Feline Immunodeficiency Virus Antibody Lateral Flow Test Kit

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Background

Feline Immunodeficiency Virus (FIV) is a retrovirus of the genus Lentivirus that causes life-long infections in cats world-wide [1]. The primary method of disease transmission is through cat bites, making disease prevention difficult. Animals infected with FIV produce high levels of the FIV antibody throughout their lifetime, making it advantageous to diagnose the disease through serological testing [2]. Many serological techniques exist as aids in the diagnosis of FIV with varying levels of technical expertise required.

The national incidence of diagnosed FIV infection in the United States is 4.56%. FIV is predominantly in the south and eastern regions of the US; however, it can be found world-wide [3]. For cats that are already sick or at risk of infection, the prevalence rate can be as high as 15% [4].

Symptoms and Risk Factors

Since FIV is transmitted primarily through cat bites, aggressive cats are at a higher risk of becoming infected. Indoor cats that live alone see little risk of becoming infected. Outdoor cats that engage in fights often are at a much higher risk. Rarely, the infection can be transmitted from a mother cat to her kittens [4].

FIV infections occur in three stages [5]. The first stage can last weeks to months, and the animal may display malaise and have enlarged lymph nodes. During the second stage, which can last many years or even indefinitely, the animal may not present any symptoms, and may appear to be clinically healthy.

The third phase is secondary infection, when the virus becomes terminal. Common symptoms include fever, loss of appetite, and poor coat condition, as well as infections of the skin, eyes, urinary bladder, and upper respiratory tract. Other symptoms may include gingivitis, stomatitis, persistent diarrhea, eye conditions, seizures, behavioral changes, and other neurological disorders. Weight loss, as well as several kinds of cancer and blood diseases, are more common in cats affected with FIV.

Diagnostics

Common methods of diagnostic include enzyme-linked immunosorbent assay (ELISA), western blot, and immunofluorescent assay (IFA). These tests detect the presence of FIV antibodies in the sample, providing a positive result if the antibodies are present [4].

After infection, it can take eight to twelve weeks for antibodies to be detectable in an animal. As such, animals should be retested a minimum of 60 days after exposure [4].

If an animal has no history of FIV vaccination, then presence of FIV antibodies indicates that the animal is FIV-positive. However, if the animal has been vaccinated for FIV or has an unknown vaccination history, then presence of the antibodies does not necessarily indicate that the animal is infected [6].

In order to determine a vaccinated animal's true infection status, a polymerase chain reaction (PCR) test can be used. However, PCR tests have a relatively low sensitivity and specificity, and should be used for confirmation only, not diagnostics [4]. Additionally, some point-of-care antibody test kits (Witness® FIV, Zoetis, Parsippany, NJ and Anigen Rapid, BioNote, Inc., Korea) are reported to be able to differentiate FIV-vaccinated and FIV-infected cats [5] [7].

Lateral Flow Test Methodology

Biotech Laboratories U.S.A. LLC offers a lateral flow test kit, the RapidSTATUS™ FIV antibody test kit, which detects antibodies against the FIV glycoprotein gp40 and provides rapid on-site results intended for use in diagnostics.

The Feline Immunodeficiency Virus Antibody Lateral Flow Test Kit uses a nitrocellulose membrane-based lateral flow test strip. A drop of a feline's serum, plasma, or anticoagulated whole blood is added to the sample well of the test device. The sample reconstitutes conjugates that have been dried in the test device. The sample and the reconstituted conjugates migrate along the test strip. Two to three drops of chase buffer are then added to force reagent flow down the strip.

The test results can be observed visually by the user. The presence of a test and control line are interpreted as a positive result, the presence of only a control line is interpreted as a negative result, and any test without a control line is invalid.

Sensitivity and Specificity

The sensitivity and specificity of the test kit are based on the data generated for the intent of regulatory submission. All data is from naturally infected animals.

*Table 1: 2x2 Sensitivity and Specificity based on Naturally Infected Animals**

	IFA Pos	IFA Neg
RapidSTATUS ™ FIV Pos	204	4
RapidSTATUS ™ FIV Neg	2	268
Sensitivity	99.0% (95% CI: 96.5, 99.9)	
Specificity	98.5% (95% CI: 96.3, 99.6)	

* *Sensitivity and Specificity Report*

Based on the analysis, the sensitivity of the RapidSTATUS™ FIV antibody test kit is 99% and the specificity is 98.5%.

Can the RapidSTATUS™ FIV Test Kit Differentiate between FIV-Vaccinated and FIV-Infected Cats?

The RapidSTATUS™ FIV test kit can differentiate between FIV-vaccinated and FIV-infected cats tested three months post-vaccination. For samples taken 1 month after primary vaccination (which includes 2 boost vaccination), the RapidSTATUS™ FIV test kit detected only 14 out of 21 vaccinated samples as FIV positive, whereas the VetScan® (Zoetis, Parsippany, NJ) and P24-based ELISA tests detected 21 out of 21 as FIV positive. At 3 months post-vaccination, the RapidSTATUS™ FIV test kit detected only one positive result out of 17 vaccinated samples, while the VetScan® and P24-based ELISA tests gave positive results for almost all samples.

Table 2: Test Specificity for FIV-Vaccinated animals#

	1 Month Post-Vaccination	3 Month Post-Vaccination
RapidSTATUS™ FIV Pos/Total	14/21	1/17
VetScan® Felv/FIV Pos/Total	21/21	15/17
P24 ELISA Pos/Total	21/21	17/17

Internal study no 8734003

These results are consistent with published data that the Witness® and Anigen Rapid® tests (gp40-based tests) can differentiate between FIV-vaccinated and FIV-infected cats 6 months after the third (final) primary FIV vaccination, while the VetScan® and Snap® (Idexx, Westbrook, ME) FIV/FeLV tests, which detect antibodies against p24 and p15/p24 respectively, cannot [7].

Citations:

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