

CAVII II Antigen Test Kit (ocular, nasal secretions and saliva)

INTENDED USE

The CAVII Antigen Test Kit is a rapid visual immunoassay. The assay is for the direct and qualitative intended for the qualitative detection of canine adenovirus (II) (CAVII) antigens (Ag) from a dog's ocular, nasal secretions and saliva sample. The test is for professional use. Negative results do not preclude these viral infections. Testing results should not be the sole basis for treatment or other management decisions.

PRINCIPLE

This test mainly uses immunochromatographic technology to detect canine adenovirus (II) antigens. During testing, target antigens, if present in the corresponding secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the Sample Pad, the target antigens will bind to antibodies on the Conjugate Pad. Consequently, the antigen-antibody complex will be captured by the antibodies immobilized at the Test Regions. Excess colored particles will be captured at the Control Region of the NC membrane. The presence of a colored band in the test region indicates a positive result, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

MATERIALS

Materials Provided

- Individually packed test
- Package insert

Materials Required but Not provided

- Clock, timer or stopwatch

PRECAUTIONS

- For Veterinar Diagnostic Use Only.
- Caution should be taken when inserting the sample collector from ocular, nasal secretions and saliva.
- DO NOT ingest.
- Read the *Package Insert* prior to use. Directions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- All test subject specimens should be handled and discarded as if they are biologically hazardous. All specimens must be mixed thoroughly before testing to ensure a representative sample prior to testing.
- Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity. Inaccurate or inappropriate specimen collection, storage, and transport may yield false negative test results.
- Avoid skin or eyes contact with buffer before, during or after testing.
- Do not puncture the sealing membrane in the extraction tube before testing.

STORAGE AND STABILITY

- Store the canine adenovirus(II) Antigen Test Device at 2-30°C (36-86°F) in a cool, dry place and keep out of direct sunlight when not in use.
- DO NOT FREEZE.**
- The kit components are stable till the expiration dates marked on the corresponding outer packaging and containers.

TEST PROCEDURE

- Bring devices, reagents and specimens and/or controls to room temperature (15~30°C) before use.
- Remove the test device from its packing. Label the test with the patient's identification. For the best results, the

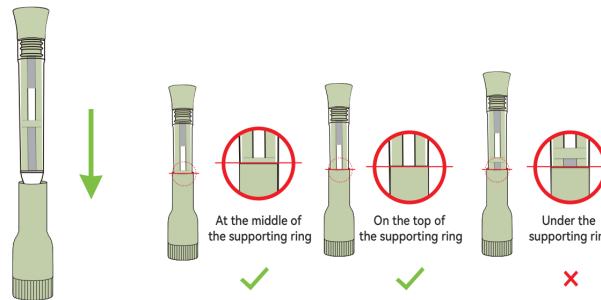
assay should be performed within one hour.

- Take the test device out. Then put the test, protector and the buffer on a clear level surface.
- Dog's ocular or nasal secretions or saliva sample Collect the sample with the provided collector as below:
 - For dog's ocular secretions**
Collector the secretions from each dog's eyes twice with the provided collector.
 - For dog's nasal secretions**
Collector the secretions from each dog's nose twice with the provided collector.
 - For dog's saliva**
Collector the corners of your dog's mouth two or three times with the provided collector.



- Testing

Place the test device vertically into the extraction tube until the edge of the extraction tube reach the middle of the supporting ring.



NOTE: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the middle or top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

- Read the results at 10 minutes. Do not read the results after 15 minutes.

NOTE: The color intensity in the test area can vary according to the concentration of the analyte present in the sample. Please note that this is only a qualitative test and cannot determine the exact concentration of the analyte in the sample result.

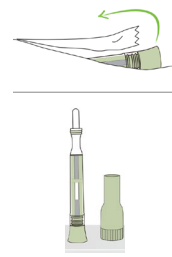
RESULT INTERPRETATION



POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

The color intensity in the test region(s) may vary depending on the concentration of analytes present in the specimen. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL

Internal Procedural Controls

The CAVII Antigen Test Kit has built-in (procedural) controls. Each test has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

External Positive and Negative Controls

Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed.

LIMITATIONS OF THE TEST

- This test is used for professional in vitro diagnosis and can only be used for qualitative detection of canine adenovirus (II) (CAVII) antigens (Ag). If there are positive results. For further clinical diagnosis, please consult a veterinarian.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.
- Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.
- Negative results do not preclude viral infections and should be confirmed via molecular assay.

PERFORMANCE CHARACTERISTICS

Clinical study

Table: CAVII Antigen Test Kit vs. PCR

		PCR			
		+	-	Total	
Relative Sensitivity: 98.1% (93.5%-99.8%)*	CAVII Antigen Test Kit	+	105	1	106
Relative Specificity: 99.5% (97.3%-100.0%)*		-	2	192	194
Overall Agreement: 99.0% (97.3%-99.8%)*		Total	107	193	300
*95% Confidence Interval					

Specificity: This product has no cross reactivity with feline calicivirus, feline herpes virus, feline parvovirus, canine distemper virus and canine coronavirus.

INDEX OF SYMBOL

REF	Catalog number	LOT	Temperature limitation
1	Consult instructions for use	LOT	Batch code
2	In vitro diagnostic medical device	W	Use by
3	Manufacturer	V	Contains sufficient for <n> tests
4	Do not reuse		