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Leishmania Diagnostic Kit

Uranotest

For veterinary use only

Technical basis

The URANOTEST Leishmania diagnostic kit is based on the immuno-chromatographic technique and is designed for the qualitative detection of antibodies for *Leishmania infantum* in whole blood, serum and plasma.
The test consists of several overlapped membranes. On one of the membranes, there are a test line (T line) and control line (C line). The lines are not visible before applying the sample. After applying the sample in the appropriate sample well, migration begins by capillarity action through the membrane. If the result is negative, one purple colour band appears in the C area. This line, called control line, always appears, as it is a control line indicating that the test has successfully performed. If the test result is positive, in addition to the control line, a second line will form in the test area (Test line).

Materials supplied

1 - Test devices individually packaged in aluminium pouch.
2 - Dropper bottle with buffer solution.
3 - Disposable capillary pipettes for sample collection. The dark band present in the capillary indicates the volume needed to run the test.

4 - Vials with anticoagulant (EDTA) for blood collection..
5 - Instructions for use.

Precautions

1 - For veterinary use only.
2 - Wear disposable gloves when handling the samples. All samples should be treated as potentially infectious. Wash and disinfect hands after handling. Avoid aerosol formation when dispensing the sample.
3 - To obtain good results, it is important to add the correct sample volume.
4 - Open the device just before use.
5 - All reagents must be at room temperature before performing the test.
6 - Do not use the test if the envelope is damaged or broken.
7 - Do not re-use.
8 - Do not use reagents after the expiry date.
9 - The quality of each component of the kit has been individually assessed for each batch. Do not mix components or reagents from kits with different batch numbers.

Preservation and stability

The kit must be stored at a temperature between 2 and 30ºC. Under these conditions, we can guarantee the stability until the expiry date printed on the box and on the individual pouch.

The kit has been developed to be stored at room temperature. Although it also can be stored in the refrigerator, we recommend store it at room temperature to avoid the need to wait for reagents to reach the room temperature.

DO NOT FREEZE. Do not exposure to direct sunlight.

Sample collection and preparation

The test can be performed with serum, plasma or whole blood (treated with anticoagulant).

WHOLE BLOOD
Take a sample of blood using traditional clinical methods in a tube containing anticoagulant (heparin, EDTA or citrate). The kit includes EDTA tubes; however, any of the aforementioned anticoagulants can be used.

The blood should be analysed within 4 hours after extraction. If is not possible, it can be kept cold between 2 and 8 ºC for no more than 24 hours. Do not freeze.
Haemolysed samples may affect the results.

PLASMA
Take a sample of blood using traditional clinical methods in a tube containing anticoagulant (heparin, EDTA or citrate).
Separate the plasma by centrifugation. The plasma can be kept refrigerated at a temperature between 2 and 8ºC up to 72 hours. For conservation over a longer period, it should be frozen under -20ºC.
If the sample has been refrigerated, wait for it to reach room temperature before testing.

SERUM
Take a sample of blood using traditional clinical methods in a tube without anticoagulant.
Separate the serum by centrifugation. The serum can be kept refrigerated at a temperature between 2 and 8ºC up to 72 hours. For conservation over a longer period, it should be frozen under -20ºC.
If the sample has been refrigerated, wait for it to reach room temperature before testing.

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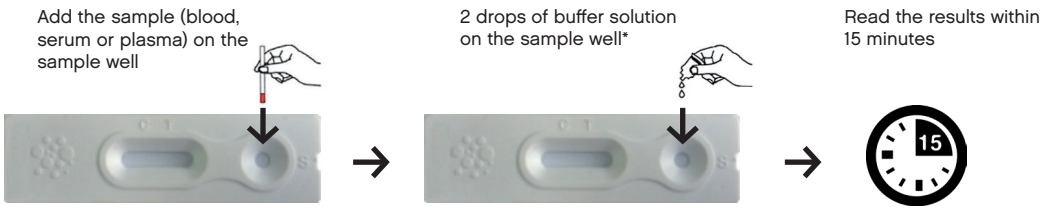
Instructions for use

1 - Remove the test device from the protective pouch and place it on a flat and dry surface.
2 - Take the sample with the capillary by pressing below the flattened end. When you stop pressing it, the volume will reach the black line marked at the end.
3 - Add the amount provided by the capillary on the sample well.
4 - Add **2 drops of buffer solution** on the sample well (*Developing buffer*)*.
5 - **Read the results within 15 minutes**. After this time, the result is not valid.



*If the migration of the sample has not occurred in 1 minute, add 1 extra drop of buffer solution.

Interpreting results

1 - Negative result
There is only a single purple line on the C area. This line should always appear.

2 - Positive result
Two lines appear on the result window. Whichever line appears first, the result is considered positive.

3 - Invalid result
The test is invalid if not coloured line appears at the Control area (C) even if a coloured line appears in the Test area (T). The reason may be due to incorrect handling or using a damaged test.

Limitations of the technique

Even though the URANOTEST Leishmania diagnostic kit shows high sensitivity and specificity, cannot be excluded a low incidence of false positive or negative results.

As any other laboratory procedure, the definitive clinical diagnosis cannot be based only on the test result. It must be based on an ensemble of clinical and laboratory procedures. If there is any doubt, repeat the test and/or contrast with other diagnostic methods.

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