



For Veterinary Use Only

Asan Easy Test[®] CCV Ag

Canine Coronavirus Antigen (CCV Ag) Test | 林特睿检™犬冠状病毒检测试纸条

Immuno chromatography



EXPLANATION OF THE TEST

Asan Easy Test[®] CCV Ag is a chromatographic immunoassay kit for rapid and qualitative detection of canine coronavirus (CCV) infection from stool specimen of dog. A nitrocellulose membrane is immobilized with a monoclonal antibody against the CCV antigen. Another anti-CCV 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 CCV antigen either in stool (feces) or in virus-cultured supernatant. When the device is loaded with assay buffer containing specimens, the solubilized conjugate migrates with the sample by passive diffusion and both the conjugate and sample come into contact with the anti-CCV Ag antibody that it absorbed 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[®] CCV Ag contains the following components:

1. Test devices individually foil-pouched with a desiccant
2. Assay solution in tube
3. Disposable dropper
4. Sterilized swab
5. Instruction manual for use

PRECAUTIONS

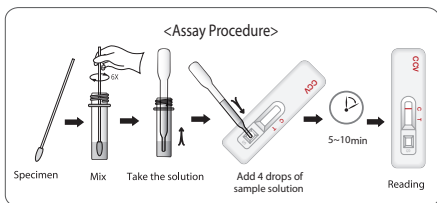
1. The presence of humidity may decrease the stability of the reagents.
2. Do not use the kit after the expiration date and do not freeze.
3. For in vitro diagnostic use only
4. Wear protective gloves while handling samples and wash hands thoroughly after the test
5. Dispose all the specimens and kits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

SPECIMEN COLLECTION AND STORAGE

Specimen of this is canine fecal material(stool). And, it should be obtained and handled by methods for the sample collection. The stool specimens must be tested as soon early they are collected. If necessary, they may be stored at 2-8°C for up to 48 hours. If longer storage is required, the sample may be frozen at -20°C

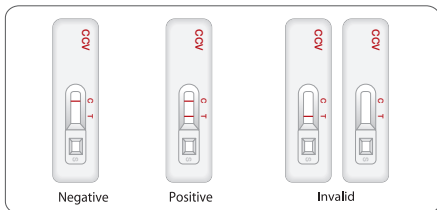
TEST PROCEDURE

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. Collect the stool specimens at 4 different points or directly take the specimens from the canine colon.
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 4 drops (approx. 120µl) of the solution taken by the disposable dropper into the sample well.
6. Within 5-10 minutes, interpret the test result(s). Do not read 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 (C), even if any shade of a pink-to-red test Line (T) 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[®] CCV Ag kit should be stored between 2~30°C (39.2~86°F).
2. Expiration date of this kit is 24 months after its manufacture date.



LIMITATIONS OF THE TEST

Asan Easy Test[®] CCV Ag is designed for primary screening test of canine parvovirus 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

犬冠状病毒是引起肠炎及呕吐，水样性或血性腹泻的病毒。本品为不需要特别的仪器，可以用简便的方法快速诊断出存在于犬粪便中的犬冠状病毒 (CCV) 抗原的诊断试纸。本品使用了可以与CCV特异性反应的2种单克隆抗体。一种单克隆抗体固定在硝酸纤维素薄膜中，另一种抗体以胶体金形式存在。如果粪便中存在CCV，CCV抗原首先与抗-CCV单克隆抗体胶体金反应通过毛细管现象在薄膜中移动，最终与固定在硝酸纤维素薄膜中的另一种抗CCV单克隆抗体结合显示出红色色带。

提供的材料

林特睿检™犬冠状病毒检测试纸条内包含以下材料：

1. 铝箔袋内装检测设备 and 干燥剂
2. 瓶装检测稀释液
3. 滴管
4. 消毒棉签
5. 使用说明书

使用注意事项

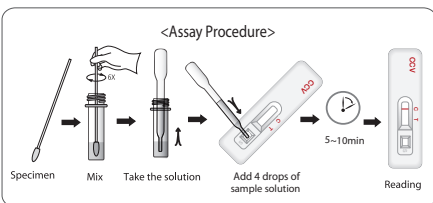
1. 试纸板对外的温度和湿度都敏感，因此请于检测前15-30分钟内将试纸板放置于室温，且试纸板从铝箔袋中取出后请立即使用。
2. 请不要使用超过保质期的试纸，且禁止冷冻试剂盒。
3. 本试纸条为兽医专用，且仅用于体外检测。
4. 所有的待测样本都应该被视为潜在污染源，所以当处理样本时，请带好防护手套，检测后立即将手清洗干净。
5. 请按照实验室规定处理检测后的样本和试纸条。
6. 请勿混用不同批次的缓冲液，且禁止重复使用试纸板。
7. 禁止使用被细菌或霉菌污染的缓冲液。

样本采集及保存

本试纸条检测样本为犬新鲜粪便。并且需按样本采集方法进行操作。采集的新鲜粪便应尽快进行检测。如果不能立即进行检测，可在2-8°C下最长保存48小时，如果需要保存更长时间，请置于-20°C进行冷冻保存。

检测方法：

1. 在开始检测前15-30分钟将所有样品、试纸条放置于室温。
2. 将装有试剂的密封袋撕开，取出试纸将其平放于干净、
3. 用试纸自带的棉棒在粪便样品的4个不同点取样或者直接 from 肛门的处直接取样。
4. 将棉棒插进样品管的稀释液里面充分混匀，将棉棒丢弃。
5. 用试纸自带的一次性滴管取3-4滴混合液 (约100 µl) 加入到试纸的检测槽 (S) 内。
6. 于5-10分钟读取结果。切勿超过10分钟读取结果。



结果判断

本产品通过检测线和对照线是否出现色带，来判断结果。无论检测样品中是否有冠状病毒抗原，对照线 (C) 都会显示出色带，如不出现色带，要考虑到操作是否有误，或试剂是否有问题，应重新检测。检测线上是否出现色带来判断，检测样品中是否含有冠状病毒抗原。

1) 阴性结果

检测线 (T) 没有出现色带，而对照线 (C) 出现色带，判断为阴性。如图所示



2) 阳性结果

检测线 (T) 与对照线 (C) 都出现色带，判断为阳性。如图所示



3) 无效结果

检测线 (T) 与对照线 (C) 都不出现色带，或只出现检测线 (T) 色带判断为无效结果。如图所示



一要考虑操作是否有误或试剂是否有问题，应重新检测。
一检测样品中犬冠状病毒抗原的效价特别高时，检测线颜色深而对照线颜色浅，这时需要将检测样品稀释10倍后再检验，这样可以得到检测线 (T) 与对照线 (C) 都出现色带的正确结果。

保存方法及有效期

- 2-30°C 密封保存，有效期为从生产之日起24个月。

检测的局限性

林特睿检™CCV Ag检测试纸条是用来初步判断犬冠状病毒抗原。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原因造成的假阳性和假阴性。因此，本结果仅作参考，兽医需要结合临床症状和其他的检测结果综合判断来确诊。



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REF Code No.: 22341, 22345
Document Code: ACCV00-S0E00
ISO13485:2003