【Product Name】

Toxoplasma (TOX) PCR Detection Kit

【Packing Specification】

10 Tests/Box

【Intended Use】

This kit is used for the qualitative detection of the Toxoplasma gene in samples, assisting in the diagnosis of infection.

【Principles of Testing】

This kit uses real-time fluorescence PCR technology, specific primers and fluorescent probes are designed targeting specific fragments of the Toxoplasma gene. An exogenous internal control is added to the reagent to monitor the entire detection process.

【Product Composition】

Number	Component	Specification
1	Test reagent	10 portions
2	Sample processing solution	10 tubes (1.5 mL/tube)
3	Self-suction dropper	20 pieces
4	Conical tube	10 pieces

【Storage】

1.Storage Conditions: 2°C~30°C, avoid light, and avoid heavy pressure.

2.Product Shelf Life: 24 months.

【Testing Instrument】

The Real-time PCR analyzer produced by Tianjin MNCHIP Technologies Co., Ltd.

【Sample Requirements】

The required sample usage is EDTA whole blood

【Procedure】

1. Sample Collection

(1) Collect whole blood into an EDTA anticoagulant tube, immediately invert slowly 8-10 times.

(2) Take out the sample processing liquid and a conical tube. Invert the conical tube with the tip downwards, puncture the membrane of the sample processing liquid tube, and set aside for later use.

2. Sample Processing※

(1) Sample aspiration：

Take a self-suction dropper, handle it gently at the top without pressing the bulb. Insert the pipette into the anticoagulant tube containing the blood sample until the black graduation line aligns with the liquid level. Hold for 3 seconds, then slowly withdraw.

※ Approximately 20 μl of sample volume should be aspirated, ensuring the liquid volume is not above or below 1/4 of the black graduation line of the pipette. A contamination-free pipettor can also be used to aspirate the sample (20 μl).

※ If excess processing liquid is inadvertently aspirated, completely expel the liquid from the pipette before reaspirating.

(2) Sample dilution：

Prepare the opened sample processing liquid. Squeeze the bulb at the top of the self-suction dropper and transfer all the sample from the pipette into the sample processing liquid. Discard the used pipette. Combine the tip of the conical tube with the sample processing liquid tube, mix slowly, and try to avoid spillage.

3. Reagent Preparation

Take out the PCR reaction tube containing the test reagent and set it aside. Do not open the tube cap.

4. Sample transfer※

Open the PCR reaction tube lid and use a new self-suction dropper. Repeat step 2(1)：Aspirate the sample from the sample processing liquid tube, squeeze the top bulb, transfer all the liquid into the PCR reaction tube. Close the cap tightly, vortex the tube twice for 10 seconds each time to ensure the reagent is fully dissolved. Gently flick the tube to remove any bubbles, then briefly centrifuge it.

※ Be careful to avoid dislodging the lyophilized bead inside the tube during the operation.

5. PCR Amplification

Place the reaction tube into a fluorescence quantitative PCR analyzer, record the addition sequence, and perform PCR amplification.

6. Sample Storage

Store at 2-8°C for no more than 3 days or at -20°C for no more than 1 month, avoiding repeated freeze-thaw cycles.

【Result Interpretation】

Toxoplasma Ct	Internal Control Ct	Result Interpretation
≤36	≤36	Positive
	>36 or NoCt[*1]	
>36 or NoCt	≤36	Negative
>36 or NoCt	>36 or NoCt	Suggest retesting [*2]

*1: When the pathogen concentration in the sample is high, due to competitive relationships, the internal control may report negative.

*2: When Toxoplasma is negative, if the internal control result is also negative, it indicates strong inhibition or operational error in the sample. It is recommended to mix 200 μL of sample processing liquid with 200 μL of sterile water, then retest according to steps 3 and 4 of the operation procedure.

【Limitations of Procedure】

1. Aerosol contamination of amplification products can lead to false positives, requiring segmented operations during testing experiments.
2. Negative results cannot completely rule out the possibility of pathogen infection; judgment should be made in conjunction with other clinical indicators.
3. The metabolic status of pathogens changes with the progression of the disease, leading to potential variations in the detection results of samples from different stages.

【Performance Indicators】

1. Limit of Detection: $3*10^3$ copies/mL
2. Precision: The same precision reference sample was tested over 5 days by 2 operators using 3 different reagent lots. The within-run and between-run precision, within-day and between-day precision, as well as within-operator and between-operator precision, all have coefficients of variation (CVs) not exceeding 5%.
3. Internal Positive Reference Sample Concordance Rate: The concordance rate for 10 positive reference samples is 100%.
4. Internal Negative Reference Sample Concordance Rate: The concordance rate for 10 negative reference samples is 100%.
5. Specificity: There is no cross-reactivity with the pathogens listed in the table below.

Cross-reactivity	
Leishmania donovani	Leishmania major

Leishmania infantum	Leishmania braziliensis
Borrelia burgdorferi	Borrelia garinii
Borrelia afzelii	Babesia canis
Babesia gibsoni	

【Notes】

1. Carefully read the instructions before starting the test and operate as required.

2. Do not cross-use items between zones to avoid contamination caused by human factors.

3. Errors in sample collection, storage, transportation conditions, and operational procedures may affect test results.

4. Replace self-suction pipettes when drawing different samples.

5. After adding samples, tightly cover the tube cap, thoroughly mix using a vortex mixer, gently tap the tube wall to remove air bubbles. Inadequate mixing may pose risks of false negatives or false positives.

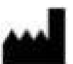
6. After the reaction is complete, the reaction tubes and other contaminants must be disposed of in accordance with local regulations.

7. Do not use expired products; reagents from different batches should not be mixed or interchanged.

【Symbols Used in Labelling】

Symbol	Explanation
Veterinary	Veterinary use only
	Manufacturer
	Use-by date
LOT	Batch code
	Date of manufacture
	Consult instructions for use
2℃ 30℃	Limit of temperature
	Do not re-use

【Manufacturer】



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