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	Version 1.3	REF 114002	

Point-of-care DOBRAVA®

Point-of-care DOBRAVA® is a simple-to-use rapid test for detection of acute Dobrava virus infection from serum, plasma (heparin or EDTA) or fingertip blood. *Point-of-care DOBRAVA®* rapid test detects IgM antibodies reactive to the Dobrava virus nucleocapsid protein. Since only the IgM-class antibodies are reactive, the test detects the acute infection. IgG does not interfere with the test result. Before using the *Point-of-care DOBRAVA®* rapid test it is important to read the instructions for use carefully. The test is for professional use only.

Dobrava virus, which belongs to the genus hantavirus, is found in most of the Asian countries. The virus is a causative agent of disease known as hemorrhagic fever with renal syndrome (HFRS). Dobrava virus is transmitted to humans via inhalation or direct contact to contaminated excretions of rodents.

KIT CONTENT

- 10 Test cassettes
- 1 Running buffer
- 1 CUT-OFF control cassette
- Instructions for use

MATERIALS NEEDED BUT NOT INCLUDED

- Pipette or capillary for the volume of 5 µl
- Equipments for the sampling and separation of blood
- Test tubes (glass or Eppendorf tubes) for procedure 2
- Timer

STORAGE

Store tests unopened in foil at +5 °C...+25°C and at 5-50% relative humidity until expiry date marked on the kit label. Do not use expired products.

TEST CONDITIONS

Perform the test at +15 °C...+30 °C and at 5-50% relative humidity most preferably in the laboratory room.

SAMPLES

Use 5 µl of serum, plasma (heparin or EDTA) or fingertip blood as sample. Serum and plasma samples can be stored for years in freezer (-20 °C) or for a few days in refrigerator (+4 °C). It is recommended to use fresh samples (not frozen). Frozen samples may cause false positive results when aggregated. If the sample is aggregated or otherwise poor in quality, please, centrifuge samples for 5 min with 3000 x g before use. Handle all biological materials as potentially infective. Discard the used tests and sampling material according to local and federal regulations.

CROSS REACTIVITY

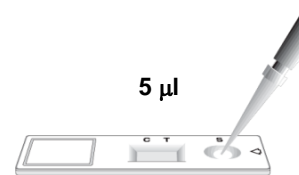
Very probable cross reactivity to Hantaan and Seoul viruses. Weak cross reactivity to Puumala, Sin Nombre, and Andes viruses. The test is not reactive to Parvo, Chlamydia, Rubella, Rubeola, Epstein Barr, Pogosta or Dengue virus infections. High rheumatoid factor (RF) may cause interference.

TEST PERFORMANCE

Specificity and sensitivity of *Point-of-care DOBRAVA®* rapid test varied from 83% to 100% when compared to the commercial EIA tests (see literature).

TEST PROCEDURE 1

1. Open the foil pouch and place the test cassette on a flat surface. Do not use the test cassette if the foil pouch is burst. Write down the patient information into the test cassette.
2. Pipette 5 µl of the sample (serum, plasma or fingertip blood) into the test cassette's sample well (S).



3. Add 3 drops of the running buffer from the dropping bottle into the test cassette's sample well.



4. Wait for 5 minutes, and read the result. You can read the result until 15 minutes (see reading the result).

TEST PROCEDURE 2

This procedure is **NOT** recommended for fingertip blood samples.

1. Open the foil pouch and place the test cassette on a flat surface. Do not use the test cassette if the foil pouch is burst. Write down the patient information into the test cassette.
2. Add 3 drops of running buffer from the dropping bottle into the test tube.



3. Add 5 µl of the sample into the test tube (serum or plasma) and mix well.



4. Transfer **all the liquid** from the test tube to the test cassette's sample well (S).

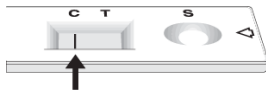


5. **Wait for 5 minutes** and read the result. You can read the result until 15 minutes (see reading the result).

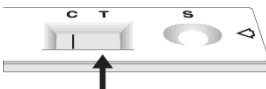
READING THE RESULT

You can read the result until 15 minutes, after which the result may change.

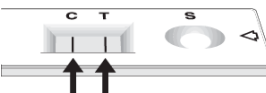
First check that the red line has appeared on the test window's **Control-position** (C, see the picture below). This means that you have performed the test correctly. If the red line has not appeared, the test result is invalid, and you have to repeat the test.



Then look at the test window's **Test-position** (T). 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).



Usually the test is positive at the same day when the first typical symptoms of the HFRS appear. If the sample is drawn at very early stage of the disease, the result may be negative. If you are uncertain about the result, take a new sample after a couple of days and repeat analysis.

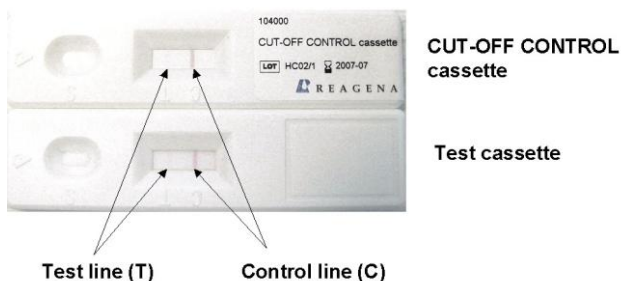
CUT-OFF CONTROL

The CUT-OFF CONTROL cassette is intended for demonstration of the faint ghost line sometimes seen in the lateral flow rapid test. The ghost line may be erroneously interpreted as positive signal. The ghost line may be caused by several serum-borne factors such as cross-reacting antibodies or protein aggregates.

CUT-OFF CONTROL cassette has been manufactured by permanently printing the control line (C) and actual test line (T) to the cassette. Visualisation of the cut-off signal line in a CUT-OFF CONTROL cassette helps users to differentiate the truly positive signals from the ghost lines and thus reduces user related variation.

USING THE CUT-OFF CONTROL CASSETTE

Place the CUT-OFF CONTROL right next to the test cassette. Compare the test line in the test cassette to the test line in the CUT-OFF CONTROL cassette.



If the test line in the test 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 test 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. Note that the intensity of the control line may be different in CUT-OFF CONTROL cassette and test cassette. Do not use CUT-OFF CONTROL cassette for analysis of samples. Do not apply sample or any liquid on it.

TROUBLESHOOTING

1. **Sample volume is too low:** If you do not get enough sample (5 µl) the result cannot be regarded reliable. This is not normally seen on serum and plasma samples.
2. **Incorrect volume of sample dilution.** The correct volume for the test is three drops of running buffer and 5 µl of sample.

If the volume of sample dilution is too low, the liquid will not start to flow on the test membrane at all. This may happen if you have added only one drop of sample buffer. If you cannot see the flow in the test cassette for 5 minutes, then add one drop of running buffer into the sample well (S).

If the volume of sample dilution is too high, the test will not function properly because of the flooding. This may happen if you have added more than three drops of running buffer into the test cassette.

3. **Do not interpret the test as positive,** if the test line appears different than usual (ie. unclear blurred, unusually broad or multiple diffuse).
4. If the background color is still red after 15 minutes, the result is not reliable. Please repeat the analysis with a new test cassette.

LITERATURE

Hujakka H, Koistinen V, Eerikäinen P, Kuronen I, Mononen I, Parviainen M, Lundkvist Å, Vahe A, Närvänen A, Vapalahti O. 2001. New immunochromatographic rapid test for diagnosis of acute Puumala virus infection. J. Clin. Microbiol. 39(6):2146-2150.

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