

Intended use

The FLASH VetID™ L. infantum test is a single-target nucleic acid test intended for use with the FLASH Base™ or FLASH Piccolo™ system for the qualitative detection of nucleic acids from *Leishmania infantum* in fine needle non-aspiration cytology and cutaneous lesions swab samples.

A positive result indicates the presence of the target pathogen nucleic acids in the sample. A positive result does not rule out co-infection with other bacteria, protozoa, or virus. Clinical correlation with medical history and other diagnostic information is necessary to determine infection status. The agent detected may not be the definite cause of the disease.

A negative result does not preclude the target pathogen infection and should not be used as the sole basis for treatment or other patient management decisions. A negative result must be combined with clinical signs and patient history. The FLASH VetID™ test is intended to be performed by qualified users in veterinary clinics and hospitals.

Test principle

The FLASH VetID™ L. infantum test is a molecular in vitro test for the qualitative detection of nucleic acids from *Leishmania infantum* in fine needle non-aspiration cytology and cutaneous lesions swab samples. The assay uses isothermal nucleic acid amplification technology, enabling rapid and sensitive detection without the need for thermal cycling.

The procedure integrates sample preparation, lysis, and amplification into a streamlined workflow using the SampleDirect cartridge and the test cartridge. The SampleDirect cartridge processes the sample to remove interferences and enrich target nucleic acids. The processed sample is then combined with lyophilized amplification reagents contained in the test cartridge, which includes enzymes, primers, and probes.

The test cartridge is placed into the FLASH Base™ or FLASH Piccolo™ device, which accurately controls reaction temperature for a set duration. After the reaction is complete, the user presses the upper section of the test cartridge into the cartridge body, releasing the reacted sample onto an integrated lateral flow strip. The strip develops within minutes: two bands (control, C, and test, T) indicate a positive result, and one band (control, C) indicates a negative result.

Materials provided

- 5 pouches ("Bag A") containing each: 1 SampleDirect cartridge and 1 plunger.
- 5 pouches ("Bag B") containing each: 1 test cartridge and 1 small disposable pipette.
- 1 Reagent T tube.
- 5 sample tubes with dropper cap.
- 5 sterile swabs.
- 5 biohazard waste bags.

Storage and handling

Store all the components of the test kit between 4°C and 25°C. Refer to the label on the test kit box for expiry date.

Warnings and precautions

1. **For veterinary in vitro use only.**
2. For professional use only. The final diagnosis should be made by a licensed veterinarian, considering other test results and clinical findings.
3. Single-use only. Do not reuse test cartridges, SampleDirect cartridges, plungers, sample tubes, pipettes, or swabs.
4. Do not use if any component is damaged, leaked, or past its expiration date.
5. Handle all animal samples as potentially infectious.
6. Wear gloves when handling animal samples.
7. Do not use a different disposable pipettes than the ones provided in the kit.
8. Dispose of all used materials as biohazard waste according to local regulations.
9. Avoid cross-contamination by using a separate set of single-use components for each sample, and working in a clean, dedicated area for sample handling.
10. Keep cartridges sealed until use. Do not remove the safety clip or press the cartridge until the instructed step in the procedure.
11. Do not expose cartridges or reagents to moisture, extreme temperatures, or direct sunlight.
12. Do not touch the internal parts of the cartridge.
13. Test promptly after loading the sample into the test cartridge. Delays may affect performance.
14. Improper handling during transport, storage, or use may reduce test sensitivity or cause incorrect results.
15. Mutations or variations in the target sequence may cause false-negative results.
16. Contamination of the laboratory environment or pipettes may lead to false-positive results.

Symbol descriptions

	Sufficient for one test		Consult instructions for use
	Manufacturer		Keep away from sunlight
	Single-use only		Keep dry
	Storage temperature limitations		Do not use if package is damaged
	Fragile, handle with care		

For the digital version of these instructions for use, please visit vetid.flashdiagnostics.com.hk

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FLASH VetID™
L. infantum

Instructions of Use

Applicable to:

Test kit	Lymph node cytology	Skin swab
FLASH VetID™ L. infantum (VID-01-14)	2-3 FNNAC samples	S

FNNAC= Fine needle non-aspiration cytology S= swab if there are cutaneous lesions

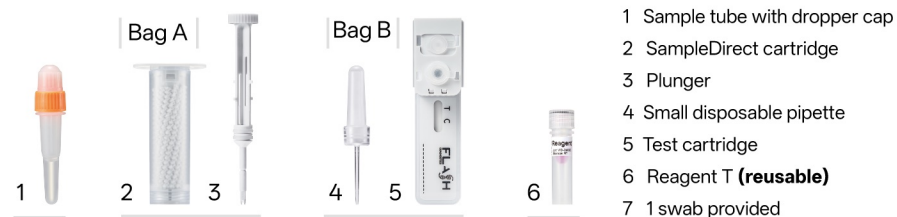
Is it recommended to watch the step-by-step instructional videos found at:

vetid.flashdiagnostics.com.hk

NOTES on FNNAC samples

- Use 23-gauge to 25-gauge needles
- Collect 2 to 3 distinct passes (samples) from different angles of the lymph node
- Stop immediately if fluid or blood appears in the syringe hub
- To avoid drying, collect samples immediately before processing them

A Place the needed components on your work surface



B Prepare the samples after collection

- If a swab sample is collected, **squeeze** and **swirl** the swab in the sample tube **FIRST**, then flush the 2-3 FNNAC samples into the sample tube.



- Re-cap and mix well by inversion.



- Add all the contents of the sample tube into the SampleDirect cartridge.



- Push the plunger into the SampleDirect cartridge until the **lower pins** go into the slots and **STOP**.



- Turn and wait for 5 minutes. Go to **step 6**.



- Fill the **small pipette** with Reagent T.
- Add Reagent T to test cartridge.



- Recap and flick to move all **liquid to the bottom**.



After the 5 minutes from Step 5 have passed:

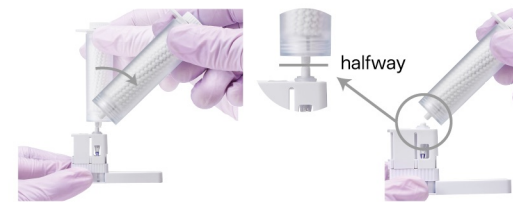
- Insert the plunger into the SampleDirect cartridge until the **Upper pins** go into the slots and **STOP**.



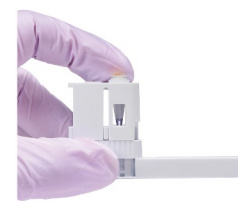
- Turn 90° clockwise and **push fully**.



- Insert **halfway** and break the tip by tilting.



- Re-cap.

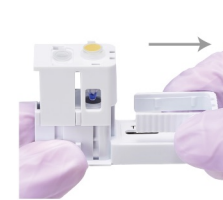


C Run the test

- Follow FLASH Base instructions to run the test.



- When the run is done, remove the safety clip.



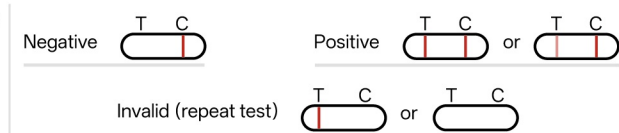
- Press the test cartridge fully.



D Read the result

Read results within 3 to 60 minutes of pressing the cartridge.

3-60 min



E Discard waste



Place all parts into the waste bag and seal it.

DO NOT discard Reagent T.