Asan Easy Test® Distemper



EXPLANATION OF THE TEST

Asan Easy Test® Distemper is a chromatographic immunoassay kit for rapid and qualitative detection of body secretions of dog. A nitrocellulose membrane is immobilized with monoclonal antibody against the CDV antigen. Another anti-CDV Ag-monoclonal 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 CDV antigen either in canine body secretions or in virus-cultured supernatant. When the device is loaded with assay buffer containing blood specimen, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and specimen come into contact with the anti-CDV Ag 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) area 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® Distemper contains the following components

- 1. Test device individually foil-pouched with a desiccant
- 2. Assay solution in tube(0.5 ml/tube)
- 3. Disposable dropper
- 4. Sterilized swab
- 5. Instruction manual for use

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. The test should be performed using canine secretion of eye mucus (in the conjunctiva) or nasal discharge.
- 2. Specimen to be tested should be obtained and handled by standard methods for the collection of body secretions.
- 3. After collecting the specimen using swab, all the specimens should be immediately extracted and tested. If necessary, they may be stored at 2~8 ℃ for up to 48hours or at -20 ℃ for longer periods.

© TEST PROCEDURE

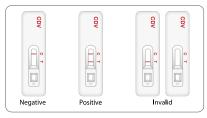
- 1. Place all specimens, test devices, and allow them to room temperature prior to testing (15~30 min).
- 2. Remove the test device from the sealed pouch, and place it on a clean and plain place.
- 3. Take a portion of secretion of eye mucus or nasal discharge, using a sterilized swab.
- 4. Insert and mix the swab with assay solution in a tube until the specimens has been dissolved. Then, discard the swab and repeat procedure for each sample.
- 5. Add 3~4 drops(approx. $100 \mu l$) of the solution taken by the disposable dropper into the sample well.

6. Interpret the test result(s) within 5~10 minutes. Do not read the result after 10 minutes.



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® Distemper kit should be stored between 2 to 30 $^{\circ}\mathrm{C}$ (35.6-86 $^{\circ}\mathrm{F}$). $^{2\mathrm{C}}$



2. Expiration date of this kit is 24 months after its manufacture date.

© LIMITATION OF THE TEST

Asan Easy Test® Distemper is designed for primary screening test of canine distemper virus 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.





林特睿检™犬瘟热抗原快速诊断试纸

Immunochromatography

atography

●产品概述及原理

林特睿检[™]犬瘟热抗原快速诊断试纸能够利用免疫层析法,快速地检测犬眼内分泌物(眼结膜上)、 鼻液、唾液中的犬瘟热病毒抗原。

检测原理: 硝基纤维薄膜的检测线(T)上固定有CDV的特异性抗体。且胶体金颗粒中含有另一种CDV的特异性抗体。胶体金颗粒与检测样品中CDV抗原进行第一次反应,形成抗原-抗体复合体,随着抗原抗体复合体以毛细作用向检测线(T)移动,与检测线(T)中另一种CDV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。

◎提供的材料

林特睿检™犬瘟热病毒检测试纸条内包含以下材料:

- 1. 铝箔袋内装检测试纸条和干燥剂
- 2. 瓶装检体稀释液
- 3. 一次性滴管
- 4. 消毒棉签
- 5. 使用说明书

◎ 注意事项

- 1. 试纸板对外界的温度和湿度都敏感,因此请于 检测前15-30分钟内将试 纸板放置于室温,且 试纸板从铝箔袋中取出后请立即使用。
- 请不要使用超过保质期的试纸,且禁止冷冻试 剂盒。
- 3. 本试纸条为兽医专用,且仅用于体外检测。
- 4. 所有的待测样本都应该被视为潜在感染源,所以当处理样本时,请带好防护手套,检测后立即将手清洗干净。
- 5. 请按照实验室规定处理检测后的样本和试纸条。
- 6. 请勿混用不同批次的缓冲液,且禁止重复使用 试纸板。
- 7. 禁止使用被细菌或霉菌污染的缓冲液。

◎样本采集及保存

- 1. 本试纸条以犬眼睛分泌物及鼻液为检测样本。
- 2. 用于检测的样本应根据样本采集方法进行操作。
- 3. 采集样本后应尽快用于检测,如果不能立即进 行检测,可在2-8℃下最长保存48小时,如果需 要保存更长时间,请置于-20℃进行冷冻保存。

◉使用方法

- 用棉签收集犬眼内分泌物(眼结膜上)、鼻液、唾液及尿液;
- 2. 使棉签上的样品和缓冲液充分混匀;
- 3. 打开包装取出试纸,将它平放于宽敞和干燥的 表面;
- 4. 使用提供的一次性滴管,吸取混匀的样品上清液:
- 5. 用滴管向样品孔中缓慢且精确地加入3~4滴混合液,缓冲液必须准确地、缓慢地、一滴一滴地加入;
- 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;
- 7.5-10分钟内读取结果,10分钟后的结果视为无效;
- 8. 检测限: 102.3TCID50/ml



◎ 结果判断

本产品通过检测线与对照线是否显色来判断结果。无论检测样品中有无CDV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CDV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。

◎ 保存及有效期

室温(2-30℃)密封保存,不可冷冻。生产日期起24个月有效。

◎ 检测的局限性

林特睿检™Distemper检测试纸条是用来初步判断犬瘟热病毒抗原。本检测方法可以提供一个快速且简单的方法得到结果,但是不能完全排除由于各种因素造成的假阳性和假阴性。因此,本结果仅作参考,兽医师需要结合临床症状和其他的检测结果综合判断来确诊。

ISO13485:2003