

Technical basis

The URANOTEST Ehrlichia-Anaplasma diagnostic kit is based on the immunochromatographic technique and is designed for the qualitative detection of antibodies for *Ehrlichia canis* and *Anaplasma platys* in whole blood, serum and plasma.

The test has a double structure; it contains two single tests: a strip for Ehrlichia antibody detection and a strip for Anaplasma antibody detection.

Each 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 - Do not use kits with different batch numbers.
- 10 - 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 30°C. 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 °C 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 8°C up to 72 hours. For conservation over a longer period, it should be frozen under -20°C. 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 8°C up to 72 hours. For conservation over a longer period, it should be frozen under -20°C. If the sample has been refrigerated, wait for it to reach room temperature before testing.

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 Ehrlichia sample well.

- 4 - Add **2 drops of buffer solution** on the Ehrlichia sample well (*Developing buffer*)*.
- 5 - Repeat exactly the same procedure for the Anaplasma sample well.
- 6 - **Read the results within 15 minutes.** After this time, the result is not valid.

Add the sample (blood, serum or plasma) on each well

2 drops of buffer solution on each well*

Read the results within 15 minutes



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

Interpreting results

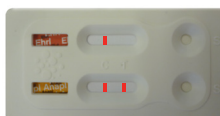
1 - Negative result

There is only a single purple line on the C area, both in the Ehrlichia test and in the Anaplasma test. This line should always appear.



4 - Positive result for Anaplasma

Two lines appear on the result window of the Anaplasma test (T and C lines), but only a single line appears on the result window of Ehrlichia test (C line).



2 - Positive result for Ehrlichia canis and Anaplasma plays simultaneously

Two lines appear on both result windows. The test is positive to Ehrlichia when two lines appear on the result window (T and C line). In the same way, the test is positive to Anaplasma when two lines appear on the result window of the Anaplasma test device. Whichever line appears first, the result is -considered positive.



5 - 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.



3 - Positive result for Ehrlichia

Two lines appear on the result window of the Ehrlichia test (T and C lines), but only a single line appears on the result window of Anaplasma test (C line).



Limitations of the technique

Even though the URANOTEST Ehrlichia-Anaplasma 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.