



# Leptospira Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF VILEP-402 English

## INTENDED USE

The Leptospira Rapid Test Cassette (Whole Blood/Serum/Plasma) is a lateral flow chromatographic immunoassay for the qualitative detection of Leptospira antibodies in animal's whole blood, serum or plasma specimen including but not limited to dog, swine, cow, horse.

For veterinary use only.

## PRINCIPLE

The Leptospira Rapid Test Cassette (Whole Blood/Serum/Plasma) is a based on lateral flow immunochromatographic assay. The test cassette has a testing window with a T (test) region and C (control) region. During testing, the specimen reacts with recombinant Leptospira antigen conjugated colloid gold. The mixture migrates upward on the membrane chromatographically and generates a colored line. Presence of this colored line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

## PRECAUTIONS

- Do not use after expiration date. Do not reuse the test kit.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test cassette from its pouch until immediately before use.
- Do not mix components from different lots and different products.

## MATERIALS

### Materials Provided

- Test Cassettes
- Droppers
- Buffer
- Package Insert

### Materials Required but Not Provided

- Timer
- Specimen collection containers
- Centrifuge

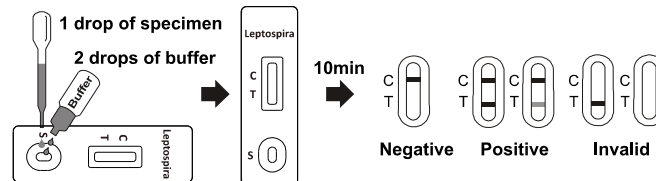
## DIRECTIONS FOR USE

**Allow the test cassette, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.**

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Collect animal's fresh whole blood, or separate serum or plasma from blood as soon as possible to avoid hemolysis. Only use clear, non-hemolyzed specimens. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8 °C for up to 3 days. For long term storage, serum and plasma samples should be kept below -20°C. Do not freeze whole blood specimens.
3. Place the cassette on a clean and level surface.

Hold the dropper vertically and transfer **1 drop of serum/plasma/ whole blood** (approximately 25 µL) to the specimen well(S), then **add 2 drops of buffer** (approximately 80 µL), and start the timer, see illustration below.

4. Wait for the colored line to appear. **Read the result at 10 minutes.** Do not interpret results after 15 minutes.



## INTERPRETATION OF RESULTS

**Positive:** The presence of both C line and T line, no matter T line is clear or vague.

**Negative:** Only clear C line appears.

**Invalid:** No colored line appears in C zone, no matter whether T line appears.

## ACCURACY

The Leptospira Rapid Test Cassette has been evaluated with specimens obtained from Veterinary hospital. Commercialcontrol test is used as the reference method for the Leptospira Rapid Test. Specimens were considered positive if commercialcontrol test indicated a positive result.

Leptospira Rapid tests	Commercialcontrol test		Total
	Positive	Negative	
Test Positive	51	1	52
Test Negative	1	48	49
Total	52	49	101

Relative Sensitivity: 98.08% (95%CI\*: 89.74%-99.95%)

Relative Specificity: 97.96% (95%CI\*: 89.15%-99.95%)

Accuracy: 98.02% (95%CI\*: 93.03%-99.76%)

\*Confidence Interval

## CROSS-REACTIVITY

The Leptospira Rapid Test Cassette has been tested by Lyme virus, Leishman, Ehrlichia, FIV positive samples.

The results showed no cross-reactivity.

## LIMITATION

1. The Leptospira Rapid Test Cassette is for veterinary diagnosis use only.
2. A negative result for an individual subject indicates absence of detectable Leptospira antibodies. However, a negative test result does not preclude the possibility of exposure to Leptospira.
3. Some specimens containing unusually high titer of heterophile antibodies or rheumatoid factor may affect expected results.
4. All results should be considered with other clinical information available from veterinarian.

## Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer	<b>LOT</b>	Batch code	<b>REF</b>	Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use

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Number: V145007001

Revision Date: 2025-07-15