

FeLV/FIV

Feline

Feline Leukemia Virus (FeLV) Ag and Feline Immunodeficiency Virus (FIV) Ab Detection kit

For in vitro veterinarian diagnostic use only

Cat.no – 80FFV205/80FFV250

Instructions for Use

Intended Use

ImmunoRun FeLV/FIV test kit is intended for the detection of Feline Leukemia Virus (FeLV) p27 antigen and Feline Immunodeficiency Virus (FIV) antibodies using cat whole blood, serum, or plasma.

Specifications

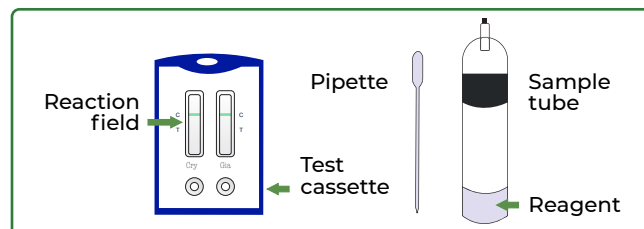
| Samples | Serum, plasma, or whole blood | | |
|----------------|-------------------------------|-------------|----------|
| Sample Vol. | 20µl. | | |
| Time to result | 10 minutes | | |
| Storage temp. | 2-30°C | | |
| Shelf life | 24 months | | |
| * | Sensitivity | Specificity | Accuracy |
| FeLV Ag | 94.59% | 99.99% | 98.00% |
| FIV Ab | 91.67% | 97.83% | 94.68% |

*According to internal comparison study 2017.

Components of the test kit

| Components | 5 Tests/ kit 80FFV205 | 50 Tests/kit 80FFV250 |
|---------------|-----------------------|-----------------------|
| Test Cassette | 5 | 50 |
| Pipette | 5 | 50 |
| Sample tube | 1 | 10 |

Components of the test kit



Note: In the reaction field, before starting the test, a green/blue line appears in the control line region. This is used for quality control and will be washed away by the sample liquid during the test.



Precautions

- **Do not freeze the kit.**
- Do not open or remove the test cassette from its individually sealed pouch until it is to be used.
- Do not use the test if the cassette pouch or the device is damaged.
- Do not touch the exposed membrane in the device window.
- Handle and dispose all contaminated materials in accordance with approved sanitary standards for biohazardous waste.
- Components in this kit have been quality control approved as a standard batch unit. Do not mix components from different lot numbers.
- Each component of the kit is intended for single use only.

STORAGE:

- Store at 2-30°C. Avoid exposure to direct sunlight.
- The kit is stable for up to 24 months, do not use beyond the expiration date.

Sample Preparation

| Sample | Recommendations |
|--|--|
|  Serum and plasma | <ul style="list-style-type: none"> ● Use freshly collected serum/plasma to achieve the highest detection sensitivity. ● Immediately separate the serum/plasma from the red blood cells. The sample should be clear and non-hemolyzed or lipemic. |
|  Whole blood | <ul style="list-style-type: none"> ● Use freshly drawn blood. ● Blood collected in heparin or EDTA is compatible with the test. |

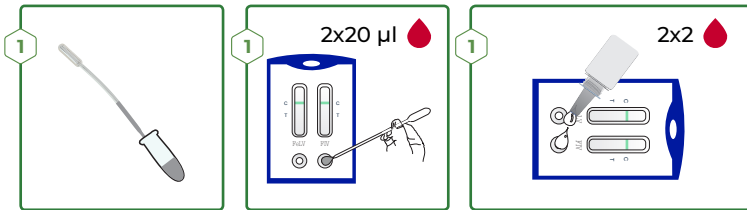
Note: Whole blood samples have a lower detection sensitivity. In case of a negative test result, the test should be repeated with a serum or plasma sample.

Test Instructions

- If stored in refrigeration, allow all kit components and specimen to reach room temperature prior to testing.
- Remove the test cassette from its pouch and place on a horizontal surface.
- Use the test cassette **within 60 minutes** of opening the pouch.

Test Procedure

1. Using the marked pipette, aspirate the sample up to the **20 µl mark**.
2. Add the sample to the first sample well and allow the liquid to be completely drained from the well. Repeat the procedure for the second well. **Avoid formation of air bubbles.**
3. Add 2 drops of reagent to each sample well. If the fluid does not migrate through test strip **within 60 seconds**, apply an additional drop of reagent into the sample well.

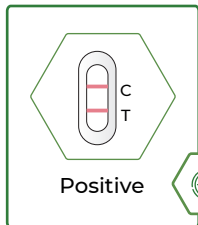


Note: An incorrect number or size of drops may lead to false results.

Test Results

The test results should be read after **10 minutes**.

Positive test result:

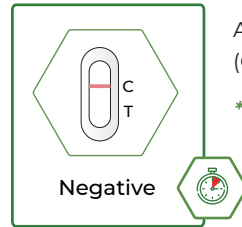


Two red bands will appear.

The upper control band (C) confirms that the test is working properly. The bottom test band (T) indicates a positive test result.

**A weak test line should also be considered a positive result.*

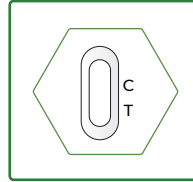
Negative test result:



A lack of a test band (T), while control band (C) is present.

**No antigen or antibodies detected.*

Invalid test result:



If no control band (C) appears the test is considered invalid.

If the test line is colored brown by feces, this test is invalid and should be repeated.

Limitations & Troubleshooting

- A low incidence of false results can occur. **All results must be considered together with additional clinical information available.**
- In the case of FIV, the test may detect antibodies derived post vaccination, therefore consider vaccination history to interpret the results correctly.*
**According to internal study 2021*
- FeLV vaccination does not interfere in the test results.
- If test results are negative and clinical signs persist, an additional diagnostic testing method is recommended.

Symbols

| | | | | | |
|--|-----------------------------|--|--|--|-----------------------|
| | Observe product information | | For one-time use only Storage temperature | | Protect against light |
| | For professional use only | | Number of Test/kit | | Shelf life |
| | | | Lot number | | Protect from humidity |
| | | | | | Manufacturer |