VECHEK™

CHW Antigen Rapid Test Cassette (Whole Blood/Serum/Plasma) Package Insert

REF VIHW-402	English

INTENDED USE

The CHW Antigen Rapid Test Cassette (Whole Blood/ Serum/Plasma) is a sandwich lateral flow immunochromatographic assay for the qualitative detection of canine heartworm antigen (CHW Ag) in canine's whole blood or serum and plasma.

For veterinary use only.

PRINCIPLE

The CHW Antigen Rapid Test Cassette is based on sandwich lateral flow immunochromatographic assay. The test cassette has a testing window with an invisible T (test) zone and C (control) zone. When sample is applied into the sample well on the test cassette, the liquid will laterally flow on the surface of the test strip. If there is enough canine heartworm antigens in the sample, a visible T line will appear in the T zone. The C line should always appear after a sample is applied, indicating a valid result. By this means, the test cassette can accurately indicate the presence of canine heartworm antigen in the sample.

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.
- 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 reuse the test kit.
- Do not mix components from different lots and different products.

MATERIALS

Materials Provided

- Test cassettes
- Droppers
- Buffer
- Package insert

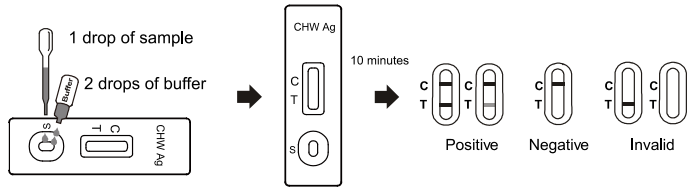
Materials Required but Not Provided

- Timer
- Sample containers
- Centrifuge

DIRECTIONS FOR USE

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

1. Collect canine'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 specimens should be kept below -20 °C. **Do not freeze whole blood specimens.**
2. Place the test cassette on a clean and level surface.
3. Hold the dropper vertically and transfer **1 drop of sample** (approximately 10 µL) and immediately add **2 drops of buffer** (approximately 80 µL) into the specimen well(S), then start the timer. See illustration below.
4. **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 CHW Antigen Rapid Test Cassette has been evaluated with specimens obtained from veterinary hospital. Commercial control test is used as the reference method for the CHW Antigen Rapid Test Cassette. Specimens were considered positive if commercial control test indicated a positive result.

CHW Antigen Rapid Test Cassette	Commercial control test		Total
	Positive	Negative	
Test Positive	60	1	61
Test Negative	7	93	100
Total	67	94	161

Relative Sensitivity: 89.55% (95%CI*: 79.65%-95.70%)

Relative Specificity: 98.94% (95%CI*: 94.21%-99.97%)

Accuracy: 95.03% (95%CI*: 90.44%-97.83%)

*Confidence Interval

CROSS-REACTIVITY

The CHW Antigen Rapid Test Cassette has been tested by LSH, Ehrlichia, Dipetalonema reconditum positive specimens. The results showed no cross-reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to CHW negative and CHW middle positive specimens, respectively.

Analytes	Conc.
Hemoglobin	1000mg/dl
Bilirubin	1000mg/dl
Gentisic acid	20mg/dl

None of the substances at the concentration tested interfered in the assay.

LIMITATION

All results should be considered with other clinical information available from veterinarian. For an accurate result, it is suggested to apply other method such as PCR or Western Blot for final determination in practice.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
	Manufacturer	LOT	Batch code	REF	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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