antigen coated microwell. After washing unbound materials, TMB is allowed to react with HRP-Conjugate. The reaction is read. If color is produced, then Toxoplasma gondii antibodies are present in the sample.

SPECIMEN REQUIREMENTS

Serum and plasma samples are acceptable. Avoid repetitive freezing and thawing of samples.

REAGENTS

Precautions & Safety Notes

- WEAR LATEX GLOVES, FACE SHIELDS AND A LAB COAT WHEN HANDLING SPECIMENS AND OTHER HAZARDOUS REAGENTS
- FOR *IN VITRO* USE, POTENTIAL BIOHAZARDOUS MATERIAL. HANDLE ASSAY REAGENTS AS IF CAPABLE OF TRANSMITTING AN INFECTIOUS AGENT.
- The Negative Control, Positive Control, Wash Buffer, and HRP-Conjugate contain 0.1% ProClin 150. Avoid contact of these reagents with skin or eyes.

Kit Components

ID	Reagent	Part Number	Quantity
	Toxoplasma gondii Antibody Test Kit	**TOXG-1000**	**96 Test**
A	HRP Conjugate [Contains: HRP Conjugate]	**TOXG-1001**	**10 ml**
B	Negative Control [Contains: Normal Feline Serum, 0.1% ProClin 150] See QC Certificate for value	**TOXG-1002**	**200 µl**
C	Positive Control [Contains: Feline Serum Positive for Toxoplasma gondii, 0.1% ProClin 150] See QC Certificate for value	**TOXG-1003**	**200 µl**
D	Toxo Microwell Plate [Contains: Toxoplasma gondii Antigen]	**TOXG-1004**	**96 Well Plate**
WBC	20X Wash Buffer Concentrate [Contains: Tris Buffer, 0.01% Tween-20, NaCl, 0.1% ProClin 150]	**WBFEA-1002**	**25 ml**
TS	TMB Solution [Contains TMB] Keep away from light	**TMBS-1001**	**10 ml**
SS	Stop Solution [Contains: 1N Sulfuric Acid]	**SSFEA-1001**	**10 ml**

MATERIALS

The following materials are needed but not supplied.

- Purified Water

PROCEDURE PRECAUTIONS

- Bring reagents to room temperature before use.
- Use clean instruments & equipments.
- Handle microwells with care.
- Minimize air bubbles in microwells.
- Microwells should not contain liquid after each wash.

REAGENT PREPARATION

1X Wash Buffer Preparation

1. Add 1 unit of volume of 20X Wash Buffer Concentrate (**WBC**) to 19 units of volume of purified water. For example, add **25 mL** 20X Wash Buffer Concentrate (**WBC**) to **475 mL** of purified water.
2. Mix the Wash Buffer Preparation well.

PROCEDURE

1. Dispense **30 µl** of samples, Negative Control (**B**), and Positive Control (**C**) into the assigned microwells.
2. Add **100 µl** of HRP Conjugate (**A**) into the microwells.
3. Incubate the microwells for **10 minutes** at **room temperature**.
4. Wash the microwells **3 times** with at least **300 µl** of **1X Wash Buffer Preparation.**
5. Dispense **100 µl** of TMB Solution (**TS**) into the microwells.
6. Incubate the microwells for **15 minutes away from light** and at **room temperature**.
7. Add **100µl** of Stop Solution (**SS**) into the microwells.
8. Read the microwells with a microplate reader at 450 nm.

Normal Sample Study

One-hundred-and-fifty-five (155) dog and cat samples were assayed. Ninety-four (94) and 25 samples were found to be negative and positive, respectively. The OD of the negative samples was found to be < 0.1. The OD of the positive samples was found to be >0.1.

S/N Ratio Evaluation of Controls and Samples

The controls and samples are evaluated with a microplate reader. The OD of the controls and samples at 450 nm is used to calculate a Sample to Negative Ratio. The Sample to Negative Ratio is used to evaluate the controls and samples. The OD of the Negative Control is multiplied by 2.5 to attain the Cutoff Value. The OD of a sample is divided by the Cutoff Value to attain the Sample to Negative Ratio. If the Sample to Negative Ratio of a sample is < 1.0, then it is negative; if it is > 1.0, then it is positive. The Positive Control is evaluated using the same calculation – by dividing the OD of the Positive Control by the Cutoff Value.

Sample to Negative Ratio Calculation

a. Cutoff Value =
(Negative Control O.D. x 2.5)

b. Sample to Negative Ratio of Samples =
(Sample O.D. / Cutoff Value)

Sample to Negative Ratio Table

Sample to Negative Ratio	Interpretation
< 1.0	Negative
≥ 1.0	Positive

CORRELATION ANALYSIS

Feline Correlation Study

One-hundred and ten (110) cat samples were assayed for the Toxoplasma gondii IgG antibody using IVD Technologies' Toxoplasma gondii Antibody Test Kit and a reference laboratory. Both laboratories found 85 samples to be negative and 24 samples to be positive. One (1) sample was found to be positive by IVD Technologies' kit and negative by the reference laboratory. The IVD Technologies' Kit is ELISA based. The reference laboratory used the IFA method.

Feline Correlation Analysis Table

		Reference Laboratory	
		Positive	Negative
IVD Tech.	Positive	24	1
	Negative		85
	Total	**24**	**86**

Canine Correlation Study

Eighty-seven (87) dog samples were assayed for the Toxoplasma gondii IgG antibody using IVD Technologies' Toxoplasma gondii Antibody Test Kit and a reference laboratory. Both laboratories found 67 samples to be negative and 18 samples to be positive. Two (2) samples were found to be positive by IVD Technologies' kit and negative by the reference laboratory. The IVD Technologies' Kit is ELISA based. The reference laboratory used the IFA method.

Canine Correlation Analysis Table

		Reference Laboratory	
		Positive	Negative
IVD Tech.	Positive	18	2
	Negative		67
	Total	**18**	**69**

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