I. INTRODUCTION

Feline Leukemia Virus (FeLV) is a contagious retrovirus which is endemic particularly among high density or close contact cat populations in many areas of the world. Transmission occurs essentially by contact, mainly through saliva or nasal secretions and by biting or licking. One major source of the virus is persistently viremic, mostly clinically healthy, carrier cats. Vertical (congenital) transmission is also described. A variety of outcomes are possible after cats are exposed to FeLV. Infected cats can become persistently viremic, and many of these cats will die from non-neoplastic diseases. Exposed cats may also develop immunity through the production of virus neutralizing antibodies. Some cats develop an atypical infection where viral replication remains incompletely contained with intermittent antigenemia and occasional shedding of virus. Diagnosis of FeLV infection is usually by detection of the viral antigen, p27, which is in high quantities in the blood of viremic cats.

II. TEST INDICATION

The STATScreen® FeLV test is indicated for use when history and/or clinical signs may suggest infection by FeLV or as a screening test prior to an FeLV vaccination. Cats should also be tested prior to entry into FeLV negative households or catteries.

III. TEST PRINCIPLE

The STATScreen® FeLV test is a simple test, based on rapid immunomigration (RIM) technology, which detects the presence of the FeLV antigen p27 in cats’ blood. Sensitized particles bound to p27 antigen present within the sample (whole blood, serum, or plasma) migrate along a nitrocellulose strip. The complex is then captured on a sensitized reaction line where its accumulation causes the formation of a clearly visible pink/purple band. A pink/purple band in the control window ensures that the test was performed correctly.

IV. SAMPLE INFORMATION AND STORAGE

- The test can be performed on whole blood, serum, or plasma.
- Whole blood samples must be anticoagulated with EDTA or heparin.
- Samples should be collected with a sterile needle and syringe.
- Hemolysis does not significantly interfere with the test, but strongly hemolyzed samples may partly obscure a weak positive band.

It is recommended to test samples immediately after collection. If samples are kept at room temperature, they should be tested within 24 hours. If testing is further delayed, samples should be refrigerated at 2°C to 7°C (35°F to 45°F) for up to 7 days. For prolonged storage, samples (serum and plasma only) should be kept frozen at -20°C (-4°F).

V. DISPOSAL OF SAMPLES AND TEST DEVICES

Handle all samples as if capable of transmitting FeLV. Dispose of samples and used devices appropriately.

VI. KIT CONTENTS

- 10 pouches, each containing 1 test device.
- 10 disposable pipettes
- 1 buffer dropper bottle (2.2 ml)
- Instructions for use

VII. PRECAUTIONS

- Do not use components after expiration date.
- Refrigeration is not required. Store the test kit at 2°C to 25°C (35°F to 77°F). Do not freeze.
- Use the test within 10 minutes after opening the sealed pouch.
- Avoid touching or damaging the membrane at Windows #1, #2 or #3.
- The STATScreen® FeLV device should be placed on a flat, horizontal surface while performing the test.
- Use a separate extraction pipette for each sample.
- Hold pipette and buffer bottle vertically when dispensing sample and buffer.
- For Veterinary Use Only.
VIII. TEST PROCEDURE AND RESULTS

IMPORTANT:

Allow sample and buffer drops to fall onto membrane at Window #1. Do not touch pipette tip, sample or buffer drops, or buffer bottle tip directly to the membrane.

1. SAMPLE APPLICATION:
   • Tear open the pouch provided and place the test device on a flat horizontal surface for the duration of the test.
   • Squeeze the provided pipette near the sealed end. Insert the open end of the pipette into an anticoagulated whole blood, serum, or plasma sample. Release the pressure slightly to draw up a small amount of sample into the pipette.
   • Holding the pipette vertically, transfer one drop of sample to the sample well, Window #1. Allow sample drop to fall onto membrane at Window #1. Do not touch pipette tip directly to the membrane. See #1 at right.

2. BUFFER DISPENSING:
   • Remove the cap from the buffer bottle, hold it vertically and add two drops of buffer to the sample well Window #1. See #2 at right.

3. READING TEST:
   • Wait ten minutes, observe the presence or absence of pink/purple bands in Windows #2 and #3. See #3 at right.
   • Sample results are read in Window #2. The control band is read in Window #3.

NOTES:

The test is complete and may be read before 10 minutes if pink/purple bands are visible in both Windows #2 and #3. The presence of a pink/purple band only in Window #3 before 10 minutes does not mean that the test is complete. A pink/purple band in Window #2 may develop slower than the control pink/purple band in Window #3.

4. RESULTS:

Validation: Test is validated if a pink/purple band is present in Window #3.

Interpretation:
   • Negative for FeLV antigen: No band in reading Window #2, with one pink/purple band in Window #3.
   • Positive for FeLV antigen: One pink/purple band in reading Window #2, with one pink/purple band in Window #3.

Invalid test: No pink/purple band in Window #3. See #4 at right.

NOTE:

A test result should always be interpreted in the context of all available clinical information and history for the cat.

TECHNICAL SERVICE:
Toll Free: 800-228-4305

MANUFACTURED BY: SYNBiotics Corporation
San Diego, CA 92127 USA
U.S. Vet. License No. 312
1-800-228-4305

DISTRIBUTED BY: Vedco, Inc.
5503 Corporate Drive
St. Joseph, MO 64507 USA