

AAFP Information Brief: In response to inquiries regarding Fel-O-Vax® FIV September 2002

Fel-O-Vax® FIV is an inactivated, dual subtype (based on strains of Petaluma subtype A and Shizuoka subtype D) feline immunodeficiency virus (FIV) vaccine. The adjuvanted whole virus vaccine was released in July 2002, and is produced by Fort Dodge Animal Health.

Testing implications

Cats vaccinated with Fel-O-Vax® FIV develop antibodies to the inactivated virus present in the vaccine.

Currently available antibody-based FIV diagnostic tests (e.g., SNAP® Feline Combo, PetChek® FIV Ab plates, and Western blot) available in the United States and Europe cannot distinguish cats vaccinated with Fel-O-Vax® FIV from FIV-infected cats or from cats that are both vaccinated and infected.

Negative FIV-antibody test results remain reliable (see the 2001 Report of the AAFP/AFM Advisory Panel on Feline Retrovirus Testing and Management at www.aafponline.org/resources/guidelines/Felv_FIV_Guidelines.pdf). But until tests that differentiate vaccinated cats from infected cats become readily available, it will be impossible to assess the significance of positive test results. (Is a positive-testing cat infected, vaccinated, or both?) Some consequences of this ambiguity:

The benefit of testing and isolating FIV-infected cats—the mainstay of reducing viral transmission—will be diminished if vaccinated cats are erroneously assumed to be non-infectious.

It will be impossible to ascertain the safety of adopting positive-testing cats into households with uninfected cats. Vaccinating all the residents prior to adoption may provide some protection, but it is unrealistic to expect all vaccinates to be protected.

Because infected cats—either healthy or ill—will be difficult to identify, the delivery of the specialized care they require will be significantly compromised.

Kittens born to vaccinated queens will likely test positive for passively acquired FIV antibody. According to studies conducted by the manufacturer, antibody levels drop to levels that won't interfere with test results by the time kittens reach 8 weeks-of-age.

Some shelters and other facilities designed to house strays often euthanize cats with positive FIV test results, so previously vaccinated uninfected cats may needlessly undergo euthanasia. Permanently identifying cats vaccinated with Fel-O-Vax® FIV (e.g., using a microchip or tattoo) has been suggested as a means of identifying vaccinated cats, thus sparing them from euthanasia. Yet previous vaccination does not rule out infection nor prevent the subsequent placement of infected cats.

Alternate test methods

Virus isolation (VI) has been suggested as another means of confirming or ruling out FIV infection, but VI has a multitude of limitations that make it impractical as a routine diagnostic

tool in private practice settings.

Polymerase chain reaction (PCR)-based tests can potentially differentiate infected cats from vaccinates by identifying proviral DNA present in blood cells. Most, if not all, PCR-based assays available at the time of this writing present the following difficulties:

- Information regarding the sensitivity, specificity, and validation is largely lacking.
- Test reagents have not been standardized.
- Ability to detect various field strains to which cats might be exposed has been inadequately explored.
- Quality control within laboratories performing PCR-based FIV tests must be stringent if accurate results are to be obtained, yet mandatory quality control standards to which diagnostic laboratories must adhere are lacking.

PCR-based tests will become increasingly available to veterinarians, and it will be difficult to assess the reliability of test results until the shortcomings noted above are addressed. Refinements of PCR-based systems may resolve some of these issues. However, at the time of this writing, a validated PCR test that will reliably identify all infected cats or that will distinguish infected cats from those vaccinated with Fel-O-Vax® FIV is not available to clinical practitioners. It should be noted that PCR test methodology cannot be modified for in-clinic use, and it is unlikely that a point-of-care test will be available in the foreseeable future.

Vaccine efficacy

FIV is commonly classified into five different subtypes (A, B, C, D, and E) based upon genetic variation within one section of the virus envelope gene. Subtypes A and B are the predominant subtypes in the United States. Substantial genetic variation exists both within and between the various subtypes (also called genotypes or clades). Experimental FIV vaccines reported thus far in the literature have demonstrated poor cross protection between subtypes (e.g., vaccines based on subtype A virus have shown decreased protection against subtype B challenge).

As a condition of licensure, the United States Department of Agriculture (USDA) requires manufacturers to determine vaccine efficacy based upon results of laboratory studies. Accordingly, 45 eight week-old specific pathogen free kittens were randomized into two groups: 25 were vaccinated with Fel-O-Vax® FIV three times three weeks apart while 20 kittens served as non-vaccinated controls. Approximately one year later, both groups were challenged intramuscularly with a subtype A virus that differed by 10% in a portion of the envelope gene from the subtype A virus used in the vaccine. The preventable fraction (defined as the proportion of cats protected by vaccination in excess of the proportion that is naturally resistant) was calculated to be 0.82 (82%).

Challenge models that accurately reflect “real world” exposures to infectious agents are difficult to design and control, expensive, and involve large numbers of cats. In addition, they often require several years of data collection to obtain meaningful results. Laboratory challenges of the kind required by the USDA provide necessary and valuable information, but for reasons of practicality and expense, they may not reflect vaccine performance in the field. Although these efficacy figures are encouraging, it is possible that fewer than 82% of vaccinated cats will be protected from the vast array of FIV genetic variants to which they may be exposed in nature. Therefore, while reasonable to expect that some cats vaccinated with Fel-O-Vax® FIV will be protected from infection, others certainly will not.

Conclusion

The absence of tests that distinguish cats vaccinated with Fel-O-Vax® FIV from infected cats, coupled with questions regarding the vaccine's ability to induce protection against all the subtypes and strains of FIV to which cats might be exposed, makes the decision to recommend use of this product far from straightforward. It is crucial that clients are adequately informed about the vaccine's impact on future test results, and their decision should be reached only after careful consideration of both positive and negative implications. If the decision ultimately falls in favor of vaccination, cats should test negative immediately prior to receiving Fel-O-Vax® FIV.