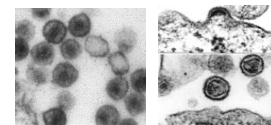
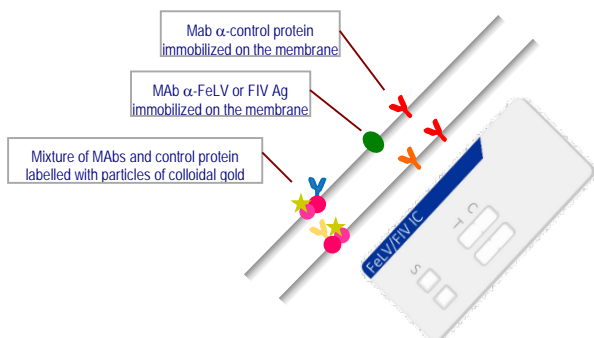


INgezim® FeLV/FIV IC

R.16.FFD.K40



INgezim® FeLV/FIV IC is a immunochromatographic assay based on the lateral flow technique to detect Feline Leukemia Virus (FeLV) antigen and antibodies specific of Feline Immunodeficiency Virus (FIV). FeLV detection is based on a direct assay using monoclonal antibodies (MAbs) specific of 2 different epitopes in FeLV p27 protein. Detection of antibodies specific of FIV is based on an indirect assay using a specific FIV antigen (Ag) and a MAb specific of feline IgG.



TECHNICAL BASIS OF THE KIT

The device consists on a plastic casing with 4 windows:

- Window for sample addition:
 - a. **FeLV:** contains a MAb specific p27 of FeLV and a Control Protein. All of them labelled with colloidal gold.
 - b. **FIV:** contains a MAb specific of feline IgG and a Control Protein. All of them labelled with colloidal gold.
- Window for results interpretation:
 - a. **FeLV:** contains a test line (T) with a FeLV specific MAb and a control line (C) with a MAb specific to the control protein.
 - b. **FIV:** contains a test line (T) with FIV antigen and a control line (C) with a MAb specific to the control protein.

APPLICATION

Detection of FeLV p27 protein and detection of antibodies specific of FIV. Samples used are serum, plasma and blood of cats.

INTERPRETATION OF THE RESULTS

Positive sample: Pink line in the Test zone and a pink line in the Control zone.

Negative sample: Only a pink line in the Control zone.

Not valid assay: No pink line in the Control zone

	FeLV (+)	FeLV (-)
FIV (+)		
FIV (-)		

SENSITIVITY AND SPECIFICITY (FeLV)

Correspondence with ELISA test.

160 serum and plasma samples from different clinicians were analyzed. Results were compared with the ones obtained by a commercial ELISA. The assay showed 100% and 95% sensitivity and specificity respectively.

FeLV IC	ELISA			TOT
	POS	NEG	TOT	
POS	35	6	41	
NEG	0	119	119	
TOT	35	125	160	

SENSITIVITY AND SPECIFICITY (FIV)

Correspondence with Western Blot (WB) test.

351 serum and blood samples from different clinicians were analyzed. Results were compared with the ones obtained by WB. The assay showed 98.5% and 99.7% sensitivity and specificity respectively.

FIV IC	WB			TOT
	POS	NEG	TOT	
POS	64	1	65	
NEG	1	285	286	
TOT	65	286	351	

COMPOSITION OF THE KIT

- Diagnostic devices individually wrapped
- Dropper vial with dilution buffer.
- Pipettes



PRODUCT MANUFACTURED BY
AGROLABO AND DISTRIBUTED BY
INGENASA



SHELF LIFE: **18 months**
Stored: 4°C-25°C

Ed.090418

INgezim FeLV/FIV IC

Prod. Ref: **1.6.FFD.K40/12**

Double immunocromatographic device for detection of FeLV antigen and specific antibodies to FIV in feline blood, serum or plasma samples.

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KIT COMPONENTS:

Componente	Unidades
Immunocromatographic devices	12
Pasteur disposable pipettes	12
Dropper containing buffer	1

OTHER MATERIALS OR REAGENSTS NEEDED NOT PROVIDED:

– None

KIT CONSERVATION:

All components of the kit should be stored between + 4 ° C and + 25 ° C, in its original packaging until use.

PRINCIPLE OF THE TEST:

The test is based on the immunocromatografic technique. In the case of FeLV, it detects antigen prom the FeLV and in case of FIV, detects the presence of specific antibodies to this virus.

PRECAUTIONS:

- Carefully follow the instructions.
- Place all reagents to room temperature at least 20 min before use.
- Never open the foil pouch containing the device if not used immediately. It could be hydrated and become unusable. Open only immediately before use.
- Do not mix instructions or reagents from different kits.
- Avoid any contamination of reagents.
- Do not use the kit once exceeded their expiration date.
- Do not eat, drink or smoke when samples and / or reagents are handled.
- Do not touch the chromatographic membrane with any object, especially with the dropper tip.

INSTRUCTIONS:

A.- SAMPLE PREPARATION:

The sample of choice for diagnostic purposes, shall be blood, serum or plasma. You can use fresh samples immediately after the extraction and you can store samples up to 5 days after extraction in refrigeration conditions. If you plan to make the assay latter, it is better to store samples under frozen conditions.

B.- TEST PROCEDURE:

Remove the diagnostic device from its envelope and place it on a flat surface. Discard the bag of silica gel. NOTE: Only open the bag at the time of going to test.

Using the Pasteur pipette provided, drop 1 drop of sample on each window "S" of the device. (strip 1 is FeLV and strip 2 is FIV)

CAUTION: The pipette should be placed vertically on the window and keeping the tip 1 cm to avoid touching the membrane.

After the sample addition, drop on each "S" window" of the device 2 drops of buffer.

CAUTION: After adding the 2 drops of buffer in the "S" window of FeLV, check carefully how the migration front go forward. If after 2 minutes of migration the front do not reach the results window, add an additional drop of buffer.



C.- READING AND RESULTS INTERPRETATION:

Keep the device on a flat surface and untouched for 10 minutes, after which proceed to reading the result:

	FeLV (+)	FeLV (-)
FIV (+)		
FIV (-)		

It is advisable not to give any negative sample definitely until you have 10 minutes elapsed from the placement of the sample into the device.