



For Veterinary Use Only

Asan Easy Test[®] Heartworm

Canine Heartworm Virus Antigen (CHW Ag) Test | 林特睿检[™]犬心丝虫抗原快速诊断试纸

Immunochromatography



EXPLANATION OF THE TEST

Asan Easy Test[®] Heartworm is a chromatographic immunoassay kit for rapid and qualitative detection of dirofilariasis antigen in canine whole blood, serum or plasma. A nitrocellulose membrane is immobilized with antibody against the D. immitis antigen. Another anti-D. immitis antibody is conjugated to colloidal gold particles. This conjugate is placed on a polyester pad as a conjugate pad. This test is aimed to the detection of D. immitis antigen in the blood. When the device is loaded with assay solution containing blood specimens, the solubilized conjugate migrates with the specimens by passive diffusion and both the conjugate and sample come into contact with the anti-D. immitis antibody that it adsorbed onto the nitrocellulose. The result is visible within 10 minutes in the form of a red or purple line on the test line (T) region of the device. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line on the control line (C) area.

MATERIALS PROVIDED

- Asan Easy Test[®] Heartworm contains the following components : (20Tests/Kit)
 1. Test devices individually foil-pouched with a desiccant : 20units
 2. Assay solution (5ml/bottle) : 1unit
 3. EDTA Tube : 20units
 4. Disposable dropper : 20units
 5. Instruction manual for use : 1sheet

PRECAUTIONS

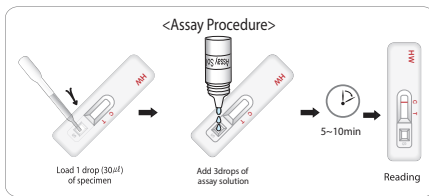
1. The presence of humidity may decrease the stability of the reagents. Thus, please carry out the test immediately after removing the device from the foil pouch.
2. Do not use the kit after the expiration date and do not freeze the kit.
3. For veterinary use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the specimens and kits properly after test, in accordance with GLP.
6. Never use reagents from another kit.
7. Discard the Assay solution if it is contaminated with bacteria or mold.

SPECIMEN COLLECTION AND STORAGE

1. Specimen to be tested should be obtained and handled by standard methods for the collection of blood from canine.
 - A. Serum : Allow the blood to clot, then centrifuge to separate the serum.
 - B. Plasma : Collect the whole blood into the tube contained anticoagulants such as heparin, citrate, or EDTA. Centrifuge the blood and separate the plasma.
 - C. Whole blood : Collect an anticoagulated blood sample in EDTA, heparin or citrate using standard clinical laboratory procedures. Anticoagulated whole blood samples should be tested within 24 hours of drawing. If delays are expected between sampling and testing, the sample should be stored refrigerated (2~8°C), but should not be frozen.
2. Serum and plasma should be tested as soon as they are prepared. If necessary, they may be stored at 2~8°C for up to 24 hours or at -20°C for longer periods.

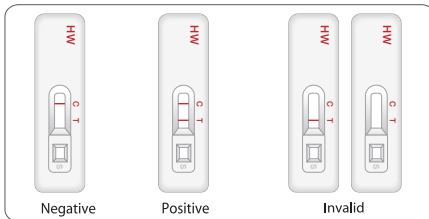
TEST PROCEDURE

1. Place all specimens, test devices, and allow them to room temperature prior to testing (15~30 min).
2. Remove the test device from the sealed pouch, and place it on a clean and flat place.
3. Take the blood sample (whole blood, serum or plasma) and load 1 drop (approx. 30µl) of the sample into sample well (S) of the device.
4. Hold the assay solution bottle vertically, add 3 drops of the solution into sample well (S) of the device.
5. Within 10 minutes, interpret the test result(s). Do not read the result after 10 minutes. Strong positive results may appear sooner.



INTERPRETATION OF THE RESULTS

1. Negative result : ONLY one band in the control line (C).
2. Positive result : Two bands are appeared in the test line (T) and control line(C).
3. Invalid result : If at 10 minutes, the red color band does not appear in the control line, even if any shade of a pink-to-red test line appears, the result is considered invalid. If the test is invalid, a new test should be performed with a new sample and a new test device.



STORAGE & EXPIRATION

1. Asan Easy Test[®] Heartworm kit should be stored between 2 to 30°C (36-86°F).
2. Expiration date of this kit is 24 months after its manufacture date.



LIMITATIONS OF THE TEST

Asan Easy Test[®] Heartworm is designed for primary screening test of canine heartworm antigen (Dirofilaria immitis antigen). This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and veterinarian's view, collectively.

产品概述及原理

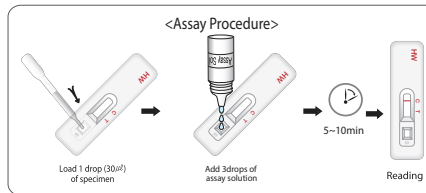
林特睿检[™]犬心丝虫抗原快速诊断试纸能够利用免疫层析法，快速检测犬血清、血浆、血液中的犬心丝虫抗原。检测原理：硝基纤维素膜的检测线 (T) 上固定有CHW的特异性抗体，且胶体金颗粒中含有另一种CHW的特异性抗体。胶体金颗粒与检测样品中CHW抗原进行第一次反应，形成抗原-抗体复合物，随着抗原抗体复合物以毛细作用向检测线 (T) 移动，与检测线 (T) 中另一种CHW的特异性抗体进行第二次抗原-抗体反应，并呈现紫红色，由此判断结果。

特征

1. 本产品只需一步便可检测CHW；
2. 本产品不需要特别的仪器，可以快速简便的进行现场检测；
3. 本产品利用高纯度原料及高品质材料，具有高特异性和敏感性；

使用方法

1. 检测物：犬的血清、血浆或血液；
2. 打开包装取出试纸，将它平放于宽敞和干燥的表面；
3. 使用提供的一次滴管吸取样品，并向样品孔缓慢且准确的加入1滴 (30µl)；
4. 之后将样品展开液，向样品孔缓慢且准确的加入3滴 (90~100µl)；
5. 当反应进行时，可看到紫红色的条带在试纸中间的反应窗中移动；
6. 10分钟的时候读取结果；
7. 检测限：5ng/ml



注意事项

1. 仅供兽医诊断使用；
2. 为了得到最佳的结果，请严格按照使用说明来操作；
3. 所有的样品必须当作具有潜在传染性来处理；
4. 在使用试纸以前请不要随便打开；
5. 如果试纸的包装袋封口有损坏请不要使用；
6. 不要使用用过的试纸；
7. 在反应之前所有的反应物必须处于室温状态；
8. 不要使用超过标签上有效期的试纸；
9. 每一批试纸中的组分经过质量控制的测试，请不要混用不同批号的试剂；
10. 收集样品后必须立刻进行测试；

结果判断

本产品通过检测线和对照线是否显色，来判断结果。无论检测样品中是否有CHW抗原，对照线 (C) 都会显色。如不显色要考虑到操作是否有误，或产品是否存在问题，应使用新的检测试剂重新检测。检测线 (T) 是否显色，用来判断检测样品中是否含有CHW抗原。

- 1) 阴性结果
对照线 (C) 显色，而检测线 (T) 不显色时判断为阴性。
如图所示



- 2) 阳性结果
对照线 (C) 与检测线 (T) 都显色时判断为阳性。
如图所示



- 3) 无效结果
对照线 (C) 与检测线 (T) 都不显色，或仅有检测线 (T) 显色，对照线 (C) 不显色时判断为无效结果。
如图所示



—检测线 (T) 处紫红色线条的颜色深浅直接与检测物多少相关。当检测物含量很高时，检测线 (T) 处的线条可能在出现后，紫红色又慢慢变淡，甚至消失。这时建议将样品稀释10倍后再进行检测，紫红色线条就可以稳定了。

判定结果时注意事项

即使林特睿检[™]试纸能极为精确地检测CHW抗原，但是也会发生极低的假阳性及假阴性。故需要将检测结果、临床症状相结合，并根据医师的经验进行综合性的判断。

保存及有效期

室温 (2-30°C) 密封保存，不可冷冻。生产日期起24个月有效。



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REF Code No.: 22301,22305

Document Code: ACHW00-S0E00

ISO13485:2003