

Point-of-care**PUUMALA®**

SERODIAGNOSTIC RAPID TEST FOR ACUTE PUUMALA VIRUS INFECTION

Product No 114001



INSTRUCTIONS FOR USE

Point-of-care PUUMALA® is a simple-to-use rapid test for detection of acute Puumala virus infection from serum, plasma (heparin or EDTA) or fingertip blood. Puumala virus belongs to the hantaviruses and it causes a disease known as nephropathia epidemica (NE). Puumala virus is transmitted to human via inhalation or direct contact to contaminated excretions of the bank vole. Puumala virus is met in the most of the European countries.

Point-of-care PUUMALA® rapid test detects virus specific IgM antibodies that react to the purified nucleocapsid protein of the Puumala virus. Since only the IgM-class antibodies are reactive, the test detects only the acute infection. IgG does not interfere with the test result.

Test performance

Specificity and sensitivity of **Point-of-care PUUMALA®** rapid test varied from 83% to 100% when compared to the commercial EIA tests (see References). Repeated freeze thawing of the samples clearly deteriorated results. Thus, fresh unfrozen samples should be preferred for the analysis. Centrifugation of the frozen and thawed samples is also recommended. Usually the test is positive at the same day when the first typical symptoms of the NE appear. If the sample is drawn at very early stage of the disease, the result may be negative. In this case take a new sample after couple of days and repeat analysis.

Possible cross reactions

Strong and very probable cross reaction to Sin Nombre and Andes viruses. Weak cross reaction to Hantaan, Dobrava and Seoul viruses.

The test is not reactive to Parvo, Chlamydia, Rubella, Rubeola, Epstein Barr, Pogosta or Dengue –virus infections.

High rheumatoid factor (RF) may cause interference.

Read the **INSTRUCTIONS FOR USE** carefully before using the test

STORAGE: +5 ... +24 °C
10 - 50 % (relative humidity)

SHELF LIFE: 18 months. Expiry date is marked on the kit label.
Do not use expired product.

CONTENT: 10 tests
1 vial of buffer
1 cut-off control cassette

PROCEDURE

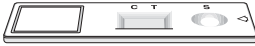


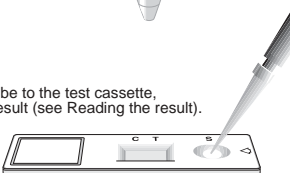
Analysis temperature: +10 ...+35 °C.

Samples: serum, plasma (heparin or EDTA) or fingertip blood

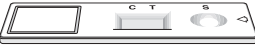


Materials needed (not included):

Pipette or capillary for the volume of 5 µl.
Equipments for the sampling and separation of blood
Test tube (glass or Eppendorf tube)

Procedure 1 (recommended)

1. Open the foil pouch and place the test on a flat surface. 
2. Add 2 drops of the buffer from the dropping vial into the test tube. 
3. Add 5 µl of the sample into the test tube (serum, plasma or fingertip blood) and mix well. 
4. Remove the liquid from the test tube to the test cassette, wait for 5 minutes, and read the result (see Reading the result). 

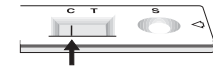
Procedure 2

1. Open the foil pouch and place the test on a flat surface. 
2. Pipette 5 µl of the sample to the test cassette. 
3. Add 2 drops of the buffer from the dropping vial to the test cassette, wait for 5 minutes, and read the result (see Reading the result). 

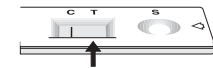
Reading the result

Wait for 5 minutes and read the result. You can read the result until 15 minutes, after which the result may change.

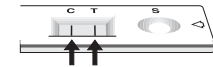
First check that the red line has appeared on the test window's C –position (see the picture below). This means that you have performed the test correctly. If the red line has not appeared, the test result is invalid, and you have to repeat the test.



Then look at the test window's T –position. If the red line does not appear in the T –position, the test is negative (see the picture below).



If the red line appears in the test window's T –position, the test is positive (see the picture below).



Using the cut-off control cassette

Place the CUT-OFF CONTROL right next to the analysis cassette. Compare the line in the test window of the analysis cassette to the one in the CUT-OFF CONTROL cassette. If the test line in the analysis cassette is more intensive than the test line in the CUT-OFF CONTROL cassette, the test result is positive. If there is no detectable test line or the line is less intensive in the analysis cassette than the test line in the CUT-OFF CONTROL cassette, the test is negative. If you are still uncertain about the result, take a new sample after few days and repeat the test.

Attention

Handle all biological materials as potentially infective. Discard the used test and sampling material into the biohazard container. The outer package is made of recyclable material.

For professional use only.

Manufacturer

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References

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