ImmunoRun

Antigen Detection Kit
FELINE LEUKEMIA VIRUS

Cat. No. 80FLV205/80FLV250
INSTRUCTION MANUAL

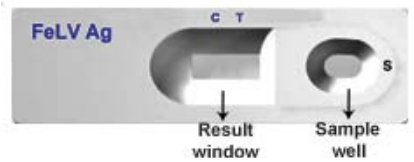
I. Intended Use

ImmunoRun FeLV Antigen Detection Kit is intended for detection of Feline Leukemia Virus (FeLV) Antigen (Ag) in cat whole blood/serum/plasma. The kit contains all components required for performing an easy and accurate test in less than 10 minutes.

II. General Information

ImmunoRun FeLV Antigen Detection Kit contains devices intended for performing 5 individual immuno-chromatographic assay to qualitatively detect FeLV-Ag in cat whole blood/serum/plasma specimens. Each device contains 2 main windows. A round window, which is the sample application well and a square result window, marked by 2 letters: "C" for Control line and "T" for Test line (**See figure1**). Both lines are invisible before reaction takes place. The control purple line should appear with each ongoing reaction as it is used for validation of the test. A specific antibody to FeLV is conjugated with gold particles and another specific antibody is immobilized as a band on a nitrocellulose membrane. Virus in specimen binds to the gold conjugated and forms a virus-conjugate complex that migrates to the result area, where it is captured and its accumulation creates a band. A purple test line will be visible in the result window in case of enough FeLV-Ag in the specimen. The specially selected anti-FeLV antibodies are used in test band as both capture and detector materials. These enable FeLV-Ag device to identify FeLV with a high degree of accuracy.

Figure 1: FeLV-Ag device.



III. Description Of The Disease

Feline Leukemia Virus (FeLV) is a retrovirus which causes diseases manifesting leukemia, immunodeficiency and additional cancers. It usually spreads through infected saliva, nasal secretions, urine, tears, feces, and from an infected mother to her kittens during gestation and nursing. FeLV can affect all cats, but kittens and sick cats are more susceptible to infection. While FeLV is the most common cause of cancer in cats, it may cause various blood disorders, and may lead to a state of immune deficiency that hinders the cat's ability to protect itself against other infections. Early stages of infection are usually symptomless. Clinical signs are variable since many body systems can be affected. Loss of appetite, fever, weight loss and weakness are the first signs most commonly seen in infected cats.

IV. Diagnosis Of The Disease

The ImmunoRun FeLV Antigen Test Kit is the simplest screening diagnostic method available to detect the presence of FeLV. Compared with a leading commercial antigen test, it has given accuracy greater or equal to 99.0%. Other Immuno - diagnostic methods may be used to quantitate antibody titer, while PCR may be used to verify the presence of the virus.

V. Kit Contents

Component	5 Tests Kit (80FLV205)	50 Tests Kit (80FLV250)
FeLV Ag test device	5	50
Dropping bottle containing assay diluent	1	5
Disposable capillary tube with a 10µl marked line (See Fig. 2)	5	50
Instruction manual	1	1

Figure 2: 10µl marked line on a disposable capillary tube.

VI. Essentials Not Included

- Syringes or vacutainers for blood collection.
- Tubes for specimen collection.

VII. Storage And Handling

- Shipment may be performed at room temperature.
- Store at 2-30°C (room temperature or refrigerated). Avoid exposure to direct sunlight.
- Kit is stable for up to two years, do not use beyond expiration date stated on the package label.
- **Do not freeze!**
- Do not open or remove test kit from their individually sealed pouches until immediately before their use (do not use kit if the pouch or the device are damaged).
- Avoid touching exposed membrane in device windows.
- Components in this kit have been quality control approved as standard batch unit. Each component in the kit is for a single use only. Do not mix components from different lot numbers, and do not try to reuse a device.
- Handle and dispose of used samples, swabs, extraction buffer and used device in accordance with accepted sanitary requirements designated for bioharazardous waste.

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VIII. Step By Step Protocol

For best results, strict adherence to these instructions is required:

Specimen Preparation:

1. **Whole blood**: Collect blood from cat using suitable anticoagulant.
2. **Serum or Plasma:** Centrifuge blood in order to obtain serum/plasma.
3. Specimen not used immediatey should be kept at 2-8°c up to 3 days. Serum or plasma specimens may be stored at -20°c or below if kept longer.
4. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified by centrifugation prior to assaying.
5. Only cat specimens should be used with this test.

Test Protocol:

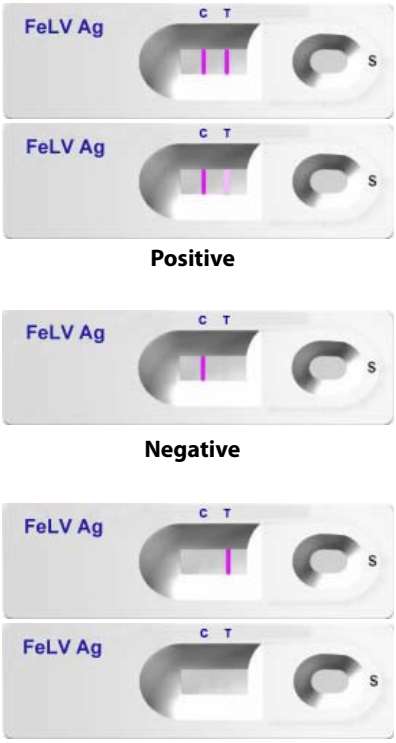
1. If stored in refrigeration, allow all components and specimen to reach room temperature prior to testing.
2. Remove the test cassette from the foil pouch prior to use. Place the test cassette horizontally.
3. Using the **disposable capillary tube** apply **10µl specimen** into the sample well. Slowly add **3 drops** of **Diluting Buffer** into the sample well.
4. If migration through result window (purple color) does not start within a minute, apply another drop of diluent.
5. Follow the control line as it appears in the result window. In case of a positive result, a test line should appear as well.

Results should be read within **5-10 minutes** from sample application. Clear positive result may be accepted earlier. Interpretation should not be based on reading accepted beyond 20 mintues.

IX. Reading And Interpreting The Results

- See Figure 3.
- The presence of any two visible bands: the test band (T) and the control band (C) within the result window (no matter which band appears first) indicates a **positive** result, regardless of test band intensity.
- The presence of only one band **marked as "C"** in the result window indicates a **negative** result.
- If the control band "C" is not visible within the result window, the result is considered **invalid** (even if the test band appears).

Figure 3: FeLV-Ag bands interpretation



X. Limitations And Troubleshooting

- For veterinary *in vitro* use only. Do not use internally or externally in humans or animals.
- As with all diagnostic tests, all results must be considered with other clinical information available to the veterinarian. Do not use this test as sole criteria for diagnosis of FeLV infection.
- The test is not selective and may detect post FeLV derived from vaccination. Be aware of vaccination history in order to be able to interpret the results correctly.
- If test result is negative and clinical symptoms persist, additional testing using other diagnostic methods is recommended. A negative result does not preclude the possibility of FeLV infection.

XI. References

- Hartmann K (2006) Feline Leukemia Virus Infection. In: Infectious Diseases of the dog and cat. Greene CE, Saunders - 3rd Ed.: 105-131.
- Swango L J (1991) Evaluation of feline leukemia virus diagnostic tests available for in-office use by veterinarian. J Am Vet Med Assoc. 199(10):1386-1389.

For further information and assistance please contact your local distributor or Biogal Galed Labs. Acs. Ltd. Directly by e-mail: info@biogal.co.il or by tel: 972-4-9898605 / fax: 972-4-9898690.

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