VET Diagnostix

FIV-FeLV

feline immunodeficiency virus antibody and feline leukemia virus antigen

VD186Q

01 Intended Use

The Felivet Immunodeficiency Virus Ab-Leukemia Virus Ag Duo-Test enables the rapid differential diagnosis of these pathogens by detecting antibodies specific to feline immunodeficiency virus, and antigens of feline leukemia virus in feline serum, plasma, or whole blood. It offers two options for result reading: visual judgment or semi-quantitative analysis with the FIC-Q100N Dry Immunoassay Analyzer (required only for Method 2).

02 Principle

The Felivet Immunodeficiency Virus Ab-Leukemia Virus Ag Duo-Test is based on immunoassay method features a testing window for observing assay progress and result reading. The window contains a control (C) zone, and the test zone named I-L (I represented FIV, L represented FeLV). As the treated sample is applied, the liquid flows laterally across the NC membrane on the test strip. It interacts with the pre-coated antigens of feline immunodeficiency virus and the antibodies specific to feline leukemia virus, which capture the corresponding antibodies or antigens from the sample, forming a visible signal at the test zones. If the sample contains antibodies against feline immunodeficiency virus or antigens of feline leukemia virus, a visible test line (I or L) or two lines (I and L) appear, which can also be recognized by the FIC-Q100N Dry Immunoassay Analyzer.

03 Material Provided


FIV-FeLV test card


Assay buffer


Capillary dropper


Disposable dropper

- 10T Kit:
  - 10 FIV-FeLV test cards
  - 10 Vials of assay buffer
  - 10 Disposable droppers
  - 10 Capillary droppers
  - 1 Instruction for use
- 1T Kit:
  - 1 FIV-FeLV test card
  - 1 Vial of assay buffer
  - 1 Disposable dropper
  - 1 Capillary dropper
  - 1 Instruction for use

04 Materials Required but Not Provided

- FIC-Q100N Dry Immunoassay Analyzer (for Method 2 only)
- Pipette (volume range of 2-20 μL, 10-100 μL)
- Timer

05 Storage And Stability

Store the test kit at 2-30°C, away from direct sunlight, until the expiration date(24 months) .
Use the test card immediately after removing it from the foil pouch (within one hour).

06 Precautions

- Do not use the test if the foil pouch is broken.
- Remove the test card from the pouch only before use.
- Avoid touching the testing window. Contamination can affect results.
- Do not mix components from different lot numbers.
- Use the QR code with tests from the same lot only.
- Treat all specimens and samples as protentially infectious. Wear gloves and follow local disposal regulations.

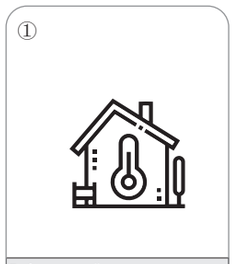
07 Sample Preparation

- Specimen Types: Serum, plasma, or whole blood.
  - Whole Blood: Collect with an anticoagulant tube and use immediately. If anticoagulated whole blood is not immediately tested, it should be refrigerated at 2 - 8°C and used within 24 hours.
  - Serum: Collect with a collection tube (without anticoagulants). Allow blood to clot and centrifuge to obtain serum supernatant. Refrigerate at 2 - 8°C for up to one week. For longer storage, freezing is recommended.
  - Plasma: Collect with a collection tube (with anticoagulants). Centrifuge to obtain plasma. Refrigerate at 2 - 8°C for up to one week. For longer storage, freezing is recommended.
- Frozen Sample Handling (serum/plasma): Frozen sample should be thawed to room temperature (15 - 25°C) before use. Avoid repeated freeze-thaw cycles as they may affect sample integrity.

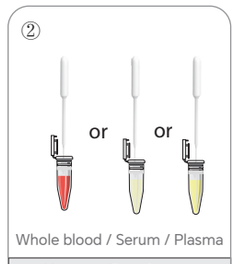
08a Test Procedures & Interpretation of Results (Method 1: Visual Interpretation)

Test procedures of visual interpretation

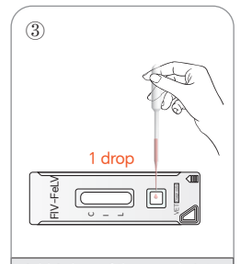
1. Remove the test card from the foil pouch and place it flat on a work surface.
2. Transfer 1 drop (using a capillary dropper) of the treated sample into the sample well.
3. Transfer 3 drops (using a disposable dropper) of the assay buffer into the sample well.
4. Start the timer. Wait for 10 minutes to read the result.



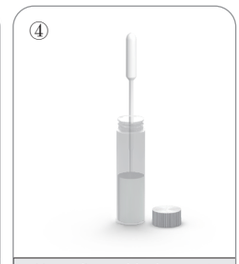
Before use, all components must equilibrate to room temperature (15 - 25°C) for 10 minutes.



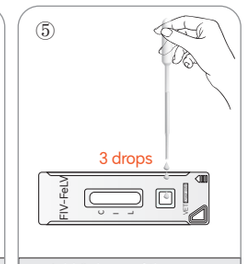
Use a capillary dropper to aspirate the sample.



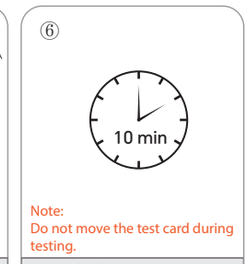
Add 1 drop of the sample into the sample well of the test card.



Use a disposable dropper to aspirate the assay buffer.



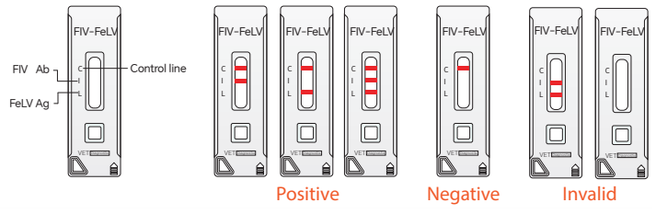
Add 3 drops of the assay buffer into the sample well of the test card.



Note:
Do not move the test card during testing.
Wait for 10 minutes to interpret the test result.

Interpretation of visual interpretation results

The sequence of the T line is shown in the figure (I-L): FIV-FeLV.



Positive (+): Feline immunodeficiency virus positive, C line and I line appear.

Feline leukemia virus positive, C line and L line appear.

Feline immunodeficiency virus and Feline leukemia virus positive, C line, I line and L Line appear.

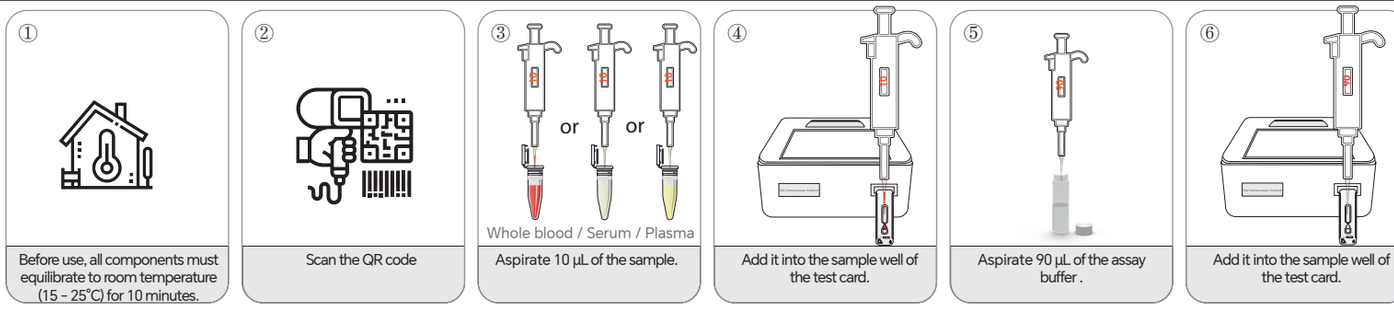
Negative(-): The C line is visible, but the I and L line is not visible.

Invalid: No line appears in the C zone.

08b Test Procedures & Interpretation of Results (Method 2: Instrumental Interpretation)

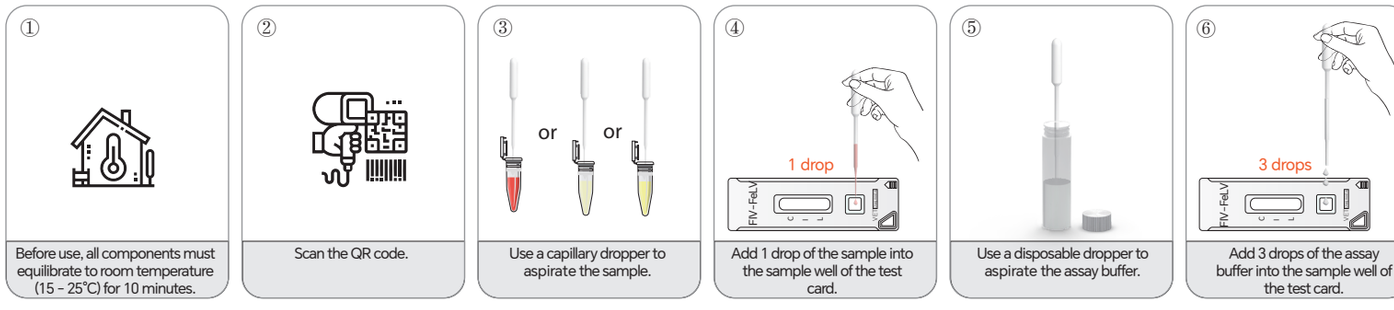
Test procedures of instrumental interpretation (Standard Test)

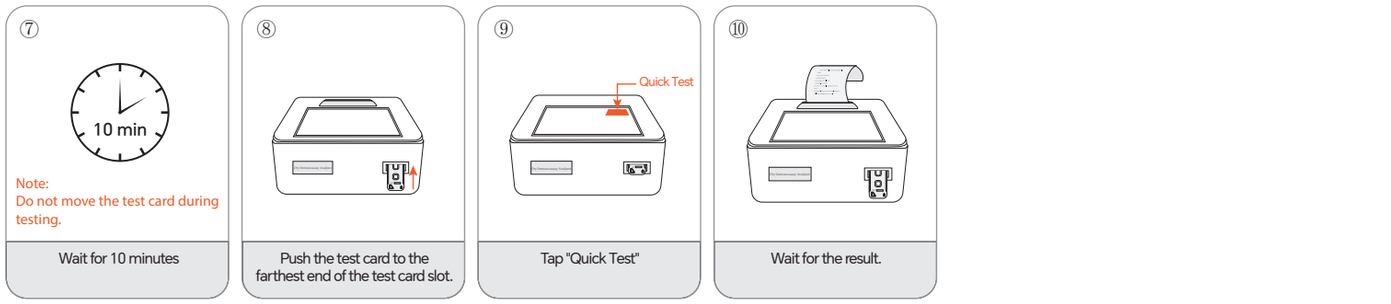
1. Turn on the FIC-Q100N Dry Immunoassay Analyzer.
2. Use the analyzer's scanner to scan the QR code on the inner label of the box or the label of bag to import the calibration curve into the analyzer.
3. Remove the test card from the foil pouch.
4. Position the front of the card facing up, ensuring that the sample well is oriented towards the outside of the analyzer's test card slot.
5. Insert the card into the test card slot of the analyzer.
6. Use a pipette with a range of 2-20 μL to place 10 μL of the prepared sample into the sample well. Then, use a pipette with a range of 10-100 μL to place 90 μL of the assay buffer into the sample well.
7. Push the test card to the farthest end of the test card slot.
8. Tap "Standard Test" on the screen to start the testing. Please refer to the analyzer's operation manual for detailed instructions.



Test procedures of instrumental interpretation (Quick Test)

1. Turn on the FIC-Q100N Dry Immunoassay Analyzer .
2. Use the analyzer's scanner to scan the QR code on the inner label of the box or the label of bag to import the calibration curve into the analyzer.
3. Remove the test card from the foil pouch.
4. Transfer 1 drop (using a capillary dropper) of the treated sample into the sample well.
5. Transfer 3 drops (using a disposable dropper) of the assay buffer into the sample well.
6. Wait for 10 minutes, then push the test card to the farthest end of the test card slot.
7. Tap "Quick Test" on the screen to start the testing. Please refer to the analyzer's operation manual for detailed instructions.





Interpretation of instrumental interpretation results

With the assistance of the FIC-Q100N Dry Immunoassay Analyzer , the test result can be classified into five phases: negative, suspicious (grey zone), weak positive, positive, and strong positive. This method provides better judgment and more objective interpretation than visual judgment. The symbols in the following table represent the different results and their interpretations.

Symbol	Result	Interpretation (FIV)	Interpretation (FeLV)
-	Negative	There is a low likelihood of infection with FIV.	There is a low likelihood of FeLV infection.
+/-	Suspicious	The result is indeterminate. Repeat testing is recommended.	The result is indeterminate. Repeat testing is recommended.
+	Weak positive	Low antibody titer for FIV.	Low FeLV viral load.
++	Positive	Middle antibody titer for FIV.	Middle FeLV viral load.
+++	Strong positive	High antibody titer for FIV.	High FeLV viral load.

09 Interfering Substances

At concentrations up to the following levels, no interference from any of the following substances were observed:

Substance	Concentration	Substance	Concentration	Substance	Concentration
Ribavirin	5 ug/mL	Ampicillin sodium	2 mg/mL	Albendazole	30 μg/mL
Gentamicin Sulfate	0.5 mg/mL	Augmentin	0.5 mg/dL	Natural Vitamin C	20 mg/dL
Feline Interferon	300 IU/mL	Ivermectin	30 ng/mL		

10 Limitations

1. The Felivet Immunodeficiency Virus Ab-Leukemia Virus Ag Duo Test is for in vitro veterinary use only. Results should be considered alongside other clinical information.
2. The FIC-Q100N Dry Immunoassay Analyzer operates based on visible light detection. Stains or dirt on testing window may cause discrepancies. Repeat the test if the result of the analyzer is conflicting with the visual judgement.

Version:1150189201

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