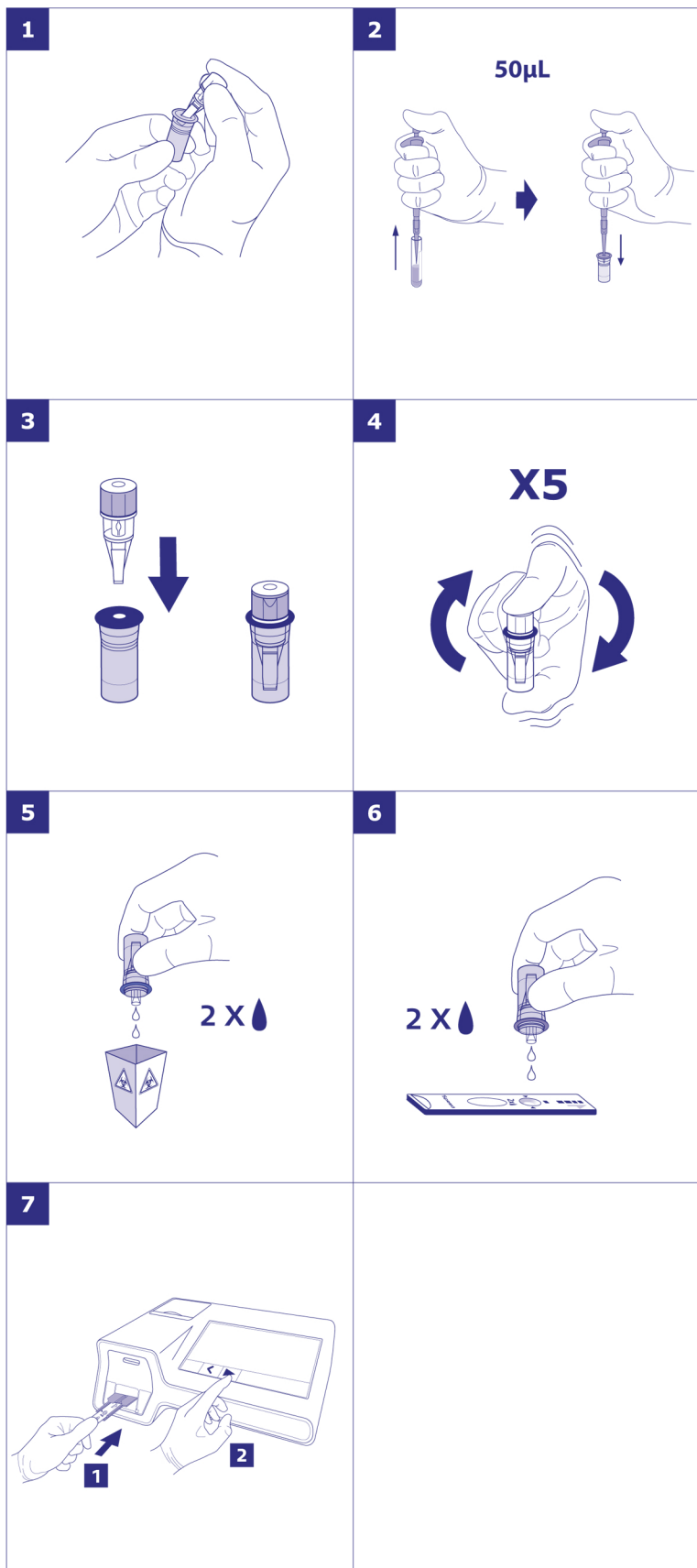


Speed CPSE™

Veterinary diagnostic test
For *in vitro* use only

Fluorescence immunoassay test for the quantitative measurement of Canine Prostate-Specific Esterase (CPSE) in canine serum or plasma.



CLINICAL APPLICATION

Benign prostatic hyperplasia (BPH) is one of the most frequent prostatic diseases in dogs, characterized by proliferation (hyperplasia) and increased size (hypertrophy) of the prostatic cells. Such structural changes result in an increased blood level of Canine Prostate-Specific Esterase (CPSE), an enzyme secreted by the prostate.

PRINCIPLE

Speed CPSE™ is a rapid immunochromatographic quantitative test providing an assay of the circulating CPSE by laser-induced fluorescence analysis.

PRECAUTIONS AND WARNINGS

SAMPLE

- Use only **serum or plasma** (Heparin-Li) samples. Do not use whole blood or EDTA treated samples.
- No interference with haemolysis or hyperlipaemia has been seen.
- If the test is not performed within an hour, transfer the serum or plasma to a dry tube.
- Samples can be stored in a refrigerator (+2°C to +8°C) for up to 24 hours.
- For testing beyond 24 hours, the serum or plasma should be stored in a freezer (-20°C).
- Stored samples should be allowed to reach room temperature (18°C to 27°C) and be centrifuged before analysis.
- The presence of fibrin strands in the sample may lead to erroneous assay results due to pipette clogging and reduced volume of aspirated sample. In this case, recentrifuge the sample.

PROPER PIPETTE USAGE

- Hold the pipette, the sample and reagent tubes vertically at all times, to ensure the correct sampling volume.
- Use a new disposable pipette tip for each test.
- Press and hold the pipette plunger and insert the tip into the sample, being careful not to touch the walls of the tube. Release the pipette plunger slowly while keeping the end of the tip in the sample.
- Remove the pipette from the sample tube and check for air bubbles in the tip. If air bubbles are present, discard the sample and repeat the sampling.

REAGENT AND SAMPLE MIXTURE

- To ensure correct migration of the sample, place the test device on a horizontal surface.
- The reagent tube contains a standard quantity of reagent. Any alteration of this quantity can lead to erroneous assay results.
- **Use the sample/reagent mixture immediately after reconstitution.**
- Do not keep the mixture for subsequent analysis.

RECOMMENDATIONS

- Before using the first test of each box, register the batch calibration chip at the Speed Reader™.
- The expiry date is indicated on the box and on each test pouch.
- Store the tests and the reagents between +2°C and +8°C.
- The specimen and all the materials used for the test procedure should be considered as potentially infectious and they should be disposed of in accordance with local regulations.
- Use appropriate and clean protective equipment (gloves and gown).
- In case of skin or eye contact with the reagent, rinse immediately with clean water and ask for medical advice.

TEST PROCEDURE

Speed CPSE™ cannot be visually interpreted and should be read only with a Speed Reader™ analyser. For complete instructions, please refer to the Speed Reader™ analyser operator's guide.

- **Do not mix test devices, reagent tubes and calibration chips from different batches.**
- Allow the reagent and the test device to reach room temperature (18°C to 27°C) for at least **30 minutes before use.**

MATERIALS FOR EACH TEST

1 test device, 1 reagent tube, 1 dropper cap, 1 pipette tip and the 50µL pipette

SPEED READER™ PREPARATION

- Press "New Test" on the main screen **before starting the test procedure.**
- Follow the on-screen instructions.

SAMPLE TRANSFER

- Using the tip of the dropper cap, perforate the aluminium foil in order to open the reagent tube.
- Place a new disposable tip on the pipette.
- **Transfer 50 µL of the sample into the reagent tube**, following the instructions for correct pipette usage. Be careful not to touch the walls of the reagent tube with the tip.
- **Carefully seal the reagent tube with the dropper cap.**
- **Gently mix** the contents by inverting the tube **at least 5 times. DO NOT SHAKE.**

SAMPLE APPLICATION

- Remove the plastic cover from the dropper cap and **discard the first 2 drops** of the mixture, to wash out the dead space of the dropper cap.
- Completely remove the cartridge from Speed Reader™ and **add 2 drops of the mixture into the sample well** of the test device.

READING

- Insert the test device into the Speed Reader™'s cartridge holder, when prompted by the analyser, in the direction indicated by the arrow (the sample well first) and follow the on-screen instructions.
- Read the result on the screen.

INTERPRETATION

CPSE concentration is measured in ng/mL, between 5 ng/mL and 500 ng/mL.

Reference values:	
Normal: ≤ 50 ng/mL	=> BPH unlikely
Doubtful: 50-70 ng/mL	=> BPH possible
High: ≥ 70 ng/mL	=> consistent with BPH

These recommendations are for guidance only. The aim of this test is to measure canine CPSE blood concentrations. Interpretation of the result by the veterinarian should always take into account the history, clinical examination, and any further diagnostic test results, as no diagnostic method is 100% accurate. The definitive diagnosis is the prerogative and responsibility of the veterinarian. Bio Veto Test and its distributors cannot be held responsible for any consequences linked to incorrect use of this test or misinterpretation of the results.