FELINE LEUKEMIA VIRUS ANTIGEN TEST KIT

ASSURE™ FELV ENGLISH

For the detection of Feline Leukemia virus (FeLV) antigen in feline saliva, whole blood, plasma and serum.

GENERAL INFORMATION AND INTENDED USES

The bulbous ends of the plastic wands are coated with an antibody directed against the FeLV specific antigen, p27. A monoclonal antibody directed against p27 is labeled with the enzyme horseradish peroxidase (HRP). The specimen (saliva, whole blood, plasma or serum) is incubated simultaneously with both the antibody-coated wand and enzyme-labeled antibodies. If present, p27 specific antigen is captured by the wand. The enzyme-labeled antibodies are in turn captured by the antigen on the wand. Any free enzyme linked antibody is washed away and the wand is placed into a chromogenic substrate. The development of a distinctly blue color in the solution specifically indicates the presence of FeLV. In the absence of FeLV, no color will be observed.

When a **saliva** sample is used, ASSURE™ FeLV can detect antigen in cats actively shedding virus within 15-20 minutes. When **whole blood, serum,** or **plasma** samples are used, ASSURE™ FeLV can detect circulating antigen in infected cats within 10-15 minutes.

KIT COMPOSITION AND CONSERVATION

Contains materials sufficient to perform 25 tests.

ITEM	REAGENT NATURE	DESCRIPTION
1	Anti-FeLV Antibody coated wands	25 wands. Ready to use.
2	Transfer pipettes	25 pipettes. Ready to use.
A	HRP-Monoclonal Antibody Conjugate; preserved with Cosmoquil CQ and Phenol	25 tubes. Ready to use.
B	Substrate Buffer; preserved with Benzoic acid	25 tubes. Ready to use.
C	Chromogen	3.0 mL vial. Ready to use. (White cap)
D	Saliva Enhancing Reagent; preserved with Cosmoquil CQ	3.0 mL vial. Ready to use. (Blue cap)

Store all reagents provided in the kit at 2 – 7 °C. Reagents should not be frozen.

REAGENTS REQUIRED TO PERFORM 25 TESTS

a) 25 Anti-FeLV Antibody Coated Wands
b) 25 Transfer Pipettes
c) 25 tubes HRP-Monoclonal Antibody Conjugate
d) 25 tubes Substrate Buffer
e) 3.0 mL Chromogen
f) 3.0 mL Saliva Enhancing Reagent (S.E.R.)

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

a) Marking Pen
b) Timer
c) Wash Bottle
d) Deionized or distilled water or normal saline

WARNINGS TO THE USERS OF REAGENTS AND ANTIGEN COATED MICROPLATES

- Handle all reagents and samples as biohazardous material. It is recommended to dispose reagents and contaminated material according to the applicable regulations.
- Take care not to contaminate any test reagents with samples or bacterial agents.
- The best results are achieved by following the protocols described below, using good, safe laboratory techniques.
- Do not use this kit or any of its contents after the expiration date and do not intermix components from different serial numbers.
- Do not expose kit to direct sunlight.
- Hold reagent vials vertically for proper drop volume.
- NEVER PIPETTE BY MOUTH. Harmful if swallowed.
- For veterinary use only

NOTE: Allow all components to come to 21 °C – 25 °C before starting.

SAMPLE COLLECTION AND STORAGE

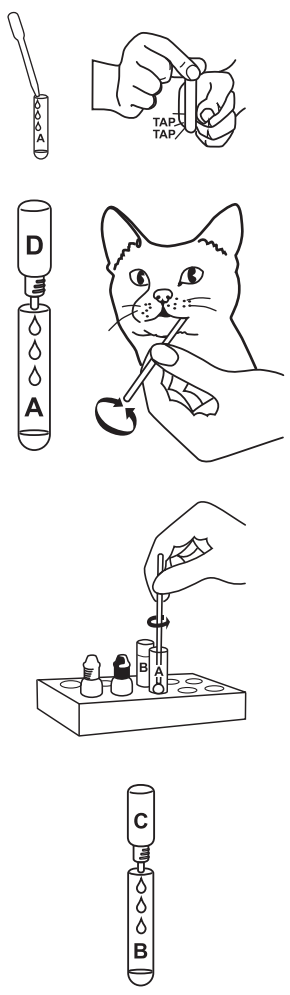
- Follow proper sample collection procedures.
- Saliva or 100 µL (0.10 mL) of whole blood, plasma, or serum is required. Whole blood and plasma must contain an anticoagulant.
- Harvest sample and store properly (up to seven days at 2 °C - 7 °C for serum and plasma, up to 24 hours at 2 °C - 7 °C for whole blood)
- For prolonged storage, serum and plasma samples should be kept frozen (-20 °C or colder).
- Saliva samples cannot be stored or preserved. Saliva cell debris or abrasions on the wand's surface will not affect test results. Do not chemically induce salivation.
- Test only good quality samples (i.e. avoid bacterial contamination, heavy hemolysis or lipemia). Hemolyzed or lipemic samples may be used; however severely hemolyzed or lipemic samples may produce background color. When in doubt, obtain a better quality sample.

TEST PROCECURE

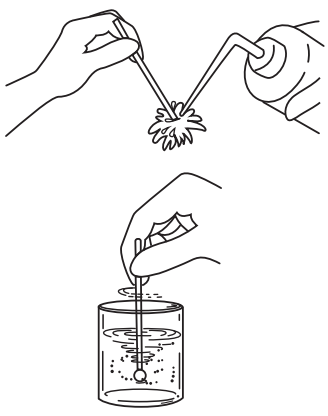
STEP	NOTES
SAMPLE COLLECTION	
1A	**Whole Blood/Serum/Plasma Procedure:** • Pipette 3 drops sample to A Tube • Tap to mix • Proceed to Step 2
	OR

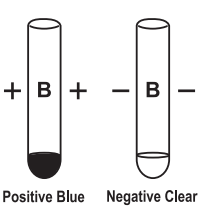
1B	**Saliva Procedure:**
	• Add 3 drops Bottle D (Blue Cap) to A Tube
	• Tap to mix
	• Set in workstation
	• Sample collection
	  • Obtain labeled wand
	  • Place bulbous end of wand between cheek and gum in the back of the mouth
	  • Gently rotate for 5-10 seconds
	• Proceed to Step 2

CONJUGATE INCUBATION	
2	• Place bulbous end of labeled wand in A Tube • Twirl 1-3 seconds to mix • WAIT 5 - 20 MINUTES for blood samples, or • WAIT 10 - 20 MINUTES FOR saliva samples.
PREPARE B TUBE	
3	**During waiting period:** • Remove stopper from B Tube • Add 3 drops Bottle C (White Cap) to B Tube • Tap to mix • Set aside for use in Step 5



STEP	NOTES
WASH	
4	**NORMAL SALINE MUST BE USED WITH WHOLE BLOOD SAMPLES** Distilled/deionized water or normal saline can be used with serum, plasma or saliva samples. • Remove Wand from A Tube • Wash bulbous end and tip by using Method I or II I. SQUIRT BOTTLE METHOD • Direct a forceful stream of the *appropriate washing agent* against bulbous end and top of Wand and work up handle. • Shake off excess water • Repeat 5-7 times totaling 200-250 mL of *appropriate washing agent* II. CUP METHOD • Perform initial rinse of Wand with a forceful stream of *appropriate washing agent* • Swirl/Swish vigorously in 100 mL of *appropriate washing agent* for a minimum of 30 seconds • Shake off excess liquid • Replenish liquid between Wands
DEVELOP	
5	• Place washed Wand in B Tube • Twirl 1-3 seconds to mix • WAIT 5 MINUTES (Weak positives may be verified by waiting up to 10 minutes) • Remove wand • READ RESULTS
INTERPRETATION OF RESULTS	
6	• Observe solution against workstation window or a white background for blue color *NOTE*: Color intensity may vary with level of FeLV antigen present.

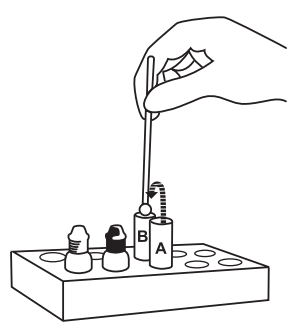




OPTIONAL PROCEDURAL CONTROL

To verify technique and kit performance when a negative/clear result is obtained:
- Place Wand back into A Tube
- Twirl to mix for 1-3 seconds
- Remove Wand
- Do not wash
- Place back into B Tube

Blue color will develop within 1 minute indicating reagents were added correctly and kit is performing properly. If color does not develop, repeat the test. (This is a procedure and reagent check only. FeLV antigen is not present).



INTERPRETATION OF RESULTS

Controls:
- **POSITIVE** control should be distinctly blue.
- **NEGATIVE** control should be completely clear.

Samples:
- **POSITIVE** samples will be blue. Color intensity will vary with level of FeLV antigen present.
- **NEGATIVE** samples will be clear. Compare directly with the negative control against a white background.

NOTES

- Whole blood and plasma samples must contain anticoagulant.
- **Washing is the most important step. Wands cannot be overwashed.** Underwashing will result in nonspecific blue color development in the B Tube.
- Prolonged incubation for more than 10 minutes in Step 5 may result in non-specific blue color development. Read results at 5 minutes. If no color is seen at 5 minutes, the sample is negative. Weak or suspected positives at 5 minutes may be verified by waiting up to 10 minutes.

SYMBOL DESCRIPTIONS

	Use by Date (expiration date)	EC REP	Authorized Representative in the European Community
LOT	Batch Code		Consult Instructions for Use
SN	Serial Number	IVD	*In Vitro* Diagnostics
	Temperature Limitations (storage temperature range)		Manufacturer

zoetis

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