

## BIOCARD™ Parvo B19

Cat.no. 3-031-000

Biocard Parvo B19 is a one-step immunochromatographic test for the rapid and convenient screening of *Parvo B19* antibodies in serum, plasma or whole blood samples in acute phase of disease.

### Introduction

Human *parvovirus B19* is small nonenveloped DNA virus, the icosahedral capsid of which consists of structural proteins of two types. The minor protein is called VP1 and the major protein VP2.

Infection by the *parvo B19 virus* may lead to a wide range of diseases. In the early phase of infection, virus-induced cessation of erythropoiesis among predisposed subjects can lead to abrupt anemia, aplastic or hypoplastic crisis. In immunocompromised individuals persistent parvovirus infection can cause prolonged bone marrow failure. Fifth disease (erythema infectiosum) occurs frequently in children and young adults and its associated with varying forms of autoimmune phenomena and transient, sometimes prolonged arthropathy, especially older individuals. *B19* infection during the first two trimester of pregnancy can lead to fetal hydrops and/or fetal death.

### Test principle

The functional parts of Biocard Parvo B19 are the filter and the chromatographic membrane. Both contain immunological reagents in a dehydrated state which are rehydrated by the diluted sample during the assay process. A stationary reagent line has been applied into the membrane. The reagent line is otherwise invisible, but if the serum or whole blood sample passing through membrane contains antibodies to the acute phase specific *Parvo B19 peptide*, the line turns distinctly red under formation of a dyed antigen-antibody-anti human IgG-complex in the test line (=reagent line). The membrane contains also another stationary line in the control window invisible before use of the test. This control line turns red during the assay process, thus indicating proper performance of the test device.

### Materials provided with the Biocard Parvo B19 kit,

#### cat.no. 3-031-000:

10 pcs aluminium sachets containing a test card and a pipette  
10 pcs Sample diluent tubes (1,0 ml in each)  
10 pcs Capillary tubes  
10 pcs Automatic lancets  
10 pcs Alcohol soaked swabs  
Instruction for use

**Materials needed but not provided with the kit:** Pipettes for diluting the serum and plasma samples and timer.

### Storage and shelf life

Biocard test units shall be stored at ambient temperature (+2...+27°C) in original unopened foil pouches. The tests are sensitive to moisture. Each test unit contains a desiccant. The test shall be used without delay when the pouch has been opened. If the test pouch is considerably colder than surrounding air and if the humidity of air is high, it is advisable to let the test unit reach the room temperature before opening the pouch. Expiry date is indicated on the box.

The sample dilution buffer and the positive control shall be stored refrigerated (+2...+27°C). Expiry date is indicated on the labels. The sample dilution buffer contains a preservative and short-term storage (under 3 months) at ambient room temperature is acceptable. Avoid contamination of the buffer and dispose it if signs of contamination are observed.

### Sample collection and storage

Serum, plasma and whole blood can be used as a sample. EDTA and heparin in ordinary concentrations are acceptable as anticoagulants. Sodium azide (0,09 %) can be used as preservative.

Samples shall be stored refrigerated (+2...+ 8 °C). Sera can be frozen (under -20 °C) for long-term storage. The diluted samples shall be used during the same working day.

### Controls

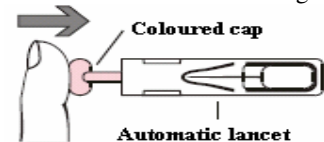
Proper performance of the Biocard Parvo B19 can be checked by a pool of known positive sera. The sample diluent and a pool of negative sera are recommended as negative controls. Note that the positive controls shall be of human origin. The sera used for the negative control ought to be tested for negativity before pooling,

### TEST PROCEDURE FOR WHOLE BLOOD SAMPLES

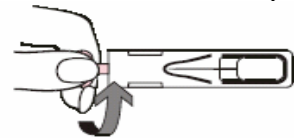
All components required for the test should be at room temperature.

Before taking the blood sample, prepare all the test components: the automatic lancet, the alcohol-soaked swab and the glass capillary. Open the tube containing the buffer by removing the cap. Then take the test card and the pipette out of the aluminium sachet. Place the test card horizontally on a level dry surface (with application fields up). When the aluminium sachet has been opened you should carry out the test within 15 minutes.

1. Press slowly the coloured cap of the automatic lancet until it clicks into the casing.

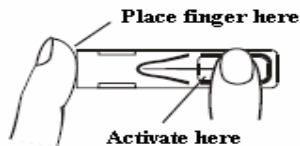


2. After the audible click, twist off the coloured cap.

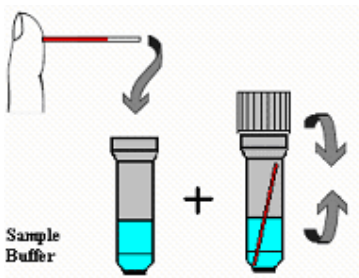


3. Gently massage the fingertip then clean it with the alcohol-soaked swab. Leave until the finger is dry.

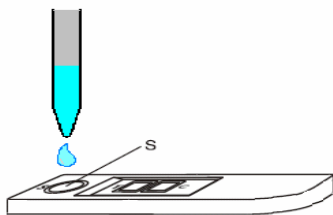
- Press the automatic lancet with the round opening firmly against the cleaned fingertip, and activate it with the button. The puncture is practically painless.



- Press a drop of blood out of the fingertip. Open the plastic vessel and remove with caution the glass capillary. Hold the glass capillary horizontally in the drop of blood until it has completely filled.
- Place the filled glass capillary in the tube containing buffer and close the tube firmly with the cap. Shake the tube several times until the blood from the capillary is mixed completely with the buffer.



Remove the cap of the buffer tube again and remove a few drops of diluted sample with the pipette. Hold the pipette containing the diluted blood sample vertically over the round application field (S) and drop 3 drops onto it. After applying the drops, do not touch and move the test card for 2 minutes.

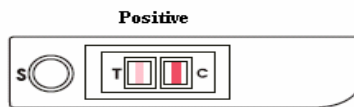


The test result can be read after 10 minutes. Note that a positive result can be read as soon as the test and control lines are clearly visible.

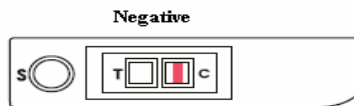
## TEST PROCEDURE FOR SERUM AND PLASMA SAMPLES

- If the sample diluent is refrigerated, bring it to room temperature.
- Dilute the serum and plasma sample with the Sample Diluent 1/150 (6,7 µl of the sample to the Sample Diluent tube). Mix the dilutions properly. Continue from the point 6 after the picture.

## Interpretation of the results



A positive result (the antibody activity of the sample is above the cut-off level of the test) is indicated as a distinctly visible red line in the test indicator window and a red line in the control indicator window. Note that a positive result can be read as soon as the test and control lines are clearly visible.



A negative result (the antibody activity of the sample is below the cut-off level of the test) is indicated by the absence of a distinctly visible red line in the test indicator window and the presence of a red line in the control indicator window.

## Invalid test results

The absence of a distinctly visible red line in the control indicator window is a sign that the test unit is damaged. In such a case, repeat the testing with a new test unit.

## Precautions and limitations

Biocard Parvo B19 shall be used only for *in vitro* detection of *Parvo B19* antibodies in accordance with the instructions for use and by following the rules of good laboratory practice. Biocard test will give positive test result only in an acute phase of disease. A final diagnosis should in principle only be made in conjunction with the clinical symptoms and further laboratory data.

General laboratory procedures and precautions shall be followed in handling and disposal of samples and used testing material.

After the aluminium sachet has been opened, the test should be carried out within the next 15 minutes. Do not reuse Biocard test units. Do not use expired tests or tests from a lot not showing proper performance when tested by controls. Do not use a test from a pouch which has been damaged during transportation or storage. Do not use damaged or broken accessories.

## Warnings

If the instructions for use or the rules of good laboratory practice are not strictly followed, false and misleading results may occur. Poor observation of the general laboratory precautions in conjunction with the use of the Biocard tests can expose persons to microbial hazards.

The Sample Diluent contains 0,09 % sodium azide. Avoid swallowing and contact with the skin.

## Bibliography

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- Enders M., Schalsta G., Baisch C., Weidner A., Pukkila L., Kaikkonen L., Lankinen H., Hedman L., Söderlund-Vennamo M., Hedman K. (2006) Human parvovirus B19 infection during pregnancy—Value of modern molecular and serological diagnostics J Clin Virol: Vol. 35 400-406
- Enders M., Weidner A., Rosenthal T., Baisch C., Hedman L., Söderlund-Vennamo M., Hedman K. Improved diagnosis of gestational B19 parvovirus infection at the non-immune fetal hydrops J Infect Dis in press

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