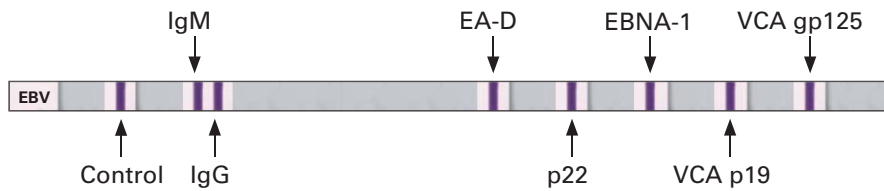




## EUROLINE EBV Profile 2 (IgG/IgM)

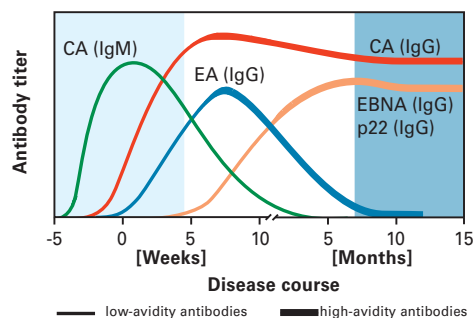


**Indications:** Test system for in vitro determination of antibodies against Epstein-Barr virus in human serum or plasma for diagnosis of the following diseases: infectious mononucleosis, Burkitt's lymphoma, nasopharyngeal carcinoma.

**Clinical significance:** EBV (Epstein-Barr virus) and herpes simplex virus types 1 and 2 belong to the most ubiquitous human-pathogenic herpes viruses in adults. EBV is the causative agent of infectious mononucleosis, a febrile disease usually accompanied by pharyngitis and lymphadenopathy, frequently by hepatosplenomegaly and more rarely by an exanthema. EBV infections are also found in connection with Burkitt's lymphoma and nasopharyngeal carcinoma. Infectious mononucleosis must be differentiated from cytomegalic inclusion body disease and toxoplasmosis and, in the case of atypical progress, also from HIV or other infections. In pregnancy EBV can cause infection of the placenta, leading to damage to the foetal heart, eyes and liver. In children, accompanying infections of the kidney have been observed with symptoms from microscopic haematuria to acute kidney failure.

The IgG immune response against EBV-CA (EBV capsid antigen) is an indication of the presence of an EBV infection. An acute EBV infection can be characterised by a titer increase of IgG. An increase in titer of at least twofold and the absence of antibodies against EBNA-1 (EBV nuclear antigen 1) indicate an early phase of infection. An IgM immune response to EBV-CA with a titer increase of EBV-CA (IgG) antibodies is a reliable indicator of the presence of an acute EBV infection, although this is not obligatory. Antibodies against EBNA (EBV nuclear antigen) are generally only detectable during the late phase of infection. In more than 90% of patients with an acute EBV infection low-avidity IgG antibodies against EBV-CA can be found during the first 10 days after the onset of symptoms. After 30 days, 50% of patients still exhibit these antibodies.

IgG antibodies against early EBV-EA (EBV early antigens) occur in 70% to 80% of patients with infectious mononucleosis, although only temporarily during the acute phase. Although EBNA-1 to EBNA-6 are synthesised earlier after infection than the other EBV antigens (EBV-EA and EBV-CA), they are presented to the immune system only after the destruction of B-cells, so that, timewise, antibodies against EBV-CA and EBV-EA are detectable before antibodies against EBNA.



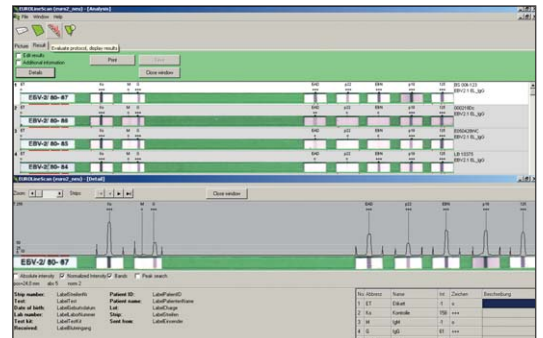
**Application of the EUROLINE EBV Profile 2 (IgG/IgM):** Infectious mononucleosis can be easily confused clinically with infections with cytomegalovirus, Toxoplasma gondii or hepatitis viruses. The direct detection of Epstein-Barr virus is difficult. Therefore, the detection of specific antibodies against the virus is of great significance for diagnosis. Various virus-specific antibodies occur during the course of an infection. The parallel detection or exclusion of these antibodies with the EUROLINE EBV Profile 2 enables differentiation between an acute and a past infection in one test. The configuration of the EUROLINE EBV Profile 2 using both native antigens purified by affinity chromatography and recombinant Epstein-Barr virus antigens results in outstanding test sensitivity and specificity. Serologically rare and difficult constellations such as persisting anti-EBV-CA IgM antibodies or their absence in an acute infection can be clearly differentiated using the EUROLINE EBV Profile 2.



## Test Characteristics EUROLINE EBV Profile 2 (IgG/IgM)

**Test principle:** The EUROLINE is a qualitative in vitro immunoassay, in which membrane strips printed with lines of purified, biochemically characterised antigens are used as solid phase. Each antigen is coated onto a separate membrane fragment, enabling the production process and thereby the efficiency of antibody detection to be optimised for each protein. Since antigen bands are located at defined positions, results can be evaluated visually without the need for additional equipment. Correct performance of all test steps is confirmed by staining of the control band.

**Computer-based evaluation:** The EUROLine-Scan programme from EUROIMMUN provides automated evaluation of EUROLINE analyses and detailed documentation of results. The incubated membrane strips are either scanned onto a protocol sheet using a flatbed scanner (EUROBlotScanner) or photographed directly in the incubation tray using a camera system (EUROBlotCamera). EUROLineScan recognises the position of the strips, even if they have been laid inexactly. It then identifies the bands and measures their intensity. The EUROLine-Scan programme facilitates data management and eliminates the need to archive potentially infectious material. A separate results sheet can be produced for each patient. Online connection to other programmes is possible, e.g. laboratory management systems (LIMS).



**Clinical data:** 127 sera from patients at different stages of an EBV infection (clinically and serologically characterised, Dr. Gärtner, University Clinic Saarland, Germany; EUROIMMUN AG) were investigated for antibodies of class IgG and IgM against VCA gp125, VCA p19, EBNA-1, p22 and EA-D using the EUROLINE EBV Profile 2.

| Infection status (n=127) | Anti-VCA IgG pos. | Anti-VCA IgM pos. | Anti-EBNA-1 IgG pos. | Anti-p22 IgG pos. | Anti-EA-D IgG pos. |
|--------------------------|-------------------|-------------------|----------------------|-------------------|--------------------|
| Acute infection (n=22)   | 100%              | 96%               | 9%                   | 27%               | 72%                |
| Late infection (n=72)    | 100%              | 13%               | 99%                  | 97%               | 19%                |
| Negative (n=8)           | 13%               | 0%                | 0%                   | 0%                | 0%                 |
| Reactivation (n=25)      | 100%              | 8%                | 92%                  | 100%              | 68%                |

Fresh infections are characterised by antibodies of class IgG and IgM against the VCA antigens VCA gp125 and/or p19. Antibodies of class IgG against EA-D can also occur. The late phase of infection is characterised by antibodies of class IgG against VCA gp125 and/or p19 as well as against EBNA-1. With secondary loss of antibodies against EBNA-1 the presence of antibodies of class IgG against p22 indicates the late phase of infection.

### Technical data:

|                 |   |
|-----------------|---|
| Antigens        | <b>VCA gp125:</b> native VCA gp125 antigen, purified by affinity chromatography; <b>VCA p19:</b> recombinant VCA p19 antigen; <b>EBNA-1:</b> recombinant EBNA-1 antigen; <b>p22:</b> recombinant p22 antigen, belongs to group of capsid proteins; <b>EA-D:</b> recombinant EA-D antigen. |
| Sample dilution | Serum or plasma; 1:51 in universal buffer.  |
| Test procedure  | 30 min / 30 min / 10 min. Room temperature.   |
| Automation      | The test can be performed using all commercially available blot processing systems, e.g. the EUROBlotMaster from EUROIMMUN.   |
| Test kit format | 16 or 64 membrane strips<br>Kits include all necessary reagents.  |
| Order number    | DN 2790-1601-2 G or M (IgG or IgM, 16 strips)<br>DN 2790-6401-2 G or M (IgG or IgM, 64 strips)  |